

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Ammar Al-Ali
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Title: PHYSIOLOGICAL MONITORING DEVICES, SYSTEMS,
AND METHODS

DECLARATION OF DR. BRIAN W. ANTHONY

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I, Brian W. Anthony, of Cambridge, MA, declare that:

1. My name is Dr. Brian W. Anthony. I am an Associate Principal Research Scientist at the Institute of Medical Engineering & Science at Massachusetts Institute of Technology (MIT). I am also a Principal Research Scientist at MIT's Mechanical Engineering department, Director of the Master of Engineering in Advanced Manufacturing and Design Program at MIT, Director of Health Technology at the MIT Center for Clinical and Translational Research, a Co-Director of the Medical Electronic Device Realization Center of the Institute of Medical Engineering & Science, and Associate Director of MIT.nano. My current *curriculum vitae* is attached and some highlights follow.

2. I earned my B.S. in Engineering (1994) from Carnegie Mellon University. I earned my M.S. (1998) and Ph.D. (2006) in Engineering from MIT. My research focused on high-performance computation, signal processing, and electro-mechanical system design.

3. In 1997, I co-founded Xcitex Inc., a company that specialized in video-acquisition and motion-analysis software. I served as the Chief Technology Officer and directed and managed product development until 2006. Our first demo product was an optical ring for human motion measurement used to capture user hand motion in order to control the user's interaction with a computer. Many of the structural elements of our optical ring addressed the same system issues as

those described and claimed in the patent at issue. For example, our optical ring included multiple light emitting diodes, multiple photodetectors, techniques for modulation and synchronization, and noise reduction algorithms. We estimated human hand-motion based on how that motion changed the detected light. In our application, we did not try to eliminate motion artifact, we tried to measure it. In developing our ring, we considered well-known problems such as ambient light and noise. Motion Integrated Data Acquisition System (MiDAS) was our flagship video and data acquisition product which relied upon precise synchronization of multiple clocks for optical sensor and video acquisition, data acquisition, and external illumination.

4. I joined MIT in 2006 and was the Director of the Master of Engineering in Advance Manufacturing and Design Program for over ten years. The degree program covers four main components: Manufacturing Physics, Manufacturing Systems, Product Design, and Business Fundamentals. Many of the courses, projects, and papers my students undertake involve technologies relevant to the patent at issue, for example, sensor devices including non-invasive optical biosensors.

5. In 2011, I co-founded MIT's Medical Electronic Device Realization Center ("MEDRC") and currently serve as co-director. The MEDRC aims to create and deploy revolutionary medical technologies by collaborating with

clinicians, the microelectronics, and medical devices industries. We combine expertise in computation; communications; optical, electrical, and ultrasound sensing technologies; and consumer electronics. We focus on the usability and productivity of medical devices using, for example, image and signal processing combined with intelligent computer systems to enhance practitioners' diagnostic intuition. Our research portfolio includes low power integrated circuits and systems, big data, micro electro-mechanical systems, bioelectronics, sensors, and microfluidics. Specific areas of innovation include wearable, non-invasive and minimally invasive optical biosensor devices, medical imaging, laboratory instrumentation, and the data communication from these devices and instruments to healthcare providers and caregivers. My experience with these devices is directly applicable to the technology in the patent at issue.

6. I am currently the Director of the Device Realization Lab, Co-Director of the Medical Electronic Device Realization Center (MEDRC), and Director Technical Operation of the Center for Clinical and Translational Research (CCTR) at the Institute of Medical Engineering & Science at MIT. The Device Realization Lab designs instruments and techniques to sense and control physical systems. Medical devices and manufacturing inspection systems are a particular focus. We develop and combine electromechanical systems, complex algorithms,

and computation systems to create instruments and measurement solutions for problems that are otherwise intractable.

7. The research of the Device Realization Lab focuses on product development interests cross the boundaries of computer vision, acoustic and ultrasonic imaging, large-scale computation and simulation, optimization, metrology, autonomous systems, and robotics. We use computation, and computer science, as methodology for attacking complex instrumentation problems. My work combines mathematical modeling, simulation, optimization, and experimental observations, to develop instruments and measurement solutions.

8. My record of professional service includes recognitions from several professional organizations in my field of expertise.

9. I am a named inventor on 10 issued U.S. patents. Most but not all of these patents involve physiological monitoring and other measurement technologies.

10. I have published approximately 100 papers, and have received a number of best paper and distinguished paper awards. A number of papers that I have published relate to physiological monitoring and other measurement and instrumentation technologies.

11. I have been retained on behalf of Apple Inc. to offer technical opinions relating to U.S. Patent No. 10,722,159 (“the ’159 patent,” APPLE-1001)

and prior art references relating to its subject matter. I have reviewed the '159 Patent and relevant excerpts of the prosecution history of the '159 Patent (EX1002). I have also reviewed the following prior art references and materials, in addition to other materials I cite in my declaration:

- APPLE-1004: U.S. Pat. No. 8,670,819 (“Iwamiya”)
- APPLE-1005: U.S. Pat. No. 9,392,946 (“Sarantos”)
- APPLE-1006: U.S. Pat. No. 8,446,275 (“Utter”)
- APPLE-1007: U.S. Pat. No. 6,483,976 (“Shie”)
- APPLE-1008: U.S. Pat. Pub. No. 2016/0058312 (“Han”)
- APPLE-1009: Design of Pulse Oximeters, J.G. Webster; Institution of Physics Publishing, 1997 (“Webster”)
- APPLE-1014: Pang et al., A Neo-Reflective Wrist Pulse Oximeter, IEEE Access, Volume 2 (January 12, 2015)
- APPLE-1015: Li et al., A Wireless Reflectance Pulse Oximeter With Digital Baseline Control for Unfiltered Photoplethysmograms, IEEE Transactions on Biomedical Circuits and Systems, Vol. 6, No. 3 (June 2012)
- APPLE-1016: Cai et al., Implementation of a Wireless Pulse Oximeter Based on Wrist Band Sensor, 3rd International Conference on Biomedical Engineering and Informatics

- APPLE-1017: International Publication No. WO 2001/17421 to Lindberg et al.
- APPLE-1018: Maattala et al., Optimum Place for Measuring Pulse Oximeter Signal in Wireless Sensor-Belt or Wrist-Band, 2007 International Conference on Convergence Information Technology
- APPLE-1019: U.S. Patent No. 5,663,264 to Kawai
- APPLE-1020: U.S. Patent No. 5,449,731 to Suzuki
- APPLE-1021: U.S. Patent No. 4,149,776 to Everett
- APPLE-1022: U.S. Patent No. 5,171,085 to Jaksich
- APPLE-1023: Definition of “resin” from Chambers Dictionary of Science and Technology, Chambers Harrap Publishers Ltd. (2007)
- APPLE-1024: Definition of “resin” from Concise Encyclopedia of Science & Technology, Sixth Edition, McGraw Hill (2009)
- APPLE-1025: Definition of “resin” from A Dictionary of Chemistry, Sixth Edition, Oxford University Press (2008)
- APPLE-1026: Definition of “resin” from Longman Dictionary of American English, Fifth Edition, Pearson Education Ltd. (2014)

- APPLE-1027: Definition of “resin” from Dictionary of Science and Technology, Second Edition, A&C Black Publishers Ltd. (2007)
- APPLE-1028: U.S. Pat. Pub. No. 2006/0253010 (“Brady”)
- APPLE-1029: Excerpt of The American Heritage Dictionary of the English Language, Fifth Edition, Houghton Mifflin Harcourt Publishing Company (2011)
- APPLE-1030: Excerpt of Collins Dictionary, HarperCollins Publishers (2010)
- APPLE-1031: Excerpt of Merriam-Webster’s Collegiate Dictionary, Eleventh Edition, Merriam-Webster, Incorporated (2014)
- APPLE-1032: U.S. Patent No. 6,580,086 to Schulz et al.
- APPLE-1033: U.S. Pat. No. 6,801,799 (“Mendelson”)
- APPLE-1034: Mendelson et al., A Wearable Reflectance Pulse Oximeter for Remote Physiological Monitoring, Proceedings of the 28th IEEE EMBS Annual International Conference (Sept. 3, 2006)
- APPLE-1035: U.S. Patent Application Publication No. 2013/0267854 (“Johnson”)

- APPLE-1036: U.S. Patent Application Publication No. 2005/0116820 (“Goldreich”)
- APPLE-1037: U.S. Patent No. 5,164,858 (“Aguilera”)
- APPLE-1038: U.S. Pat. No. 5,830,137 (“Scharf”)
- APPLE-1039: U.S. Patent Application Publication No. 2005/0267346 (“Faber”)
- APPLE-1040: ITC Inv. No. 337-TA-1276 Exhibit RX-0508 (Jianchu Yao and Steve Warren, Stimulating Student Learning with a Novel “In-House” Pulse Oximeter Design (2005))
- APPLE-1041: U.S. Patent Application Publication No. 2014/0323829 (“LeBoeuf”)
- APPLE-1042: Fontaine et al., Reflectance-Based Pulse Oximeter for the Chest and Wrist, Worcester Polytechnic Institute (April 2013) *available at* <https://digital.wpi.edu/show/6969z2326>
- APPLE-1043: U.S. Patent No. 7,468,036 (“Rulkov”)
- APPLE-1044: International Publication No. WO 2011/051888 (“Ackermans”)
- APPLE-1045: International Publication No. WO 2012/140559 (“Shmueli”)
- APPLE-1046: U.S. Patent No. 7,650,176 (“Sarussi”)

- APPLE-1047: U.S. Patent Application Publication No. 2002/0095092 (“Kondo”)
- APPLE-1048: U.S. Patent Application Publication No. 2015/0355604 (“Fraser”)
- APPLE-1049: U.S. Patent No. 6,398,727 (“Bui”)

12. Counsel has informed me that I should consider these materials through the lens of one of ordinary skill in the art related to the ’159 patent at the time of the earliest possible priority date of the ’159 patent, and I have done so during my review of these materials. The ’159 patent claims priority to an application filed July 2, 2015 (the “Critical Date”). Counsel has informed me that this Critical Date represents the earliest priority date to which the challenged claims of ’159 patent are possibly entitled, and I have therefore used that Critical Date in my analysis below.

13. I have no financial interest in the party or in the outcome of this proceeding. I am being compensated for my work as an expert on an hourly basis. My compensation is not dependent on the outcome of these proceedings or the content of my opinions.

14. In writing this Declaration, I have considered the following: my own knowledge and experience, including my work experience in the fields of mechanical engineering, computer science, biomedical engineering, and electrical

engineering; my experience in teaching those subjects; and my experience in working with others involved in those fields. In addition, I have analyzed various publications and materials, in addition to other materials I cite in my declaration.

15. My opinions, as explained below, are based on my education, experience, and expertise in the fields relating to the '159 patent. Unless otherwise stated, my testimony below refers to the knowledge of one of ordinary skill in the fields as of the Critical Date, or before. Any figures that appear within this document have been prepared with the assistance of Counsel and reflect my understanding of the '159 patent and the prior art discussed below.

I. Background

16. The '159 patent, entitled "Advanced Pulse Oximetry Sensor," describes a "non-invasive, optical-based physiological monitoring system[.]" APPLE-1001, Face, Abstract.

17. Independent claim 1 of the '159 patent is generally representative:

1. A physiological monitoring device comprising:

a plurality of emitters configured to emit light in a first shape;

a material positioned between the plurality of emitters and a

tissue measurement site on a wrist of a user when the physiological

monitoring device is in use, the material configured to change the first

shape into a second shape by which the light emitted from one or

more of the plurality of emitters is projected towards a surface of the tissue measurement site;

a plurality of detectors configured to detect at least a portion of the light after passing through tissue, the plurality of detectors further configured to output at least one signal responsive to the detected light;

a surface comprising a dark-colored coating, the surface positioned between the plurality of detectors and the tissue when the physiological monitoring device is in use, wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface;

a light block configured to prevent at least a portion of the light emitted from the plurality of emitters from reaching the plurality of detectors without first reaching the tissue; and

a processor configured to receive and process one or more signals responsive to the at least one outputted signal and determine a physiological parameter of the user responsive to the one or more signals.

18. With respect to FIG. 7A, the '159 patent describes a "3D reflective pulse oximetry sensor 700." APPLE-1001, 10:40-42. "The 3D sensor 700

includes an emitter 702, a light diffuser 704, a light block 706, a light concentrator 708, and a detector 710.” *Id.*, 10:49-51. The ’159 patent explains that “[t]he light block 606 is necessary because the emitter 602 and the detector 610 are located on the same side of the tissue measurement site 102. Accordingly, the light block 606 prevents incident emitter light, which did not enter the tissue measurement site 102, from arriving at the detector 610.” *Id.*, 10:20-27.

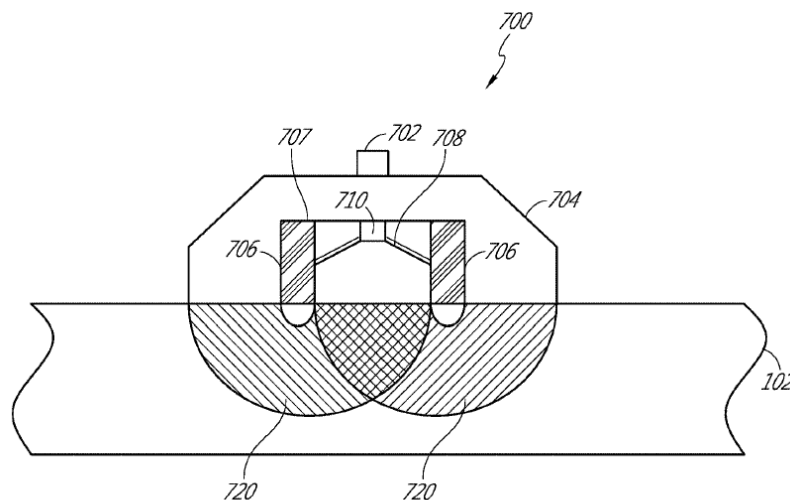


FIG. 7A

APPLE-1001, FIG. 7A.

19. With respect to the sensor of FIG. 7A, the ’159 patent describes that “[t]he 3D sensor 700 can be placed on a portion of the patient's body that has relatively flat surface, such as, for example a wrist, because the emitter 702 and detector 710 are on located the same side of the tissue measurement site 102.” APPLE-1001, 10:45-49. Notably, the ’159 patent does not identify any adjustments that need to be made to the sensor to allow for detection at the wrist

as opposed to other flat surfaces of the patient, such as the forehead. APPLE-1001, 12:16-20.

II. Level of Ordinary Skill in the Art

20. Based on the foregoing and upon my experience in this area, a person of ordinary skill in the relevant art as of the Critical Date (a “POSITA”) would have been a person with a working knowledge of physiological monitoring technologies. The person would have had a Bachelor of Science degree in an academic discipline emphasizing the design of electrical, computer, or software technologies, in combination with training or at least one to two years of related work experience with capture and processing of data or information, including but not limited to physiological monitoring technologies. Alternatively, the person could have also had a Master of Science degree in a relevant academic discipline with less than a year of related work experience in the same discipline.

21. Based on my experiences, I have a good understanding of the capabilities of a POSITA. Indeed, I have taught, participated in organizations, and worked closely with many such persons over the course of my career.

22. I have performed my analysis through the lens of a POSITA as of the Critical Date.

III. Interpretations of the '159 Patent Claims at Issue

23. I understand that, for purposes of my analysis in this *inter partes* review proceeding, the terms appearing in the patent claims should generally be interpreted according to their “ordinary and customary meaning.” *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). I understand that “the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.” *Id.* at 1313. I also understand that the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification. *Id.*

IV. Prior Art Analysis

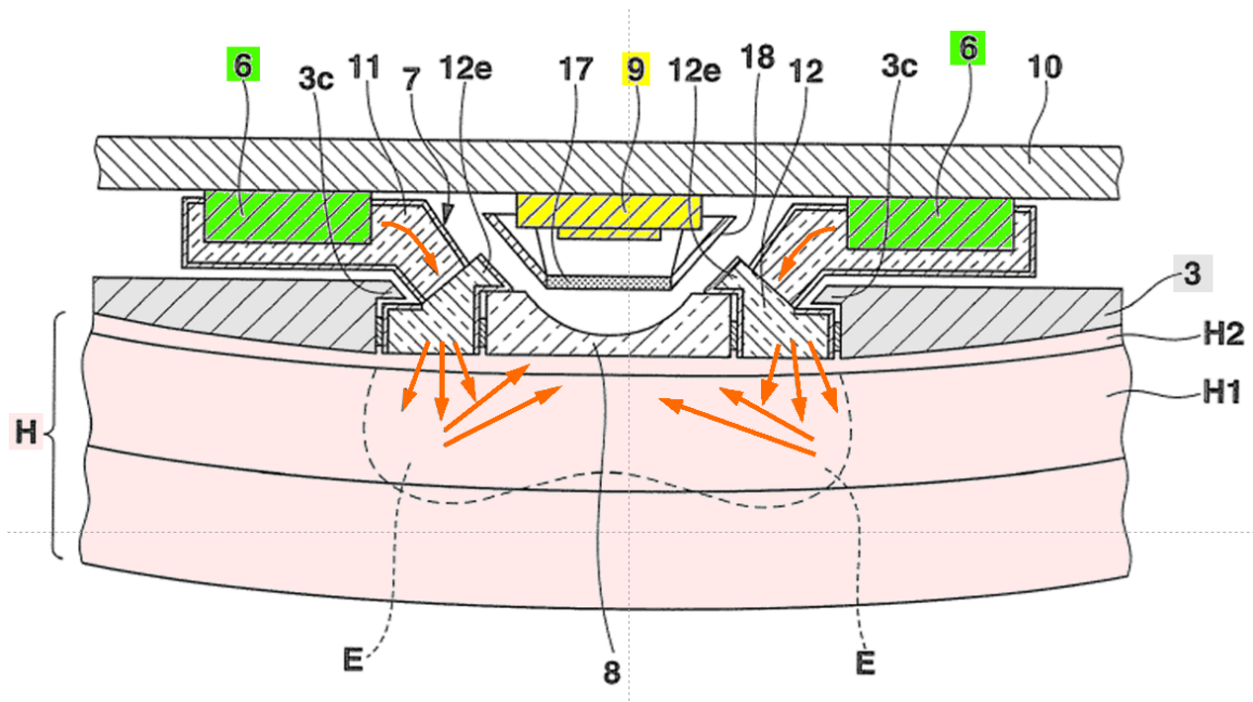
A. Ground 1A: Claims 1-2 and 4-13 are obvious over Iwamiya in view of Sarantos

1. Overview of Iwamiya

24. Iwamiya discloses an “optical biological information detecting apparatus [that] includes a light emitting unit which emits observation light of a specific wavelength band to optically observe a desired portion of a tissue of a skin of a human body, and an annular light guide unit which guides the observation light to a desired area of a surface of the skin corresponding to the desired portion of the tissue of the skin, and which annularly irradiates the observation light onto

the desired area of the surface of the skin.” APPLE-1004, Abstract. A POSITA would have recognized such a device as a physiological monitoring device. In one implementation of its physiological monitoring device, Iwamiya describes that the “optical biological information detecting apparatus” is provided in “a central portion of the back cover” of “a wristwatch” (*i.e.*, facing the wearer’s wrist).

APPLE-1004, 5:54-66, FIG. 1. As shown in the following annotated FIG. 4 from Iwamiya, the device includes LEDs 6 (shown in green) that emit light (orange) that is reflected by the tissue of the wearer’s wrist (pink) and detected by photodiodes 9 (yellow).



APPLE-1004, Detail of FIG. 4 (annotated)

25. Iwamiya goes on to describe that the optical biological information detecting apparatus includes “a light shielding frame¹⁸” with an “optical filter ¹⁷” surrounding the light receiving units 9 (e.g., photo diodes). APPLE-1004, 8:38-47, FIG. 4. Together the optical filter and light shielding frame work to guide light reflected from the skin toward the light receiving units 9 for measurement while eliminating noise from external light, such as sunlight or other ambient light in the environment of the device. *Id.* at 8:38-9:7. Iwamiya further describes that “the light receiving unit 9 outputs a current signal according to the amount of received light.” *Id.*, 9:28-32. “The I/V converting circuit 22 converts the current signal output from the light receiving unit 9 into a voltage signal and inputs the signal to an A/D1 port of the CPU 20.” *Id.*, 9:32-35. The CPU then processes the received signal and “outputs the data as biological information such as a pulse wave to the display unit 23, and displays the data on the display unit 23.” *Id.*, 9:36-43.

2. Overview of Sarantos

26. Sarantos describes a “wristband-type wearable fitness monitor” that includes multiple light sources for emitting light into tissue of a wearer to measure “physiological parameters” of the wearer, such as the person’s “heart rate measurement” and “blood oxygenation levels” based on “one or more light intensity measurements.” APPLE-1005, 2:5-14, 5:55-59, 7:12-14, 13:39-47.

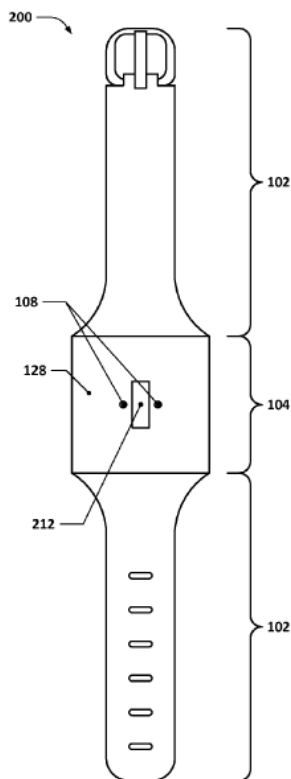


FIG. 2

APPLE-1005, FIG. 2

27. The monitor performs these measurements using a photoplethysmographic (PPG) sensor, which includes one or more light sources (e.g., LEDs) and an array of photodetectors. *Id.*, 1:9-10, 43-47, 7:12-16, 15:23-43. Sarantos describes that when the monitor “is worn by a person in a manner similar to a wristwatch, the back face” of the monitor “may be pressed against the person's skin, allowing the light sources” of the PPG sensor “to illuminate the person’s skin.” *Id.*, 1:48-51, 7:12-23. Sarantos describes that “there may be a plurality of photodetector elements arranged in a pattern, and the plurality of light-emitting devices may be collocated at a center point of the pattern of photodetector

elements. In some such implementations each photodetector element in the pattern may be equidistant from the center of the light source and/or evenly spaced within the pattern.” APPLE-1005, 2:20-29.

28. The light emitted by the one or more emitters “diffuses through the person's flesh and a portion of this light is then emitted back” (i.e., reflected) “out of the person's skin in close proximity to where the light was introduced into the flesh.” *Id.*, 7:24-28. The photodetector array of the PPG sensor measures the “intensity” of this reflected light, and provides signals representing the intensity to “control logic” of the monitoring device. APPLE-1005, 2:5-14, 7:12-23, 13:39-47.

29. For example, “FIG. 25 depicts an example of an annular photodetector element 2512 with a light source 2508 in the middle, in accordance with an example implementation. The annular photodetector element 2512 may have an exterior periphery defined by a first boundary 2532 and a central opening defined by a second boundary 2534; the first boundary 2532 and the second boundary 2534 may be offset from one another by a first distance 2584 along a radius of the annular area.” *Id.*, 19:33-40.

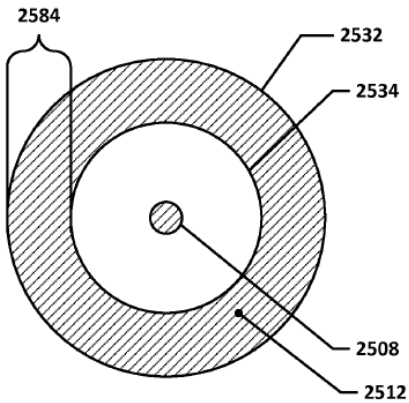


FIG. 25

APPLE-1005, FIG. 25.

Sarantos further describes that “it is to be understood that any of the implementations discussed above with respect to a single photodetector element spaced apart from a light source may also be implemented using a plurality of photodetector elements arranged about the light source, as discussed with respect to various other implementations discussed herein.” *Id.*, 20:52-57. Sarantos describes embodiments in which reflected light travels through transparent/translucent windows regions in a dark-colored coating applied to a window adjacent to the photodetector. APPLE-1005, 5:55-58, Fig. 22.

Specifically, Sarantos discloses that “in-mold label 2276 may be black or otherwise rendered opaque to light to prevent light from entering or exiting the PPG sensor through the window 2278 except through window regions 2226.”

