

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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**ZEPP HEALTH CORPORATION**

Petitioner

v.

**WORCESTER POLYTECHNIC INSTITUTE;  
THE RESEARCH FOUNDATION  
FOR THE STATE UNIVERSITY OF NEW YORK**

Patent Owners

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Case No. IPR2025-00522  
U.S. Patent No. 9,713,428

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**DECLARATION OF DR. GEORGE E. YANULIS  
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW  
OF U.S. PATENT NO. 9,713,428**

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## EXHIBIT LIST<sup>1</sup>

Exhibit No.	Description
Ex-1001	U.S. Patent No. 9,713,428
Ex-1002	Declaration of Dr. George E. Yanulis (“Yanulis Decl.”)
Ex-1003	Curriculum Vitae of George E. Yanulis
Ex-1004	File History of U.S. Patent No. 9,713,428
Ex-1005	Asada, H. Harry, Phillip Shaltis, Andrew Reisner, Sokwoo Rhee, and Reginald C. Hutchinson. “Mobile Monitoring with Wearable Photoplethysmographic Biosensors.” <i>IEEE Engineering in Medicine and Biology Magazine</i> , vol. 22, no. 3 (July 1, 2003): 28-40. (“Asada”)
Ex-1006	International Patent Application Publication No. WO 2009/018570, filed on August 4, 2008 and published on February 5, 2009 (“Chon-570”)
Ex-1007	Delorme, Arnaud, Scott Makeig, and Terrence Sejnowski. “Automatic Artifact Rejection for EEG Data Using High-Order Statistics and Independent Component Analysis.” <i>Proceedings of the 3rd International Independent Component Analysis and Blind Source Decomposition Conference</i> (pp. 9-12). San Diego, CA: Institute for Neural Computation, University of California (April 4, 2003) (“Delorme”)
Ex-1008	Chon, Ki H., Yuru Zhong, Leon C. Moore, Niels H. Holstein-Rathlou, and William A. Cupples. “Analysis of Nonstationarity in Renal Autoregulation Mechanisms Using Time-Varying Transfer and Coherence Functions.” <i>American Journal of Physiology. Regulatory, Integrative and Comparative Physiology</i> , vol. 295, issue 3 (May 21, 2008): R821–R828. (“Chon-2008”)
Ex-1009	Chon, Ki H., Shishir Dash, and Kihwan Ju. “Estimation of Respiratory Rate from Photoplethysmogram Data Using Time–Frequency Spectral Estimation.” <i>IEEE Transactions on Biomedical Engineering</i> , vol. 56, no. 8 (July 28, 2009): 2054-2063. (“Chon-2009”)

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<sup>1</sup> In this Declaration, 4-digit pin citations that begin with “0” refer to the branded numbers added by Petitioner in the bottom right corner of the exhibits. All other pin citations in this Declaration refer to original page, column, paragraph, or line numbers.

Ex-1010	Greco, Antonino, Nadia Mammone, Francesco Carlo Morabito, and Mario Versaci. “Kurtosis, Renyi’s Entropy and Independent Component Scalp Maps for the Automatic Artifact Rejection from EEG data. <i>International Journal of Signal Processing</i> , vol. 2, no. 4 (January 31, 2006): 240-244. (“Greco”)
Ex-1011	U.S. Patent Application Publication No. 2007/0100246, filed on October 31, 2006 and published on May 3, 2007 (“Hyde”)
Ex-1012	U.S. Patent No. 4,510,944 was filed on December 30, 1982 and published on April 16, 1985 (“Porges”)
Ex-1013	Zhao, He, Sheng Lu, Rui Zou, Kihwan Ju, and Ki H. Chon. “Estimation of Time-Varying Coherence Function Using Time-Varying Transfer Functions.” <i>Annals of Biomedical Engineering</i> , vol. 33, no. 11 (November 30, 2005): 1582–1594. (“Zhao”)
Ex-1014	Declaration of Dr. Sylvia Hall-Ellis (“Hall-Ellis Decl.”)
Ex-1015	Judge Robert W. Schroeder, III (E.D. Tex.) – Calendar Events Set for 2/17/2026
Ex-1016	Judge Robert W. Schroeder, III (E.D. Tex.) – Case Statistics
Ex-1017	Docket entries in <i>Research Foundation for The State University of New York v. Xiaomi Corporation et al.</i> , No. 2:23-cv-00353-RWSRSP (E.D. Tex.)
Ex-1018	Zepp Health Corporation’s Stipulation Regarding Invalidity Challenges
Ex-1019	Docket Control Order (Dkt. 58) in <i>Research Foundation for The State University of New York v. Xiaomi Corporation et al.</i> , No. 2:23-cv-00353-RWS-RSP (E.D. Tex.)

I, George E. Yanulis, declare as follows:

## **I. INTRODUCTION**

### **A. Engagement**

1. I have been retained by counsel for Petitioner Zepp Health Corporation (“Zepp” or “Petitioner”) as an expert witness for the above-captioned *inter partes* review (IPR) proceeding. I have been asked to consider the validity of claims 1-11, 15-27, 29-30, 32-37, 39-40, 42-46 of U.S. Patent No. 9,713,428 (the “’428 Patent”) in view of prior art, obviousness considerations, and the understanding of a person of ordinary skill in the art at the time of the invention as it relates to the ’428 Patent. I have personal knowledge of the facts and opinions set forth in this declaration and believe them to be true. If called upon to do so, I would testify competently thereto.

### **B. Compensation**

2. For my time working on this matter, I am being compensated at my standard hourly consulting rate. I do not have any personal or financial stake or interest in the outcome of the present proceeding, and the compensation is not dependent on the outcome of this IPR and in no way affects the substance of my statements in this Declaration. I do not have any expectation or promise of additional business with the Petitioner in exchange for the positions explained herein. My analysis here is based on my years of education, research and

experience, as well as my investigation and study of relevant materials, including those cited herein.

**C. Qualifications and Experience**

3. I have over 35 years of experience in biomedical engineering and designing medical devices. Particularly, I have direct experience within the field of medical monitors that measure physiological parameters and provide statistical analyses relating to the parameters. My experience is related specifically to electrocardiograms, cardiac echo imaging, and cardiac pressure/volume analysis, which are closely related to pulse oximetry, oxygen saturation, and pulse rate. Through my experience, I have learned how to integrate medical monitoring technology into the medical profession.

4. I received my Bachelor of Arts in Pre-medicine degree in 1977 from Syracuse University, which included a minor in Chemistry. Originally, I planned to go to medical school, but I found that my interests aligned more closely to medical devices than practicing medicine. So, I pivoted to biomedical engineering, and I received a Master's degree in Biomedical Engineering from the University of Virginia in 1981. I closely studied medical devices while in graduate school at Virginia, including using preamplifiers to record evoked cortical signals to better understand the etiology of Epilepsy.

5. For approximately the next two decades, my professional experience included serving in the armed services as a 1st Lieutenant and Clinical Engineer for the Air Force (stationed at the Malcolm Grow Medical Center, Andrews Air Force Base), working as a Logistics Engineer for RCA, and conducting research within the education industry (at Syracuse, Alabama-Birmingham, Drexel, and the University of Pennsylvania). I was a Clinical Engineering Consultant involved with the Y2k Program at the Hospitals of the University of Pennsylvania from 1999-2000. I continued as a research assistant at the University of Pittsburgh, but in 2002, I decided to pursue a doctorate. Even though I was leaving, my mentor at Pitt awarded me a Master of Science in Bioengineering for my research work rather than leave without a degree. I studied medical devices at Pitt, but also implantable devices, such as using elastomeric polymers to design artificial diaphragm muscles.

6. Still continuing my education, I received a Doctor of Engineering (D.Eng.) from Cleveland State University in 2008. For my Doctorate, I focused on Applied Biomedical Engineering. It was during my Doctorate that I developed a specialty in cardiovascular medical devices and treatments, with a focus on treating atrial fibrillation. At Cleveland State, we studied electrical stimulation (i.e., coupled pacing applied near the end of the T-wave, which represents the repolarization of the ventricles in electrocardiography to prevent rapid ventricle

conduction during atrial fibrillation (AF)), and whether the benefits of coupled pacing could be used during persistent AF.

7. Since obtaining my D.Eng., I have taught the next generation of bright minds. From 2009-2013, I was an adjunct professor at the College of Staten Island teaching Engineering and Physics, and since 2015, I have been an Adjunct Professor at Temple University teaching Bioengineering.

8. In my career, I have had multiple research projects focusing on clinical assessment of medical devices and monitoring systems. For example, I had experience in the research and development of a heart rate monitoring system based on my earlier bench studies conducted related to my Doctoral research at the Cleveland Clinic (2005-2008) and now with Medical Device Consulting, LLC (2016-Present). I have consulted on heart bypass systems (2017-2018), and I served as a consultant on several cardiac pacemaker device related cases which involved monitoring heart rate, pulse rate, ECG. I was involved in reviewing critical monitoring systems as both a member and peer reviewer of submitted manuscripts of the association for the advancement of Medical Instrumentation (2012-present). At Cleveland State, I was involved in the research and design of critical care monitoring systems used for heart failure therapy patients both from 2005-2008, as part of my D.Eng. and since 2014, as part of my research and the development of a heart monitoring system. Further still, from 2015-2017, I was

also involved in mentoring Temple bio-engineering students in the design of critical care monitoring systems for both cardiac systems courses and biomedical instrumentation design courses. Finally, I was involved in reviewing clinical care monitoring system as a clinical engineer with the USAF from 1987-1989.

9. I also have continued to study cardiovascular devices and other medical devices as a consultant. Particularly, I collaborated with Data Science Corporation to design a device that used a time elapsed interval between two consecutive R-waves of the QRS heart signal (R-R interval) to potentially use on heart failure therapy patients. I have assisted with 250 Cardiac Pacemaker Device Implants on dogs to develop pacing algorithms for heart failure therapy patients. Also, I have performed over 500 ECG signal detection sessions and cardiac pressure-volume analysis on dogs. Further still, I have intensely studied Heart Failure Cardiac Pressure/Flow Sensor Monitoring Systems.

10. Lastly, I have written six peer-reviewed articles in this area and other areas of medical device development. My publications from the last 10 years are listed in my CV where my CV is submitted as Ex-1003 to the Petition.

11. Thus, my background demonstrates an expertise and strong understanding of medical devices and how they can improve the health of patients.

**D. Information Considered and Relied Upon**

12. My opinions in this declaration are based on my years of education, training, research, knowledge, and experience, as well as my investigation and study of relevant materials. In forming my opinions, I have studied the materials mentioned in this Declaration, such as, e.g., the prior art, the file history and the patent. I have relied on these materials to varying degrees. Citations to these materials that appear below are meant to be exemplary but not exhaustive.

13. Each of these materials is a type of document that experts in my field would have reasonably relied upon when forming their opinions and would have had access to either through the applicable patent office and/or well-known libraries, conferences, publications, organizations and websites in the field as further discussed herein.

14. I may rely upon these materials, my knowledge and experience, and/or additional materials to respond to arguments raised by the Patent Owner. I may also consider additional documents and information in forming any necessary opinions — including documents that may not yet have been provided to me.

15. My analysis of the materials produced in this matter is ongoing and I will continue to review any new material as it is provided. This Declaration represents only those opinions I have formed to date. I reserve the right to revise,

supplement, and/or amend my opinions stated herein based on new information and on my continuing analysis of the materials already provided.

## **II. PERSON OF ORDINARY SKILL IN THE ART**

16. A person of ordinary skill in the art (“POSITA”) at the time of the purported invention of the ’428 Patent would have had a working knowledge of physiological monitoring technologies and/or signal processing as used in physiological monitoring technologies. The POSITA would have had a bachelor’s degree in an academic discipline related to electrical, computer, software, optical, or biomedical technologies, in combination with two years of work experience related to the capture and processing of data or information signals, or designing and using biomedical sensors or systems, including but not limited to physiological monitoring technologies. Alternatively, a POSITA would have had a master’s degree in one of the above academic disciplines with one year of work experience as described above. Additional education can substitute work experience, and vice versa.

17. The proposed level of skill for the POSITA would not change if a different priority of the invention date is found.

## **III. LEGAL STANDARDS**

18. I am not an attorney, and I have not been asked to offer any legal opinions. In preparing and expressing my opinions in this Declaration, I have

applied the legal standards described below, which were explained to me by counsel for Petitioner.

**A. Claim Construction**

19. I have been informed that in an IPR proceeding, claim terms are usually given their plain and ordinary meaning, as understood by a person of ordinary skill in the art, in view of the patent's specification and prosecution history.

20. I have been informed that patent claims are construed from the viewpoint of a person of ordinary skill in the art of the patent at the time of the alleged invention. I have been informed that patent claims generally should be interpreted consistent with their plain and ordinary meaning as understood by a person of ordinary skill in the art in the relevant time period (i.e., at the time of the purported invention, or the so called "effective filing date" of the patent application), after reviewing the patent claim language, the specification and the prosecution history (i.e., the intrinsic record).