APPLE-1005, 17:1-16. Sarantos explains that various masking techniques may be

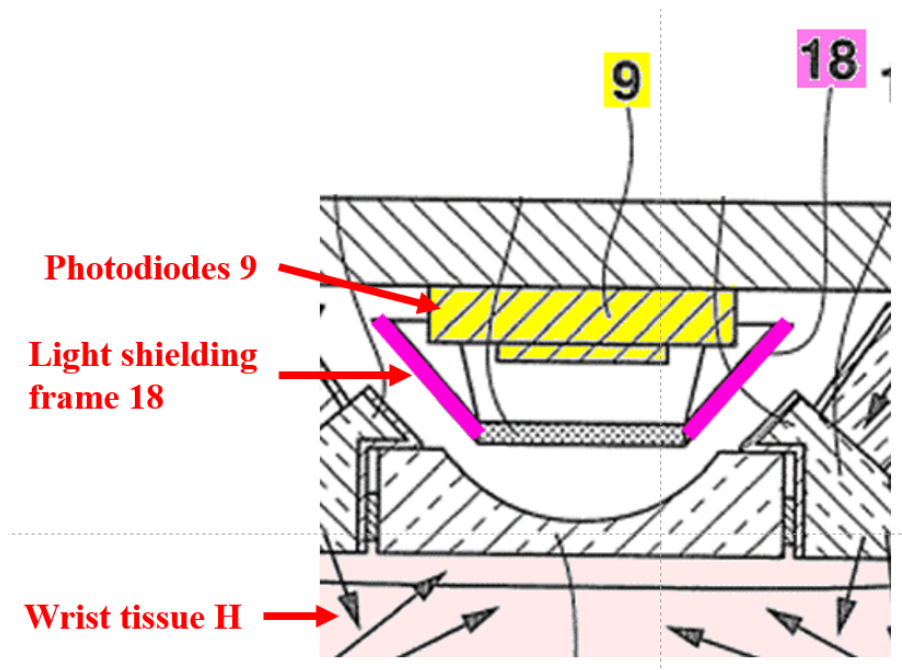
used to block stray light from reaching the photodetector elements 2212, including “a painted or silk-screened mask” applied to the window 2278. *Id.*

30. Sarantos’ device includes control logic that calculates various physiological parameters based on characteristics of the reflected light signal. *Id.*, 1:54-56, 7:12-23. For example, the person’s heart rate can be calculated based on “fluctuations in the amount of light from the light source that is emanated back out of the flesh” that correspond fluctuations in blood volume associated with each beat of the person’s heart. *Id.*, 7:23-60. Sarantos goes on to describe well-known “photoplethysmographic techniques...to measure other physiological parameters besides heart rate, such as blood oxygenation levels” by providing “light-emitting devices that are each able to emit different wavelengths of light” including “light in the red or infrared spectrum” to facilitate such blood oxygen saturation measurement. APPLE-1005, 13:44-58. Sarantos further describes that that “techniques for measuring blood oxygenation levels, may be most effective using light of...red wavelengths, e.g., 660 nm, or in the infrared spectrum.” APPLE-1005, 18:44-48.

3. Combination of Iwamiya with Sarantos

31. A POSITA would have found it obvious and beneficial to enhance the wrist-worn biological information detecting apparatus of Iwamiya to implement the light shielding frame 18 to include a dark-colored coating, as suggested by

Sarantos, to enhance the light blocking functionality of the shielding frame 18. As I discussed above, Iwamiya's physiological parameter monitoring device includes a "light shielding frame 18" surrounding the photo diodes/light receiving units 9. APPLE-1004, 8:38-47, FIG. 4 for blocking environmental light from reaching the light receiving units. For example, as demonstrated by FIG. 4 of Iwamiya, the light shielding frame 18 (pink) is positioned between the photo diodes/light receiving units 9 (yellow) and the tissue (light pink) and functions to prevent errant light from reaching the light receiving units 9:



APPLE-1004, Detail of FIG. 4 (annotated)

32. As would have been recognized by a POSITA, Iwamiya lacks detail on suitable materials that could be used to achieve the desired "light shielding" function of frame 18. Sarantos provides these details that are missing from the

disclosure of Iwamiya and a POSITA would have had a reasonable expectation of success in implementing the light shielding frame of Iwamiya to include an opaque, dark-colored coating, as taught by Sarantos. Based on my review, a POSITA would have recognized that an opaque, light-absorbing material in the form of a dark-colored coating like that taught in Sarantos to be an obvious and well-known option for implementing the light shielding function of Iwamiya's frame 18. Indeed, the use of such a dark-colored coating was common practice well before the '159 Patent. APPLE-1005, 17:1-25; *see also* APPLE-1009, 96-97¹ (“coat the housing around the photodiode with a material that does not scatter or reflect light”), 111 (“cover the sensor site with opaque material”); APPLE-1032, 9:58-10:23.

33. Much like Iwamiya, Sarantos discloses a wrist-worn reflectance-based physiological sensor that has a dark-colored coating 2276 to block light. APPLE-1005, 5:55-58, Fig. 22. Sarantos, like Iwamiya, discloses that its light source 2208 emits light through a window 2278 into a user's skin, wherein the light is reflected back to the sensor and detected by photodetector elements 2212. APPLE-1005, 17:1-25. The light travels through window regions 2226 in a dark-colored coating 2276 applied to window 2278. *Id.* Specifically, Sarantos discloses that “in-mold label 2276 may be black or otherwise rendered opaque to light to prevent light

¹ Numbers refer to page numbers of the PDF document.

from entering or exiting the PPG sensor through the window 2278 except through window regions 2226.” APPLE-1005, 17:1-16. Sarantos explains that various masking techniques may be used to block stray light from reaching the photodetector elements 2212, including “a painted or silk-screened mask” applied to the window 2278. *Id.* Like Iwamiya, the masking techniques block ambient light from reaching the photodetector elements to minimize interference with the obtained heartrate signal. *Id.* at 17:1-25. A POSITA would have known that the light shielding frame 18 or holder portion 43 of Iwamiya can be of various proportions, materials, and that a thin surface could be coated and therefore the teachings of Sarantos were directly applicable to Iwamiya.

34. A POSITA also would have found the selection of a light-absorbing material for Iwamiya’s light shielding frame 18 to be a simple matter of design choice given that light-shielding materials must either absorb or reflect light, and the use of a “dark” coating would be particularly obvious to absorb the broadest spectrum of light. APPLE-1059, 94:14-95:10. A POSITA would have therefore been motivated to implement Iwamiya’s light shielding frame 18 to include a black or opaque dark-colored coating such as an in-mold label, silk-screened mask, or other technique (as taught by Sarantos) such that the resulting coated light shielding frame has improved characteristics for shielding the photodiodes from stray light, thereby minimizing the amount of light that reaches the photodiodes 9

from LEDs 6 without first being reflected off the user's skin, thus increasing accuracy of the sensor. APPLE-1004, 8:38-47, FIG. 4; APPLE-1005, 5:55-58, 17:1-25, FIG. 22. A POSITA would have known how to apply the dark-colored coating in any suitable manner that would ensure light is effectively blocked from reaching the photodiodes except through the filter 17, e.g., by coating the exterior of the frame 18 with a dark, light-absorbing material. APPLE-1005, 17:1-25.

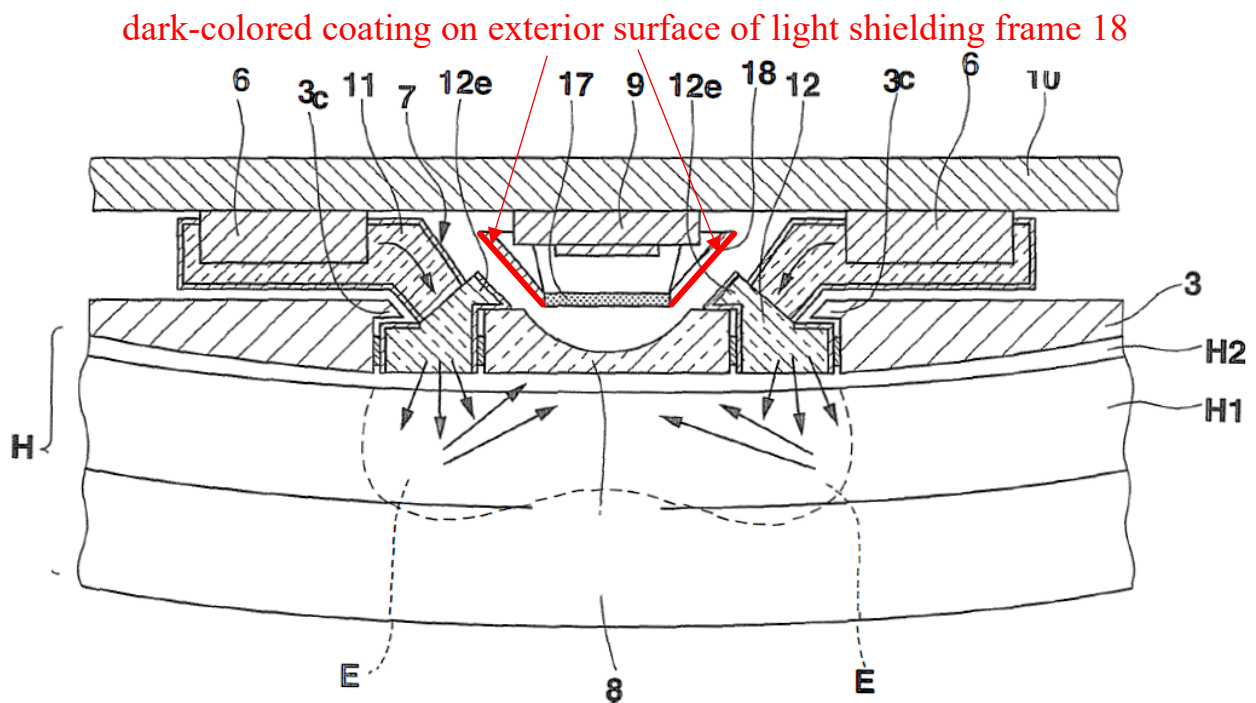


FIG.4

APPLE-1004, FIG. 4²

² Annotations and color added to figures unless otherwise noted.

35. A POSITA would have understood that a dark-colored coating, such as that described by Sarantos, would have served this purpose by not only blocking light but also by limiting reflections, which could lead to stray light (such as light from LEDs that has not yet been reflected by the user's skin) being incident on the photodiodes 9, thus improving the light blocking functionality of the resulting device.

36. The Patent Owner has asserted in other proceedings regarding patents related to the '159 patent that a POSITA would be led by Iwamiya to select a reflective rather than absorptive material for use on the light-shielding frame 18. I disagree with this assessment. Based on my review, a Sarantos-like dark-colored coating would have been more effective than a reflective material at reducing light scatter in the empty space surrounding the frame 18, and this in turn would have been beneficial to reduce the amount of light that could reflect back from the empty space through the optical filter 17 and the photodiodes. A POSITA would have sought to reduce these effects since any light that reflected back from the space surrounding frame 18 and through the optical filter 17 to the photodiodes would have different path lengths that could increase optical interference and reduce measurement accuracy. APPLE-1009, 69, 96-97; APPLE-1032, 1:65-2:16, 9:58-10:23. Additionally, a POSITA looking to implement such a device would

make a choice between absorptive or reflective surfaces/materials based on the specific design needs and constraints for a given device.

37. The Patent Owner has also asserted in the above mentioned related proceedings that Iwamiya's light-shielding frame 18 must be reflective since holder portion 43 is reflective. I once again disagree. These components are not even used in the same embodiments. Iwamiya describes the "holder portion 43" with respect to "second," "third," and "fourth" embodiments. APPLE-1004, 18:61-65, 28:64-29:1, 39:20-24. These embodiments are substantially different from the "first embodiment" that uses light shielding frame 18, as shown below in the FIG. 3 first embodiment and the FIG. 13 second embodiment.

38. By way of example, the first embodiment with light shielding frame 18 includes a cavity or channel through which light reflected from the tissue may travel around a periphery of the frame 18 if it is not initially directed through optical filter 17. As noted above, this cavity introduces greater risk of multiple scattering and pathlength variations not present in the embodiments that employ holder portion 43 (where no comparable cavity exists).

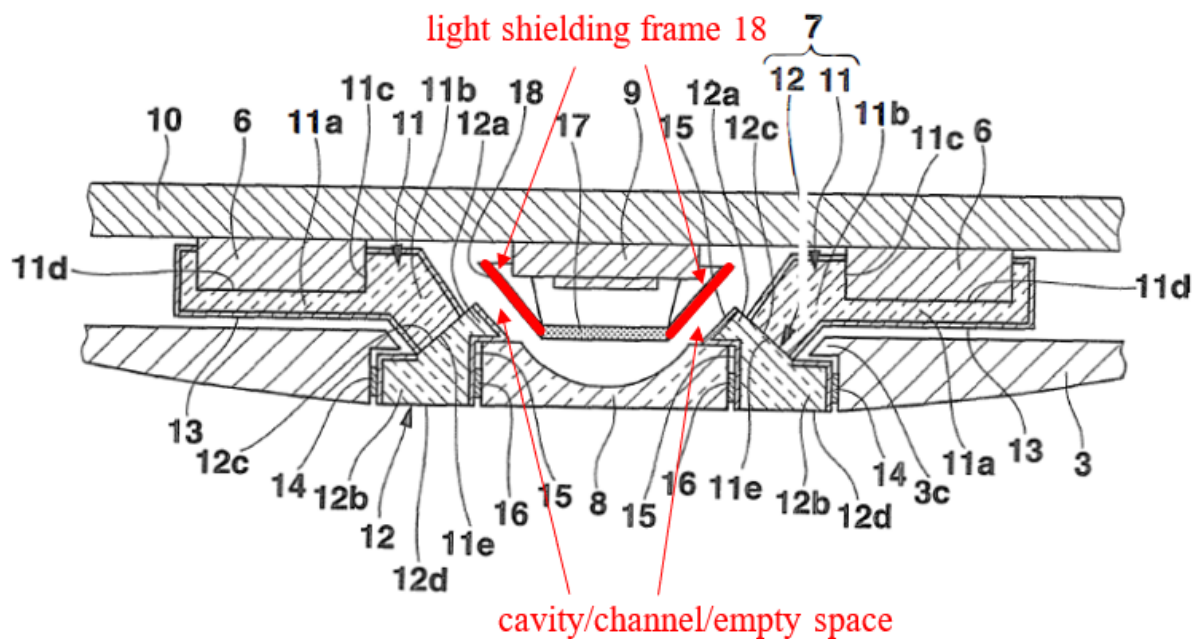


FIG.3

APPLE-1004, FIG. 3

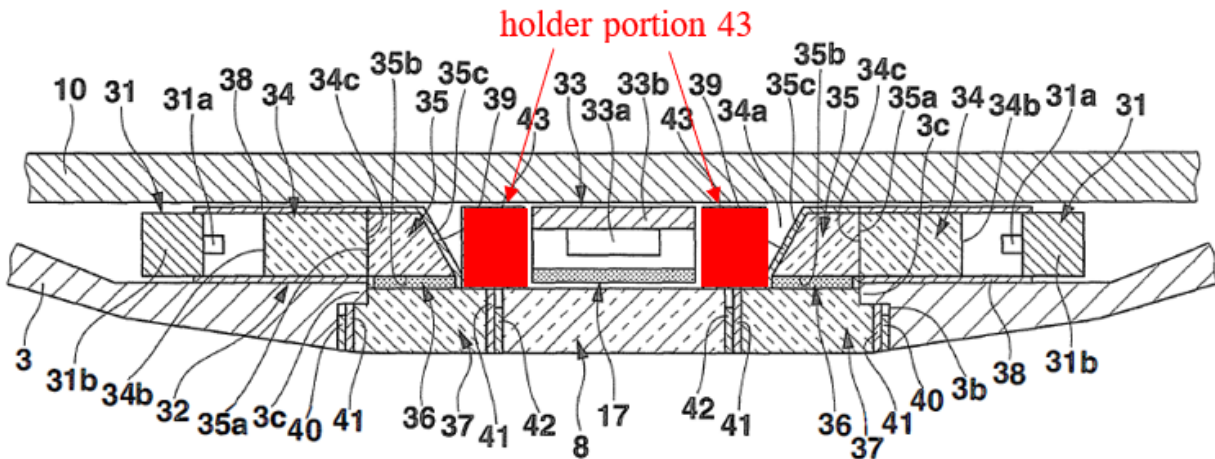


FIG.13

APPLE-1004, FIG. 13

39. The geometrical aspects of components across various embodiments and diverse design considerations would have prompted a POSITA to make

distinct choices for each component. Consider, for instance, the coatings on different sides of a structure. On one side, a coating can be light-blocking and reflective, while on the other side, a different coating could be light-blocking and absorptive. These design choices stem from the desired light trajectories and the intricate specifics of the system's overall configuration and geometry. In the case of the large obtuse angle geometry of the light shielding frame 18 of FIG. 3, using a reflective surface could potentially introduce multi-path artifacts more readily, in contrast to the arrangement in FIG. 13. In the embodiment shown in FIG. 13, employing a reflective light-blocking surface on holder portion 43 might enhance the signal as the specific geometry likely has a reduced risk of multi-pass or multi-path artifacts.

40. In contrast to Iwamiya's specific description of reflective materials for layers 13 and 15 and holder portion 43, Iwamiya leaves the choice of a suitable material for light shielding frame 18 to a POSITA. *Compare* APPLE-1004, 6:62-7:3, 7:41-49, 18:61-65, 28:64-29:1, 39:20-24 *with* APPLE-1004, 8:38-42. A POSITA would have found a dark-colored coating as taught in Sarantos to be an obvious and beneficial option for achieving the light-shielding function desired by Iwamiya, for multiple reasons.

41. The light shielding frame 18 of Iwamiya and Sarantos's in-mold label 2276 serve complimentary functions within their respective physiological

measurement devices: blocking errant light from reaching the light detectors.

APPLE-1004, 8:38-47; APPLE-1005, 17:1-16. Yet, while Iwamiya is silent as to the material or coating used to implement the light shielding frame 18, Sarantos teaches that a dark-colored coating or material provides the best light blocking functionality. APPLE-1005, 17:1-16. Even if some other benefits might flow from use of a reflective material over a dark-colored coating in some cases as alleged by Patent Owner, the mere existence of design tradeoffs would not have detracted from the obviousness of using a dark-colored coating to shield external light from reaching the photodetectors.

42. A POSITA would have recognized that the black or dark-colored mask or in-mold label would have provided a suitable coating material that would have enhanced the light blocking function of Iwamiya's light shielding frame 18. Furthermore, a POSITA would have recognized that use of a dark-colored coating (as taught by Sarantos) rather than another material, such as a reflective coating, would have reduced the amount of errant light that could reflect back from the empty space through the optical filter 17 to the photodiodes. A POSITA would have sought to reduce these effects since any light that reflected back from the space surrounding frame 18 and through the optical filter 17 to the photodiodes would have different path lengths that could increase optical interference and reduce measurement accuracy. APPLE-1009, 69, 96-97.

43. Finally, A POSITA would have been prompted to implement Iwamiya's light shielding frame to include the dark-colored coating described by Sarantos because doing so would be merely the application of a known technique to a known system (e.g., Iwamiya's physiological monitoring device) ready for improvement to yield predictable results. Here, Sarantos provides straightforward evidence of known materials for enhancing the light blocking functionality of a light-shielding frame, and Iwamiya's teaching provides a known system that would have been improved by application of Sarantos's suggested technique for at least the reasons described above.

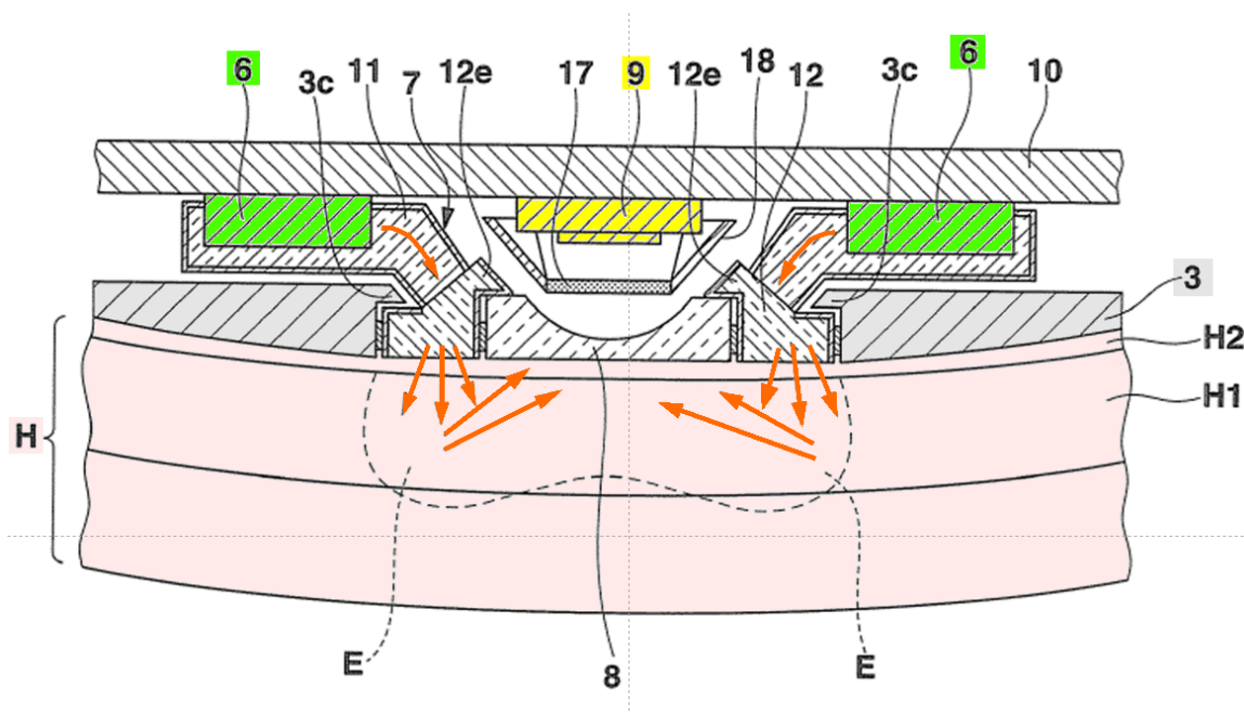
44. Based upon my knowledge and experience in this field and my review of Iwamiya and Sarantos, I am confident a POSITA would have recognized that such a modification would have yielded predictable results, and these modifications would have been within the ordinary level of skill of a POSITA at the time of the '159 patent disclosure. Based on my review, it is clear that at least because using dark-colored coatings in light blocks was well-known in the art, and Iwamiya and Sarantos describe similar and compatible wrist-worn reflectance-based physiological sensors, a POSITA would have reasonably expected success in applying the dark-colored coating from Sarantos to the light shielding frame of Iwamiya. A POSITA would have understood such a combination would be successful with no unexpected results.

4. Application of the combination of Iwamiya with Sarantos to the claims

(a) Claim 1

[1.0] A physiological monitoring device comprising:

45. In the combination, Iwamiya discloses an “optical biological information detecting apparatus” which is a physiological monitoring device. APPLE-1004, Abstract. For example, Iwamiya describes that the “optical biological information detecting apparatus” is provided in “a central portion of the back cover” of “a wristwatch” (*i.e.*, facing the wearer’s wrist). APPLE-1004, 5:54-66, FIG. 1. As shown in the following annotated FIG. 4 from Iwamiya, the device includes LEDs 6 (shown in green) that emit light (orange) that is reflected by the tissue of the wearer’s wrist (pink) and detected by photodiodes 9 (yellow).

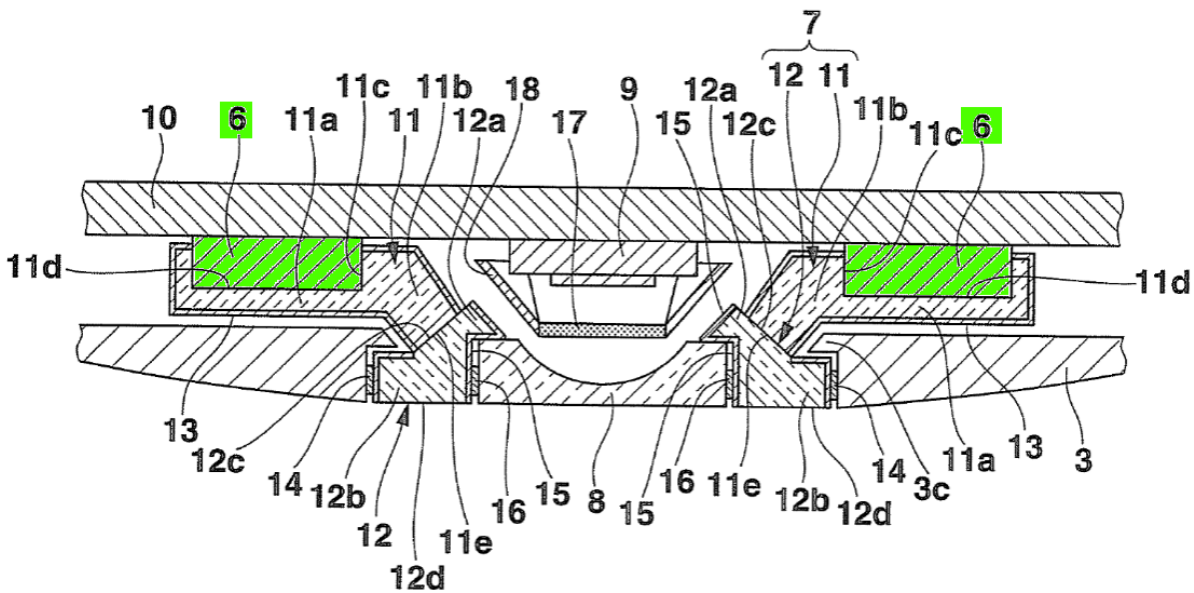


APPLE-1004, Detail of FIG. 4 (annotated)

46. A POSITA would have recognized that the wrist-worn device described by Iwamiya is a physiological measurement device at least because it can be used to obtain a physiological measurement or “biological information, such as a pulse wave” reflected from the surface of the skin of a person. APPLE-1004, Abstract, 9:1-7, 19:25-30, 4:42-54. Accordingly, the combination of Iwamiya and Sarantos renders obvious a “physiological monitoring device.”

[1.1] a plurality of emitters configured to emit light in a first shape;

47. Iwamiya’s physiological monitoring device includes “light emitting units 6” that are each “composed of a light emitting diode (LED).” APPLE-1004, 6:7-11, 6:32-39. LEDs are identified as an express example of “emitters” in the specification of the ’159 patent. APPLE-1001, 2:4-8, 7:30-35. The light emitting units 6 of Iwamiya’s physiological monitoring device are shown in green in the following annotated version of FIG. 3 from Iwamiya:



APPLE-1004, Detail of FIG. 3 (annotated)

48. Iwamiya's light emitting units 6 "emit observation light of a specific wavelength band to optically observe a skin tissue of a human body." *Id.*, 6:7-11. A POSITA would have recognized that the emitted observation light is in a first shape characterized by the specific location of each light emitting unit, *e.g.*, the "3 o'clock" and "9 o'clock" positions as shown in FIGS. 3 and 4 of Iwamiya. *See id.*, 6:7-11, FIGS. 3-4. Iwamiya gives further examples of additional configurations in which "the light emitting units 6 may be provided in three places or more in the bottom surface of the circuit board 10 corresponding to the light guiding ring portion 11." APPLE-1004, 14:21-28. A POSITA would have recognized that this example is describing that the light emitting units emit light in a different shape due to the different arrangement of the three or more light emitting units.

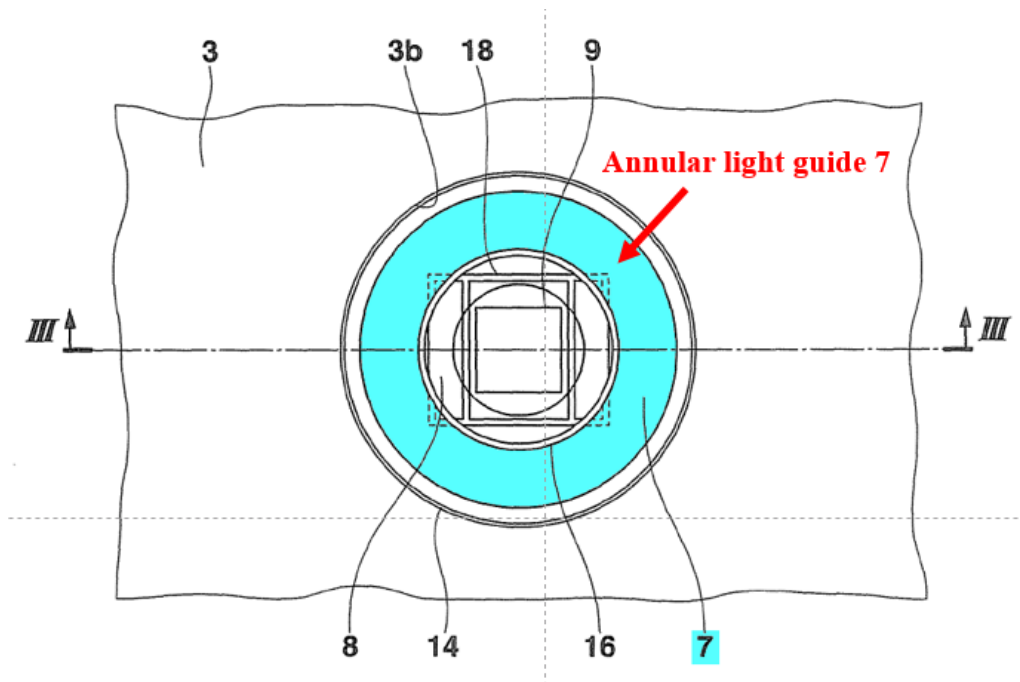
Furthermore, it would have been apparent to a POSITA based on the descriptions of Iwamiya as a whole that the light emitted by the light emitting units has a first shape. This claim element does not recite any requirement for a particular shape for the first shape of the emitted light and a POSITA would have understood that the arrangement of LEDs in Iwamiya's device would have defined the shape of the emitted light.

[1.2] a material positioned between the plurality of emitters and a tissue measurement site on a wrist of a user when the physiological monitoring device is in use, the material configured to change the first shape into a second shape by which the light emitted from one or more of the plurality of emitters is projected towards a surface of the tissue measurement site;

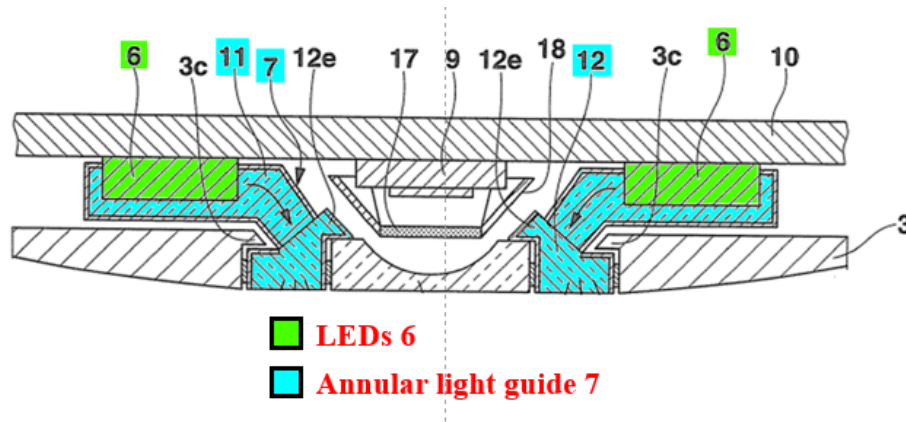
49. In reviewing the specification of the '159 patent with respect to this claim element, it is clear that this claim recitation is referring to a diffuser. For example, the '159 patent describes that "the diffuser is further configured to define a surface area shape by which the emitted spread light is distributed onto a surface of the tissue measurement site." APPLE-1001, 3:4-13, 4:22-27. In a further example, the '159 patent states that "the light diffuser 304 is a beam shaper." 7:44-56.

50. With this in mind, it becomes clear that Iwamiya describes a highly similar diffuser that demonstrates that the combination of Iwamiya with Sarantos meets this claim element. For example, Iwamiya describes that the physiological sensor includes "an annular light guide unit 7 that guides the observation light

emitted from the light emitting units 6 and annularly diffuses and irradiates the observation light with respect to a skin H.” APPLE-1004, 6:7-14, Fig. 4. The annular light guide unit 7 includes “a light guiding ring portion 11” formed “using a material such as transparent glass or a transparent resin with a high light transmitting property.” *Id.*, 6:40-45. The annular light guide unit 7 also includes “a diffusion/irradiation ring portion 12” that is “formed in almost a ring shape, using a clouded or milky resin with a light diffusing property.” *Id.*, 6:40-42, 7:4-6. This description matches this claim language. The following annotated FIGS. 2 and 4 from Iwamiya show top and cross-section views of physical monitoring device the annular light guide unit 7 (annotated in teal).



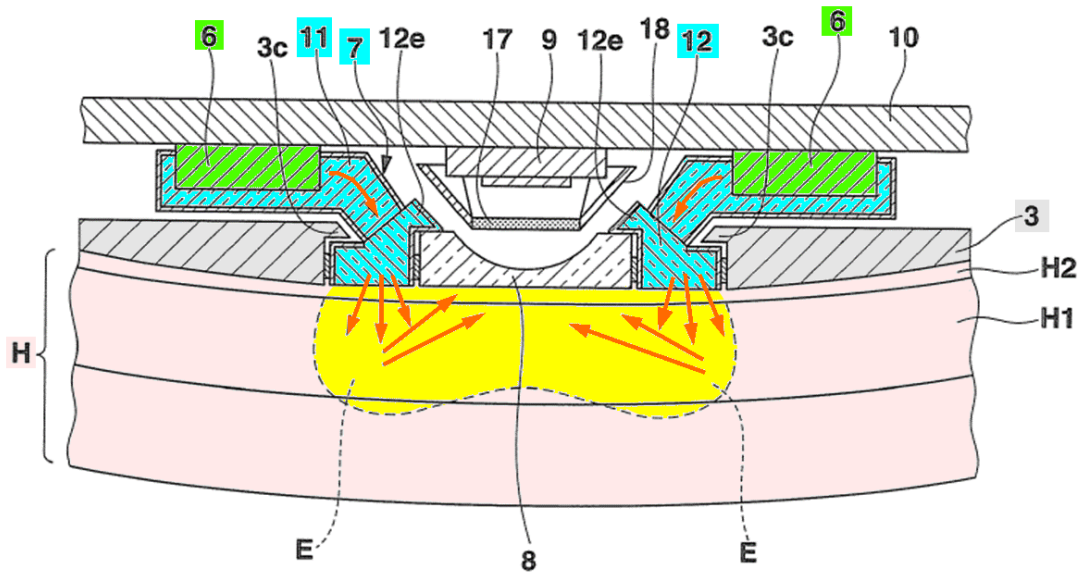
APPLE-1004, Detail of FIG. 2 (annotated)



APPLE-1004, Detail of FIG. 4 (annotated)

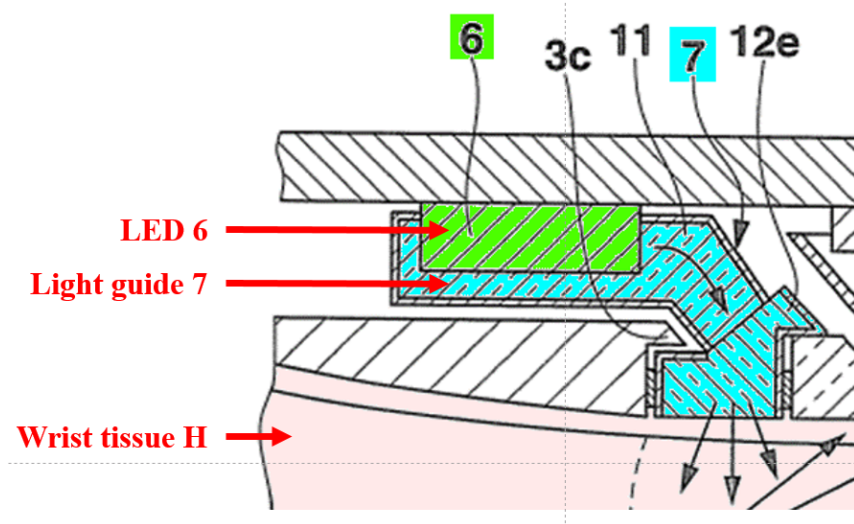
51. Annular light guide unit 7 changes the shape of the light emitted from individual light emitting units 6 to an annular shape (a second shape) and causes the light to irradiate an annular portion of tissue. *Id.*, 11:55-12:36. Iwamiya describes that the physiological monitoring device is a “wristwatch case” that is “mounted on the arm and the bottom surface of the back cover 3 is made to contact the skin H of the arm.” APPLE-1004, 9:61-65. Furthermore, the “bottom surface of each of the diffusion/irradiation ring portion 12 of the light guide unit 7” forms “a flat surface” positioned on the user’s wrist between the light emitting units 6 and the wrist. *Id.*, 9:65-10:5.

52. As shown in the following annotated FIG. 4 from Iwamiya, the light from the light emitting units (the orange arrows) irradiates “an irradiation area E” in the user tissue “having a ring shape” (shown in yellow). *Id.*, 7:61-65:



APPLE-1004, Detail of FIG. 4 (annotated)

53. As previously discussed (*see* [1.0], *supra*), Iwamiya's physiological sensor in Figure 4 is a wristwatch. *See, e.g.*, APPLE-1004, 6:22-31. Therefore, annular light guide unit 7 is positioned between light emitting units 6 and tissue on the wrist, as shown in annotated FIG. 4 below:



APPLE-1004, Detail of FIG. 4 (annotated)

54. The annular light guide unit 7 of Iwamiya's device changes the shape of the light emitted from individual light emitting units 6 (a first shape) to an annular or ring shape (a second shape) and causes the light to irradiate an annular portion of tissue. *Id.*, 11:55-12:36, 6:8-8:13. For example, Iwamiya specifically describes that the diffusion/irradiation ring portion 12 changes the light emitted from the light emitting units 6 from its initial shape into a "ring shape" toward a surface of the user's wrist:

Thereby, the diffusion/irradiation ring portion 12 is configured to take the observation light discharged from the emission surface 11 *e* of the inclined ring portion 11 *b* of the light guiding ring portion 11 in the inner portion of the incident surface 12 *c* of the inclined ring portion 12 *a*, annularly guide the taken observation light while diffusing the observation light by the inclined ring portion 12 *a*, diffuse and discharge the observation light from the emission surface 12 *d* of the bottom surface in the flat ring portion 12 *b*, and ***uniformly diffuse and irradiate the observation light over a wide area of a ring shape with respect to the skin H.***

APPLE-1004, 7:14-24.

55. As I discussed with respect to element [1.1], above, it would have been obvious to a POSITA that light emitted from the light emitting units 6 would have had a first shape, with the various different disclosed examples of light emitter arrangements providing different first shapes. The shape of this initial light pattern is altered to an annular or ring shape (the claimed "second shape") as it is

irradiated onto an annular portion of tissue. As Iwamiya describes, the light guide “annularly irradiates the observation light onto the desired area of the surface of the skin.” APPLE-1004, Abstract, 7:14-24, 7:61-65, 11:55-12:36, 10:15-11:31.

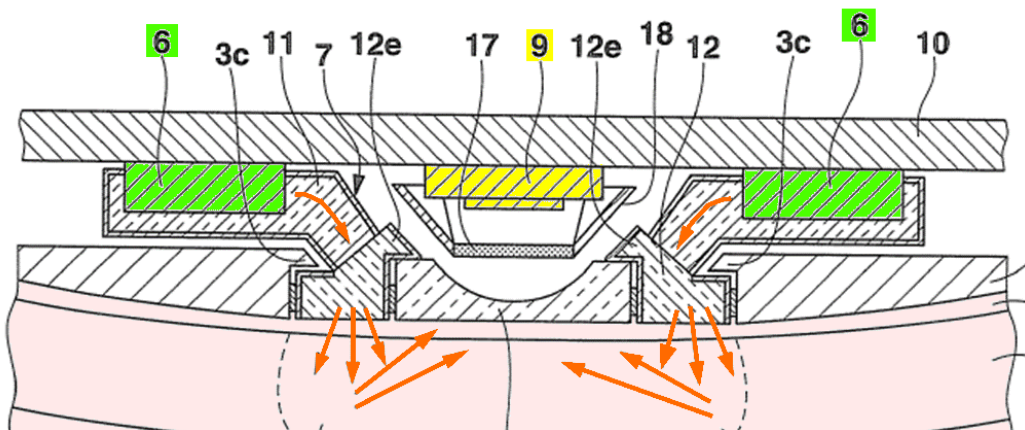
[1.3] a plurality of detectors configured to detect at least a portion of the light after passing through the tissue, the plurality of detectors further configured to output at least one signal responsive to the detected light;

56. Iwamiya describes that the physical monitoring device includes a plurality of photodiodes, stating that the device includes “plural light receiving units 9” and describing that each light receiving unit is “composed of a silicon photo diode.” APPLE-1004, 14:36-41, 8:20-23. A POSITA would have recognized that the term “detector(s)” as used in the ’159 patent refers to photodetectors and therefore the light receiving units/photo diodes disclosed in Iwamiya provide this limitation. For example, the ’159 patent describes that “detector 310 can be implemented using one or more photodiodes” and Iwamiya includes a similar disclosure that each light receiving unit “is composed of a silicon photo diode.” APPLE-1001, 9:25-27, 11:37-38; APPLE-1004, 8:20-23.

57. Iwamiya’s photodiodes are configured to detect light after the light passes through tissue and output a signal responsive to the detected light. As Iwamiya describes, “the observation light emitted from the light emitting unit 6 is irradiated onto the skin H and the scattered light thereof is received by the light receiving unit 9” which “outputs a current signal according to the amount of

received light.” APPLE-1004, 9:28-32. This signal is used to determine a physiological parameter for the user such as heart rate. For example, Iwamiya’s physiological monitoring device includes “an I/V converting circuit 22 that converts a current signal output from the light receiving unit 9 of the photoelectric signal detecting module 26 into a voltage signal [and] a display unit 23 that displays a measurement result of biological information, such as a pulse wave.” APPLE-1004, 8:61-9:7.

58. The following annotated FIG. 4 from Iwamiya shows that the light (shown as orange arrows) emitted by the light emission units 6 (in green) is reflected by the tissue H (in pink) and received by the photodiodes 9 (in yellow).

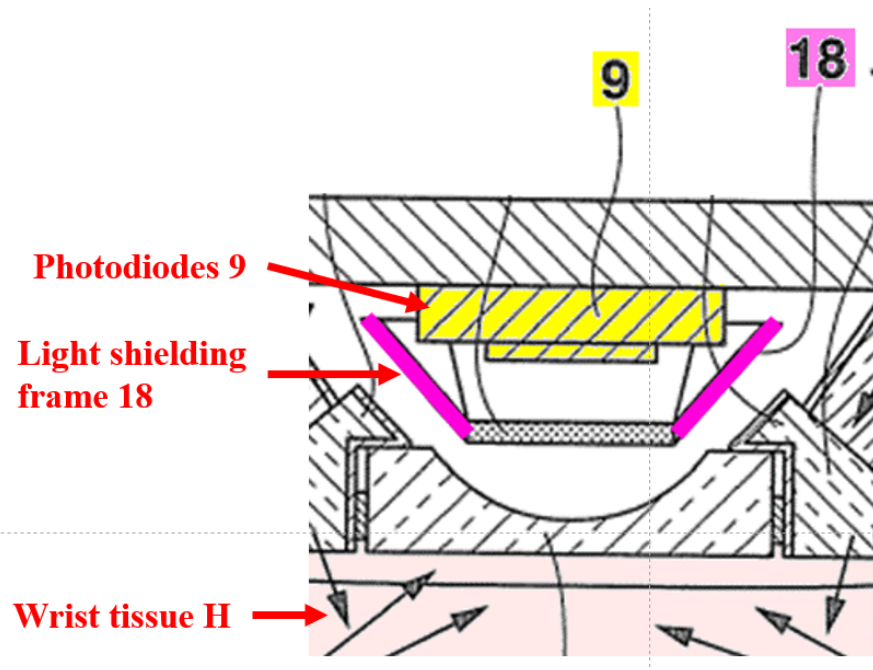


APPLE-1004, Detail of FIG. 4 (annotated)

[1.4] a surface comprising a dark-colored coating, the surface positioned between the plurality of detectors and the tissue when the physiological monitoring device is in use,

59. In the combination, Iwamiya describes a “light shielding frame 18” surrounding the photodiodes 9. APPLE-1004, 8:38-47, FIG. 4. A POSITA would

have recognized that the light shielding frame of Iwamiya provides the claimed surface. As shown in FIG. 4 from Iwamiya, the light shielding frame 18 (shown in pink) is positioned between the photodiodes 9 (in yellow) and the tissue (in pink):

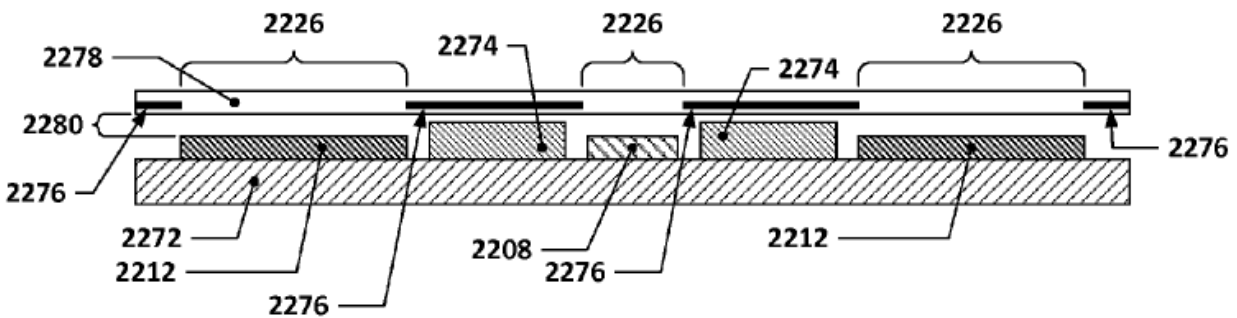


APPLE-1004, Detail of FIG. 4 (annotated)

As shown in FIG. 4, the light shielding frame 18 surrounds the optical filter 17 to allow light reflected from the tissue of the wearer to pass through the light shielding frame 18 and reach the detectors 9.

60. Also in the combination, Sarantos discloses a wrist-worn reflectance-based physiological sensor that has a dark-colored coating 2276 to block light.

APPLE-1005, 5:55-58, Fig. 22.



APPLE-1005, FIG. 22.

61. Saranto's also discloses that light source 2208 emits light through a window into a user's skin, wherein the light is reflected from the skin and back to the sensor and detected by photodetector elements 2212. APPLE-1005, 17:16-25. The light travels through window regions 2226 in the dark-colored coating 2276 applied to window 2278. *Id.* Specifically, Sarantos discloses that "in-mold label 2276 may be black or otherwise rendered opaque to light to prevent light from entering or exiting the PPG sensor through the window 2278 except through window regions 2226." APPLE-1005, 17:1-16. Sarantos explains that various masking techniques may be used to block stray light from reaching the photodetector elements 2212, including "a painted or silk-screened mask" applied to the window 2278. *Id.*

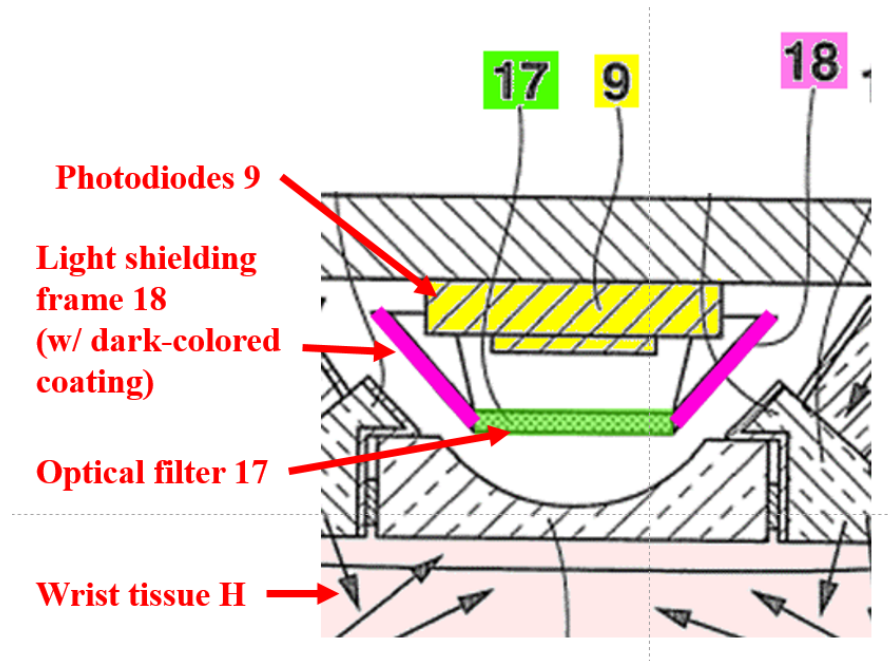
62. As I explained above, a POSITA would have been motivated to implement the light shielding frame of Iwamiya to include an in-mold label or other black or opaque material/coating as disclosed by Sarantos to serve the purpose indicated by the component's name: shielding the photodiodes 9 from

stray light (one of the dominant noise sources), and thereby ensuring accuracy of the sensor. *See, e.g.*, APPLE-1004, 8:38-47, FIG. 4; APPLE-1005, 5:55-58, 17:1-25, FIG. 22. A POSITA would have applied the teachings of Sarantos to Iwamiya in this fashion for the reasons previously discussed.

63. For example, A POSITA would have understood that a dark-colored coating, such as that described by Sarantos, would have furthered the light-blocking functionality of Iwamiya's light shielding frame 18 by not only blocking light but also by limiting reflections, which could lead to stray light being incident on the photodiodes 9. It also would have been obvious to a POSITA to use a dark-colored coating for light shielding frame 18 because dark-colored coatings and materials were well-known to effectively block light. *See, e.g.*, APPLE-1005, 17:1-10. A POSITA would have known that a light shielding frame 18 or holder portion 43 as disclosed by Iwamiya can be of various proportions, and a thin surface is a coating. *See id.* Because using dark-colored coatings in light blocks was so well-known, and Iwamiya and Sarantos are both wrist-worn reflectance-based physiological sensors, a POSITA would have reasonably understood the combination of Iwamiya with Sarantos to be successful with no negative/detrimental results. APPLE-1009, 96-97; APPLE-1032, 9:58-10:23.