21. I have further been informed that a person of ordinary skill in the art must read the claim terms in the context of the claims themselves, the patent specification and the prosecution history. The patentee may specifically define a claim term in a way that differs from the plain and ordinary meaning. I also understand that during the prosecution of a patent application, an application may

limit the scope of the claims to overcome prior art or to overcome an examiner's rejection, by clearly and unambiguously arguing to overcome or distinguish a prior art reference, or to clearly and unambiguously disavow claim coverage.

22. In interpreting the meaning of the claim language, I understand that a person of ordinary skill in the art may also consider "extrinsic" evidence, including expert testimony, inventor testimony, dictionaries, technical treatises, other patents, and scholarly publications. I understand extrinsic evidence is sometimes considered to interpret a claim in light of the understanding of those skilled in the art at the time of the invention. I understand that extrinsic evidence may not be relied on if it contradicts or varies the meaning of claim language provided by the intrinsic evidence, particularly if the applicant has explicitly defined a term in the intrinsic record.

#### **B. Obviousness**

23. I understand that a patent claim is obvious if the differences between the patented subject matter 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. Relevant considerations for an obviousness determination include the level of ordinary skill in the art; the scope and content of the prior art; differences between the prior art and the claims at issue; and the so-called objective secondary factors of nonobviousness.

24. I understand that a claim can be found to be obvious if all the claimed elements were known in the prior art and that one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art.

25. I understand that hindsight must not be used when comparing the prior art to the invention for obviousness. Thus, a conclusion of obviousness must be firmly based on knowledge and skill of a POSITA at the time the invention was made without the use of post-filing knowledge.

26. I understand that in order for a claimed invention to be considered obvious, there must be some motivation to combine the cited references as proposed.

27. I understand that obviousness may also be shown by demonstrating that it would have been obvious to modify what is taught in a single piece of prior art to create the patented invention. Obviousness may be shown by showing that it would have been obvious to combine the teachings of more than one item of prior art, with a reasonable expectation of success in doing so. In determining whether a piece of prior art could have been combined with other prior art or with other information within the knowledge of one of ordinary skill in the art, the following are examples of approaches and rationales that may be considered:

- (a) Combining prior art elements according to known methods to yield predictable results;
- (b) Simple substitution of one known element for another to obtain predictable results;
- (c) Use of a known technique to improve similar devices (methods, or products) in the same way;
- (d) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (e) Applying a technique or approach that would have been “obvious to try” (choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success);
- (f) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art; or
- (g) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

28. I further understand that certain factors may support or rebut the obviousness of a claim. I understand that such secondary considerations include,

among other things, commercial success of the patented invention, skepticism of those having ordinary skill in the art at the time of invention, unexpected results of the invention, any long-felt but unresolved need in the art that was satisfied by the alleged invention, the failure of others to make the alleged invention, praise of the alleged invention by those having ordinary skill in the art, and copying of the alleged invention by others in the field. I understand that there must be a nexus—a connection—between any such secondary considerations and the alleged invention (i.e., the features that are alleged to make the claim patentable).

#### **IV. OVERVIEW OF THE '428 PATENT**

##### **A. Brief Summary of the '428 Patent**

29. The '428 Patent describes systems and methods for obtaining physiological signals, such as PPG, EKG signals, and detecting motion artifacts in the signal data. '428 Patent, Abstract. The '428 Patent obtains raw signal data, apply signal processing techniques such as bandpass filters and detrending to preprocess segments to preprocess the signal data. '428 Patent, 5:32-39. The specification identifies an example bandpass filter as “a finite impulse response (FIR) band pass filter of order 64 with cut-off frequencies of 0.1Hz and 10Hz.” '428 Patent, 5:35-36. As to detrending, the specification defines it as “the process of finding a best polynomial fit to a time series and subtracting that best polynomial fit from the time series.” '428 Patent, 3:46-48. After the preprocessing,

the system applies high order statistics such as Kurtosis and Shannon Entropy on the preprocessed segments. '428 Patent, 5:57-6:22. It then determines whether this segment of the data should be accepted or rejected by comparing the result of the analyses with a threshold. '428 Patent, 6:33-46.

30. The '428 Patent also describes obtaining a measure of atrial fibrillation by a time-varying coherence function (TVCF). '428 Patent at 13:3-5. The TVCF is obtained by multiplying two time-varying transfer functions (TVTFs), the two TVTFs are obtained using two adjacent data segments with one data segment as input signal and the other data segment as output to produce the first TVTF, and the second TVTF is produced by reversing the input and output signals. '428 Patent at 13:5-13. The patent then compares the TVCF with a threshold to detect atrial fibrillation. '428 Patent at 13:10-20.

#### **B. Summary of Claims**

31. Claims of the '428 Patent can be divided into two sets: (1) Claims 1-11, 15, 21-27, 29-30, 37, 39-40, which are sometimes referred to as Shannon Entropy Claims; (2) Claims 16-20, 32-36, 42-46 which are sometimes referred to as the "TVCF claims."

32. I copied and pasted Claim 21 from the "Shannon Entropy Claims" as an example. Other claims, such as Claim 1 can also be used as a representative claim.

21[pre]. A system for physiological parameter monitoring, the system comprising:

[i] a physiological indicator signal sensing component; the physiological indicator signal sensing component being one of an image acquisition component, a photoplethysmographic (PPG) sensor and an electrocardiogram sensor; and a handheld mobile communication device comprising:

[ii] at least one processor; and

[iii] at least one computer usable medium, the computer usable medium having computer readable code embodied therein, the computer readable code causing the at least one processor to:

[iv] analyze the physiological indicator signal;

[v] obtain, from results of analyzing, measurements of one or more physiological parameters; and

[vi] detect effects of motion artifacts in the measurements of the one or more physiological parameters;

[vii] wherein the computer readable code, in causing the at least one processor to detect effects of motion artifacts, causes the at least one processor to:

a. bandpass filter and detrend a segment from the measurement of one physiological parameter; wherein a bandpass filtered and detrended segment is hereinafter referred to as a preprocessed segment;

b. obtain a value of at least one indicator of volatility, used in determining whether motion artifacts are present, for the preprocessed segment; the at least one indicator of volatility being at least Shannon entropy (SE) for the preprocessed segment; where

$$SE = - \sum_{i=1}^k \frac{p(i) \cdot \log(p(i))}{\log\left(\frac{1}{k}\right)}$$

and where i represents the bin number, and p(i) is the probability distribution of the preprocessed segment;

- c. include the segment in analyses of physiological measurements when comparison of the value of the at least one indicator of volatility with a predetermined threshold indicates noise/motion artifacts are not present; and
- d. select another segment of the signal from the physiological measurement and proceeding to step (a) when the value of the at least one indicator of volatility is less than a predetermined threshold and another segment is available.

33. As shown above, Claim 21 recites receiving and analyzing physiological signals to detect motion artifacts. It detects motion artifacts by processing a signal segment with bandpass filter and detrending it, and applying a statistical method such as Shannon Entropy to obtain a value for volatility. The Claim also recites comparing the value for volatility with a threshold value to determine whether the signal segment should be accepted, and the system proceeds to another segment.

34. Below I copied and pasted Claim 32 as an example, although other claims such as Claim 16 can also be used as a representative claim.

32[pre]. A system for physiological parameter monitoring, the system comprising:

[i] a physiological indicator signal sensing component; and a handheld mobile communication device comprising:

[ii] at least one processor; and

[iii] at least one computer usable medium, the computer usable medium having computer readable code embodied therein, the computer readable code causing the at least one processor to:

[iv] analyze the physiological indicator signal; the physiological indicator signal being obtained from one of an image acquisition component, a photoplethysmographic (PPG) sensor and an electrocardiogram sensor;

[v] wherein analysis does not include Independent Component Analysis;

[vi] obtain, from results of analyzing, measurements of one or more physiological parameters; and

[vii] detect effects of motion artifacts, using only the measurements of one or more physiological parameters, in the measurements of the one or more physiological parameters; wherein the one or more physiological measurements comprise a measure of atrial fibrillation; and wherein the computer readable code, in causing the at least one processor to analyze the physiological indicator signal, causes the at least one processor to:

[viii] obtain a time-varying coherence function by multiplying two time-varying transfer functions (TVFTs), the two time-varying transfer functions obtained using two adjacent data segments from the physiological indicator signal, one of the two adjacent data segment as an input signal and another of the two adjacent data segment as an output signal to produce a first TVTF; a second TVTF is produced by reversing the input and the output signals, using said another of the two adjacent data segment as the input signal and said one of the two adjacent data segment as the output signal; and

[ix] determine whether the time-varying coherence function is less than a predetermined quantity.

35. Claim 32 recites generally detecting motion artifacts from physiological signals. It also analyzes physiological signals using time-varying coherence function and determines whether the time-varying coherence function is less than a threshold value, to detect atrial fibrillation.

### C. Prosecution History of the '428 Patent

36. In the prosecution history, the examiner found that “[n]oise reduction processes are well-known in the art.” Ex-1004 (0144), 2013-11-01 Office Action (pg. 10). Preprocessing a signal segment was also found by the examiner as well-known in the art. Ex-1004 (0570) at 2016-04-28 Office Action at pg. 8, *citing* Reisfeld (U.S. Publ. No. 2007/0213624) (which “teaches detrend / detrending a segment from the measurements of one physiological parameter (physiological signals, [0003] and detrend, [0080-0081]); *id.* at 0571, *citing* Muthuswamy et. al. “Spectral analysis methods for neurological signals”, *Journal of Neuroscience Methods* 83 (1998)1-14) (“It is commonly known in the art that detrending is a data preprocessing step for analyzing EEG signals ... for removing the mean and linear trends in the segment of the signal.”). The examiner also found that preprocess with a bandpass filter is known in the art. Bandpass filtering is known in the art. Ex-1004 (0684), 2016-09-22 Office Action at pg. 14 (“Muthuswamy teaches to bandpass filter/filtering and detrend/detrending a segment from the measurements of one physiological parameter (detrend and bandpass filtering, see page 2).”)

37. Separately, the examiner found that Shannon entropy analysis was known in the art. Ex-1004 (0142), 2013-11-01 Office Action, pg. 8, *citing* Zhang (U.S. Publ. No. 2009/0112110) at [0042]; *Id.* (0503) at 2015-11-13 Interview

Summary, discussing Greco et al. “Kurtosis, Renyi's Entropy and Independent Component Scalp Maps for the Automatic Artifact Rejection from EEG data”. International Journal of Computer, Information, Systems and Control Engineering 2(9), January 2008: 180-184. (Examiner pointed out that Greco acknowledges Shannon entropy is used in the analysis of physiological data). Patentee also admitted that Shannon entropy has been around for a long time. Ex-1004 (0550) at 2016-03-01 Office Action Response at pg. 20.

38. The examiner also stated that “Time-varying coherence function(s) for analyzing two signals are known in the art as evidenced by Buck et. al. (USPN 2010/0150375).” Ex-1004 (0142) at 2013-11-01 Office Action, pg. 8.

39. During prosecution, examiner issued rejections under 35 U.S.C. Section 101. In an attempt to overcome the Section 101 rejection, Patentee argued that “The claimed invention is an improvement in the technology of physiological parameter monitoring in home or ambulatory environment.” Ex-1004 (0547) at 2016-03-01 Office Action Response at pg. 17.

40. In the last office action response on December 22, 2016, the patentee, in an effort to overcome Greco, added the element “the physiological indicator signal being obtained from one of an image acquisition component, a PPG sensor, and an electrocardiogram sensor” to all independent claims. The patentee additionally added the following to the Shannon Entropy Claims: “

$$SE = -\sum_{i=1}^k \frac{p(i) * \log(p(i))}{\log\left(\frac{1}{k}\right)}$$

and where i represents the bin number, and p(i) is the probability distribution of the preprocessed segment.” And the patentee added the element “wherein analysis does not include independent component analysis” to the TVCF Claims. Ex-1004 (0715) at 2016-12-22 Office Action Response. The Examiner subsequently allowed the claims. Ex-1004 (0749-0756) at Notice of Allowance.

#### **D. Claim Interpretation**

41. For this declaration, I do not believe that any claim term of the ’428 Patent requires explicit construction to resolve the issues presented in this Petition. I apply the plain and ordinary meaning to each claim term, as that plain and ordinary meaning would have been understood by a POSITA.

42. I reserve the right to offer opinions on any claim constructions proposed in this proceeding or to offer opinions on constructions in the district court litigation.

#### **V. SCOPE AND CONTENT OF THE PRIOR ART**

43. In my opinion, the claims of ’428 Patent fail to identify anything new or significantly different from what was already known to those skilled in the art

prior to the filing of the '428 Patent<sup>2</sup>. Indeed, detecting motion artifacts or AF are not new problems at the time.

44. Numerous prior art taught using statistical methods to detect motion artifacts or atrial fibrillation (AF) in physiological data. The statistical methods in the claim, such as Shannon Entropy, time varying coherence function (TVCF), are well-known in the art. The techniques such as comparing the results of statistical analyses with a threshold to determine whether to keep or reject data or determine whether the data is statistically meaningful are also commonly known to a POSITA. The concept of “physiological parameter monitoring in home or ambulatory environment,” “real-time monitoring with a handheld device,” or using a camera, PPG, ECG/EKG to gather physiological data are not new either.