[1.5] wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface;

64. As I discussed with respect to element [1.4], above, in the predictable combination of Iwamiya with Sarantos, the “light shielding frame 18” of Iwamiya is implemented using a dark-colored coating or in-mold label, such as that described by Sarantos. Iwamiya further describes an “an optical filter 17” that “is mounted on the lower side of a light shielding frame 18” between the photodiodes 9 and the tissue H. APPLE-1004, 8:39-42. This configuration is shown in the following detail of FIG. 4 from Iwamiya:



APPLE-1004, Detail of FIG. 4 (annotated)

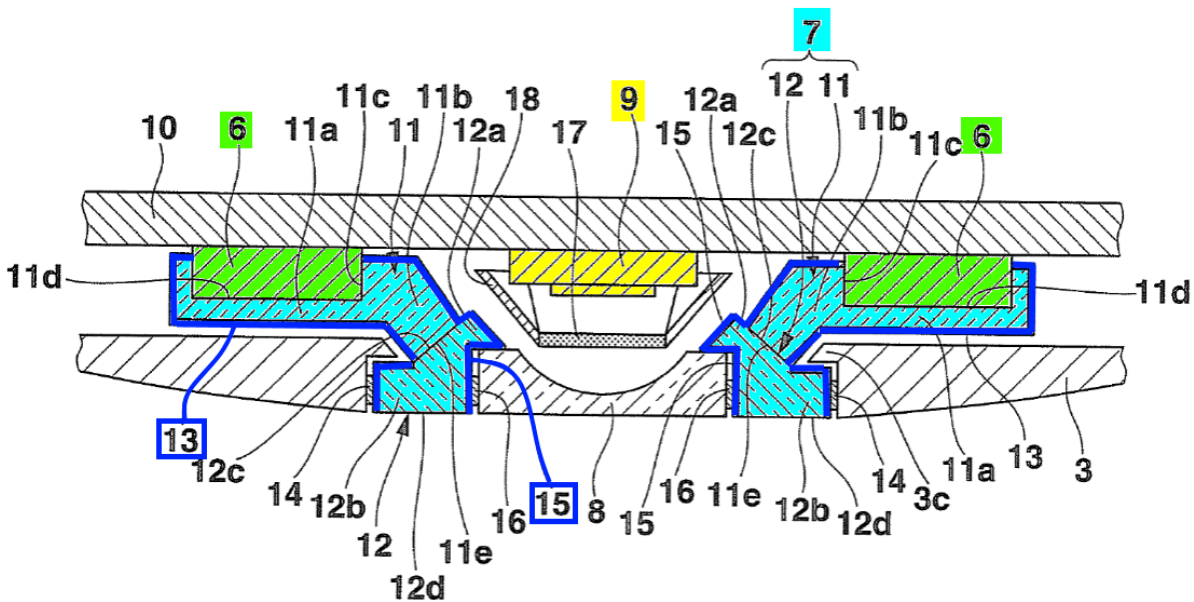
65. Iwamiya describes that the “optical filter 17 is configured to transmit light of a specific wavelength band of 900 nm or more,” and thus is configured to

allow at least a portion of light reflected from the tissue to pass through to the photodiodes 9. APPLE-1004, 8:42-44. I note that this disclosure in Iwamiya of “900 nm or more” is merely an example of “a portion of the light.” Modifying Iwamiya’s optical filter to transmit red and infrared light (as discussed with respect to claim 8 below), or even removing the optical filter altogether, would still satisfy element [1.5].

[1.6] a light block configured to prevent at least a portion of the light emitted from the plurality of light-emitting diodes from reaching the plurality of photodiodes without first reaching the tissue; and

66. Iwamiya demonstrates that the physiological monitoring device resulting from the combination of Iwamiya with Sarantos includes the claimed light block in the form of reflection layers 13 and 15 (annotated in dark blue) that prevent light within annular light guide 7 from leaking outside of the annular light guide (teal), as demonstrated in FIG. 3, reproduced below. APPLE-1004, 6:62-7:3,

7:41-49, FIG. 3:



APPLE-1004, Detail of FIG. 3 (annotated)

67. A POSITA would have recognized that the reflection layers 13 and 15 act as light blocks by preventing the light emitted from light emitting unit 6 from leaking outside of the light guide 7 and directly reaching the photodiodes 9 without first reaching the tissue. APPLE-1004, 6:62-7:3, 7:41-49, FIG. 3.

[1.7] a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal.

68. In the combination, Iwamiya discloses a central processing unit (CPU) 20 that controls the disclosed biological information detecting apparatus. APPLE-1004, 8:61- 9:7. The CPU receives a current signal from the photodiodes of Iwamiya, processes it into a voltage signal, and then determines and displays a

physiological parameter of the user, such as a heart rate, based on the signal.

APPLE-1004, 8:61-9:7, 9:36-43. FIG. 10 shows an example of the CPU:

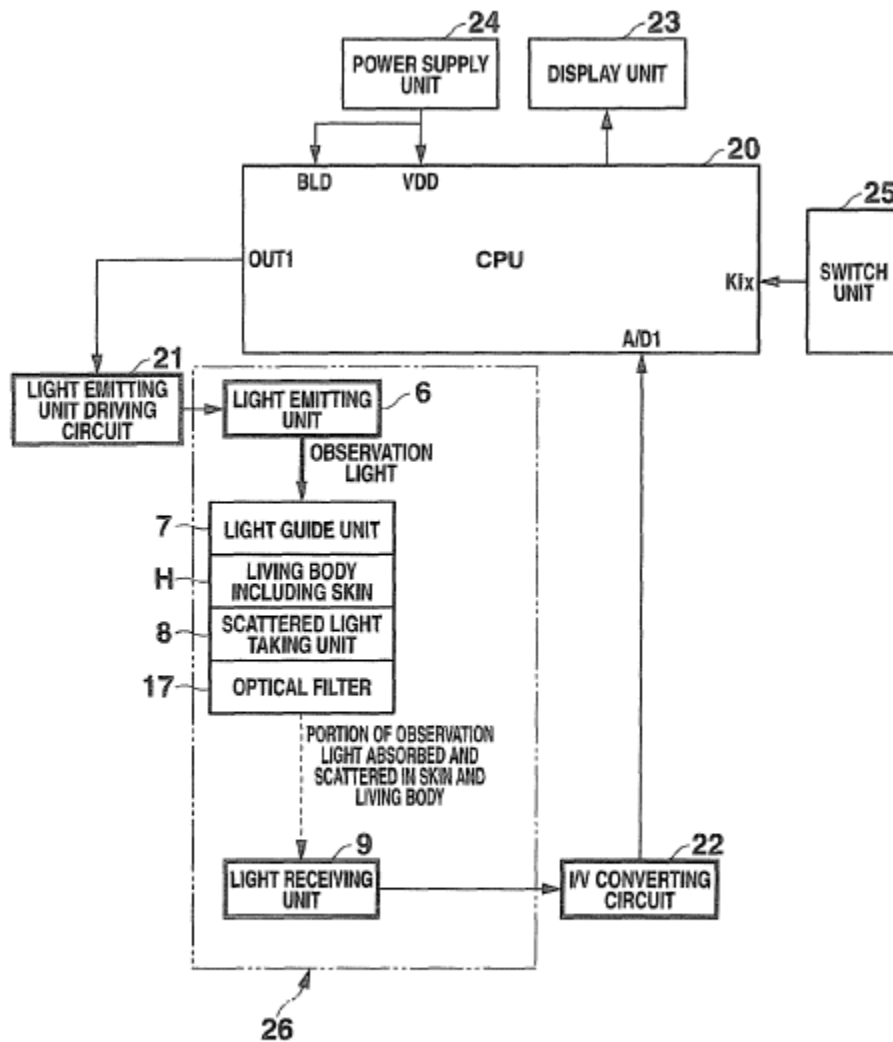


FIG.10

APPLE-1004, FIG. 10.

69. Iwamiya describes that the light receiving unit (the claimed detector) outputs a current signal corresponding to the amount of light received from the tissue (the claimed at least one outputted signal). *Id.* at 9:28-32. Next, an I/V

converting circuit “converts a current signal output from the light receiving unit 9 of the photoelectric signal detecting module 26 into a voltage signal” (i.e., one or more signals responsive to the at least one outputted signal) and inputs the signal to the CPU. *Id.* at 9:32-35. There, the CPU of Iwamiya receives and processes the voltage signal (i.e., the one or more signals responsive to the at least one outputted signal) from the detectors (i.e., the at least one outputted signal), and then determines and displays a physiological parameter of the user, such as a heart rate, based on the signal. APPLE-1004, 8:61-9:7, 9:36-43 11:9-18, 19:16-31. For example, as Iwamiya describes, “[t]he CPU 20 performs a frequency analysis on the time-series data, outputs the data as biological information such as a pulse wave to the display unit 23.” *Id.*, 9:36-43. Sarantos provides similar disclosure, describing that the processor “determine[s] a heart rate measurement based, at least in part, on the at least one light intensity measurement” APPLE-1005, 4:44-50, 20:7-29.

(b) Claim 2

[2.0] The physiological monitoring device of claim 1, further comprising a display configured to present visual feedback responsive to the determined physiological parameter.

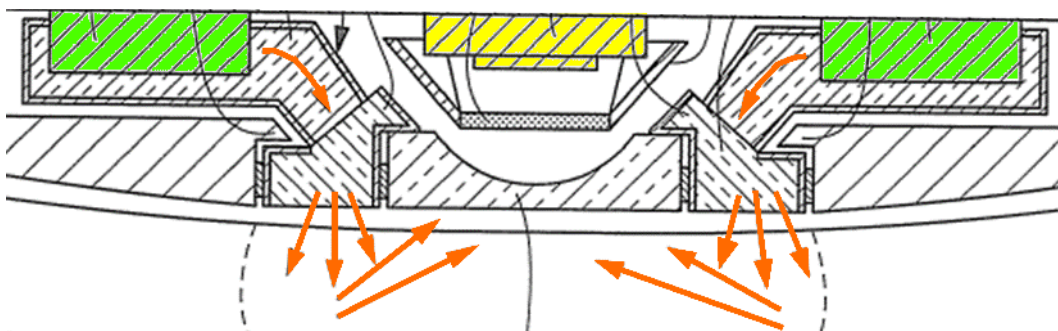
70. Iwamiya’s physiological monitoring device includes “a CPU (central processing unit) 20 that performs whole control of the apparatus” and “a display unit 23 that displays a measurement result of biological information, such as a

pulse wave.” APPLE-1004, 8:61-9:7. Iwamiya describes that “[t]he CPU 20 performs a frequency analysis on the time-series data, outputs the data as biological information such as a pulse wave to the display unit 23, and displays the data on the display unit 23.” APPLE-1004, 9:28-43. In other words, the CPU of Iwamiya receives and processes voltage signals derived from current signals generated by the light receiving units 9 to derive a physiological parameter (“biological information”) and provides this information to the display unit for display.

(c) Claim 4

[4.0] The physiological monitoring device of claim 1, wherein the plurality of emitters and the plurality of detectors are arranged in a reflectance measurement configuration.

71. In the combination, Iwamiya discloses multiple LEDs and a plurality of photodiodes wherein light is shone into tissue and reflected back to the photodiodes. APPLE-1004, 6:7-21, 13:49-64, FIG. 4. This configuration is shown in FIG. 4 of Iwamiya, which shows the LEDs in green, the photodiodes in yellow, and the reflected light in orange:



APPLE-1004, Detail of FIG. 4 (annotated)

72. As described by Iwamiya, the “optical biological information detecting apparatus” is provided in “a central portion of the back cover” of “a wristwatch” (*i.e.*, facing the wearer’s wrist). APPLE-1004, 5:54-66, FIG. 1. “For example, plural light receiving units 9 may be two-dimensionally disposed in the places positioned at the side opposite to the skin H in the scattered light taking unit 8.” APPLE-1004, 14:32-41.

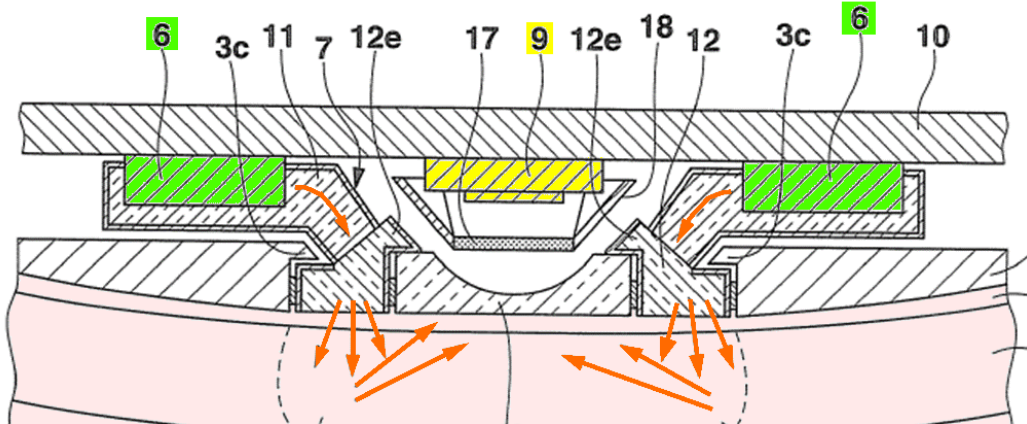
73. A POSITA would have understood the configuration shown in FIG. 4 of Iwamiya in which light is emitted from LEDs 6 into the user’s wrist and reflected back from the wrist tissue toward the light receiving units 9 to be a reflectance measurement configuration. *See, e.g.*, APPLE-1009, 87-88, Figure 7.2.

(d) Claim 5

[5.0] The physiological monitoring device of claim 1, wherein the plurality of detectors are arranged in an array having a spatial configuration corresponding to a shape of a portion of the tissue measurement site bounded by the light block.

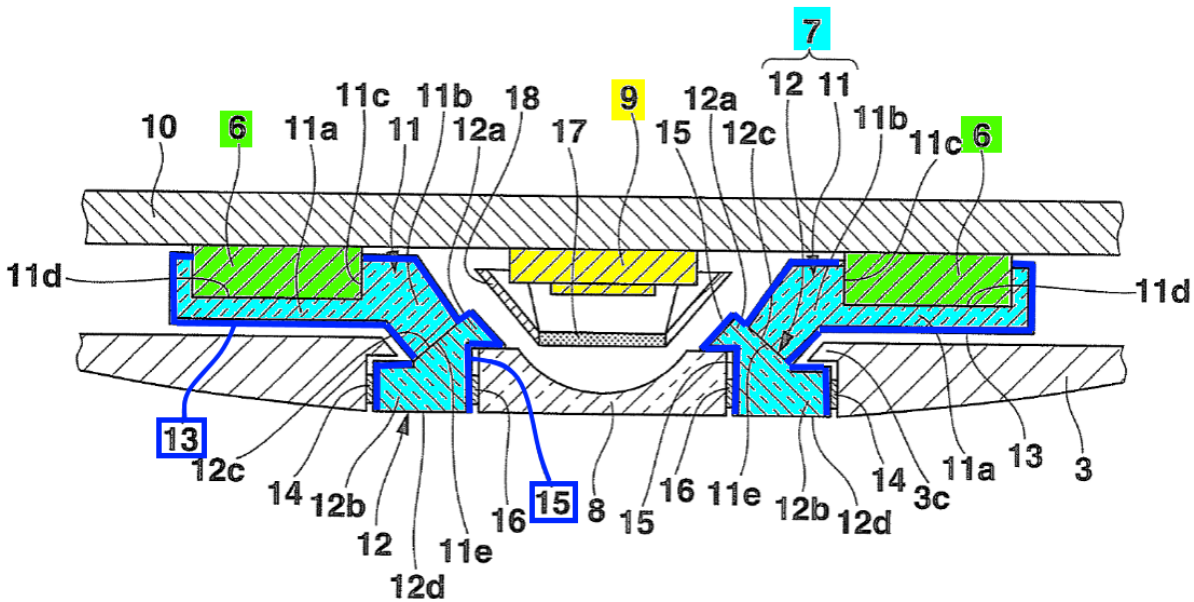
74. As I previously discussed with respect to element [1.3], above, in the combination, Iwamiya describes that light emitted from light emitting units 6 travels through light diffusing material (annular light guide unit 7) and then passes into skin tissue that is encircled by the light block (reflection layers 13 and 15). APPLE-1004, 6:7-14, 12:3-17, FIGS. 3-4. As Iwamiya describes the “light guiding ring portion 11...annularly guides the observation light, and annularly

discharges the annularly guided observation light...and annularly irradiates the observation light onto the skin.” APPLE-1004, 11:55-12:36. For example, Iwamiya describes that “[t]he observation light incident in the inner portion of the dermis H1 is uniformly irradiated over a wide area of *a ring shape*.” *Id.*, 10:44-53. As shown below in the annotated FIG. 4 from Iwamiya, the light from the light emitting units (the orange arrows) irradiates “an irradiation area E” in the user tissue “having a ring shape” (shown in yellow) bounded by the light block (reflection layers 13 and 15, not labeled in FIG. 4). *Id.*, 7:61-65.



APPLE-1004, Detail of FIG. 4 (annotated)

75. Reflection layers 13 and 15, which form the light block, encircle a portion of patient tissue, shown in Iwamiya FIG. 4 as irradiation area E. APPLE-1004, FIGS. 3-4. FIG. 3 (below) and FIG. 4 (above) also show that the annular/ring shaped portion of the tissue measurement site bounded by the light block (reflection layers 13 and 15) is centered on the optical axis of the device.



APPLE-1004, Detail of FIG. 3 (annotated)

76. Iwamiya describes that the physiological monitoring device includes a plurality of photodiodes configured to detect light reflected by the encircled tissue. APPLE-1004, 6:7-14, 8:20-23, 12:3-17, 14:36-41, FIGS. 3-4. The photodiodes “may be two-dimensionally disposed in the places positioned at the side opposite to the skin H in the scattered light taking unit 8.” APPLE-1004, 14:36-39. “In this case, the plural light receiving units 9 are preferably disposed *on the same circumference centered on an optical axis of the scattered light taking unit 8.*” APPLE-1004, 14:39-41. A POSITA would thus have understood that the photodiodes described in Iwamiya are arranged in an array having a spatial configuration corresponding to a shape of the portion of the tissue measurement site encircled by the light block. *See, e.g.,* APPLE-1004, 14:36-41, FIGS. 2-4.

77. Iwamiya's light block is circular, and the fact that Iwamiya's plural photodiodes 9 are arranged in "in an array having a spatial configuration corresponding to a shape of the portion of the tissue measurement site encircled by the light block" is evident from the fact that the photodiodes 9 are arranged "on the same **circumference** centered on an optical axis" of the circular light taking unit 8. APPLE-1004, 14:36-41. From this disclosure, a POSITA would have understood, and it would have been obvious, that the photodiodes 9 are thus arranged in an array having a spatial configuration corresponding to the circular shape of the tissue measurement site encircled by the circular light block, as illustrated below.

photodiodes 9 arranged “on the same circumference centered on an optical axis” of the circular light taking unit 8

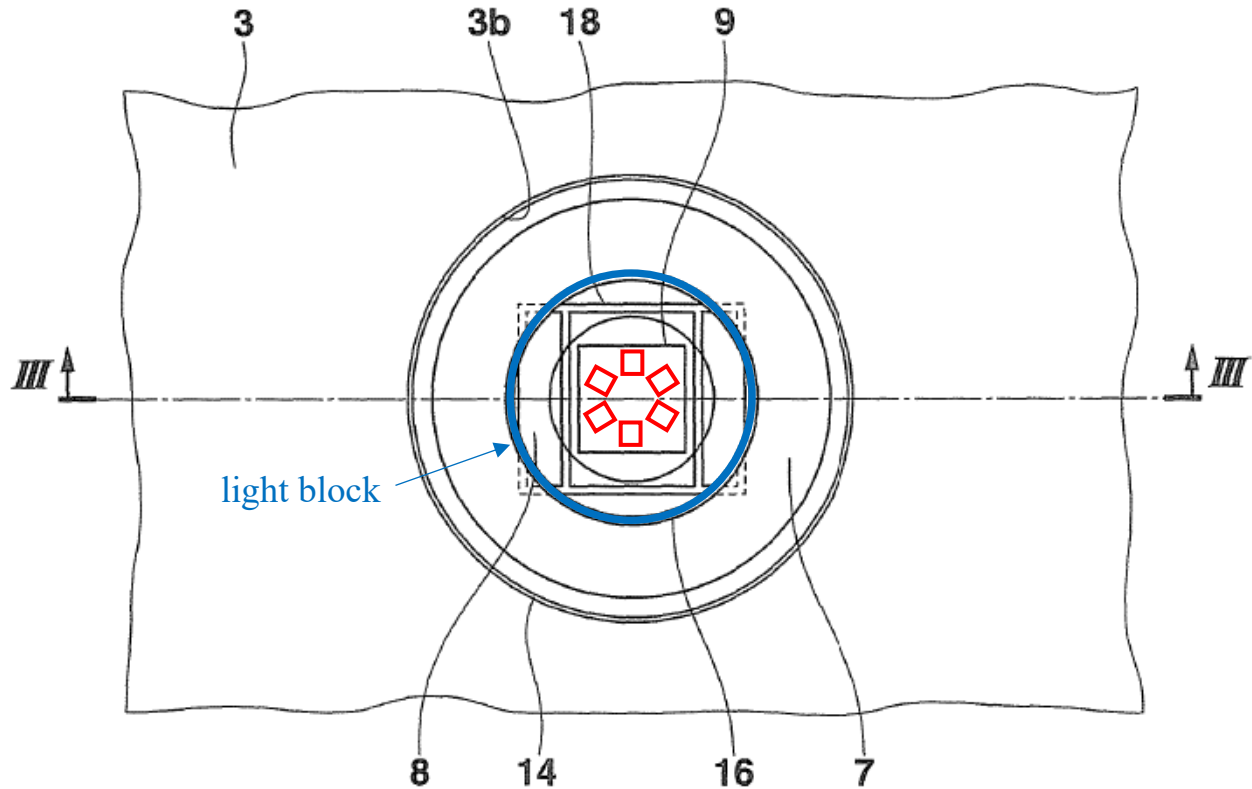


FIG.2

APPLE-1004, FIG. 2 (annotated according to Iwamiya’s teachings)

78. Furthermore, Iwamiya does not limit the number of photodiodes in its “plural[ity]” and therefore a POSITA would have understood, and it would have been obvious, to select any suitable number of photodiodes, including six or more, that could be “two-dimensionally disposed... on the same circumference centered on an optical axis of the scattered light taking unit 8.” APPLE-1004, 14:36-41.

Iwamiya leaves the choice of the number of photodiodes to a POSITA, who would have known that more than just a “small plurality” of photodiodes (e.g., more than

2-3) were commonly employed in pulse oximeters before the '159 Patent for purposes such as increasing detection area, light sensitivity, and overall signal-to-noise ratio, and with consideration to cost and manufacturability. For example, Webster states that:

In a reflectance oximeter, the incident light emitted from the LEDs diffuses through the skin and the back scattered light forms a circular pattern around the LEDs. Thus if we use multiple photodiodes placed symmetrically with respect to the emitter instead of a single photodiode, a large fraction of back scattered light can be detected and therefore larger plethysmograms can be obtained.

APPLE-1009, 107; *see also* APPLE-1033, 4:6-9 (“the total amount of backscattered light that can be detected by a reflectance sensor is directly proportional to the number of photodetectors”), 4:59-62 (“a radially-symmetric photodetector array can help to maximize the detection of backscattered light from the skin and minimize differences from local tissue inhomogeneity”); APPLE-1034, 4 (“a concentric array of either discrete PDs, or an annularly-shaped PD ring, could be used to increase the amount of backscattered light detected by a reflectance type pulse oximeter sensor”); APPLE-1035, [0022] (“the circular array of detectors 106 may prove advantageous in enlarging the detection area of the device 100 and therefore increasing the probability of detecting a reflected signal.”), FIG. 1A.

79. I note that Iwamiya provides a similar disclosure to the specification of the '159 Patent itself. The '159 specification merely refers to a “plurality” of photodetectors 310/710, but never expressly discloses that any minimum number of photodetectors is required to form an array. *Cf.* APPLE-1001, 9:25-30, 11:37-43. Iwamiya substantially mirrors the '159 specification in disclosing “plural photodiodes 9” two-dimensionally arranged around a “circumference” of an optical axis. APPLE-1004, 14:36-41. To the extent a POSITA would have understood the disclosure of the '159 Patent as teaching more than a small number of photodetectors (e.g., at least six), a POSITA would have understood Iwamiya’s disclosure as encompassing the same. The '159 Patent describes no critical number or range of numbers of photodiodes required to achieve any particular performance standard or to achieve unexpected results. A POSITA would have found Iwamiya’s disclosure of a plurality of photodiodes sufficient to render obvious more than two or three (e.g., six or more) photodiodes in this context, even though such a number of photodiodes is not required by this claim.