**A. Asada (Ex-1005)**

45. Asada is titled “Mobile Monitoring with Wearable Photoplethysmographic Biosensors.” Asada was publicly available no later than July 1, 2003. Hall-Ellis Decl. (Ex-1014), §§IV.A & V. Asada is thus prior art to the '428 Patent under pre-AIA 35 U.S.C. §102(b).

46. Asada describes wearable biosensors (WBS) for real-time monitoring of patient’s physiological parameters. Asada at 28 (“a Ring Sensor for

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<sup>2</sup> In this declaration, I do not provide an opinion as to whether the '428 Patent is entitled to claim priority of one or more of its provisional applications.

Ambulatory, Telemetric, Continuous Health Monitoring in the Field, Hospital, and Home.”), 29 (the system can measure “cardiopulmonary ‘vital signs’: heart rate, arterial blood pressure, arterial oxygen saturation, respiratory rate, temperature, and even cardiac output.”). The WBS includes PPG sensors to acquire signals, although it can also offer physiologic measurements “including acoustic sensors, electrochemical sensors, optical sensors, electromyography and electroencephalography, and other bioanalytic sensors.” Asada envisions the WBS technology as “a platform upon which a new paradigm of enhanced healthcare can be established.” Asada at 29. And the WB can offer physiological measures including, e.g., “acoustic sensors, electrochemical sensors, optical sensors, electromyography and electroencephalography, and other bioanalytical sensors.” Asada at 29.

47. Asada addresses technical issues of reducing motion artifacts. Asada at 28. Asada stated that “[t]here must exist data processing and decision-making algorithms for the waveform data” so that WBS can process the physiological measurements. Asada at 28. Asada describes the ring sensor of WBS having a PIC microcomputer which performs device controls, data acquisition and signal processing. *See, e.g.*, Asada at 34, 35.

**B. Chon-570 (Ex-1006)**

48. Chon-570 is an international patent publication (WO 2009/018570) filed on August 4, 2008 and published on February 5, 2009. Chon-570 is prior art to the '428 Patent under pre-AIA 35 U.S.C. § 102(b).

49. Chon-570 discloses techniques for detecting atrial fibrillation (AF). Chon-570 at 1:8-10. It performs analyses on data segments such as RR intervals, and employs statistical analyses such as Root Mean Square of Successive RR interval differences to quantify variability (RMSSD), a Turning Points Ratio to test for randomness of the time series (TPR), a Shannon Entropy (SE) to characterize AF's complexity and an autocorrelation (ACORR) index to characterize correlation between the first two RR intervals. Chon-570 at 3:23-29, 4:6-18. As described in Chon-570, SE is used to detect outliers in the signal data. Chon-570 at 6:27-7:20. The results of the calculations are then compared with thresholds. *See* Chon-570 at 8:5-6, 8:28-9:22, 10:14-17.

**C. Delorme (Ex-1007)**

50. Delorme is titled "Automatic artifact rejection for EEG data using high-order statistics and independent component analysis." Delorme was publicly available no later than April 4, 2003. Hall-Ellis Decl. (Ex-1014), §§IV.C & V. Delorme is prior art to the '428 Patent at least under pre-AIA 35 U.S.C. §102(b).

51. Delorme describes using higher order statistics such as Shannon Entropy and Kurtosis to detect motion artifacts. Delorme at Section 2. Delorme states that rejecting artifacts based on low-order signal statistics (min, max) might not be sufficient “to detect muscle activity” and it finds that “[h]igher order statistical properties of EEG signals might contain more relevant information about this and other types of artifacts.” Id. Delorme uses probability measures, such as Shannon entropy to detect outliers. Id. It also uses kurtosis to spot other artifacts based on “unusually peaky distribution of potential values.” Id. Delorme also teaches using thresholds for Shannon entropy and kurtosis to reject values. Id. Although Delorme used independent component analysis (ICA) to isolate the data segment, it also identified other algorithms such as principal component analysis (PCA) for similar purposes. Delorme at Section 3.1.

**D. Chon-2008 (Ex-1008)**

52. Chon-2008 is titled “Analysis of Nonstationarity in Renal Autoregulation Mechanisms Using Time-Varying Transfer and Coherence Functions.” Chon-2008 was publicly available no later than May 21, 2008. Hall-Ellis Decl. (Ex-1014), §§IV.F & V. Chon-2008 is thus prior art to the ’428 Patent at least under pre-AIA 35 U.S.C. §102(b). Chon-2008 describes statistical methods such as time-varying transfer functions (TVTF) and time-varying coherence functions (TVCF). Chon-2008 at Abstract. Chon-2008 teaches obtaining TVCF

from 2 TVTFs. Chon-2008 at R827. The first TVTF is obtained with a first signal segment as input  $x$  and the second signal segment as output  $y$ . Chon-2008 at R827, Formula A8. The second TVTF is obtained by reversing “the input and output relationship such that the variables  $y$  and  $x$  represent input and output signals, respectively.” Chon-2008 at R827, Formula A9. The paper uses TVCF and TVTFs to analyze nonstationarity in whole kidney blood flow data collected from animal studies. Chon-2008 at R822.

#### **E. Other Background Art**

53. Chon-2009 (Ex-1009) is a 2009 prior art paper. *See* Ex-1014 at Page 49. It describes estimating respiratory rate from pulse oximeter signal. Chon-2009 at Abstract. As acknowledge in Chon-2009, “[a] noninvasive means to monitor arterial oxygen saturation ( $SaO_2$ ) on a continuous basis is pulse oximetry, a well-established technology based on photoplethysmography (PPG) that has become one of the most commonly used patient monitors during anesthesia and in intensive care units.” Chon-2009 at 2054. Chon-2009 also teaches that “[g]iven the ubiquity and simplicity of pulse oximetry, it is desirable to maximize its potential by exploring additional measurements that we can derive from the pulse oximeter. Extraction of respiratory rate from pulse oximetry data is one example, as the signal from the pulse oximeter contains not only the heart beat but also a respiratory signal.” Chon-2009 at 2054. Chon-2009 teaches using variable

frequency complex demodulation (VFCDM) to estimate respiratory rate. Chon-2009 at Abstract. The VFCDM method involves a two-step process where the first step is to obtain an estimate of TFS using complex demodulation (CDM) or fixed frequency CDM (FFCDM). The second step is to select only the dominant frequencies of interest for further refinement of the time-frequency resolution using the VFCDM approach. Chon-2009 at 2055.

54. Greco (Ex-1010) is a 2006 prior art paper. *See* Ex-1014 at Page 49. It also teaches using higher order statistics for processing physiological data signals, such as the EEG data signals. Greco acknowledges that applying kurtosis and Shannon entropy for signal processing have been around for a long time. Greco at Abstract (“a technique for the automatic artifact rejection, based on the Independent Component Analysis (ICA) for the artifact extraction and on some high order statistics such as kurtosis and Shannon’s entropy, was proposed some years ago in literature.”), 244 (“kurtosis together with Shannon’s entropy, have been used as markers for the automatic artifact detection.”).

55. Hyde (U.S. Publ. No. 2007/0100246) (Ex-1011) describes a physiological monitoring device for monitoring a cardiac signal, such as an ECG signal. Hyde at abstract, [0034], [0054], FIGS. 1 and 2. Hyde further discloses using well-known techniques, such as bandpass filtering and detrending to preprocess physiological data. Hyde at [0055], [0064]. These techniques are used

to preprocess the raw physiological data to obtain usable spectrum of data so that subsequent statistical analyses can be performed. Hyde at [0055]. Hyde further discloses that “[i]t will be appreciated by those skilled in the art that various mathematical algorithms may be substituted for any of the signal processing steps listed above, including digital filters such as FIR and IIR filters, and analog filters or bandpass filters. Hyde at [0064].

56. Porges (U.S. Pat. No. 4,510,944) (Ex-1012) also discloses using bandpass filtering and detrending on physiological data such as EKG data. Porges at 2:24-34, 5:10-28, 7:14-40. As an example of detrending, Porges describes “the removal of the effect of baseline drift by detrending the baseline activity with a ‘moving polynomial filter’ (MPF). The moving polynomial filter consists of two stages: first, it smooths the baseline pattern by fitting a piece-wise polynomial to the baseline; second the smoothed baseline pattern is subtracted from the original data set.” Porges, at 5:15-22. “The output of this procedure is then bandpassed to allow only the variance of the data set associated with the frequency of interest to pass.” Porges at 5:23-25.

57. Zhao (Ex-1013) is a 2004 prior art paper (*see* Ex-1014 at Page 49) which teaches estimating time-varying coherence functions (TVCF) with time-varying transfer functions (TVTF). Zhao at Abstract. The TVCF is estimated by the multiplication of the two TVTFs. The two TVTFs are obtained using signal  $x$  as

the input and signal y as the output to produce the first TVTF, and signal y as the input and signal x as the output to produce the second TVTF. Zhao at Abstract. According to Zhao, this approach “provides higher time-frequency resolution TVCF than afforded by the short time Fourier transform based TVCF.” Zhao at Abstract.

**VI. GROUND 1 – CLAIMS 1, 3-11, 15, 21, 23-27, 29-30, 37, 39-40 ARE OBVIOUS OVER ASADA IN VIEW OF CHON-570**

58. In my opinion, the above referenced claims are obvious in view of Asada (Ex-1005) and Chon-570 (Ex-1006).

59. A POSITA would be motivated to combine Asada and Chon-570 because they are in the same field of monitoring and analyzing physiological data in real-time, particularly those parameters related to heart conditions. Asada at 28; Chon-570 at 4:1-4. The algorithm in Chon-570 is platform agnostic and can run on general hardware, which the WBS in Asada provides. As stated in Asada, “WBS, in conjunction with appropriate alarm algorithms, can increase surveillance capabilities of CV catastrophe for high-risk subjects.” Asada at 28. Thus, a POSITA reading Asada would be motivated to combine it with the algorithms in Chon-570 to enhance detections. Combining Asada and Chon-570 involves applying a known technique, such as the Shannon Entropy technique in Chon-570 to a known device, such as the WBS in Asada, to achieve a predictable result. Furthermore, Asada seeks to address issues related to motion artifacts. Asada at 28.

Chon-570 discloses algorithms such as Shannon Entropy, which have long been used in detecting motion artifacts as evidence by others in the field. *See* Delorme at Section 2 (using Shannon Entropy to reject motion artifacts). As there is a finite number of Shannon Entropy methods, and Chon-570 teaches one of them, a POSITA would be motivated to use the Shannon Entropy's formula in Chon-570 in Asada's system to detect or reduce motion artifacts. Thus, a POSITA reading Asada would be motivated to combine it with the algorithms in Chon-570 such as Shannon Entropy to enhance detections by WBS.

60. A POSITA would be motivated to apply the VFCDM method in Chon-2009 with Asada and Chon-570 because they are all in the same field of art, i.e., processing and analyzing physiological data. Chon-2009 acknowledges using PPG (which is also used in Asada) to obtain respiration rate. Chon-2009 at 2054 (“The reason why many researchers feel that it is possible to obtain respiratory rate from the PPG signal is due to evidence that the respiration rate modulates both amplitude and frequency of the signal [5]–[8]. This phenomenon is similar to the respiratory sinus arrhythmia modulating the heart rate signal.”). It would be obvious to use a known algorithm, such as the VFCDM method disclosed in Chon-2009, on the known system of Asada which monitors patient physiological parameters, to achieve a predictable result of extracting respiratory rate.

**A. Independent Claims 1, 21, 37 are obvious in view of Asada and Chon-570**

**1. Preamble**

1. A method for physiological parameter monitoring, the method comprising:	21. A system for physiological parameter monitoring, the system comprising:	37. A non-transitory computer usable medium having computer readable code embodied therein, the computer readable code causing at least one processor to:
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61. While I understand that a claim’s preamble is not limiting, Asada discloses this element. *See Asada at 28, 34.*

62. For example, Asada teaches the use of a wearable biosensor, specifically a “ring sensor,” that is designed to continuously monitor cardiovascular parameters in real-time. *Asada at 28, 34.* The biosensor can measure cardiovascular parameters such as heart rate, oxygen saturation, and heart rate variability, which meet the “physiological parameter monitoring” element. *Asada at 28, 35.*

63. Similarly, Chon-570 also discloses techniques for monitoring physiological parameters such as heart rate, beat-to-beat variabilities, and other parameters related to atrial fibrillation (AF) using piezoelectric or ECG signals. *Chon-570 at 3:23-4:18.* Chon-570 discloses algorithms which meet “computer readable code” element and can be executed by one or more processors.