80. Furthermore, I observe that the term “correspond” has broader meanings than those represented by the applicant to the Office during prosecution of the parent application, and merely requires, for example, that the spatial configuration of the photodiodes “be in agreement, harmony, or conformity” with to the circular shaped light block. APPLE-1029, 3; APPLE-1030, 3; APPLE-1031,

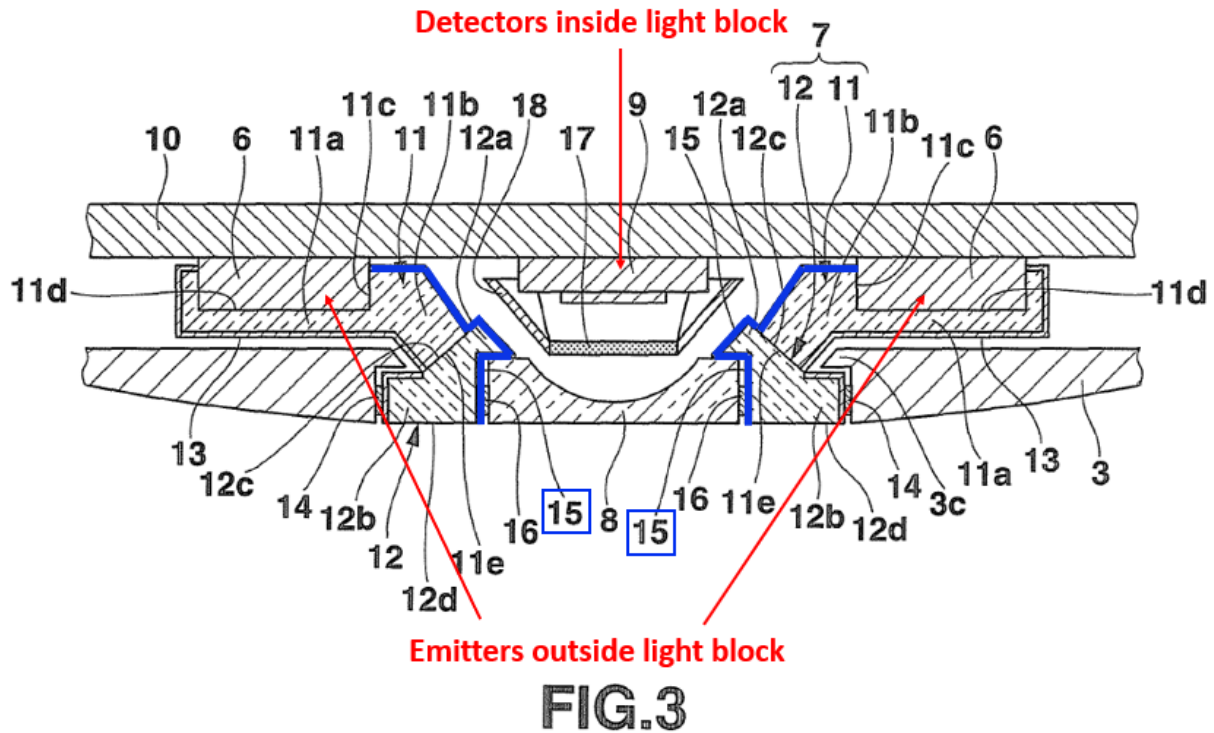
3. Iwamiya's photodiodes arranged "on the same circumference centered on an optical axis" of the circular light taking unit 8 is consistent with the plain meaning of "correspond," for example, because the photodiodes are in agreement, harmony, or conformity with the circular shape of the light taking unit 8 bounded by the circular light block by being on the same circumference of a circle.

81. A POSITA would have understood that in "a reflectance oximeter, the incident light emitted from the LEDs diffuses through the skin and the back scattered light forms a circular pattern" and thus, using "multiple photodiodes placed symmetrically with respect to the [emitted light] instead of a single photodiode, a large fraction of back scattered light can be detected and therefore larger plethysmograms can be obtained." APPLE-1009, 107; APPLE-1033, 4:6-9 ("the total amount of backscattered light that can be detected by a reflectance sensor is directly proportional to the number of photodetectors"), 4:59-62 ("a radially-symmetric photodetector array can help to maximize the detection of backscattered light from the skin and minimize differences from local tissue inhomogeneity"); APPLE-1034, 4 ("a concentric array of either discrete PDs, or an annularly-shaped PD ring, could be used to increase the amount of backscattered light detected by a reflectance type pulse oximeter sensor").

(e) Claim 6

[6.0] The physiological monitoring device of claim 1, wherein the light block comprises an at least partially circular shape, and wherein the plurality of emitters are positioned outside the light block and the plurality of detectors are positioned inside the light block.

82. In my analysis of claim 1, above, I identified the combination of the reflection layers 13 and 15 of Iwamiya as providing the claimed light block. While this mapping of the disclosures of Iwamiya to the claims of the '159 patent holds true, a POSITA would have recognized that the light reflection layer 15 also provides the claimed light block of claim 1. This is demonstrated, for example, by FIG. 3. FIG. 3 shows that the light reflection layer 15 is positioned between the LEDs 6 (emitters) and light guide 7 and photo diodes 9 (detectors) to prevent at least a portion of the light emitted from LEDs 6 from reaching the plurality of photo diodes 9 without first reaching the user's wrist tissue. APPLE-1004, 6:62-7:3, 7:41-49.



APPLE-1004, FIG. 3 (annotated)

83. As FIG. 3 demonstrates, the LEDs 6 (emitters) are positioned outside the light block while the photo diodes 9 (detectors) are inside of light reflection layer 15 (the claimed light block). As I discussed with respect to claim 5, above, the light reflection layer 15 has a circular shape in the form of an annular/ring shape defined by the light reflection layer 15. APPLE-1004, 11:55-12:36, 9:65-10:5, 10:44-53, 7:61-65.

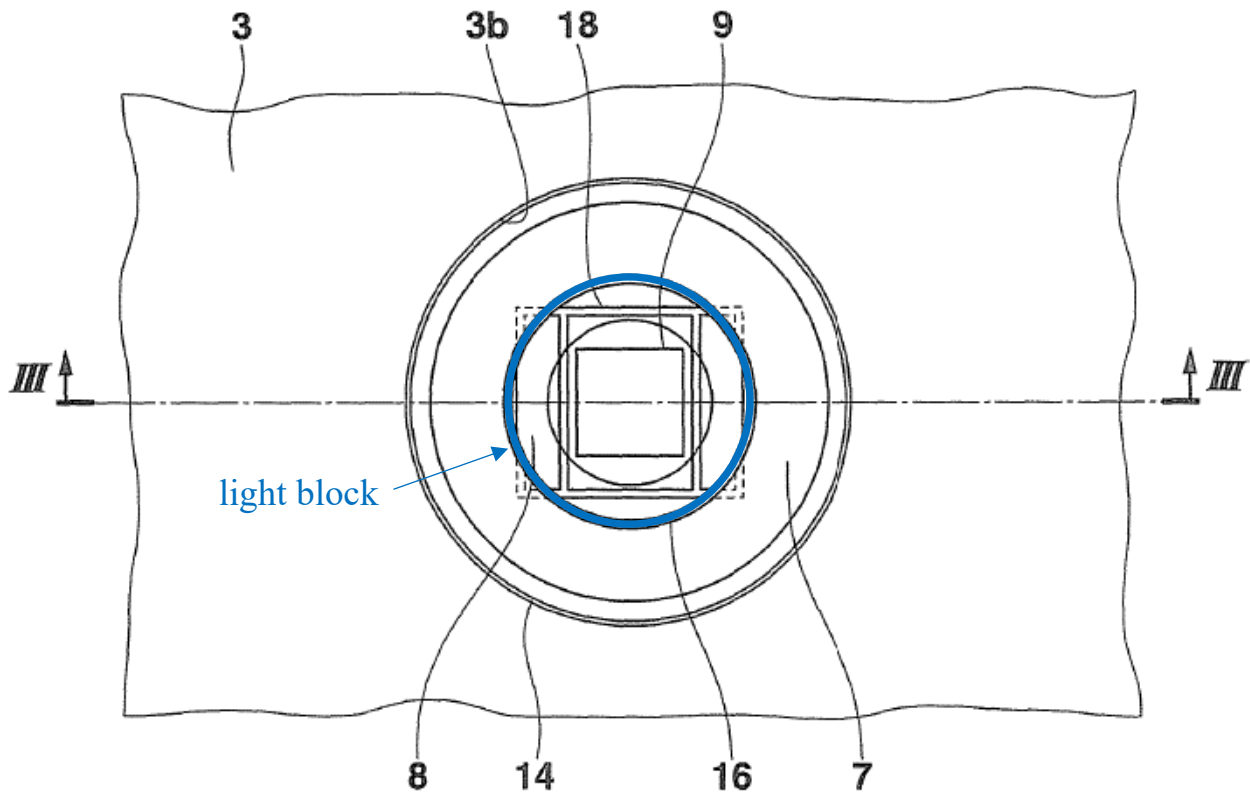


FIG.2

APPLE-1004, FIG. 2 (annotated)

(a) Claim 7

[7.0] The physiological monitoring device of claim 1, wherein the physiological parameter comprises pulse rate.

84. Iwamiya discloses that the physiological parameter measured by its wrist-worn physiological parameter monitoring device is a pulse rate. For example, Iwamiya discloses that “biological information, such as a pulse wave, is detected by the optical biological information detecting apparatus.” APPLE-1004, 5:26-28. In another example, Iwamiya describes that the “display unit 23 []

displays a measurement result of biological information, such as a pulse wave.”

APPLE-1004, 8:61-9:7. As yet another example, Iwamiya describes that the CPU processes signals received from the I/V converting circuit 22 and “outputs the data as biological information such as a pulse wave to the display unit 23, and displays the data on the display unit 23.” *Id.*, 9:36-43.

This is also demonstrated by FIGs. 29A-29C:

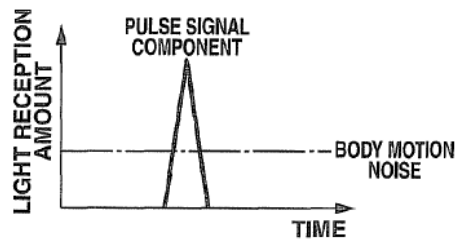


FIG.29A

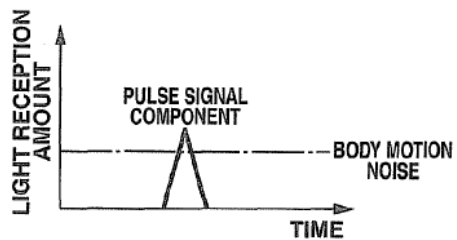


FIG.29B

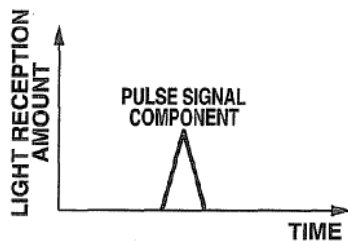


FIG.29C

APPLE-1004, FIGs. 29A-29C.

85. A POSITA would have recognized that a “pulse wave” is a heart rate/pulse rate and therefore Iwamiya provides this claim. Additionally, Sarantos similarly discloses that the resulting physiological sensor “determine[s] a heart rate measurement based, at least in part, on the at least one light intensity measurement.” APPLE-1005, 4:44-50, 20:7-29.

(b) Claim 8

[8.0] The physiological monitoring device of claim 1, wherein the physiological parameter comprises oxygen saturation.

86. In the combination, Iwamiya discloses a sensor that detects “biological information,” which includes oxygen saturation, and provides the example of a “pulse wave” or heart rate, wherein oxygen saturation comprises heart rate sensing at different wavelengths. APPLE-1004, 8:61-9:7.

87. Also in the combination, Sarantos discloses well-known techniques for measuring oxygen saturation using two wavelengths of light (i.e., red and infrared wavelengths) in a wrist-worn physiological monitoring device. APPLE-1005, 13:40-14:22. Furthermore, a POSITA would have been motivated to implement Iwamiya’s wrist-worn physiological sensor to measure blood oxygen saturation based on the teachings of Sarantos, in order to expand the range of physiological parameters measured by Iwamiya’s sensor, thereby improving the functionality and utility of the sensor. *See, e.g.*, APPLE-1005, 13:40-14:22. A POSITA would have reasonably expected success in adapting Iwamiya’s sensor to

this purpose because wrist-worn pulse oximetry sensors, such as that described in Sarantos, were well-known in the art. *See, e.g.*, APPLE-1005, 13:40-14:22, FIG.

2.

88. Multiple reasons would have prompted a POSITA to modify the wrist-worn physiological monitoring device to measure and display blood oxygen saturation of the user based on the suggestion of Sarantos. As I mentioned above, as a first reason, a POSITA would have recognized that adding the capability to measure blood oxygen saturation (in addition to the ability to detect heart rate of the user) would have expanded range of physiological parameters measured by Iwamiya's sensor, thereby improving the functionality and utility of the resulting device. A POSITA would, for example, have recognized that determining additional physiological parameters such as blood oxygen saturation, and conveying those additional physiological parameter measurements to users would have increased the overall utility of the resulting device while "improving the quality and safety in patient monitoring," while at the same time negating the need to purchase and utilize additional devices to obtain those additional physiological parameter measurements. APPLE-1017, 3-4.

89. As a second reason, a POSITA would have been aware that providing this additional functionality of measuring blood oxygen saturation in Iwamiya's device would have benefited users of the sensor in a variety of ways; for example,

by allowing “[p]eople with cardiac or pulmonary disease [to] check on their blood oxygenation continuously, especially while jogging or exercising,” so as to ensure that blood oxygen levels are within acceptable ranges to avoid injury or medical emergencies. APPLE-1014, 1.

90. As a third reason, a POSITA would have appreciated that such functionality would have beneficially allowed pilots to use the resulting device “to determine if they need supplemental oxygen, especially when they fly a non-pressurized airplane.” APPLE-1014, 1. Such functionality would therefore readily and conveniently prevent dangerous flying situations, leading to a decrease in the likelihood of a crash.

91. As a fourth reason, a POSITA would have understood that providing this additional functionality of measuring blood oxygen saturation in Iwamiya’s device would have allowed alpinists “climbing on high altitudes” to ensure that their blood oxygen levels are within a safe range, thereby allowing such climbers to avoid serious injury or death. APPLE-1014, 1.

92. As a fifth reason, a POSITA would have understood that modifying Iwamiya’s device in this manner would have provided “a safe, reliable, real time and continuous measurement” method improving the device’s overall utility. APPLE-1016, 1. Such increased utility would have increased user satisfaction

with such a device thereby increasing good will toward such a product and increasing sales and brand recognition.

93. As a sixth reason, the POSITA would have understood that the resulting wrist-worn reflectance oximeter would “increase[] the flexibility” of Iwamiya’s device in a manner enabling blood oxygen levels to be determined outside of hospital settings. APPLE-1016, 1. Such functionality would have allowed the resulting device to effectively and continuously monitor “symptoms of decreased ability to ventilate” such as “cyanosis, dyspnea, tachypnea, decreased level of consciousness, increased work of breathing and loss of protective airway reflexes.” APPLE-1018, 1. Such a POSITA would have recognized that “it is extremely important to be able to offer solutions which can be used also when supervising moving patients in different kinds of environments” and that the resulting device would have provided just such a solution by allowing for wrist-based blood oxygen measurement “in real-life situations.” *Id.*

94. A POSITA also would have had a reasonable expectation of success in implementing Iwamiya’s wrist-worn physiological monitoring device to measure blood oxygen saturation based on the suggestions of Sarantos. Sarantos clearly contemplates embodiments where its wrist-worn device would measure blood oxygenation levels using red and infrared light. This is evident from Sarantos’s express description of structural modifications that would be made to

accommodate multiple LEDs of different wavelengths, including that “multiple light-emitting devices ... may[] ... be spaced apart from one another, as shown in FIGS. 1 and 2, or may be closely grouped.” APPLE-1005, 13:34-36, 13:44-14:22. And although Sarantos notes that, with respect to the exemplary embodiments, its disclosed “ratios and dimensional values” are “tailored based on the green/yellow light spectrum” rather than the “red or infrared spectra” (*see* APPLE-1005, 18:48-51), Sarantos does not criticize, discredit, or otherwise discourage investigation into the use of red/infrared light for measuring blood oxygen levels. To the contrary, Sarantos expressly discloses such embodiments. APPLE-1005, 13:44-14:22. Based on my review, Sarantos’s description of green/yellow light (APPLE-1005, 18:48-51) merely indicates that Sarantos chose to illustrate its exemplary embodiments with respect to devices sensitive to green/yellow light rather than other spectra. A POSITA reviewing Sarantos’s alternative embodiments for measuring blood oxygen levels (APPLE-1005, 13:36-14:22) would have understood and found obvious that the ratios and dimensions of Sarantos’s HAR photodetectors could and would be suitably adjusted to optimize for the detection of red and infrared light as appropriate for measuring blood oxygen saturation levels.

95. Furthermore, a POSITA would have had the ordinary skill and creativity to modify Iwamiya’s device based on the teachings of Sarantos. This is

especially true given the conventional nature of basic pulse oximetry techniques that had been known for decades before the '159 Patent. I understand that a showing of obviousness does not require a detailed explanation of every predictable structural modification that a POSITA would make to implement a proposed combination. Nonetheless, a POSITA would have known how to adapt Iwamiya's device to measure oxygen saturation levels using red/infrared light as taught in Sarantos. Iwamiya's device already includes 940 nm infrared LEDs that would be suitable for measuring blood oxygen levels; it would have been obvious and straightforward to augment the device with one or more LEDs emitting red light. *See, e.g.*, APPLE-1009, 94 ("The designer should keep in mind the wavelengths of interest in pulse oximetry (660 nm and 940 nm) when deciding on an appropriate photodiode."). For example, it would have been obvious and straightforward to add one or more red LEDs, as shown below.

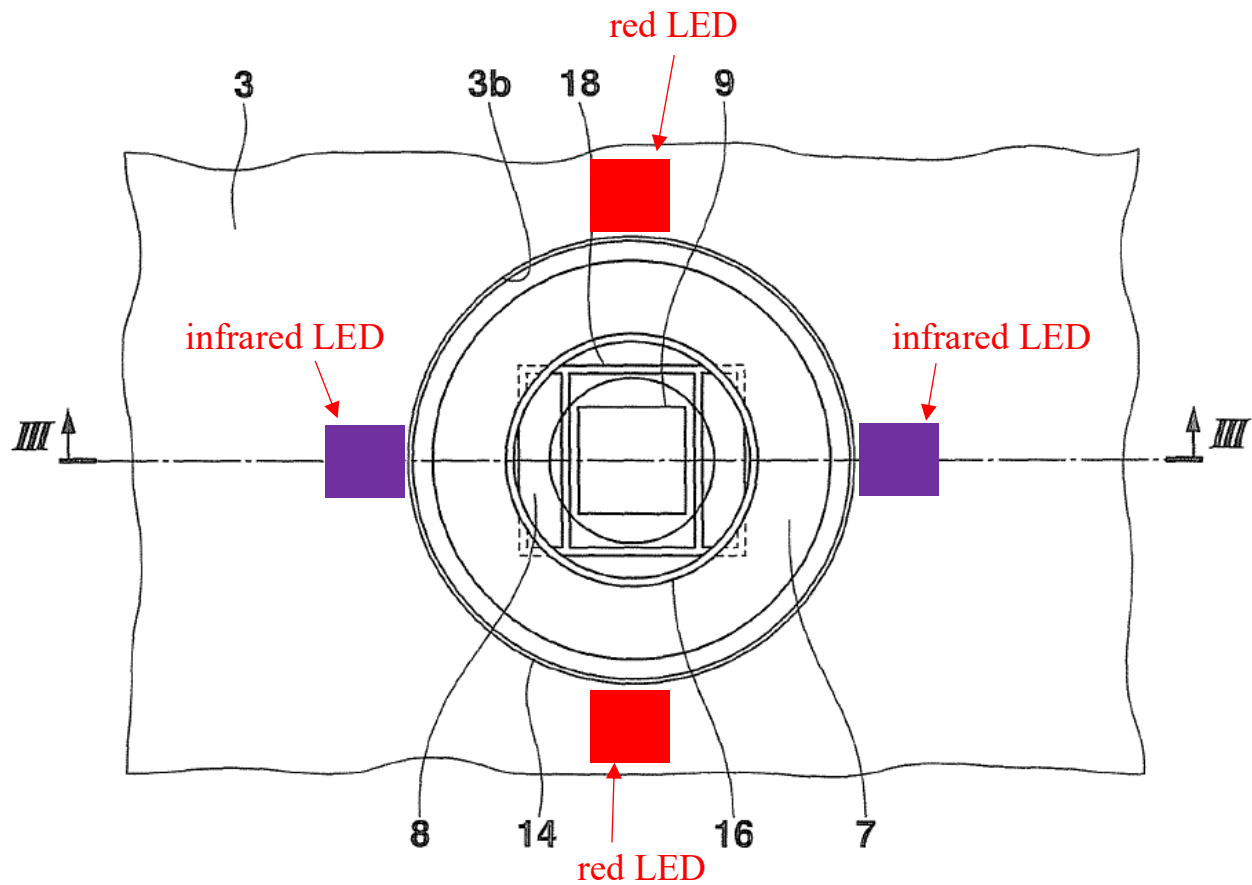


FIG.2

APPLE-1004, FIG. 2 (modified based on Sarantos's teachings)

As another example, it would have obvious and straightforward to replace one of Iwamiya's two original infrared LEDs with a red LED, as shown below.

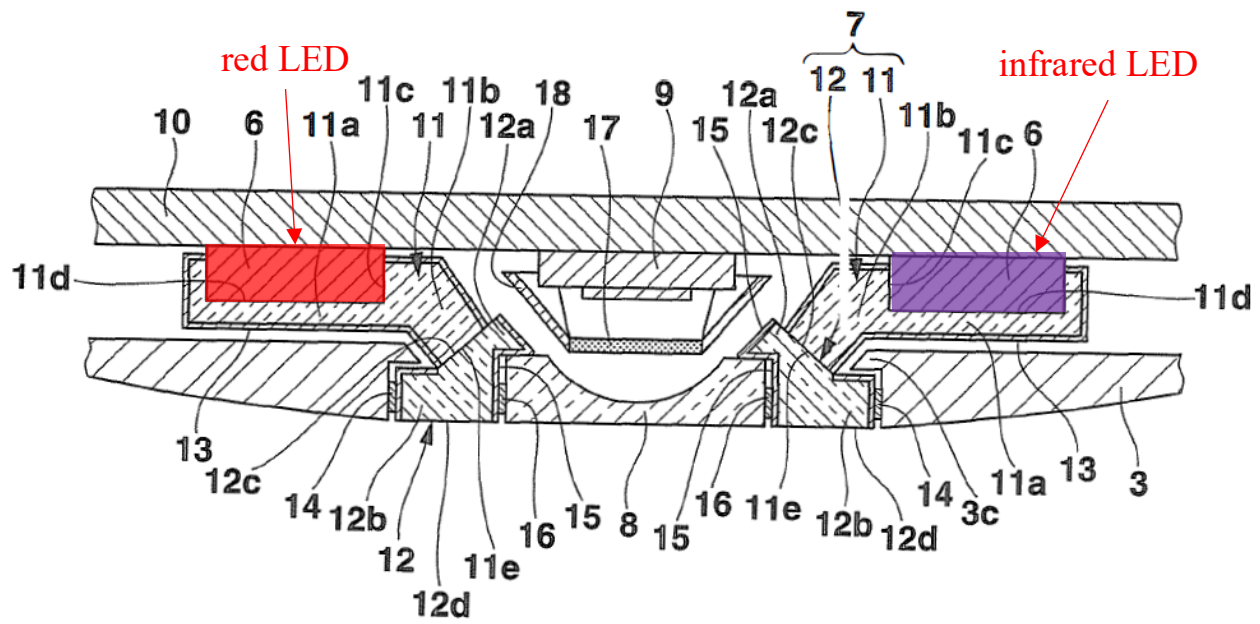


FIG.3

APPLE-1004, FIG. 3 (modified based on Sarantos's teachings)

As yet another example, it would have obvious and straightforward to replace Iwamiya's two original infrared LEDs with a red LED and an infrared LED, as shown below.

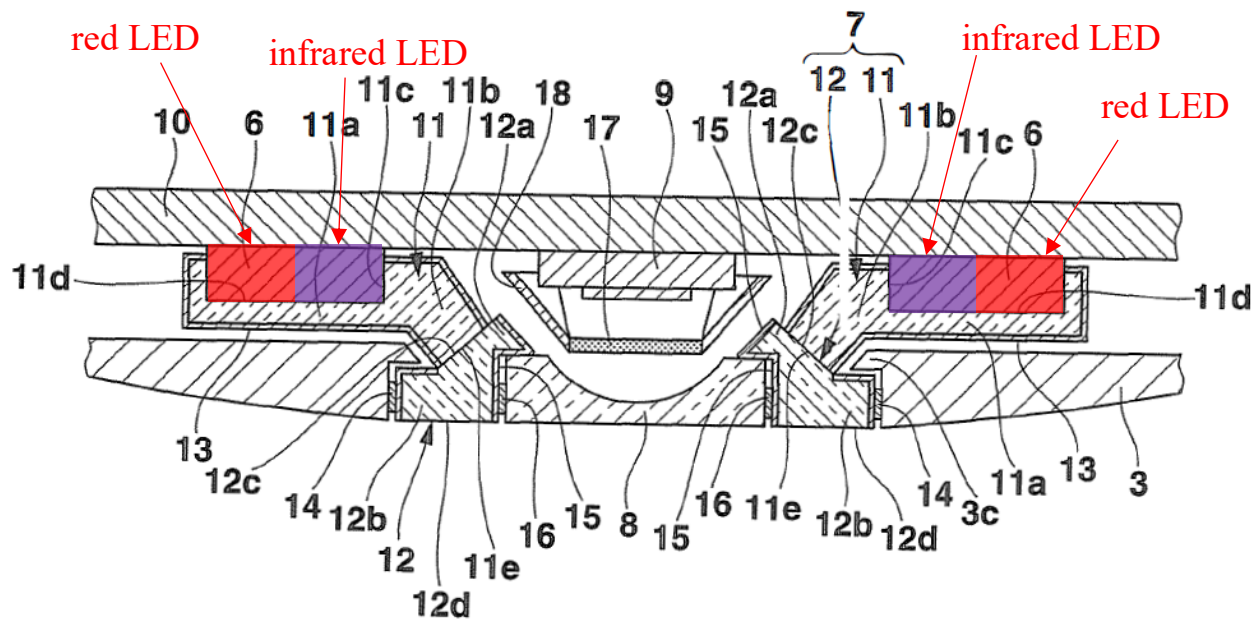


FIG.3

APPLE-1004, FIG. 3 (modified based on Sarantos's teachings)

Such modifications are merely examples, and a POSITA would have known of and been able to implement other readily predictable arrangements in the device of Iwamiya and such modifications would have been well-within the knowledge and skill of a POSITA.