64. As to claim 37, Asada and Chon-570 teaches this element for reasons mentioned in subsection 2 below.

**2. “providing a physiological indicator signal ...” / “a physiological indicator signal sensing component ...”**

1[i]. providing a physiological indicator signal to a handheld mobile communication device; the physiological indicator signal being obtained from one of an image acquisition component, a photoplethysmographic (PPG) sensor and an electrocardiogram sensor;	21[i] a physiological indicator signal sensing component; the physiological indicator signal sensing component being one of an image acquisition component, a photoplethysmographic (PPG) sensor and an electrocardiogram sensor; and a handheld mobile communication device comprising: [ii] at least one processor; and [iii] at least one computer usable medium, the computer usable medium having computer readable code embodied therein, the computer readable code causing the at least one processor to:
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65. Asada discloses a wearable biosensors system (WBS) which has a handheld mobile communication device. Asada at 28. Asada discloses providing a physiological indicator signal to the ring sensor to monitor, for example, the patient’s heart rate, oxygen saturation, and heart rate variability. Asada at 28-29. Asada also works with handheld devices such as PDA, cellphones which access the data for storage and clinical diagnosis. Asada at 34.

66. One example of such physiological indicator signal is PPG signal from a PPG sensor. Asada at 28 (the system “combines miniaturized data

acquisition features with advanced photoplethysmographic (PPG) techniques to acquire data related to the patient's cardiovascular state.”). Asada discloses a dual photodetector design (as shown in the figure below), where one of the photodetector serves as a motion sensor to reduce noise in the signal acquired by the other photodetector. Asada at 33.

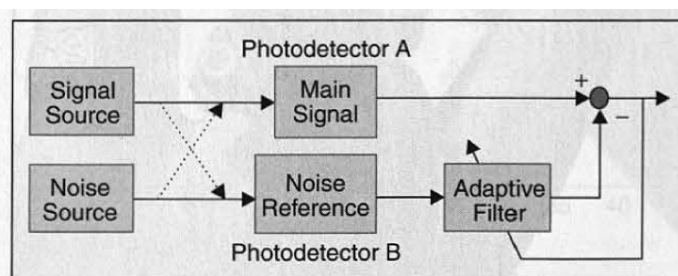
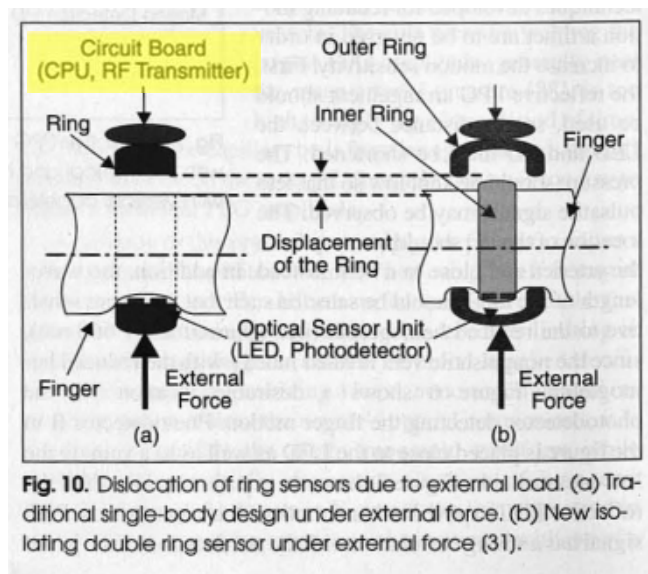


Fig. 8. Block diagram of adaptive noise cancellation using second PPG sensor as noise reference.

(Asada (Ex-1005), Fig. 8)

67. Asada also mentions that the system works with data acquired from other components such as optical sensor, electrochemical sensors, etc. Asada at 29. With the knowledge of POSITA at the time, it would be obvious for Asada to be modified to acquire physiological signals from various sensors providing physiological signal to the WBS system. For example, optical sensors, PPG, EKG are typical sensors which have existed for a long time, and they are typical sensors for patient monitoring. Since WBS is integrated with other platforms, it is obvious to supplement WBS with other conventional sensors, all of which achieve the purposes of monitoring the patient. Asada at 29 (WBS is “a platform upon which a new paradigm of enhanced healthcare can be established.”).

68. The WBS also has hardware such as processor, memory and executes code, which meets elements of “at least one processor; and at least one computer usable medium, the computer usable medium having computer readable code embodied therein, the computer readable code causing the at least one processor to” perform the recited functions in Claim 21. Asada at 28 (“WBS hardware solution must be adequate to make reliable physiological measurements during activities of daily living...”); 34 (“The ring has a PIC microcomputer performing all the device controls and low-level signal processing, including LED modulation, data acquisition, filtering, and bi-directional RF communication”); Figure 10 (emphasis added).



(Asada (Ex-1005), Fig. 10)

69. Asada’s data can also be sent to devices such as PDA and cellphone for further analysis. Asada at 34. These devices are understood as handheld devices. They have memory, processor and can execute code.

70. Thus, it would be obvious to provide the signals from these sensors to WBS for patient monitoring.

71. Chon-570 discloses using piezoelectric or ECG signals. Chon-570 at 4:2-3. It would be obvious to provide the signals to the WBS or handheld device described in Asada for processing. Furthermore, it would be obvious to use statistical analyses disclosed in Chon-570 in the system described in Asada since Chon-570’s algorithms are designed to run on a general-purpose computer.

72. Claim 37 similarly recites “the physiological indicator signal being obtained from one of an image acquisition component, a photoplethysmographic (PPG) sensor and an electrocardiogram sensor.” Thus, Asada and Chon-570 teach this element of Claim 37 for the same reasons mentioned above.

**3. “analyze ...” / “analyzing ...”**

<p>1[ii]. analyzing, using the handheld mobile communication device, the physiological indicator signal;</p>	<p>21[iv]. analyze the physiological indicator signal;</p>	<p>37[i]. analyze a physiological indicator signal; the physiological indicator signal being obtained from one of an image acquisition component, a photoplethysmographic (PPG) sensor and an electrocardiogram sensor;</p>
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73. Asada discloses this element. For example, the WBS system performs analyses such as signal processing and filtering. Asada at 34 (“The ring has a PIC microcomputer performing all the device controls and low-level signal processing, including LED modulation, data acquisition, filtering, and bi-directional RF communication”). WBS in Asada receives the PPG signals, and analyzes them to monitor a patient’s cardiovascular data. Asada at 28, 30, 35 (monitor “a patient’s heart rate, oxygen saturation, and heart rate variability.”). WBS also works with a PDA and Cellphone which performs clinical diagnosis. Asada at 34.

74. Asada describes techniques for reducing motion artifacts, which involves analyzing the physiological signal. Asada at 28 (“Technical issues, including motion artifact ... will be addressed”). Chon-570 also describes analyzing physiological signals such as piezoelectric or ECG signals for processing. Chon-570 at 4:1-4.

75. Additionally, for Claim 37, Asada with Chon-570 discloses the element “the physiological indicator signal being obtained from one of an image acquisition component, a photoplethysmographic (PPG) sensor and an electrocardiogram sensor” for reasons discussed in the subsection 2 above.

**4. “obtain ...” / “obtaining ...”**

1[iii]. obtaining, from said analyzing, measurements of one or more physiological parameters; and	21[v]. obtain, from results of analyzing, measurements of one or more physiological parameters; and	37[ii]. obtain, from said analyzing, measurements of one or more physiological parameters; and
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76. I incorporate my analysis from subsection 3 above. As discussed above, Asada analyzes PPG signals, and obtains measurements of physiological parameters, such as those related to a patient’s heart rate, oxygen saturation, and heart rate variability. Asada at 28, 30, 35 (monitor “a patient’s heart rate, oxygen saturation, and heart rate variability.”).

77. Chon-570 also describes obtaining measurements from analyzing physiological parameters, such as obtaining various measurements from ECG data (e.g., RR intervals, heart rate variability, etc.). Chon-570 at 3:23-31; 4:6-18. A POSITA would understand that the analysis of the patient’s physiological data, such as those from PPG and ECG would result in measurements of the physiological parameters.

**5. “detect ...” / “detecting ...”**

1[iv]. detecting, using the handheld mobile communication device and using only the measurements of one or more physiological parameters, effects of	21[vi]. detect effects of motion artifacts in the measurements of the one or more physiological parameters;	37[iii]. detect, using only the measurements of one or more physiological parameters, effects of motion artifacts in the measurements of the one
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motion artifacts in the measurements of the one or more physiological parameters and deciding whether to retain the measurements based on detected effects of motion artifacts;		or more physiological parameters;
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78. Asada discloses detecting and reducing motion artifacts using the signals from the PPG sensors. Asada at 28 (“Technical issues, including motion artifact, ... will be addressed”), 30 (the header states “Techniques for Reduced Motion Artifact”), 34 (“The dual photodetector design shown in Figure 6 provides both main signal and noise reference that are distinct. This allows us to implement noise-canceling filters effectively despite complex motion artifact.”). Furthermore, Asada with Chon-570 teaches detecting effects of motion artifacts using only the measurements of the one or more physiological parameters. The prior art does not require another parameter to detect motion artifacts, and thus, Asada with Chon-570 teaches the situation where only the measurements of the one or more physiological parameters are used to detect motion artifacts.

79. Asada also teaches eliminating artifacts which includes performing the element of “deciding whether to retain the measurements based on detected effects of motion artifacts.” *See* Asada at 30 (“the development of the ring sensor has stressed first an understanding of and then the subsequent elimination of front-

end signal artifacts.”). A POSITA would understand that the elimination of unwanted motion artifacts would render it obvious to reach a decision on retaining the non-eliminated measurements.

**6. “wherein ...”**

1[v]. wherein detecting effects of motion artifacts in the measurements comprises:	21[vii]. Wherein the computer readable code, in causing the at least one processor to detect effects of motion artifacts, causes the at least one processor to:	37[iii]. Wherein the computer readable code, in causing the at least one processor to detect effects of motion artifacts, causes the at least one processor to:
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80. I incorporate my analysis from subsections 7-10 below. As discussed below, the prior art teaches detecting motion artifacts using the claim recited methods.

**7. “bandpass filter/[ing] and detrend[ing]”**

81. Independent Claims 1, 21, and 37 all recite “bandpass filter/[ing] and detrend/[ing] a segment from the measurement of one physiological parameter; wherein a bandpass filtered and detrended segment is hereinafter referred to as a preprocessed segment.”

82. Bandpass filter is a common technique in signal processing. Detrending which is defined in the '428 Patent as “the process of finding a best polynomial fit to a time series and subtracting the best polynomial fit from the time series”. '428 Patent, 3:46-48. Detrending is a commonly known technique for data

analysis as acknowledged by the art at the time. Hyde at [0037] (“Detrending and covariance techniques are both known method of data analysis.”)

83. Asada acknowledges that a bandpass filter can be used to eliminate large segments of DC signal. Asada at 30. Asada also mentions that “[t]here are other techniques for reducing motion artifact for general-purpose PPG.” Asada at 30. In the context of filtering PPG data, Asada teaches the use of “adaptive filtering and “noise cancellation filters” along with its dual photodetector design, as well as “adaptive noise cancelling methods ... to recover the true pulsation signal from corrupted waveforms.”. Asada at 33, 34 (“The dual photodetector design shown in Figure 6 provides both main signal and noise reference that are distinct. This allows us to implement noise-canceling filters effectively despite complex motion artifact.”).

84. Furthermore, Bandpass filter and detrending are common techniques to reduce noise in signal processing. It would be obvious to apply commonly known techniques of noise reduction to physiological signals to pre-process the signal to allow for more accurate analyses. Hyde at [0054]-[0056]; Porges at 5:10-28. (describing a procedure which “provides an accurate evaluation of the amplitude of a rhythmic oscillation on a frequency band when the rhythmic oscillation is superimposed on an aperiodic response pattern”, where the procedure “involves the removal of the effect of baseline drift by detrending the baseline

activity with a "moving polynomial filter" (MPF).”). A POSITA would have understood that, in order to perform accurate calculations and analyze data in a meaningful way, it is often necessary to eliminate outliers and noise. Bandpass filtering and detrending are two very well-known techniques for accomplishing those goals. The use of signal pre-processing techniques, such as bandpass filtering and detrending, to detect noise and motion artifacts in physiological signals was routine and conventional. It would be obvious to incorporate or substitute the adaptive filters and noise cancelling filters in Asada with bandpass filters and detrending to achieve the same result, i.e., to preprocess the data.

**8. “obtain/[ing] a value of at least one indicator of volatility ...”**

85. Independent Claims 1, 21, and 37 all recite “obtain/[ing] a value of at least one indicator of volatility, used in determining whether motion artifacts are present, for the preprocessed segment; the at least one indicator of volatility being at least Shannon entropy (SE) for the preprocessed segment; where

$$SE = -\sum_{i=1}^k \frac{p(i) * \log(p(i))}{\log\left(\frac{1}{k}\right)}$$

and where i represents the bin number, and p(i) is the probability distribution of the preprocessed segment.”

86. As discussed in subsection 5, Asada is directed to detecting and reducing motion artifacts in physiological signals. *See, e.g.*, Asada at 28, 30. It is

obvious to a person of ordinary skill in the art to combine Asada with other known methods to detect motion artifacts, such as Shannon Entropy.

87. While Chon-570 does not explicitly apply this Shannon Entropy formula to detecting motion artifacts, but it would be obvious to do so in light of the art at the time. Shannon Entropy essentially measures the probability that a segment contains an outlier (e.g., a noise or a motion artifact).

88. The particular formula for Shannon entropy in the claim was already known in the art. For example, Chon-570 already discloses this formula as follows.

The SE is then calculated utilizing Equation (4):

$$SE = - \sum_{i=1}^{16} p(i) \frac{\log(p(i))}{\log(\frac{1}{16})} \dots\dots\dots(4)$$

Chon-570 at 7:20.

89. A POSITA at the time already knew that Shannon entropy is applied to detect motion artifacts. *See* Delorme generally (which uses Kurtosis and Shannon entropy for automatic artifact rejection); Greco at abstract (“A technique for the automatic artifact rejection, based on the Independent Component Analysis (ICA) for the artifact extraction and on some high order statistics such as kurtosis and Shannon’s entropy, was proposed some years ago in literature.”). Thus, it would be obvious to a POSITA to use the Shannon entropy formula in Chon-570 to probabilistically detect outlier (i.e. motion artifacts) in light of the teachings in the

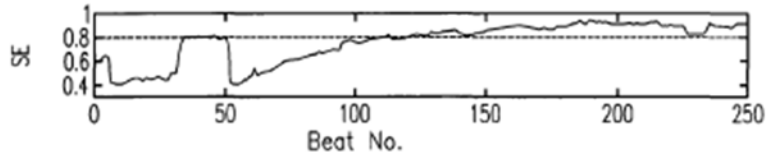
art. This process merely involves applying a known formula in a known way to achieve a predictable result.

**9. “includ[e]/[ing] the segment ... when comparison ... with a predetermined threshold indicates noise/motion artifacts are not present; and”**

90. Independent Claims 1, 21, 37 all recite “include / [including] the segment in analyses of physiological measurements, when comparison of the value of the at least one indicator of volatility with a predetermined threshold indicates noise/motion artifacts are not present; and”.

91. Asada discloses this element. As discussed in subsection 5 above, Asada determines whether to retain a segment, such as when the segment does not have noise or motion artifacts. *See* Asada at 30 (“the development of the ring sensor has stressed first an understanding of and then the subsequent elimination of front-end signal artifacts.”). This teaching in Asada coupled with Chon-570’s teaching on Shannon Entropy thresholding, would therefore disclose the step of including a signal segment if a comparison of a volatility indicator value to a threshold indicates that the signal segment does not have motion artifacts.

92. Chon-570 discloses applying thresholds with Shannon Entropy. Figure 1(d) in Chon-570 demonstrates an example Shannon Entropy threshold. Chon-570 at 9:14-18.



*FIG. 1(d)*

Chon-570 at FIG. 1(d).

93. A person skilled in the art would recognize that comparing the results of a statistical analysis with a threshold is nothing new. It would be obvious to a POSITA to predetermine a threshold linked to detection of motion artifacts, and compare that threshold with the result of Shannon entropy analysis.

**10. “select/[ing] another segment ... when the value of the at least one indicator of volatility is less than a predetermined threshold and when another segment is available.”**

94. Independent Claims 1, 21, 37 all recite “select/[ing] another segment of the signal from the physiological measurement and proceeding to step (a) when the value of the at least one indicator of volatility is less than a predetermined threshold and another segment is available.”

95. I incorporate my analysis from subsection 9. As discussed above, Asada determines whether to retain a segment, such as when the segment does not have noise or motion artifacts. *See* Asada at 30 (“the development of the ring sensor has stressed first an understanding of and then the subsequent elimination of front-end signal artifacts.”).

96. Chon-570 discloses applying thresholds with Shannon entropy. Figure 1(d) in Chon-570 demonstrates an example threshold for Shannon Entropy. Chon-570 at 9:14-18.

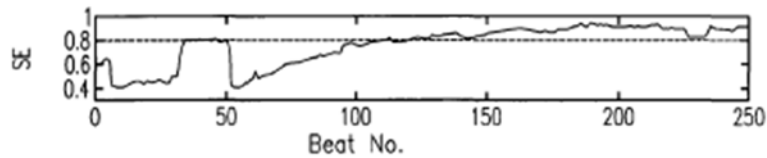


FIG. 1(d)

Chon-570 at FIG. 1(d).

97. Both Asada and Chon-570 disclose continuously monitoring of patient, which involves multiple segments of signals. It is commonly known to a POSITA to compare a result of a statistical analysis with a threshold and to determine what to do with the data. A POSITA recognizes that artifacts distort the analysis of the signals. *See Greco at Abstract* (“Artifact rejection is a key topic in signal processing. The artifacts are unwelcome signals that may occur during the signal acquisition and that may alter the analysis of the signals themselves.”). Thus, if the artifact is present in one segment, a POSITA would be motivated to apply the statistical analysis on another segment, if the other segment is available.

**B. Dependent Claims**

**1. Claims 3, 23**

<p>3. The method of claim 1 wherein the predetermined threshold is determined using receiver operator characteristic (ROC) analysis.</p>	<p>23. The system of claim 21 wherein the predetermined threshold is determined using receiver operator characteristic (ROC) analysis.</p>
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98. Asada and Chon-570 render this element obvious. As discussed in Claim 1, Asada and Chon-570 both disclose comparing the result of SE analysis with a predetermined threshold. Chon-570 discloses determining thresholds for root mean square of successive RR differences (RMSSD), Shannon entropy (SE), and Turning Points Ratio (TPR) using receiver operator characteristic (ROC) curves. Chon-570 at 10:11-17. For example, Figure 1(d) of Chon-570 discloses a chart with Shannon entropy values, where the dotted line represents a “threshold value[] as determined by the ROC.” Chon-570 at 10:14-16.

**2. Claims 4, 24, 25**

<p>4. The method of claim 1 wherein providing a physiological indicator signal comprises:</p> <p>placing a portion of a subject's body over an objective lens of a camera in a handheld mobile communication device; and</p> <p>obtaining video images of the portion of the subject's body.</p>	<p>24. The system of claim 21 wherein the physiological indicator signal sensing component comprises an image acquisition component, said acquisition component capable of acquiring a number of frames, each frame acquired at a predetermined time.</p> <p>25. The system of claim 24 wherein the handheld mobile communications device comprises said image acquisition component.</p>
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99. Asada discloses that “there are numerous WBS modalities that can offer physiological measurements” and an example of which is optical sensors. Asada at 29. Asada also discloses that the WBS works with handheld devices such as PDAs, cellphones. Asada at 34.

100. It would be obvious to a POSITA substitute the optical sensors mentioned in Asada’s with camera in a handheld communication device. This substitution uses known elements, where camera on a handheld device is a type of optical sensor. *See* Ex-1004 (0736), 2016-12-22 Affidavit under Rule 132 (patentee stated that “the image acquisition component in a camera is a sensor.”). The substitution achieves the same results.

101. Claim 24 included the phrase “acquisition component capable of acquiring a number of frames, each frame acquired at a predetermined time” which does not change my opinion because a camera or optical sensors are capable of acquiring videos which are frames acquired at predetermined time.

**3. Claims 5, 26**

<p>5. The method of claim 1 wherein providing a physiological indicator signal comprises obtaining a signal from a physiological monitoring sensor.</p>	<p>26. The system of claim 21 wherein the physiological indicator signal sensing component comprises a physiological monitoring sensor.</p>
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102. Asada and Chon-570 both disclose this element. For example, Asada obtains a signal from a physiological sensor such as PPG. Asada at 28 (“This WBS combines miniaturized data acquisition features with advanced photoplethysmography (PPG) techniques to acquire data related to the patient’s cardiovascular state ...”), 31 (describing two sets of PPG sensors attached to the same finger). Chon-570 obtains data from piezoelectric or ECG signals. Chon-570 at 4:1-4, 11:20-22, Fig. 4.

**4. Claims 6, 27**

6. The method of claim 5 wherein the physiological monitoring sensor is a photoplethysmographic (PPG) sensor or an electrocardiogram sensor.	27. The system of claim 26 wherein the physiological monitoring sensor is a photoplethysmographic (PPG) sensor or an electrocardiogram sensor.
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103. I incorporate my analysis from claims 5 and 26 above. As discussed above, Asada teaches using PPG sensors to monitor a patient. Asada at 23, 31. Chon-570 also discloses this element where it obtains data from ECG sensors. Chon-570, 4:1-4, 11:20-22, Fig. 4.

**5. Claims 7, 29[i], 39[i]**

7. The method of claim 1 wherein the one or more physiological measurements comprise heart rate and heart rate variability.	29[i]. The system of claim 21 wherein the one or more physiological measurements comprise heart rate and heart rate variability;	39[i]. The computer usable medium of claim 37 wherein the one or more physiological measurements comprise heart rate and heart rate variability;
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104. Asada discloses this element.

105. For example, Asada discloses that the “sensor is capable of reliably monitoring a patient's heart rate, oxygen saturation, and heart rate variability.” Asada at 28, 35 (“[t]hese modifications greatly improved the ability of the device to measure traditionally difficult variables such as heart rate variability.”).

**6. Claims 8, 29[ii]-[v], 39[ii]-[v]**

<p>8[i]. The method of claim 7 wherein obtaining measurements of heart rate and heart rate variability comprise:</p> <p>8[ii]. determining beats for the physiological indicator signal;</p> <p>8[iii]. determining beat to beat intervals; and</p> <p>8[iv]. applying a cubic spline algorithm to obtain a substantially continuous beat to beat interval signal indicative of heart rate.</p>	<p>29[ii] and wherein the computer readable code, in causing the at least one processor to analyze the physiological indicator signal, causes the at least one processor to:</p> <p>29[iii]. determine beats for the physiological indicator signal;</p> <p>29[iv]. determine beat to beat intervals; and</p> <p>29[v]. apply a cubic spline algorithm to obtain a substantially continuous beat to beat interval signal indicative of heart rate.</p>	<p>39[ii]. and wherein the computer readable code, in causing the at least one processor to analyze the physiological indicator signal, causes the at least one processor to:</p> <p>39[iii]. determine beats for the physiological indicator signal;</p> <p>39[iv]. determine beat to beat intervals; and</p> <p>39[v]. apply a cubic spline algorithm to obtain a substantially continuous beat to beat interval signal indicative of heart rate.</p>
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106. Chon-570 detects the presence of AF using “piezoelectric or ECG signals” which involves determining beats from the signals. Chon-570 at 4:1-7. Chon-570 determines beat to beat intervals as it “select[s] a beat segment of RR intervals centered on that beat for each analyzed heart beat.” Chon-570 at 4:7-8.

107. It would be obvious to a POSITA to apply a cubic spline algorithm or any other interpolation or smoothing measures known in the art to obtain a substantially continuous beat to beat interval signal indicative of heart rate. As discussed above, detrending is a common technique applied to prefilter data, and cubic spline algorithm was well-known in the art to remove undesired low

frequency noise. Hyde at [0063] (“the data are detrended with a numeric analytical technique known as cubic spline approximation. The cubic spline parameters are selected to remove the undesired low frequency noise.”). Thus, it would be obvious to apply a known algorithm to a typical data processing (i.e. detrending), to obtain useable data for subsequent analyses.

#### **7. Claim 11**

108. Claim 11 recites: “The method of claim 1 wherein the one or more physiological measurements comprise a measure of oxygen saturation.” Asada in discloses this element.

109. For example, Asada states that “WBS solutions, in various stages of technologic maturity, exist for measuring established cardiopulmonary ‘vital signs’: ... arterial oxygen saturation. Asada at 29.

#### **8. Claim 15**

110. Claim 15 recites: “The method of claim 1 wherein the one or more physiological measurements comprise a measure of atrial fibrillation.” Asada describes that WBS can monitor patients living alone and to detect arrhythmias. Asada at 37 (with automated defibrillators for home, “the general public will be increasingly able to respond to victims of life-threatening arrhythmias when such catastrophes are detected.”).

111. Chon-570 specifically describes detecting AF using Shannon Entropy. Chon-570 at 4:5-18 (“it is again identified as an AF candidate, a third identification of the beat segment is performed by calculating a Shannon Entropy (SE) of the segment and determining whether the SE is greater than an SE threshold.”).

**C. Dependent Claims 9-10, 30, 40**

<p>9. The method of claim 1 wherein the one or more physiological measurements comprise respiratory rate.”</p>	<p>30. The system of claim 21 wherein the one or more physiological measurements comprise respiratory rate; and</p>	<p>40. The computer usable medium of claim 37 wherein the one or more physiological measurements comprise respiratory rate; and</p>
<p>10. The method of claim 9 wherein measurement of respiratory rate comprises:</p> <p>obtaining time-frequency spectrum of the physiological indicator signal utilizing variable frequency complex demodulation (VFCDM); and</p> <p>obtaining respiratory rates by extracting a frequency component that has a largest amplitude for each time point at a heart rate frequency band.</p>	<p>wherein the computer readable code, in causing the at least one processor to analyze the physiological indicator signal, causes the at least one processor to:</p> <p>obtain time-frequency spectrum of the physiological indicator signal utilizing variable frequency complex demodulation (VFCDM); and</p> <p>obtain respiratory rates by extracting a frequency component that has a largest amplitude for each time point at a heart rate frequency band.</p>	<p>wherein the computer readable code, in causing the at least one processor to analyze the physiological indicator signal, causes the at least one processor to:</p> <p>obtain time-frequency spectrum of the physiological indicator signal utilizing variable frequency complex demodulation (VFCDM); and</p> <p>obtain respiratory rates by extracting a frequency component that has a largest amplitude for each time point at a heart rate frequency band.</p>

112. Asada discloses “wherein the one or more physiological measurements comprise respiratory rate.” For example, Asada states that “WBS solutions, in various stages of technologic maturity, exist for measuring established cardiopulmonary ‘vital signs’: ... respiratory rate”. Asada at 29.