96. A POSITA would have considered the specific placement of the red LED(s) relative to the infrared LED(s) to be a design choice, especially since a POSITA knew that the red and infrared LEDs could be alternately illuminated to measure the light absorbed from each wavelength one at a time. For example, Sarantos expressly describes structural modifications that would be made to accommodate multiple LEDs of different wavelengths, including that “multiple

light-emitting devices ... may[] ... be spaced apart from one another, as shown in FIGS. 1 and 2, or may be closely grouped.” APPLE-1005, 13:34-36, 13:44-14:22, FIGS. 1, 2. Thus, the red and infrared LEDs can be located near each other or in different locations, so long as each set of LEDs adequately illuminates the measurement site as they would in Iwamiya. Alternate illumination is described in Webster, Scharf, and Goldreich, for example. APPLE-1009, 16, 53, 103, 114; APPLE-1038, 1:63-2:7; APPLE-1036, [0126].

97. Likewise, a POSITA would have known how to, and would have found it obvious to optimize the sensitivity of the photodiodes, implement an optical filter that would pass both red and infrared light, and implement commonly known signal processing algorithms for calculating oxygen saturation from the detected light signals. The physics behind pulse oximetry and algorithms necessary to implement it had been known for decades before the '159 Patent. Indeed, the “BACKGROUND” section of the '159 Patent itself acknowledges as much in its overview of spectroscopy and the Beer-Lambert law. APPLE-1001, 1:30:2-26. The '159 “BACKGROUND” discussion expressly recognizes that a known application of the Beer-Lambert law was for “pulse oximetry, which utilizes a noninvasive sensor to measure oxygen saturation and pulse rate, among other physiological parameters.” *Id.*, 1:53-56. As to optical filtering, Webster’s textbook confirms that optical filtering was likewise well-known in pulse oximetry

before the '159 Patent. APPLE-1009, 96 (“Optical filtering, placed between sources of light and the photodiode, is used to limit the spectral response of the photodiode.”). Webster further observes that optical filters are often not even necessary in pulse oximeters. *Id.*, 96 (“these external filters do not appear to be used much”). Even if an optical filter were retained in the Iwamiya-Sarantos combination, it would have been obvious and well within the skill of a POSITA to select an optical filter configured to pass not just the infrared light that Iwamiya proposes for heart rate monitoring but also red light that would be used together with the infrared light for oxygen saturation measurements.

98. A POSITA would have known of a range of techniques that could be employed to pass both red and infrared light. A straightforward solution, for example, would be to simply adjust the cutoff frequency of the optical filter to pass light in both the red and infrared spectra while still blocking wavelengths shorter than the light of the red LED(s). Dichroic filters and multi-band pass filters capable of selectively passing light in discontinuous bands were also known and would have been obvious to use in the resulting combination. *See, e.g.*, APPLE-1038, Abstract (“An optical thin film filter for the spatial and spectral separation of two or more transmitting bands of radiant energy.”); APPLE-1039, [0052] (“filter wheel” composed of “multilayer thin films deposited onto an optically transmitting substrate”); APPLE-1041, [0137] (“The optical detector 1709 may contain optical

filters to selectively detect light at key wavelengths relating to the presence or absence of the aforementioned optical absorption bands.”).

99. Iwamiya’s disclosed embodiments focus on accurately detecting a pulse wave for measuring a pulse rate (heart rate), which requires only a single wavelength of light. Iwamiya thus describes using a **single** wavelength of infrared light at 940 nm, instead of light at 600 nm or less, for measuring **a pulse wave**. APPLE-1004, 1:62-2:6, 6:32-35. But Iwamiya never criticizes, discredits, or otherwise discourages investigation into the use of **two** wavelengths of red and infrared light for measuring **oxygen saturation**, and does not criticize, discredit, or otherwise discourage investigation into using an additional wavelength of light as required to make different measurements in different operating modes. A POSITA looking to implement Iwamiya to measure oxygen saturation would not have been led away from modifying Iwamiya’s device to include red and infrared LEDs or from implementing any of the other obvious optimizations to Iwamiya’s device as described in the preceding section for the purpose of adding a capability to measure blood oxygen saturation. Indeed, Iwamiya’s 940 nm wavelength pulse rate measurements could still be retained in the device since 940 nm light is commonly used for measuring oxygen saturation as well. APPLE-1009, 16, 52, 62-63, 73, 79-80; APPLE-1040, 4; APPLE-1042, 16; APPLE-1014, 1; APPLE-1016, 3-4; APPLE-1028, [0007]. A POSITA’s desire to expand the capabilities of

Iwamiya's device by adding a red wavelength to measure oxygen saturation in addition to pulse rate also would have justified any design tradeoffs necessary to implement oxygen saturation measurements.

100. Responsive to Patent Owner's arguments raised in another IPR proceeding involving a patent related to the '159 Patent, I reviewed over a dozen references that antedate the '159 Patent and that underscore how determining oxygen saturation at the wrist was not only well known, but had actually been successfully and repeatedly performed before the '159 Patent's earliest priority date.³

³ In reviewing these references, a variety of wrist locations were proposed as suitable measurement sites for obtaining PPG signals useful for measuring blood oxygen levels of the user. Some references propose measuring from the outer portion of the wrist while others propose measuring from the inner portion of the wrist. Based on my review, measurements from both the inner and outer portions of the wrist would have been obvious and suitable in the prior art combinations proposed here in a manner that would meet the requirements of claims 8, 17, and 22 (which do not limit where the measurements must be taken on the wrist). For example, Iwamiya's emitters/detectors are disposed on the back cover of a wristwatch case 1. APPLE-1004, 5:57-64, 9:61-63, FIG. 1. A POSITA would

101. For example, Maattala et al. published an article titled “Optimum Place for Measuring Pulse Oximeter Signal in Wireless Sensor-Belt or Wrist-Band” for the IEEE 2007 International Conference on Convergence Information Technology. APPLE-1018 (“Maattala”). Maattala proposed to find “the optimum place for integrated pulse oximeter in case of a belt around human chest or wrist so that it would provide reliable oxygen saturation (SpO₂) readings.” APPLE-1018, Abstract. Maattala used an “adjustable probe” from which “it was possible to obtain visible pulse oximeter signal from almost every spot on patient’s skin.” APPLE-1018, 3. As shown in Maattala’s Figures 8 and 9, four spots from the wrist were chosen and measurements from those areas were done. APPLE-1018,

have known that the body of a wristwatch case can be worn to contact either the inner or outer portions of the wrist. Even if a user prefers to wear the wristwatch upwards on the outer portion of the wrist ordinary use in telling time, it would be a simple task to rotate the watch such that the back cover of the case would contact the inner portion of the wrist when the user desires to take an oxygen saturation measurement. Some of the references observed that a stronger signal could be obtained from the inner wrist rather than the outer wrist. Notably, the claims of the ’159 Patent do not require measuring from the outer wrist.

4. Each of these measurement spots “were resulting close to each other[] and gave similar results.” *Id.*

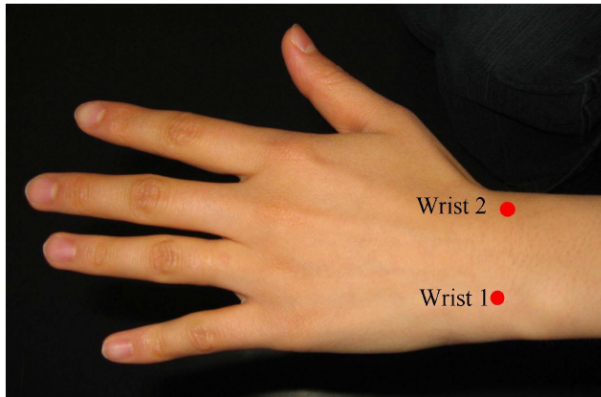


Figure 8. Measurement spots on the outer wrist

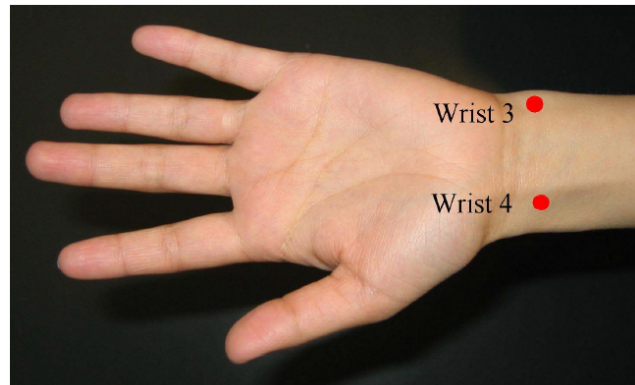


Figure 9. Measurement spots on the inner wrist

APPLE-1018, 4

Maattala shows normalized SNRs for the measurements in Figure 11. APPLE-1018, 4. Maattala concluded that “wireless integrated pulse oximeter implanted in a ... wrist band is possible to achieve with many benefits and practical applications.” APPLE-1018, 5.

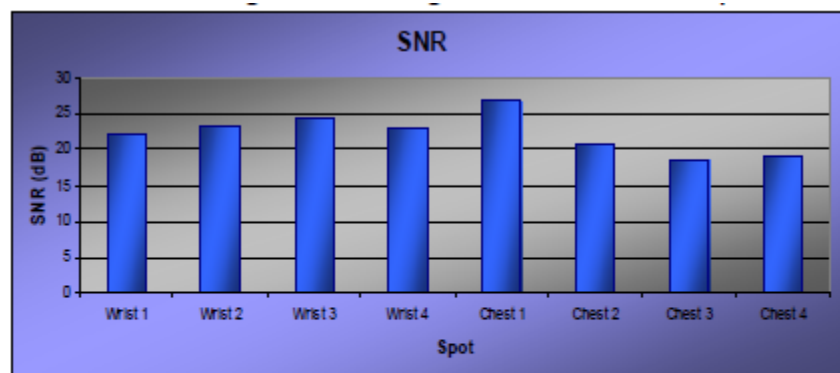


Figure 11. The signal-to-noise –ratio of the pulse oximeter signal in all eight measurement spots

APPLE-1018, 4

102. In 2010, Cai et al. published a feasibility study for 3rd International Conference on Biomedical Engineering and Informatics titled “Implementation of a Wireless Pulse Oximeter Based on Wrist Band Sensor.” APPLE-1016 (“Cai”). Cai describes an “oxygen saturation measurement system” used to conduct experiments, with results confirming “the feasibility of this wrist-band oximeter.” APPLE-1016, Abstract. APPLE-1016, 3. Cai illustrates the wrist band sensor in Figure 3:

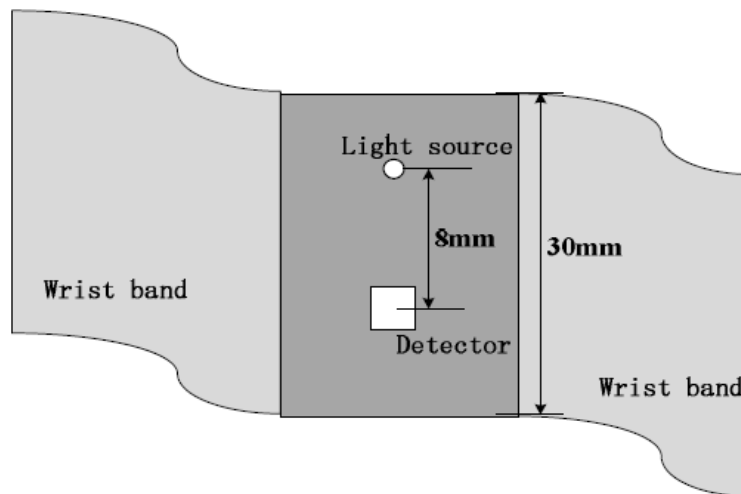


Figure 3. Wristband sensor

APPLE-1016, 3

Cai’s Figure 5 shows “the initial pulse wave signal extracted by the built-in amplifier and effective pulse wave signal after filtering” and that “the system efficiently detected the human pulse wave signal, indicating that the incident light can visit the arterial vessel.” APPLE-1016, 3. Cai discloses that “the oxygen saturation is deduced by computing the ratio of the light intensity change rates

under two different wavelengths.” *Id.* In Cai, the “experimental results indicate that this system can effectively detect the change of oxygen saturation.” APPLE-1016, 4. Cai concludes that its wristband pulse oximeter can obtain oxygen saturation and heart rate information continuously and non-invasively through a wearable reflection sensor” *Id.*

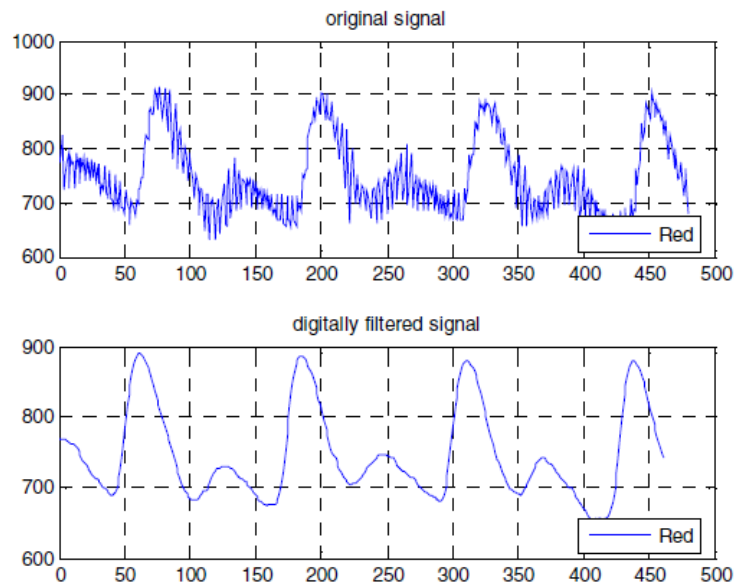


Figure 5. Original signal(upper) and filtered signal(lower) of pulse wave
APPLE-1016, 3

103. Li et al. published an IEEE article in 2012 titled “A Wireless Reflectance Pulse Oximeter With Digital Baseline Control for Unfiltered Photoplethysmograms.” APPLE-1015 (“Li”). Li discloses a “small, low-cost pulse oximeter design appropriate for wearable and surface-based applications that also produces quality, unfiltered photo-plethysmograms (PPGs)” and that “demonstrated an ability to gather high-integrity data at fingertip, wrist, earlobe,

palm, and temple locations from a group of 48 subjects (20 to 64 years old).”

APPLE-1015, Abstract. Li provides in Figure 13 below “experimental data from the wrist at the three placement locations depicted in Fig. 14” below that shows that the “signal quality in location 2 is obviously lower relative to the SNR in locations 1 and 3, but *all three are suitable PPGs*.” APPLE-1015, 8. Li’s approach confirms that a POSITA, at the time of the ’159 Patent, had the “capability to acquire quality PPG data from the wrist (where the SNR dramatically improves with post-filtering).” *Id.*

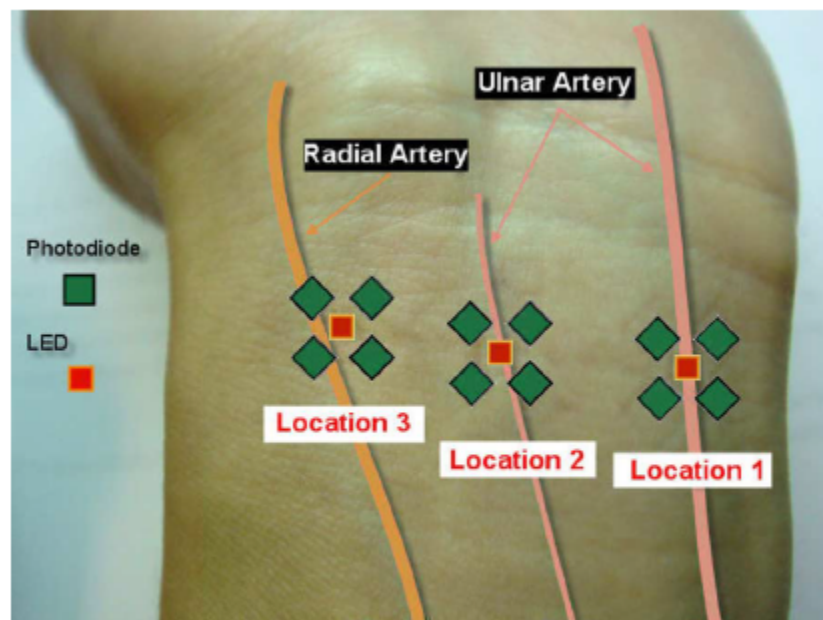


Fig. 14. Pulse oximeter measurement locations on the left wrist.

APPLE-1015, 8

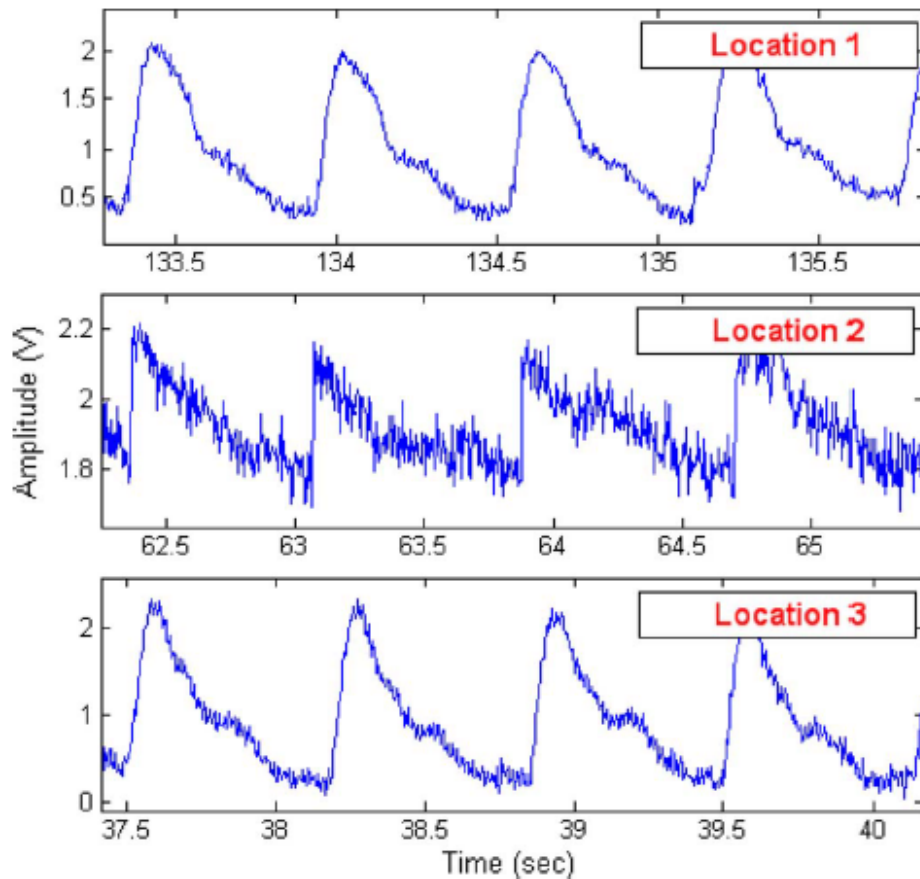


Fig. 13. Wrist PPGs corresponding to the placement locations in Fig. 14.

APPLE-1015, 8

104. In April 2013, the Worcester Polytechnic Institute published an undergraduate project report titled “Reflectance-based Pulse Oximeter for the Chest and Wrist” by Fontaine et al. APPLE-1042 (“Fontaine”). Fontaine describes a reflectance-based pulse oximeter “prototype [that] was able to accurately measure within an error of + 1% and $\pm 3\%$ for SpO_2 and PR [pulse rate] respectively from the wrist” as compared to the measurements taken by a HOMEDIC Deluxe Pulse Oximeter. APPLE-1042, Abstract. Figure 5.17 below left shows the application of the prototype sensor to the wrist.

105.

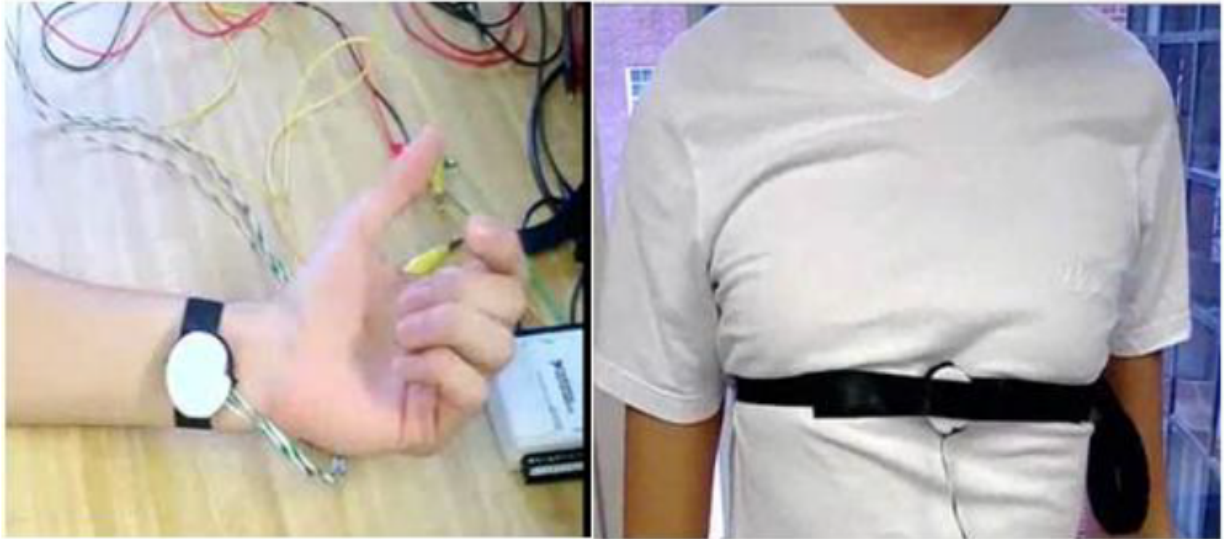


Figure 5.17: Application of the sensor to the wrist (left) and the chest (right)

APPLE-1042, 50

Fontaine describes its experimental results and shows the calculated accuracy for the average SpO_2 and pulse rate (PR) for each data set in Table 7.1 reproduced below. APPLE-1042, 60-101.

Table 7.1: Calculated accuracy for the average SpO₂ and PR for each data set

Average Measurements	Reference		Prototype		Percent Errors	
	SpO ₂ (%)	PR (bpm)	SpO ₂ (%)	PR (bpm)	SpO ₂	PR
Wrist Standing	97.9	92.6	97.3	92.8	0.6	0.2
Wrist Sitting	98.2	82.4	98.4	83.3	0.2	1.1
Chest Standing	98.1	96.7	98.5	96.5	0.4	0.1
Chest Sitting	97.8	83.8	98.1	83.9	0.3	0.1

APPLE-1042, 60

106. In early 2015 before the '159 Patent, Pang et al. published a paper in IEEE Access titled “A Neo-Reflective Wrist Pulse Oximeter.” APPLE-1014 (“Pang”). Pang presents “another novel reflective wrist pulse oximeter that has been developed.” APPLE-1014, 2. Pang describes “a genuine wrist pulse oximeter” having “a concave structure for housing the optical source and sensor.” APPLE-1014, Abstract. Pang’s wrist pulse oximeter is shown in Figure 2 reproduced below.



FIGURE 2. Wireless transmission of sensor data from the wrist pulse oximeter.

APPLE-1014, 3

107. Pang also shows “experimental results of the AC pulse signals obtained by red LED and infrared LED” in Figures 11 and 12 and states that the “two recorded photoplethysmograms both display the cardiovascular cycle clearly.” APPLE-1014, 5. As Pang explains, Figures 11 and 12 show that the “system has detected the pulse wave signal efficiently, which indicates that the incident light can indeed visit the arterial vessel” and that “oxygen saturation can then be calculated by the ratio of the light intensity change rates under the two different wavelengths.” *Id.*

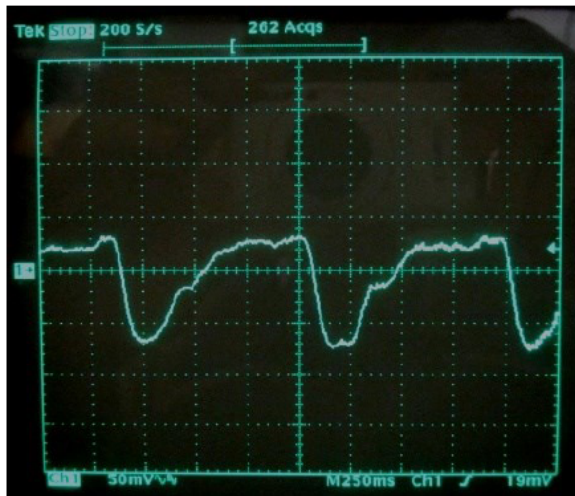


FIGURE 11. The pulse signal obtained by the red LED.