113. The ’428 Patent admitted that VFCDM analysis claimed has already been disclosed in the prior art, such as Chon-2009. ’428 Patent at 7:36-8:35 (“The development of the VFCDM algorithm has been previously disclosed in” Chon-2009...). The ’428 Patent further summarizes the VFCDM method as follows:

Thus, the VFCDM method involves a two-step procedure. At first, the fixed frequency complex demodulation technique identifies the signal's dominant frequencies, shifts each dominant frequency to a center frequency, and applies a low-pass filter (LPF) to each of the center frequencies. The LPF has a cutoff frequency less than that of the original center frequency and is applied to each dominant frequency. This generates a series of band-limited signals. The instantaneous amplitude, phase and frequency information are obtained for each band-limited signal using the Hilbert transform and are combined to generate a time-frequency series (TFS). Finally, the second step of the VFCDM method is to select only the dominant frequencies and produce a high-resolution TFS.

’428 Patent at 8:21-35. A similar description of the VFCDM method is also in Chon-2009. Chon-2009 at 2055.

114. Chon-2009 describes that “[t]he VFCDM method has been published and tested with different physiological signals”. Chon-2009 at 2055. It then went on summarizing using VFCDMs for estimating TFS. Chon-2009 at 2055-2056

(Section A). It also described using VFCDM to extract respiratory rate where “[o]nce the TSF is obtained via the VFCDM method as described before, respiratory rates are determined by extracting the frequency component that has the largest amplitude for each time point at the heart rate frequency band.” Chon-2009 at 2056-2057 (Section B). Thus, a POSITA at the time would have been motivated to use an existing method, i.e., VFCDM, and combine it with Asada’s teaching of measuring respiratory rate, so that respiratory rate in Asada is extracted using the VFCDM approach.

## **VII. GROUND 2 – CLAIMS 1-11, 15, 21-27, 29-30, 37, 39-40 ARE OBVIOUS OVER ASADA, CHON-570, AND DELORME**

115. A POSITA would be motivated to combine Asada (Ex-1005), Chon-570 (Ex-1006), and Delorme (Ex-1007). I incorporate my analysis on why a POSITA is motivated to combine Asada and Chon-570 from Ground 1 above. A POSITA is also motivated to combine Asada with Delorme because both references are to improve processing of physiological data and reduce or eliminate the effect of motion artifacts. Asada explicitly contemplates such a combination in that Asada states that the “WBS, in conjunction with appropriate alarm algorithms, can increase surveillance capabilities ...” Asada at 28. Here, Delorme’s algorithm can be combined with Asada so that it runs on Asada’s system to improve detection. Accordingly, combining Delorme’s algorithm with Asada’s platform is simply to

combine known elements in the prior art to improve the detection of patient's conditions and motion artifacts.

116. A POSITA would also be motivated to improve Delorme with Chon-570. Delorme discloses that Shannon Entropy can be used to detect motion artifacts. Both formulae already known in the art at the time of the '428 Patent, and they both detect irregularities in signals. Thus, in search to improve Delorme's Shannon Entropy formula, a POSITA would be motivated to search for another formula that also calculates the Shannon Entropy. Thus, it would involve minimal efforts for a POSITA to implement Chon-570's formula in the context of detecting motion artifacts learned from Delorme.

**A. Independent Claims 1, 21, 37**

**1. Preamble**

1. A method for physiological parameter monitoring, the method comprising:	21. A system for physiological parameter monitoring, the system comprising:	37. A non-transitory computer usable medium having computer readable code embodied therein, the computer readable code causing at least one processor to:
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117. I incorporate my analysis from Ground 1 above.

118. In addition, Delorme is part of a system or method that monitors physiological parameters and reject motion artifacts. Delmore Section 4 ("We believe that one may detect artifacts more accurately using high-order statistical measures of the signals, regardless of the exact implementation of these measures.

This approach allows experimenters to use information in the data that was taken into account by standard rejection methods.”). Delorme is designed to run with computer executable code which is executed on a processor. *See* Delorme at § 4 (mentioning a software the authors developed for performing the analysis in Delorme).

**2. “providing a physiological indicator signal ...” / “a physiological indicator signal sensing component ...”**

<p>1[i]. providing a physiological indicator signal to a handheld mobile communication device; the physiological indicator signal being obtained from one of an image acquisition component, a photoplethysmographic (PPG) sensor and an electrocardiogram sensor;</p>	<p>21[i] a physiological indicator signal sensing component; the physiological indicator signal sensing component being one of an image acquisition component, a photoplethysmographic (PPG) sensor and an electrocardiogram sensor; and a handheld mobile communication device comprising:          [ii] at least one processor; and          [iii] at least one computer usable medium, the computer usable medium having computer readable code embodied therein, the computer readable code causing the at least one processor to:</p>
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119. I incorporate my analysis from Ground 1 above.

120. Furthermore, it would be obvious to use statistical analyses disclosed in Delorme in the system described in Asada since Delorme’s algorithms are designed to run on a general-purpose computer. *See* Delorme at Section 4 (describing the software Delorme developed).

**3. “analyze ...” / “analyzing ...”**

1[ii]. analyzing, using the handheld mobile communication device, the physiological indicator signal;	21[iv]. analyze the physiological indicator signal;	37[i]. analyze a physiological indicator signal; the physiological indicator signal being obtained from one of an image acquisition component, a photoplethysmographic (PPG) sensor and an electrocardiogram sensor;
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121. I incorporate my analysis from Ground 1 above.

122. Delorme also describes analyzing physiological signals such as detecting motion artifacts in the EEG data. Delorme at Abstract.

**4. “obtain ...” / “obtaining ...”**

1[iii]. obtaining, from said analyzing, measurements of one or more physiological parameters; and	21[v]. obtain, from results of analyzing, measurements of one or more physiological parameters; and	37[ii]. obtain, from said analyzing, measurements of one or more physiological parameters; and
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123. I incorporate my analysis from Ground 1 above.

124. Delorme also describes obtaining measurements from analyzing physiological parameters, such as obtaining measurements from EEG data. Delorme at Abstract and Section 1.

**5. “detect ...” / “detecting ...”**

1[iv]. detecting, using the handheld mobile communication device and using only the measurements of one or	21[vi]. detect effects of motion artifacts in the measurements of the one or more physiological parameters;	37[iii]. detect, using only the measurements of one or more physiological parameters, effects of motion artifacts in the
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more physiological parameters, effects of motion artifacts in the measurements of the one or more physiological parameters and deciding whether to retain the measurements based on detected effects of motion artifacts;		measurements of the one or more physiological parameters;
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125. Asada and Chon-570 disclose this element for the same reasons as Ground 1 above. Delorme also discloses detecting motion artifacts. *See* Delorme at Abstract (“isolating both artifacts and cognitive related activations in EEG data.”); Section 2 (“Isolating artifacts thus involves detecting such events.”). It decides whether to retain measurements based on detected motion artifacts by analyzing the EEG signals with high order statistics. Delorme at title (“Automatic Artifact Rejection for EEG Data using High-Order Statistics and Independent Component Analysis”), Section 2 (using rejection thresholds to determine whether to reject a measurement due to motion artifacts). Delorme’s technique decides not to retain the measurements if the effects of motion artifacts are too significant.

**6. “wherein ...”**

1[v]. wherein detecting effects of motion artifacts in the measurements comprises:	21[vii]. Wherein the computer readable code, in causing the at least one processor to detect effects of motion	37[iii]. Wherein the computer readable code, in causing the at least one processor to detect effects of motion
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	artifacts, causes the at least one processor to:	artifacts, causes the at least one processor to:
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126. I incorporate my analysis from subsections 7-10 below. As discussed below, the prior art teaches detecting motion artifacts using the claim recited methods. Both Asada and Delorme are directed to detecting motion artifacts. See, e.g., Asada, 28, 30 (“Techniques for Reduced Motion Artifact”), 33 (“Questionable data can be rejected if the wearable sensor has a means to monitor the hand motion and other sources of disturbances.”); Delorme, Abstract. While Asada did not specify a statistical algorithm on detecting motion artifacts, a POSITA would be motivated to apply existing algorithms in view of Asada, such as Shannon Entropy and Kurtosis. Indeed, as Delorme observed, “[h]igher order statistical properties of the EEG signals might contain more relevant information about [muscle activity] and other types of artifacts.” Delorme, §1. Thus, recognizing higher order statistics is more relevant to isolate and identify motion artifacts, a POSITA would be motivated to use the high order statistical methods, such as Kurtosis or Shannon Entropy to improve Asada’s detection of motion artifacts. A POSITA would also be motivated to improve the Shannon Entropy in Delorme, in light of Greco’s finding that Delorme’s Shannon Entropy technique did not identify all motion artifacts. Greco, 241 (Delorme’s method “showed some failures of the procedure in detecting some artifactual signals, thus we wonder whether any entropy

definition would improve the performance of the method.”). While the Shannon Entropy method in Chon-570 was not available at the time Greco, at the time of the '428 Patent's invention, a POSITA in search for optimizing Shannon Entropy calculations would be motivated to use Chon-570's approach, since as it provides a more rigorous entropy calculation that is specifically suited for detecting irregularities in the physiological data.

**7. “bandpass filter/[ing] and detrend[ing]...”**

127. I incorporate my analysis from Ground 1 above.

128. A person of ordinary skill in the art would recognize that motion artifact is considered “noise” in the signal. *See* Delorme at Section 2 (“Most artifacts are typically ‘odd’ data in the sense that they are transient and unexpected events.”). As bandpass filter and detrending are common techniques for to filter noise, it would be obvious to a POSITA to use these commonly known techniques to achieve the same result.

**8. “obtain/[ing] a value of at least one indicator of volatility ...”**

129. I incorporate my analysis from Ground 1 above.

130. Delorme, for example, teaches using high order statistics including Kurtosis and Shannon Entropy for automatic artifacts rejection. *See* Delorme at Section 2 (“Isolating artifacts thus involves detecting such events. To do so, we chose two measures: probability distribution and kurtosis”), Section 3.3 (“We used

three high-order statistical measures for each component: the entropy of the activity of the component (over all trials), kurtosis of the activity, and the kurtosis of the components' spatial map.”); *see also* Greco at 241 (in discussing Delmore, states that Delmore “proposed the joint use of kurtosis and entropy, in particular the Shannon entropy, for the detection of the artifactual signals, once they have been isolated by means of ICA.”).

131. In Delorme, the entropy is measured using the following formula:

$$H(i) = - \sum_{x \in D_i} p_{D_i}(x) \log(p_{D_i}(x)) \quad (5)$$

where  $p_{D_i}(x)$  is the probability of observing the activity values  $x$  in the observed probability distribution of activity  $D_i$  from component  $i$ . Delorme at Section 3.3, *id.* (“this measure should be able to detect these outlier components” ... “If the component contains a homogenous distribution of high frequencies, it is likely to be an artifact component...”).

132. A POSITA would be motivated to improve the Shannon Entropy formula in Delorme with the Shannon Entropy formula taught in Chon-570. A POSITA would find it obvious to use the SE formula found in Chon-570 to improve the detection of motion artifacts because both methods use entropy to quantify signal irregularities (Delorme for EEG artifact detection, Chon-570 for atrial fibrillation in ECG data), i.e., measuring the unpredictability of a probability

distribution. Since both references teaches Shannon Entropy, a POSITA would recognize that improving Delorme’s formula with Chon-570’s formula requires minimal efforts which improved the interpretation of signal irregularity without changing the underlying mathematical concept.

133. Furthermore, it would be obvious to try to improve a known formula with another formula directed to calculating the same type of information to yield to a better result for determining motion artifacts.

**9. “includ[e]/[ing] the segment ... when comparison ... with a predetermined threshold indicates noise/motion artifacts are not present; and”**

134. I incorporate my analysis from Ground 1 above.

135. Delorme teaches rejection thresholds for Shannon Entropy and Kurtosis. Delorme, §2, §3.3 (“one can also set a rejection threshold for relevant higher order statistics”). Delorme “define[s] thresholds in terms of a number of standard deviations from the mean” (show in the figure below) after normalizing the entropy and kurtosis “to 0-mean and standard deviation 1.” Delorme, §2; Figure 1 (demonstrating rejection thresholds and segments marked for rejection). Based on the comparison of Shannon Entropy to the rejection threshold, Delorme determines whether to keep a segment. A POSITA would understand that the non-rejected segments are considered “clean” and should be included in the analyses of physiological measurements.

**10. “select/[ing] another segment ... when the value of the at least one indicator of volatility is less than a predetermined threshold and when another segment is available.”**

136. I incorporate my analysis from Ground 1 above.

137. As discussed above, Delorme discloses a rejection threshold for detecting motion artifacts. Delorme at Section 3.3 (“it is possible to reject artifact trials from component activity” ... “We will then be able to automatically detect and reject such components by setting an adequate rejection threshold.”). A POSITA would recognize that modifying the rejection threshold to function as “acceptance” threshold would involve minimal efforts, where a smaller number indicates signal corruption and a bigger number indicates a clean signal. This modification would be a simple logical inversion of the same rejection principle that leads to the same result. *Id.* It would further be obvious to a POSITA that if motion artifacts are present in one segment, the system would proceed to another component to determine if that component is clean or not.

**B. Dependent Claims**

**1. Claims 2, 22**

2. The method of claim 1 wherein said at least one indicator of volatility also comprises kurtosis.	22. The system of claim 21 wherein said at least one indicator of volatility also comprises kurtosis.
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138. I incorporate my analysis from Ground 1 above.

139. Asada in combination with Chon-570 and Delorme disclose these elements. For example, Delorme teaches using kurtosis to analyze signals. Delorme at Section 2 (use “probability distribution and kurtosis” for artifact rejection and “In some artifact trials, the distribution of activation is very peaky ... [t]o measure this peakyness, we used the kurtosis of the activity values in each trial).

**2. Claims 3, 23**

3. The method of claim 1 wherein the predetermined threshold is determined using receiver operator characteristic (ROC) analysis.	23. The system of claim 21 wherein the predetermined threshold is determined using receiver operator characteristic (ROC) analysis.
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140. Asada, Delorme, and Chon-570 render this element obvious. As discussed in claim 1, Asada and Delorme both disclose comparing the result of SE analysis with a predetermined threshold. Chon-570 discloses determining thresholds for root mean square of successive RR differences (RMSSD), Shannon entropy (SE), and Turning Points Ratio (TPR) using receiver operator characteristic (ROC) curves. Chon-570 at 10:11-17. For example, Figure 1(d) of Chon-570 discloses a chart with Shannon entropy values, where the dotted line represents a “threshold value[] as determined by the ROC.” Chon-570 at 10:14-16.

**3. Claims 4, 24, 25**

4. The method of claim 1 wherein providing a physiological indicator signal comprises:	24. The system of claim 21 wherein the physiological indicator signal sensing component comprises an image
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<p>placing a portion of a subject's body over an objective lens of a camera in a handheld mobile communication device; and</p> <p>obtaining video images of the portion of the subject's body.</p>	<p>acquisition component, said acquisition component capable of acquiring a number of frames, each frame acquired at a predetermined time.</p> <p>25. The system of claim 24 wherein the handheld mobile communications device comprises said image acquisition component.</p>
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141. I incorporate my analysis of Asada from Ground 1 above.

**4. Claims 5, 26**

<p>5. The method of claim 1 wherein providing a physiological indicator signal comprises obtaining a signal from a physiological monitoring sensor.</p>	<p>26. The system of claim 21 wherein the physiological indicator signal sensing component comprises a physiological monitoring sensor.</p>
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142. I incorporate my analysis from Ground 1 above.

143. Delorme also discloses this element. For example, Delorme teaches obtaining EEG data which is obtained from a physiological monitoring sensor. Delorme at Section 1 (discussing recording brain activities with electrodes).

**5. Claims 6-8, 27, 29, 39**

144. I incorporate my analysis from Ground 1 above.

**6. Claims 9-10, 30, 40**

145. I incorporate my analysis from from Ground 1 above.

**7. Claim 11**

146. I incorporate my analysis from Ground 1 above.

## 8. Claim 15

147. I incorporate my analysis from Ground 1 above.

### **VIII. GROUND 3 - CLAIMS 16-20, 32-36, 42-46 ARE OBVIOUS IN VIEW OF ASADA, CHON-570, AND CHON-2008**

148. It would be obvious for a POSITA to combine Asada and Chon-570 to detect AF. Asada describes wearable sensors (WBS) which monitor's patient's physiological parameters, and addresses issues related to motion artifact. Asada at 28. Asada discloses arrhythmia surveillance with measuring of vital signs such as "heart rate, arterial blood pressure, arterial oxygen saturation, respiratory rate, temperature, and even cardiac output." Asada, 29. Chon-570 also measures various vital signs, particularly those related to a patient's heart, to detect atrial fibrillation (AF). Chon-570, 1:8-10. As AF is a form of arrhythmia, a POSITA would be motivated to combine Asada and Chon-570 where the known algorithm of Chon-570 is used in the known WBS system in Asada to yield predictable result, i.e., to detect AF. A POSITA would also be motivated to combine Asada, Chon-570, and Chon-2008. Chon-2008 discloses using time-varying transfer and coherence functions in the analysis of nonstationarity in renal autoregulation mechanisms. Chon-2008 at R821. There is a motivation to apply TVTF and TVCF techniques to analyze physiological signals to detect heart conditions because as Chon-2008 has described, the TVTF and TVCF can be used for nonstationary signals. Similar to Chon-2008, the physiological signals acquired in Chon-570 and

Asada also include variations due to an independent variable, such as motion artifacts. Thus, a POSITA would be motivated to combine Chon-2008 with Asada and Chon-570 so that the TVTF and TVCF methods are applied to physiological data such as PPG data. *See* Zhao at 1582 (“The characterization of physiological systems with the TVTF is important because the admittance gain between input and output signals is correctly characterized to be transient, and not stationary, as is assumed with the time-invariant transfer function.”).

**A. Independent Claims 16, 32, 42 are Obvious in View of Asada, Chon-570, and Chon-2008**

**1. Preamble**

16. A method for physiological parameter monitoring, the method comprising:	32. A system for physiological parameter monitoring, the system comprising:	42. A non-transitory computer usable medium having computer readable code embodied therein, the computer readable code causing at least one processor to:
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149. While I understand that a claim’s preamble is not limiting, Asada discloses this element. *See* Asada at 28, 34. I incorporate my analysis of Asada from Section VI.A.1. Chon-2008 also discloses this element for reasons explained below, which applies TVCF to signals. Chon-2008 at R823 (“The TVCF is important because it provides insight into the correlation over time between the input and output signals ...”). Chon-570 also discloses this element. For example,

Chon-570 provides real-time Atrial Fibrillation (AF) monitoring and detection.

Chon-570 at 4:1-12. Chon-570 teaches using piezoelectric or ECG signals to monitor physiological parameters such as those related to heart rate or heart beats.

Chon-570 at 4:1-4.

**2. “providing a physiological indicator signal ...” / “a physiological indicator signal sensing component...”**

16[i]. providing a physiological indicator signal to a handheld mobile communication device; the physiological indicator signal being obtained from one of an image acquisition component, a photoplethysmographic (PPG) sensor and an electrocardiogram sensor;	32[i]. a physiological indicator signal sensing component; and a handheld mobile communication device comprising: [ii]. at least one processor; and [iii]. at least one computer usable medium, the computer usable medium having computer readable code embodied therein, the computer readable code causing the at least one processor to:
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150. Asada discloses this element. *See* Asada 28-29, 33-34. I incorporate my analysis of Asada from Section VI.A.2.

151. Chon-570 also discloses this element. For example, Chon-570 discloses acquiring monitoring a patient’s heart beat and detects in real-time the presence of AF utilizing piezoelectric or ECG signals. Chon-570 at 4:1-4.

152. A POSITA would be motivated to combine Chon-570 because Asada’s platform is designed to work with multiple WBS modalities, including data from ECG sensor, such as that described in Chon-570. Asada at 29. Furthermore, Chon-

570’s algorithms can run on generic processors and hardware. As such, a POSITA would be motivated to combine Chon-570’s algorithms on the hardware of WBS.

**3. “analyze ...” / “analyzing...”**

16[ii]. analyzing, using the handheld mobile communication device, the physiological indicator signal;	32[iv]. analyze the physiological indicator signal; the physiological indicator signal being obtained from one of an image acquisition component, a photoplethysmographic (PPG) sensor and an electrocardiogram sensor;	42[i]. analyze the physiological indicator signal; the physiological indicator signal being obtained from one of an image acquisition component, a photoplethysmographic (PPG) sensor and an electrocardiogram sensor;
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153. Asada discloses this element. See Asada 28, 30, 34-35. I incorporate my analysis of Asada from Section VI.A.3. I also incorporate my analysis in subsection 4 immediately below.

154. Chon-570 also discloses this element. For example, Chon-570 discloses analyzing piezoelectric and ECG signals to detect AF. Chon-570 at 4:1-4.

**4. “wherein analysis does not include Independent Component Analysis”**

16[iii]. wherein analysis does not include Independent Component Analysis;	32[v]. wherein analysis does not include Independent Component Analysis;	42[ii]. wherein analysis does not include Independent Component Analysis;
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155. I incorporate my analysis from subsection 3 above. Asada, Chon-570, and Chon-2008 are not limited to independent component analysis.

156. Furthermore, the specification of the '428 Patent does not mention excluding "Independent Component Analysis" nor discuss excluding ICA for TVCF. During the prosecution, patentee argued that the description for applying a statistical method such as Shannon entropy, supports analyses both with ICA and without ICA. Ex-1004, 2016-12-22 Office Action Response at pg. 17 (Assuming, for argument's sake, that Greco discloses or suggests the Shannon entropy ..., then, by reciprocity, the applicants' disclosure discloses or suggest the Shannon entropy for the Independent Components in the Independent Component Analysis and the applicants can decide what bounds of protection to seek and can decide, within their written description requirement to exclude Independent Component Analysis.""). In other words, assuming that the patentee successfully argues that there is written descriptions for this element, a POSITA would understand that the statistical methods described therein can be applied both for ICA and non-ICA. Thus, it would be obvious to a POSITA to select either approach, in this case, without ICA to achieve the claimed invention.

157. Indeed, POSITA understands that there are many other methods, aside from ICA that can be used to identify data segment for analysis. For example, Delorme describes algorithms such as principal component analysis (PCA) for similar purposes as ICA. Delorme at Section 3.1. Thus, it would be obvious to apply known methods of identifying the data segments for analyses (i.e. those

methods without using ICA), apply the same statistical methods to achieve known results.

**5. “obtain / obtaining ... measurements of one or more physiological parameters”**

16[iv]. obtaining, from said analyzing, measurements of one or more physiological parameters; and	32[vi]. obtain, from results of analyzing, measurements of one or more physiological parameters; and	42[iii]. obtain, from said analyzing, measurements of one or more physiological parameters; and
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158. I incorporate my analysis from the other elements of these claims. I also incorporate my analysis of Asada from Section VI.A.4. Chon-570 also discloses this element. For example, Chon-570 calculates beat-to-beat variability, RR intervals from the ECG data. *See* Chon-570 at 6:17-19, 8:8-13.

**6. “detect ...” / “detecting ...”**

16[v]. detecting, using the handheld mobile communication device and using only the measurements of one or more physiological parameters, effects of motion artifacts in the measurements of the one or more physiological parameters and deciding whether to retain the measurements based on effects of motion artifacts in the measurements;	32[vii]. detect effects of motion artifacts, using only the measurements of one or more physiological parameters, in the measurements of the one or more physiological parameters; and	42[iv]. detect, using only the measurements of one or more physiological parameters, effects of motion artifacts in the measurements of the one or more physiological parameters; and
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159. Asada discloses this element. I also incorporate my analysis of Asada from Section VI.A.5.

160. Furthermore, it would be obvious to POSITA to decide whether to retain the measurements based on the effects of motion artifacts.

161. A POSITA understands that motion artifacts are noise and may distort interpretations of the data. Thus, in the analysis of physiological signals, a POSITA would decide whether to retain data depending on the effects of motion artifacts.

**7. “wherein the one or more physiological measurements comprise a measure of atrial fibrillation”**

16[vi]. wherein the one or more physiological measurements comprise a measure of atrial fibrillation;	32[viii]. wherein the one or more physiological measurements comprise a measure of atrial fibrillation;	42[v]. wherein the one or more physiological measurements comprise a measure of atrial fibrillation;
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162. Asada discloses patient monitoring for arrhythmia surveillance and measures vital signs such as “heart rate, arterial blood pressure, arterial oxygen saturation, respiratory rate, temperature, and even cardiac output.” Asada at 29. It also discloses “chronic surveillance using WBS [for] the management of heart failure” using various parameters. Asada at 38-39. A POSITA would understand that Asada teaches the physiological measurements comprise a measure of AF, which is a form of arrhythmia. Indeed, the art at the time acknowledges that “Atrial Fibrillation (AF), is one of the most common cardiac arrhythmias, affecting approximately 2-3 million Americans.” Chon-570 at 1:8-10. A POSITA would understand that the algorithms for measuring AF were known at the time. See

Chon-570 at 1:8-9 (disclosing “an algorithm for detection of atrial fibrillation (AF)”).