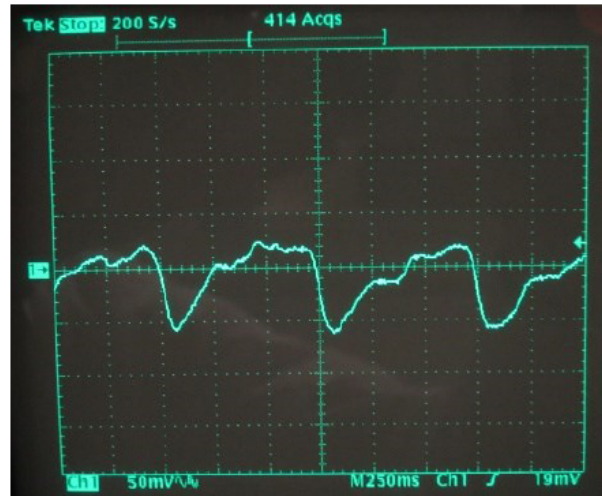


FIGURE 12. The pulse signal obtained by the infrared LED.

APPLE-1014, 5

108. These references all confirm and corroborate my opinion that a POSITA would have had a reasonable expectation of success in measuring oxygen saturation at the wrist before the '159 Patent. Notably, the references include engineering and scientific papers describing real-world studies and experimental results that conclusively establish the feasibility of measuring oxygen saturation at the wrist before the '159 Patent.

109. Further, prior art patent and patent application references publicly available years before the '159 Patent show that wrist-worn pulse oximetry sensors, such as that described in Sarantos, were well-known in the art. These prior art patent and patent application references include, for example:

- U.S. Patent Application Publication No. 2006/0253010 to Brady et al. (*see e.g.*, APPLE-1028, Abstract, [0004], [0032]-[0033], [0047], [0058]);

- International Publication No. WO 2001/17421 to Lindberg et al. (*see e.g.*, APPLE-1017, 10, 18, 49, 52, 80-81);
- U.S. Patent No. 7,468,036 to Rulkov et al. (*see e.g.*, APPLE-1043, Abstract, 4:1-22, 6:30-63, 7:14-35);
- International Publication No. WO 2011/051888 to Ackermans et al. (*see e.g.*, APPLE-1044, 1:2-5, 2:12-14, 3:8-12, 6:15-18, 10:30-11:3, FIG. 7);
- U.S. Patent Application Publication No. 2005/0116820 to Goldreich (*see e.g.*, APPLE-1036, [0002], [0014]-[0015], [0035]-[0036], [0104], [0124], FIG. 5);
- International Publication No. WO 2012/140559 to Shmueli et al. (*see e.g.*, APPLE-1045, Abstract, 2, 9, 12, FIGS. 1A-4);
- U.S. Patent No. 7,650,176 to Sarussi et al. (*see e.g.*, APPLE-1046, 3:55-61, 4:14-21, 6:63-7:22, 12:36-43, 14:50-15:3, FIGS. 15A-15C);
- U.S. Patent No. 5,830,137 to Scharf (*see e.g.*, APPLE-1038, Abstract, 3:66-5:7, 9:15-17, 17:43-45, FIGS. 3-4)
- U.S. Patent Application Publication No. 2002/0095092 to Kondo et al. (*see e.g.*, APPLE-1047, [0010], [0014], [0025], [0086], [0108]-[0109], FIGS. 1, 5A-5B); and
- U.S. Patent Application Publication No. 2015/0355604 to Fraser et al. (*see e.g.*, APPLE-1048, [0015], [0020]).

110. I also note that Sarantos provides at least the same level of disclosure with respect to performing pulse oximetry at the wrist as the '159 patent itself.

The '159 Patent describes “a noninvasive sensor to measure oxygen saturation and pulse rate, among other physiological parameters.” APPLE-1001, 1:54-56. The

'159 Patent discloses that the “system also includes a diffuser configured to receive the emitted light, to spread the received light, and to emit the spread light over a larger tissue area than would otherwise be penetrated by the emitter directly emitting light at a tissue measurement site. The tissue measurement site can include, such as, for example, a finger, a wrist, or the like.” APPLE-1001, 2:50-58. The problem that the '159 Patent appears to address is what it refers to as two-dimensional pulse oximetry. APPLE-1001, 5:41-65. The '159 Patent explains that “[a]dvantageously, by irradiating the tissue measurement site 102 with a surface area 206, the presently disclosed systems, devices, and methods apply a three-dimensional analytical model to the three-dimensional structure being measured, namely, the patient’s sample tissue 102.” APPLE-1001, 6:50-54. The '159 Patent describes the purported advantages of its sensor system as follows:

According to the Beer-Lambert law, the amount of light absorbed by a substance is proportional to the concentration of the light-absorbing substance in the irradiated solution (i.e., arterial blood). Advantageously, by irradiating a larger volume of tissue 102, a larger sample size of light attenuated (or reflected) by the tissue 102 is measured. The larger, 3D sample provides a data set that is more representative of the complete interaction of the emitted light as it passes through the patient's blood as compared to the 2D point source approach described above with respect to FIG. 1. By taking an average of the detected light, as detected over a surface area substantially larger than a single point, the disclosed pulse oximetry

systems, devices, and methods will yield a more accurate measurement of the emitted light absorbed by the tissue, which will lead to a more accurate oxygen saturation measurement.

APPLE-1001, 6:55-7:3. The '159 Patent specification does not identify any difficulties, differences in configuration, or problems associated with any of the measurement sites on the body, apart from the fact that some measurement sites would such as the finger and ear would ordinarily be measured with a transmittance-type sensor while other sites such as the wrist and forehead would ordinarily be measured with a reflectance-type sensor.

111. The '159 Patent describes various embodiments of its 3D sensor system. In one embodiment shown in FIG. 3, a “3D sensor 300 includes an emitter 302, a light diffuser 304, a light-absorbing detector filter 306, a light concentrator 308, and a detector 310.” APPLE-1001, 7:4-29. In another embodiment shown in FIGS. 7A and 7B, a “3D sensor 700 can be placed on a portion of the patient's body that has relatively flat surface, such as, for example a wrist, because the emitter 702 and detector 710 are on located the same side of the tissue measurement site 102.” APPLE-1001, 10:40-51. In yet another embodiment shown in FIG. 8, the '159 Patent discloses that the “pulse oximetry system 800 can measure analyte concentrations at least in part by detecting optical radiation attenuated by tissue at a measurement site 102. The measurement site 102 can be any location on a patient's body, such as a finger, foot, earlobe, wrist, forehead, or

the like.” APPLE-1001, 12:16-20. The ’159 Patent describes that the wrist and forehead are interchangeable but gives no details on adjustments needed to accommodate a weaker signal at the wrist compared to the stronger signal at the forehead. Throughout the specification, the ’159 Patent describes no significant distinction between selection of measurement sites and no challenges to tissue measurement unique to the wrist.

112. The ’159 Patent only mentions the wrist as a possible tissue measurement site in passing, with no acknowledgment of the alleged challenges of measuring at the wrist and no solutions specifically tailored to addressing the alleged challenges. Rather, the ’159 Patent assumes that a POSITA would have known how to implement such measurements at the wrist.

113. I understand that evaluating the reasonable expectation of success requires consideration of the appropriate scope of the patent’s claimed invention. The ’159 Patent claims do not specify a required accuracy or quality of its oxygen saturation measurements. The broad scope of the claims covers a practical use of a rudimentary pulse oximetry function that does not require the same level of functionality provided in the Watch. For example, U.S. Patent No. 6,398,727 to Bui et al. teaches an alarm/alert system for a pulse oximeter where “[t]he resolution of the pulse oximeter 214 is preferably 1% oxygen saturation and the accuracy is expected to be +/- 3% oxygen saturation” and includes a broad range

(e.g., 50-100%) for the Low and High SpO₂ limits that trigger the alarm/alert system. APPLE-1049, 15:9-11. As another example, the oxygen saturation parameter might not even need to be a measurement. It could simply be a binary indication of whether a signal sufficient for measuring oxygen saturation has been obtained or an indication that oxygen saturation above a defined level of range had been detected.

(c) Claim 9

[9.0] The physiological monitoring device of claim 1, wherein the material comprises plastic.

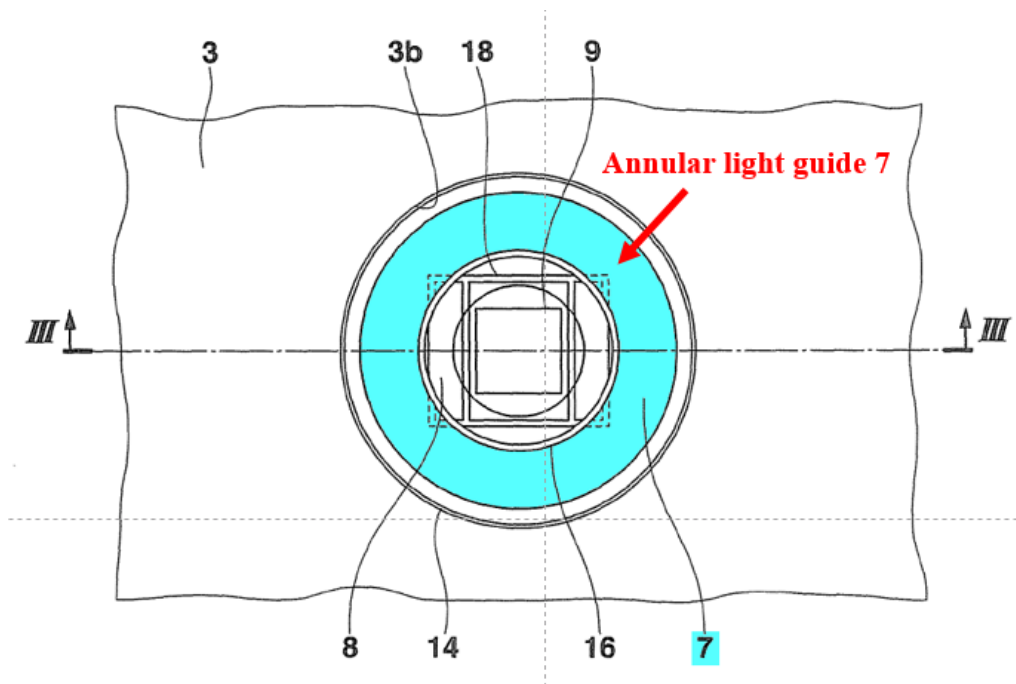
114. The combination of Iwamiya with Sarantos discloses, or at least renders obvious, that the material positioned between the plurality of emitters and a tissue measurement site on a wrist of a user when the physiological monitoring device is in use that changes the first shape into a second shape by which the light emitted from one or more of the plurality of emitters is projected towards a surface of the tissue measurement site is plastic. As I previously discussed with respect to element [1.2], Iwamiya describes that the physiological sensor includes “an annular light guide unit 7 that guides the observation light emitted from the light emitting units 6 and annularly diffuses and irradiates the observation light with respect to a skin H.” APPLE-1004, 6:7-14, Fig. 4. Iwamiya goes on to describe that the annular light guide unit 7 includes “a light guiding ring portion 11” formed “using a material such as transparent glass or a transparent resin with a high light

transmitting property.” *Id.*, 6:40-45. A POSITA would have recognized that in this context, use of the word “resin” by Iwamiya indicates that the light guiding ring portion 11 is made from plastic in at least some embodiments. This is confirmed by relevant dictionaries that identify that in the context of manufacturing and devices (as opposed to natural resins) the term “resin indicates “any synthetic plastics material” and that “common plastics may be viewed as a synthetic resin.” APPLE-1023; APPLE-1024; *see also* APPLE-1025; APPLE-1026; APPLE-1027. A POSITA also would have been aware that plastic resin was a commonly used material for manufacturing light diffusers and lenses, as is the case with the resin described by Iwamiya. APPLE-1019, Abstract, 2:15-30; APPLE-1020, 1:5-9, 2:40-50, 3:11-40, APPLE-1021, 4:20-26, 3:38-52; APPLE-1022, 4:23-27. Therefore, in the context of a diffusion/irradiation ring for a physiological monitoring device, as is the case here, a POSITA would have understood that the transparent resin disclosed by Iwamiya is a plastic material. Alternatively, it would have at least been obvious to a POSITA, based on Iwamiya’s description of using a transparent resin and the knowledge of a POSITA regarding manufacture of lenses from transparent plastics made from synthetic resins, to implement Iwamiya’s light guiding ring portion 11 from plastic.

(d) Claim 10

[10.0] The physiological monitoring device of claim 1, wherein the material comprises glass.

115. Iwamiya discloses that the annular light guide unit 7 includes “a light guiding ring portion 11” formed “using a material such as transparent glass or a transparent resin with a high light transmitting property.” *Id.*, 6:40-45. This is shown in FIG. 2:



APPLE-1004, Detail of FIG. 2 (annotated)

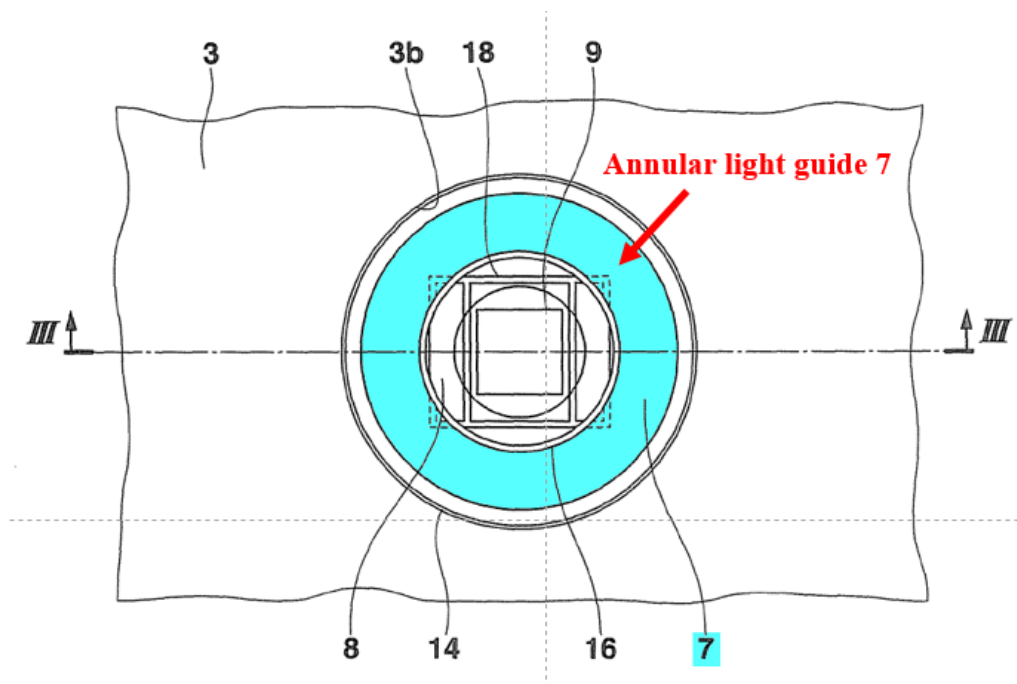
Thus, the combination of Iwamiya with Sarantos that the material positioned between the plurality of emitters and a tissue measurement site on a wrist of a user when the physiological monitoring device is in use that changes the first shape into a second shape by which the light emitted from one or more of the plurality of

emitters is projected towards a surface of the tissue measurement site is glass in at least some embodiments.

(e) Claim 11

[11.0] The physiological monitoring device of claim 1, wherein the second shape comprises a circular geometry.

116. As I discussed above with respect to element [1.2], Iwamiya describes that the physiological sensor includes “an annular light guide unit 7 that guides the observation light emitted from the light emitting units 6 and annularly diffuses and irradiates the observation light with respect to a skin H” to shape the light into a second shape. APPLE-1004, 6:7-14, 6:40-45, 7:4-24, 11:55-12:36, Fig. 4. FIG. 2 of Iwamiya shows a configuration in which the annular light guide is circular.



APPLE-1004, Detail of FIG. 2 (annotated)

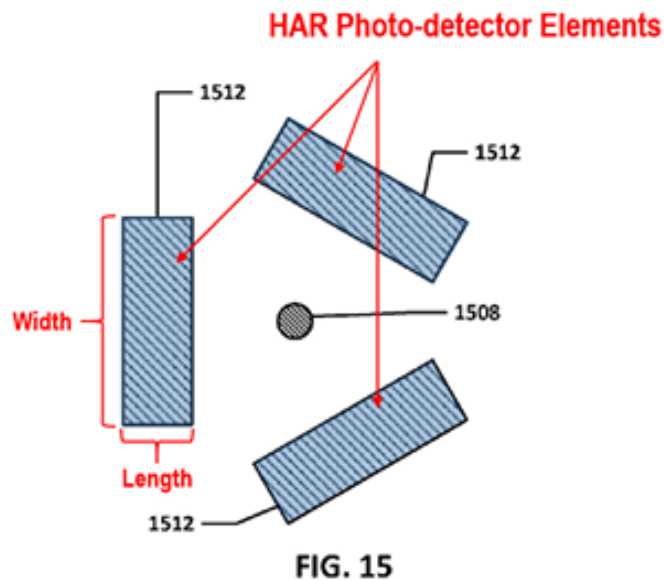
117. It is this circular shape of the annular light guide that defines the shape of the light that is emitted from the annular light guide (the second shape). Thus, the annular light guide unit 7 shapes the second shape into an annular/ring shape which a POSITA would have recognized as providing a circular geometry. For example, as described by Iwamiya, the annular light guide “uniformly diffuse and irradiate the observation light over a wide area of *a ring shape* with respect to the skin H.” APPLE-1004, *Id.*, 7:14-24. In another example, Iwamiya describes that “[t]he scattered light taking unit 8 is configured to contact the skin H positioned in a central portion of an irradiation area E having a ring shape where a bottom surface is irradiated with the observation light by the light guide unit 7.” *Id.*, 7:61-65; *see also* Abstract (“annularly irradiates the observation light onto the desired area of the surface of the skin”), 11:55-12:36, 10:15-11:31.

(f) Claim 12

[12.0] The physiological monitoring device of claim 1, wherein the opening defined in the dark-colored coating comprises a width and a length, and wherein the width is larger than the length.

118. The predictable combination provides that the opening defined in the dark-colored coating comprises a width and a length and that the width is larger than the length. Specifically, a POSITA would have recognized that it would have been obvious and beneficial to implement the window defined by Iwamiya’s light

9:47-65; 9:48-10:26, FIGS. 15-16, 18. For example, looking at FIG. 15 of Sarantos, each of the HAR photodiodes has a dimension that is greater than a perpendicular direction and a POSITA would have recognized that these perpendicular directions would have been properly identified as width and length such that the photodiodes have a width larger than their length:



APPLE-1005, FIG. 15 (annotated).

120. Sarantos goes on to describe that “the window regions 2226 through which the light reaches the HAR photodetector elements 2212 each overlap their respective HAR photodetector elements 2212” and “the window regions 2226 are mutually coextensive with their respective HAR photodetector elements 2212.” APPLE1005, 17:42-47. From this disclosure, a POSITA would have understood that the window regions defined in the dark-colored coating (the optical filter 17

positioned within Iwamiya's light shielding frame 18 in the predictable combination) each include a width and a length corresponding to the width and length of their respective HAR photodiodes, and thus have a width that is larger than the length in at least some configurations of the predictable combination of Iwamiya with Sarantos.

(g) Claim 13

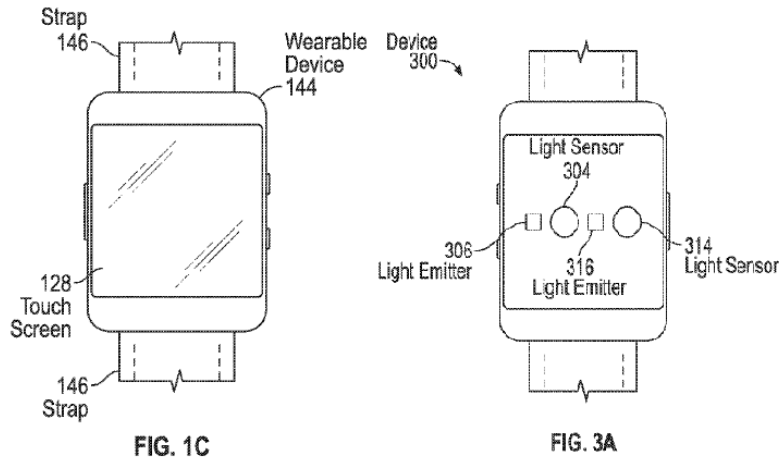
[13.0] The physiological monitoring device of claim 1, wherein the dark-colored coating comprises black.

121. Sarantos discloses that in the physiological monitoring device resulting from the combination of Iwamiya and Sarantos, the “in-mold label 2276 may be ***black***.” APPLE-1005, 17:1-16.

B. Ground 1B: Claim 3 is obvious over Iwamiya in view of Sarantos and Han

1. Overview of Han

122. Han is directed toward a “photoplethysmographic (PPG) device” that “can include one or more light emitters and one or more light sensors to generate the multiple light paths for measuring a PPG signal and perfusion indices of a user.” APPLE-1008, Abstract. FIG. 1C and FIG. 3A show front and back views of an example wrist-worn configuration of Han's PPG device:



APPLE-1008, FIGs. 1C, 3A

123. The device can perform “an accurate measurement of physiological signals such as heart rate.” *Id.*, [0032]. Han describes that “[s]uch PPG systems can be designed to be sensitive to changes in blood in a user's tissue that can result from fluctuations in the amount or volume of blood or blood oxygen contained in a vasculature of the user.” *Id.*, [0026]. For example, “[a] photoplethysmographic (PPG) signal can be measured by PPG systems to derive corresponding physiological signals (e.g., pulse rate).” *Id.* FIG. 2 shows an example of the signal that can be measured by the device:

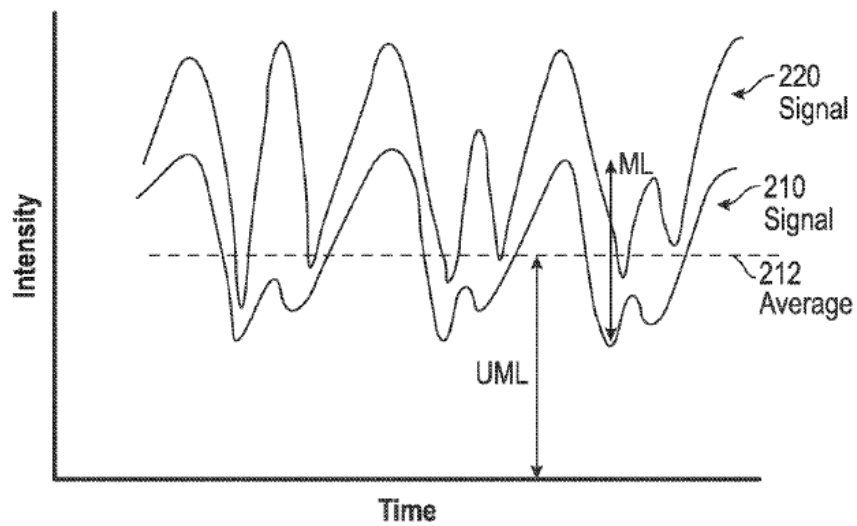


FIG. 2

APPLE-1008, FIG. 2

124. Han goes on to describe that the PPG device can be implemented as a “wearable device 144 that can include a touch screen 128 and can be attached to a user using a strap 146.” APPLE-1008, [0029]. For example, the device “can also include a touch screen 830 that can be operatively coupled to processor 810. Touch screen 830 can be a combination of sensing device 832 and display device 824, where the sensing device 832 can be a transparent panel that is positioned in front of display device 824 or integrated with display device 824. In some cases, touch screen 830 can recognize touches and the position and magnitude of touches on its surface. Touch screen 830 can report the touches to processor 810, and processor 810 can interpret the touches in accordance with its programming.” *Id.*, [0072].

2. Combination of Iwamiya and Sarantos with Han

125. A POSITA would have found it obvious and beneficial to enhance the wrist-worn biological information detecting apparatus of Iwamiya (as predictably modified based on Sarantos) to implement the display screen of the device to be a touch screen, as taught by Han. Iwamiya's device includes "a display unit 23 that displays a measurement result of biological information, such as a pulse wave" as shown, for example, in FIG. 10. APPLE-1004, 9:3-5.