**8. “wherein obtaining the measure of atrial fibrillation comprises” / “wherein the computer readable code, in causing the at least one processor to analyze the physiological indicator signal, causes the at least one processor to”**

16[vii]. wherein obtaining the measure of atrial fibrillation comprises:	32[ix]. wherein the computer readable code, in causing the at least one processor to analyze the physiological indicator signal, causes the at least one processor to:	42[vi]. wherein the computer readable code, in causing the at least one processor to analyze the physiological indicator signal, causes the at least one processor to:
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163. A POSITA would have recognized that obtaining a measure of AF or analyzing physiological indicators are well-known in the art. For example, as discussed above, Chon-570 discloses detecting AF from analyzing ECG data. Chon-570 at 4:1-4. Chon-2008 discloses analyzing physiological data such as whole blood flow kidney data to using TVTF and TVCF for the analysis of nonstationarity in renal autoregulation mechanisms. Chon-2008 at Abstract. It would be obvious to use this existing method of deriving TVCF taught in Chon-2008 in the detection AF disclosed in Chon-570. Chon-570 determines AF by measuring correlations between signals segments through the autocorrelation function. Chon-570, 7:21-8:7. Since correlation and covariance are both statistically known concepts for measuring the relationships between two segments, it is obvious to try TVCF, in addition to or as an alternative to

autocorrelation function, to measure the relationship between the two signal segments, to achieve the same purpose.

164. I further incorporate my analysis from subsections 9 and 10 below.

**9. “obtain / obtaining a time-varying coherence function ...”**

<p>16[viii]. obtaining a time-varying coherence function by multiplying two time-varying transfer functions (TVFTs), the two time-varying transfer functions obtained using two adjacent data segments, from the physiological indicator signal, one of the two adjacent data segment as an input signal and another of the two adjacent data segment as an output signal to produce a first TVTF; a second TVTF is produced by reversing the input and the output signals, using said another of the two adjacent data segment as the input signal and said one of the two adjacent data segment as the output signal; and</p>	<p>32[x]. obtain a time-varying coherence function by multiplying two time-varying transfer functions (TVFTs), the two time-varying transfer functions obtained using two adjacent data segments from the physiological indicator signal, one of the two adjacent data segment as an input signal and another of the two adjacent data segment as an output signal to produce a first TVTF; a second TVTF is produced by reversing the input and the output signals, using said another of the two adjacent data segment as the input signal and said one of the two adjacent data segment as the output signal; and</p>	<p>42[vii]. obtain a time-varying coherence function by multiplying two time-varying transfer functions (TVFTs), the two time-varying transfer functions obtained using two adjacent data segments, from the physiological indicator signal, one of the two adjacent data segment as an input signal and another of the two adjacent data segment as an output signal to produce a first TVTF; a second TVTF is produced by reversing the input and the output signals, using said another of the two adjacent data segment as the input signal and said one of the two adjacent data segment as the output signal; and</p>
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165. Chon-2008 discloses this element as follows:

To demonstrate the use of the TVTF in obtaining the TVCF, we first define the TVCF via the nonparametric time-frequency spectra

$$|\gamma(t, f)|^4 = \left( \frac{|S_{xy}(t, f)|^2}{S_{xx}(t, f)S_{yy}(t, f)} \right) \left( \frac{|S_{yx}(t, f)|^2}{S_{yy}(t, f)S_{xx}(t, f)} \right) \quad (A7)$$

where  $S_{xy}(t, f)$  and  $S_{yx}(t, f)$  represent the time-frequency cross spectrum, and  $S_{xx}(t, f)$  and  $S_{yy}(t, f)$  denote the auto spectrum of the two signals  $x$  and  $y$ , respectively....We note that for a linear time-varying system with  $x$  and  $y$  as the input and output signals, respectively, the following TVTF in terms of time-frequency spectra can be obtained

$$H_{xy}(t, f) = \frac{S_{xy}(t, f)}{S_{xx}(t, f)} \quad (A8)$$

where  $H_{xy}(t, f)$  denotes the TVTF from the input  $x$  to the output  $y$  signals. Similarly, if we reversed the input and output relationship such that the variables  $y$  and  $x$  represent input and output signals, respectively, then the following TVTF can be obtained

$$H_{yx}(t, f) = \frac{S_{yx}(t, f)}{S_{yy}(t, f)} \quad (A9)$$

The desired relationship of *Eq. A7* can be obtained by multiplying the two TVTF relationships of *Eq. A8* and *Eq. A9*, which yields

$$\begin{aligned} |H_{xy}(t, f)H_{yx}(t, f)|^2 &= \left| \frac{S_{xy}(t, f)}{S_{xx}(t, f)S_{yy}(t, f)} \right|^2 \cdot \left| \frac{S_{yx}(t, f)}{S_{yy}(t, f)S_{xx}(t, f)} \right|^2 \\ &= \frac{|S_{xy}(t, f)|^2}{S_{xx}(t, f)S_{yy}(t, f)} \cdot \frac{|S_{yx}(t, f)|^2}{S_{yy}(t, f)S_{xx}(t, f)} = |\gamma(t, f)|^4 \end{aligned} \quad (A10)$$

Thus, time-varying magnitude squared coherence,  $|y(t, f)|^2$ , is then obtained by multiplying the two transfer functions,  $|H_{xy}(t, f)H_{yx}(t, f)|$ , together.

Chon-2008 at R827.

166. In addition, this process of obtaining TVCF has been well-known in the art prior to the '428 Patent. For example, Zhao, which is a 2004 paper, discloses TVCF is estimated by the “multiplication of [] two TVTFs,” where “[t]he two TVTFs are obtained using signal  $x$  as the input and signal  $y$  as the output to

produce the first TVTF, and signal y as the input and signal x as the output to produce the second TVTF.” Zhao at Abstract.

**10. “determine ...” / “determining ...”**

16[ix]. determining whether the time-varying coherence function is less than a predetermined quantity.	32[xi]. determine whether the time-varying coherence function is less than a predetermined quantity.	42[viii]. determine whether the time-varying coherence function is less than a predetermined quantity.
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167. Chon-2008 discloses comparing TVCF with a predetermined quantity.

For example, a coherence value of less than 0.5 for frequency range 0.03-0.05Hz would “demonstrate substantial nonstationarity in autoregulatory dynamics in demonstrate substantial nonstationarity in autoregulatory dynamics” in certain animal studies. Chon-2008 at Abstract.

168. It would be obvious to a POSITA to use a threshold such as a predetermined quantity to compare the results of coherence function because applying a threshold to a statistical analysis is a typical technique to identify statistically significant data. For example, Zhao teaches that “[a] threshold value is used for the linear independent candidate term search” associated with the TVCF, “as this value is dependent on the signal-to-noise ratio as well as on whether the signal is colored or white.” Zhao at 299. Zhao explains that, “[d]ue to unknown a priori knowledge of the aforementioned conditions, we normally set the threshold value to 0.0001 and 0.001 for clean and noise-corrupted signals, respectively.” (Id.)

169. Furthermore, as to claim 16, A POSITA would understand that a lower TVCF value typically indicates that at least one of the two data segments (used to calculate TVCF) would include AF, since the two segments will have lower coherence due to the arrhythmias. Thus, it would be obvious to a POSITA to detect the presence of AF by determining whether the time-varying coherence function is less than a predetermined quantity.

**B. Dependent Claims 17-20, 33-36, 43-46 Are Obvious In View of Asada, Chon-570, and Chon-2008**

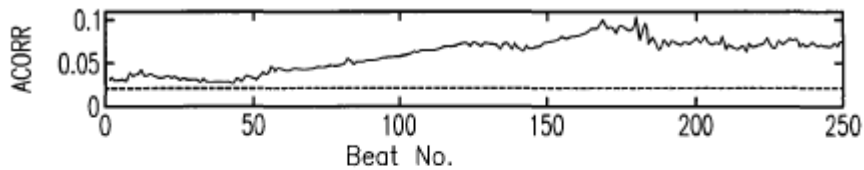
**1. Claims 17, 33, 43**

<p>17. The method of claim 16 wherein determining whether the time-varying coherence function is less than the predetermined quantity comprises:</p> <p>obtaining one or more indicators of atrial fibrillation; and</p> <p>determining whether the one or more indicators of atrial fibrillation exceed predetermined thresholds.</p>	<p>33. The system of claim 32 wherein the computer readable code, in causing the at least one processor to determine whether the time-varying coherence function is less than the predetermined quantity, causes the at least one processor to:</p> <p>obtain one or more indicators of atrial fibrillation; and</p> <p>determine whether the one or more indicators of atrial fibrillation exceed predetermined thresholds.</p>	<p>43. The non-transitory computer usable medium of claim 42 wherein the computer readable code, in causing the at least one processor to determine whether the time-varying coherence function is less than the predetermined quantity, causes the at least one processor to:</p> <p>obtain one or more indicators of atrial fibrillation; and</p> <p>determine whether the one or more indicators of atrial fibrillation exceed predetermined thresholds.</p>
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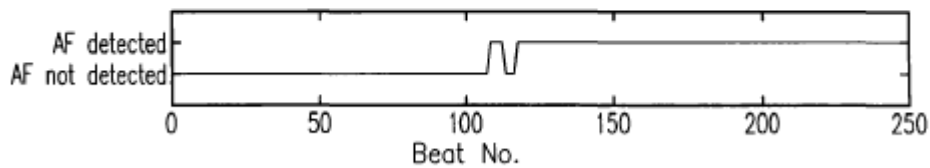
170. Chon-570 discloses this element. For example, Chon-570 describes obtaining one or more indicators of atrial fibrillation through applying algorithms

such as TPR, RMSSD, SE, and ACORR. Chon-570 at pgs. 5-8. Chon-570 also discloses that “[a] threshold of 0.02 was used for ACORR, that is any value that is greater than 0.02 is considered as AF.” Chon-570 at 8:6-7.

171. Figures of Chon-570 below show ACORR and it demonstrates the threshold for AF detection.



*FIG. 1(e)*



*FIG. 1(f)*

Chon-570 at FIGS. 1(e), 1(f).

**2. Claims 18, 34, 44**

<p>18. The method of claim 17 wherein the one or more indicators of atrial fibrillation comprise a variance of the time-varying coherence function.</p>	<p>34. The system of claim 33 wherein the one or more indicators of atrial fibrillation comprise a variance of the time-varying coherence function.</p>	<p>44. The non-transitory computer usable medium of claim 43 wherein the one or more indicators of atrial fibrillation comprise a variance of the time-varying coherence function.</p>
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172. A POSITA would understand and expect that the variance of TVCF values would be different for a signal segment, given the nature of AF. Thus, it would be obvious to look at the variance of TVCF to determine AF.

**3. Claims 19, 35, 45**

19. The method of claim 18 wherein the one or more indicators of atrial fibrillation also comprise Shannon entropy.	35. The system of claim 34 wherein the one or more indicators of atrial fibrillation also comprise Shannon entropy.	45. The non-transitory computer usable medium of claim 44 wherein the one or more indicators of atrial fibrillation also comprise Shannon entropy.
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173. Chon-570 discloses this element. For example, as shown below,

Chon-570 discloses using Shannon Entropy (SE) to detect AF.

In view of a general consideration of AF as being a random sequence of heart beat intervals with markedly increased beat-to-beat variability, the present invention combines four statistical techniques to exploit a Root Mean Square of Successive RR interval differences to quantify variability (RMSSD), a Turning Points Ratio to test for randomness of the time series (TPR), a Shannon Entropy (SE) to characterize its complexity and a autocorrelation (ACORR) index to characterize correlation between the first two RR intervals.

Chon-570 at 3:23-29.

**4. Claims 20, 36, 46**

20. The method of claim 17 wherein the predetermined thresholds are determined using receiver operator characteristic (ROC) analysis.	36. The system of claim 34 wherein the predetermined thresholds are determined using receiver operator characteristic (ROC) analysis.	46. The computer usable medium of claim 43 wherein the predetermined thresholds are determined using receiver operator characteristic (ROC) analysis.
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174. Chon-570 discloses determining thresholds for root mean square of successive RR differences (RMSSD), Shannon entropy (SE), and Turning Points Ratio (TPR) using receiver operator characteristic (ROC) curves. Chon-570 at

10:11-17. As demonstrated in figures 1(b)-1(f) of Chon-570, the threshold value is determined using ROC. Chon-570 at FIGS. 1(b)-1(f), 10:16 (“Dotted lines in (b-e) represent threshold values as determined by the ROC.”).

#### **IX. SECONDARY CONSIDERATIONS**

175. I am not aware of any evidence of secondary considerations of non-obviousness of claims 1-11, 15-27, 29-30, 32-37, 39-40, 42-46 of the ‘428 Patent. However, I reserve the right to rebut if the Patent Owner identifies any.

#### **X. CONCLUSION**

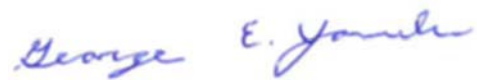
176. For the reasons set forth above, it is my opinion that claims 1-11, 15-27, 29-30, 32-37, 39-40, 42-46 of the ‘428 Patent are unpatentable in view of the prior art.

177. In signing this Declaration, I understand that the Declaration will be filed as evidence in a contested case before the PTAB.

I declare, under the penalty of perjury, that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true.

Dated: February 4, 2025

By:



George E. Yanulis