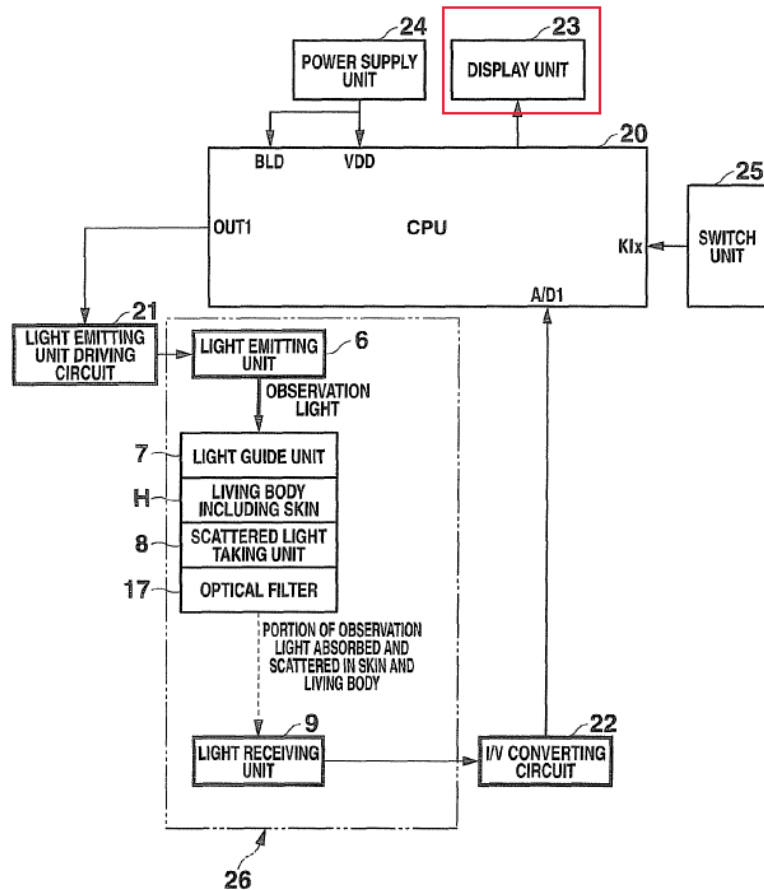


FIG.10

APPLE-1004, FIG. 10

126. Han provides additional teachings that demonstrate that such wrist-worn physiological monitoring devices can be implemented to include a touchscreen such that the display screen can both provide displayed output and receive direct input from the user. APPLE-1008, [0029], [0070]-[0072]. Multiple reasons would have prompted a POSITA to apply Han to the Iwamiya-Sarantos combination such that the resulting wrist-worn physiological monitoring device includes a touch screen. As a first reason, a POSITA would have recognized that a touchscreen user interface (as taught by Han) would have increased the utility of the resulting device by allowing for an easy and intuitive way to provide user input to the wrist-worn device, including to review menus, change views, and make selections. APPLE-1008, [0029], [0072]-[0077].

127. As a second reason, a POSITA would have recognized that touchscreen user interfaces for mobile devices, including wrist-worn watch devices, were ubiquitous by the relatively late date of 2015. Therefore most consumers would have been familiar with how to interact with computing devices, including smart watch type devices, using a touchscreen. Implementing the wrist-worn physiological monitoring device of Iwamiya to include a touchscreen interface on the display would have beneficially provided users of the resulting device with a familiar interface that they would have readily known how to use.

128. As a third reason, a POSITA would have been prompted to implement Iwamiya's device such that the display screen is a touch screen, as suggested by Han, because doing so would be merely the application of a known technique to a known system (e.g., Iwamiya's physiological monitoring device as predictably modified by Sarantos) ready for improvement to yield predictable results. Here, Han provides straightforward evidence of known techniques for providing a user input mechanism in a device having a compact design, and Iwamiya's teaching (as modified based on Sarantos) provides a known system that would have been improved by application of Han's suggested technique for at least the reasons described above. Indeed, such a compact configuration utilizing a touchscreen as the input mechanism would have negated the need for other buttons and inputs, thereby better conforming to the compact profile for such wrist-worn devices.

129. Based upon my knowledge and experience in this field and my review of Iwamiya, Sarantos, and Han, I am confident a POSITA would have recognized that such a modification would have yielded predictable results, and these modifications would have been within the ordinary level of skill of a POSITA at the time of the '159 patent disclosure. Based on my review, it is clear that at least because using touch screens for portable computing devices, such as smart watch style computing devices, was well-known in the art, and Iwamiya, Sarantos, and Han all describe similar and compatible wrist-worn reflectance-based

physiological sensors, a POSITA would have reasonably expected success in applying Han's teachings regarding utilizing a touch screen in such devices to the wrist-worn physiological monitoring device of Iwamiya. A POSITA would have understood such a combination would be successful with no unexpected results.

130. Accordingly, for at least these reasons, a POSITA would have been motivated and found it obvious to implement the combination of Iwamiya, Sarantos, and Han as described above. Such a modification would have been routine and straightforward to a POSITA, and it would have been clear that such a combination would predictably work and provide the expected functionality, because Han describes a physiological monitoring device that operated in the proposed manner. *see, e.g.*, APPLE-1008, [0029], [0072]-[0077].

3. Application of the combination of Iwamiya with Sarantos and Han to the claims

(a) Claim 3

[3.0] The physiological monitoring device of claim 2, wherein the display is a touch-screen display.

131. As shown in Han's exemplary FIG. 1C reproduced below, the device resulting from the combination of teachings of Iwamiya, Sarantos, and Han is a "wearable device" that "include[s] a touch screen 128 and can be attached to a user using a strap 146." *Id.*, [0029], [0067]. For example, the resulting device includes "a touch screen 830 that can be operatively coupled to processor 810." *Id.* [0072]-[0077].

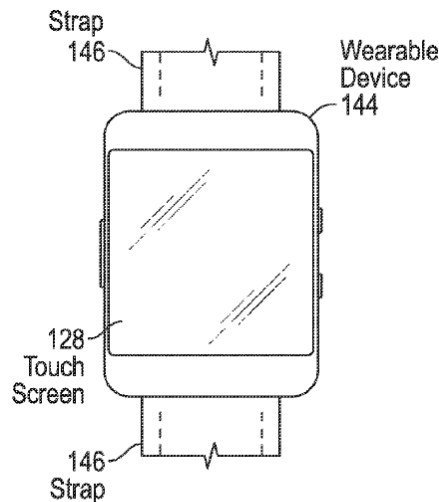


FIG. 1C
APPLE-1008, FIG. 1C.

C. Ground 1C: Claims 14-25 are obvious over Iwamiya in view of Sarantos and Utter

1. Overview of Utter

132. Utter is directed toward “[g]eneral health and wellness management techniques and devices...configured for use with a data-capable personal worn or carried device. APPLE-1006, Abstract. Similar to both Iwamiya and Sarantos, Utter describes a physiological parameter monitoring device that can be worn on the wrist. For example, Utter describes that “bands 104-112 may be implemented as wearable personal data or data capture devices (e.g., data-capable devices) that are worn by a user around a wrist, ankle, arm, ear, or other appendage, or attached to the body or affixed to clothing.” APPLE-1006, 12:34-67. Utter describes that “one or more facilities, sensing elements, or sensors, both active and passive, may be implemented as part of bands 104-112 in order to capture various types of data

from different sources.” *Id.* Utter describes that the wrist-worn bands can be configured to include “[t]emperature, environmental, temporal, motion, electronic, electrical, chemical, or other types of sensors...to gather varying amounts of data, which may be configurable by a user, locally (e.g., using user interface facilities such as buttons, switches, motion-activated/detected command structures (e.g., accelerometer-gathered data from user-initiated motion of bands 104-112), and others) or remotely (e.g., entering rules or parameters in a website or graphical user interface (“GUI”) that may be used to modify control systems or signals in firmware, circuitry, hardware, and software implemented (i.e., installed) on bands 104-112).” *Id.* As shown in FIG. 6, the wrist-worn physiological monitoring devices described by Utter can wirelessly communicate with other computing devices to exchange information. APPLE-1006, 13:57-65, 14:43-57.

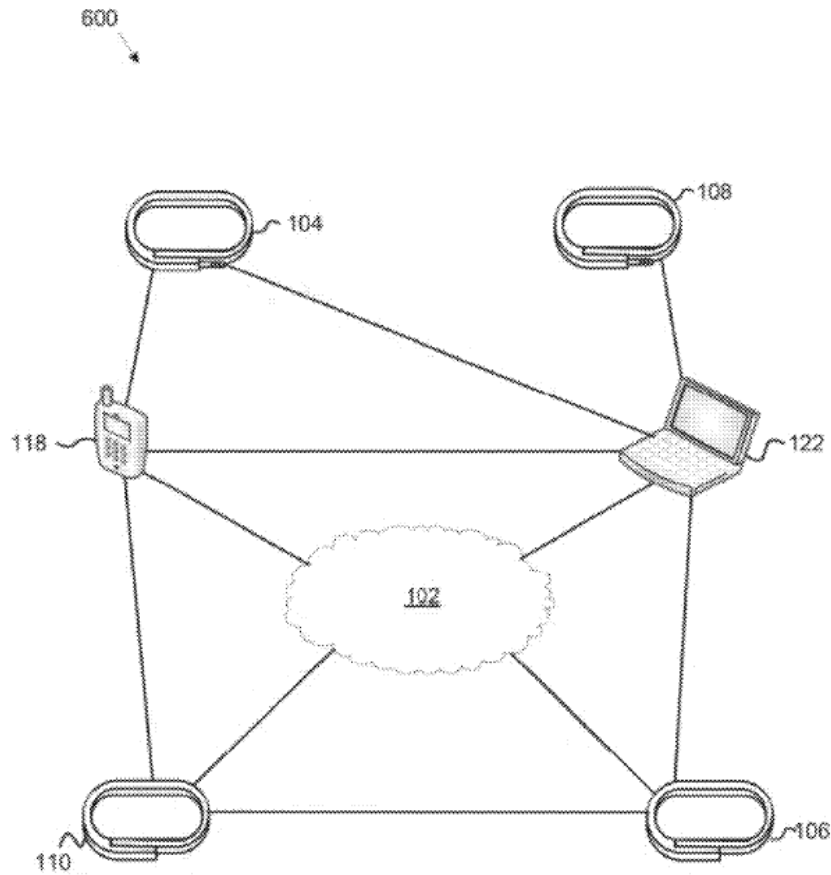
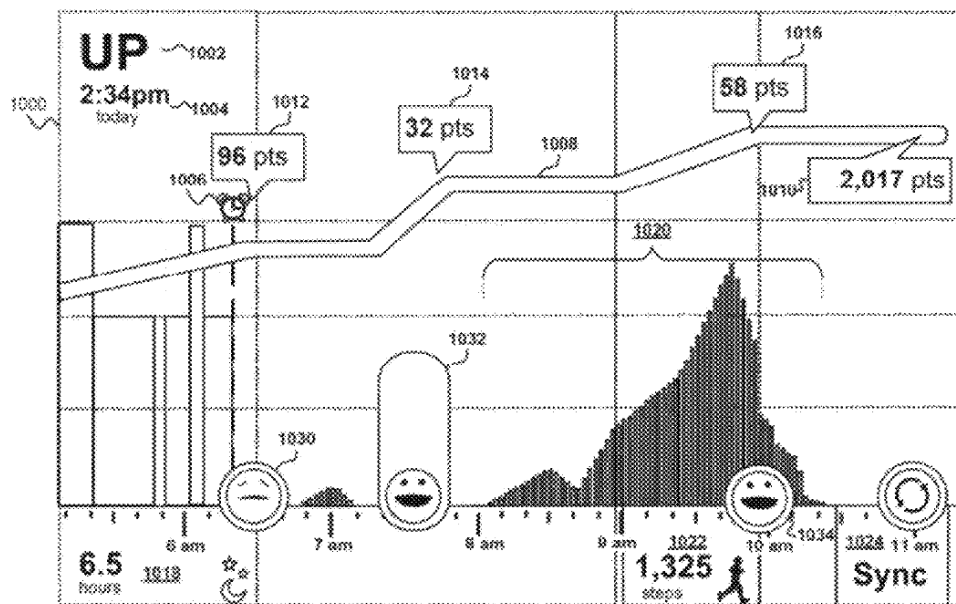


FIG. 6

APPLE-1006, FIG. 6

133. Utter's system is configured to evaluate overall wellness of a user, including physical, mental, and emotional health through collecting information about the user, including physiological information such as heart rate and blood oxygen saturation. *Id.*, 13:1-16, 13:41-43, 17:56-57, 21:6-17. For example, Utter describes that the wrist-worn monitoring devices can include a "light/infrared ('IR') sensor" to allow the device to measure and track "pulse/heart rate ('HR')." *Id.*, 17:56-57. As shown in Utter's exemplary FIG. 10 reproduced below, Utter's

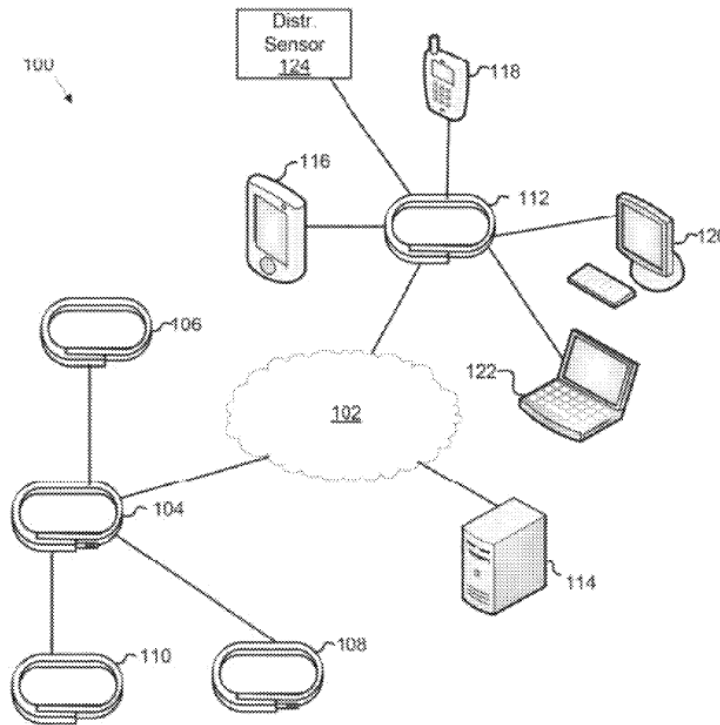
system provides “a graphical representation of a user’s wellness” based on detected and received information. *Id.*, 25:38-55, 28:24-41.



APPLE-1006, FIG. 10.

134. Utter describes that its system “is configured to process data, such as data representing parameters based on sensor measurements or the like, as well as derived parameters that can be derived (e.g., mathematically) based on data generated by one or more sensors.” APPLE-1006, 33:14-35. Utter also describes implementing its health monitoring system to include a wireless network that allows for “transfer[ing] data from one or more bands 104-112 to various destinations” including “mobile computing device 116, mobile communications device 118, [or] computer 120.” APPLE-1006, 14:42-15:3, 24:59-25:4. As shown in FIG. 1, the “[b]ands 106 and 110 may communicate with mobile

communications device 118 and laptop 122 using any number of wireless communication technologies.” *Id.*, 24:18-25.



APPLE-1006, FIG. 1

135. Utter describes that all of the computing devices in the system, which includes the wrist-worn sensors and the other peripheral computing devices such as mobile devices, smart phones, desktop and laptop computers, etc., are configured to download and execute applications to conduct “[a]nalysis, evaluation, or other operations...on data gathered by an application” which can be displayed as part of a “graphical user interface” on “mobile computing device 116 or any other type of client.” *Id.*, 21:45-65. For example, Utter describes that “[d]isplay engine 1454 can be configured to generate a graphical representation on an interface such as a

touch-sensitive screen on a mobile phone 1472.” APPLE-1006, 36:15-30. Utter further describes that any of the data collection, processing, and displaying functions can be performed on the wrist-worn device, the mobile device, or distributed between the wrist-worn device, the mobile device “or any other device” including spreading such functionality across multiple devices, as shown in FIG. 14. *Id.*, 36:23-30.

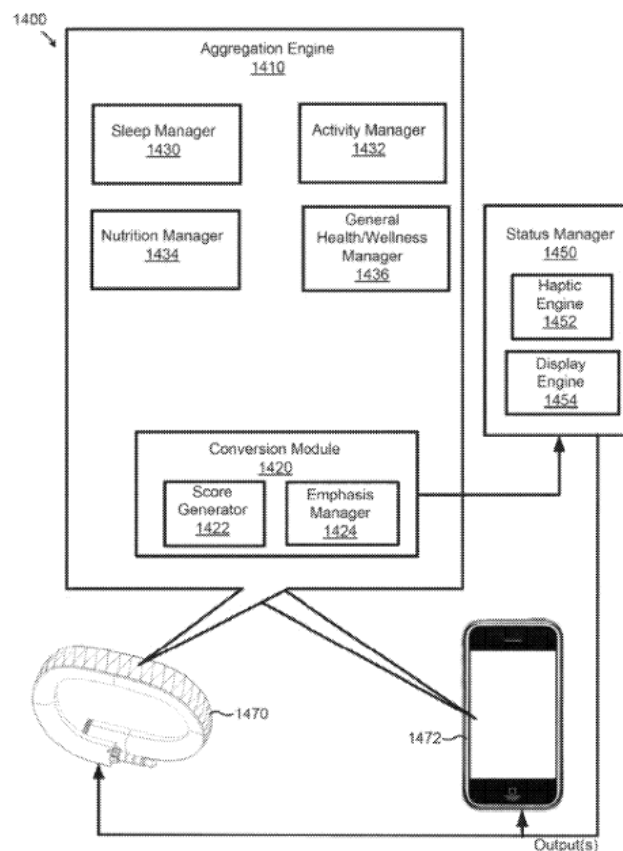


FIG. 14

APPLE-1006, FIG. 14.

2. Combination of Iwamiya with Sarantos and Utter

136. Multiple reasons would have prompted a POSITA to beneficially modify the wrist-worn physiological monitoring device resulting from the

combination of Iwamiya and Sarantos to include additional functionality, as taught by Utter, to transmit physiological data wirelessly to a secondary device such as a mobile computing device, mobile phone, or computer, in the same manner as Utter's wrist-worn wearable physiological monitoring device transmits information wirelessly from that device to a secondary device such as a mobile device or computer. APPLE-1006, 12:56-64, 13:1-16, 14:42-15:3, 24:18-25. Furthermore, a POSITA would have found such a modification to be obvious and would have had a reasonable expectation of success in applying the teachings of Utter to Iwamiya's device, especially due to the fact that both wireless communication between mobile computing devices and tracking of various wellness indicators for users of physiological monitoring devices was both well-known and widespread by 2015.

137. Utter discloses various secondary computing devices that would have been recognized to a POSITA to include commonplace components and functionality, including a touch screen user interface, a storage device, one or more processors, and a network interface configured to wirelessly communicate with the primary physiological monitoring device. APPLE-1006, 32:25-46, 36:21-23, 13:57-65, 14:42-15:3, 24:18-25, 24:59-25:4. Such devices disclosed by Utter include mobile computing devices, mobile communications devices, desktop computers, and laptop computers, as shown in FIG. 1, reproduced above. *Id.* For example, Utter describes "a touch-sensitive screen on a mobile phone 1472." *Id.*,

36:21-23. In another example, Utter describes that “[b]ands 106 and 110 may communicate with mobile communications device 118 and laptop 122 using any number of wireless communication technologies.” *Id.*, 24:18-25. Therefore a POSITA would have found it obvious and beneficial to modify the device of Iwamiya to wirelessly communicate with such secondary devices to communicate detected physiological parameter information for storage, analysis, and display by such devices.

138. This is precisely what Utter teaches. For example, Utter discloses that its configuration allows the secondary device to act as a user interface to the physiological monitoring device, disclosing that “[a]nalysis, evaluation, or other operations...on data gathered by an application” which can be displayed as part of a “graphical user interface” on “mobile computing device 116 or any other type of client.” APPLE-1006, 21:45-65, 36:15-30. For example, Utter describes that “[d]isplay engine 1454 can be configured to generate a graphical representation on an interface such as a touch-sensitive screen on a mobile phone 1472.” *Id.*, 36:15-30.

139. Utter further discloses that various data analysis can be performed by any of the devices in the system, including implementing the system such that such data analysis is spread between multiple devices. In one example, Utter describes that the secondary devices (*i.e.*, a mobile computing device or computer) can

“perform various analyses and evaluations that can generate information as to a person’s physical (e.g., healthy, sick, weakened, or other states, or activity level), emotional, or mental state” and “determine an aggregate value for producing a graphical representation of a user’s wellness.” APPLE-1006, 13:1-16, 25:38-41, 28:24-29:8.

140. Furthermore, a POSITA would have recognized multiple reasons for applying the teachings of Utter to the device of Iwamiya (as modified based on Sarantos). As a first reason, a POSITA would have been motivated to wirelessly connect the wristband-type wearable optical biological information detecting apparatus of Iwamiya to a secondary processing device, such as a mobile phone, having a user interface with a touch screen display as taught by Utter in order to increase the functionality of the system by utilizing the secondary display and processing capabilities of the secondary processing device, as described above.

141. As a second reason, a POSITA would have been motivated to configure Iwamiya’s wrist-worn physiological monitoring device to transmit the physiological parameter data determined by the wrist-worn device, which has limited display space and processing power, to a secondary device such as a smart phone, based on Utter’s suggestion, in order to increase the functionality of the system without significantly increasing the power consumption of Iwamiya’s sensor. APPLE-1004, 5:54-66, FIG. 1; APPLE-1006, 14:42-15:3, 24:18-25, FIG.

1, FIG. 14. For example, a POSITA would have understood that it is important for wearable sensors, such as that described in Iwamiya, to avoid power-consuming features, such as large amounts of data processing or elaborate graphical displays, because such added features may necessitate a power supply unit with a sufficient battery capacity to power such functionality, which would have detrimentally increased the weight of the device APPLE-1004, 5:54-66, FIG. 1.

142. Implementing Iwamiya's device to wirelessly transmit information to a mobile computing device or laptop "using any number of wireless communication technologies," based on the suggestions of Utter, would have allowed additional features to be realized, such as the calculation of additional metrics regarding the user's health, such as the aggregate wellness scores described by Utter, without the need to increase the battery capacity, and therefore weight, of Iwamiya's sensor. APPLE-1004, 5:54-66, FIG. 1; APPLE-1006, 14:42-15:3, 24:18-25, 13:1-16, 33:14-35, 25:38-41, 21:6-22, 28:23-29:8. For example, a POSITA would have known that it was imperative that physiological monitoring devices must "solve a need for the customer" and "meet the user's expectations" such as through "design of an optimal user interface" in order to be successfully adopted by users. APPLE-1009, 199.

143. As a third reason, such a configuration would have allowed for some physiological parameter information calculated by the wrist-worn device based on

various measurements detected by the wrist-worn device to be displayed on the wrist-worn device for quick viewing by the user while other, richer and more comprehensive wellness and trend data could be displayed as part of the larger interface of the secondary computing device. For example, such a configuration would have allowed the user to quickly glance at the wrist-worn device to see real-time or near real-time measurements such as heart rate and blood oxygen saturation during a workout while also transmitting such measured information (and other measured parameters) to a secondary device for further processing, including trend analysis, to give the user a deeper understanding of their overall health and activity levels. Such a configuration also would have allowed for analysis of measured physiological and other information received from multiple devices and/or sensors.

144. As a fourth reason, configuring Iwamiya's wrist-worn physiological monitoring device to transmit the physiological parameter data calculated at the wrist-worn sensor device to a secondary device to allow for combination with additional data to generate overall wellness data and trends (along with other applicable teachings of Utter) "can be used to improve user health, fitness levels, medical conditions, athletic performance, sleeping physiology, and physiological conditions." APPLE-1006, 12:56-64, 33:50-60 ("improve the user's health and wellness'), 34:15-27. For example, the resulting system can motivate the user to

improve activity levels to improve overall health. *Id.*, 34:11-19, 35:26-31. Such wireless transmittal of physiological parameters can also beneficially allow for sharing of information with other users. APPLE-1006, 14:23-42, 21:25-43,

145. Finally, A POSITA would have been prompted to implement Iwamiya's wrist-worn physiological monitoring device to wirelessly transmit measured information to a secondary device to allow for display of such information on that device and to allow for determination and display of wellness trends (based on the teachings of Utter) because doing so would be merely the application of a known technique to a known system (e.g., Iwamiya's physiological monitoring device as predictably modified by Sarantos) ready for improvement to yield predictable results. Here, Utter provides straightforward evidence of known techniques for exchanging, processing and displaying measured physiological information between computing devices, and Iwamiya's teaching provides a known system that would have been improved by application of Utter's suggested technique for at least the reasons described above.

146. Based upon my knowledge and experience in this field and my review of Iwamiya, Sarantos and Utter, I am confident a POSITA would have recognized that such a modification would have yielded predictable results, and these modifications would have been within the ordinary level of skill of a POSITA at the time of the '159 patent disclosure. Based on my review, it is clear that at least

because monitoring of physiological and other wellness parameters, wireless transmission of such data, and trend analysis of such health information were all well-known in the art, and Iwamiya, Sarantos, and Utter describe similar and compatible wrist-worn physiological sensors, a POSITA would have reasonably expected success in applying the teachings of Utter to Iwamiya (as modified by Sarantos). A POSITA would have understood such a combination would be successful with no unexpected results.

147. Accordingly, for at least these reasons, a POSITA would have been motivated and found it obvious to implement the combination of Iwamiya and Sarantos with Utter as described above. Such a modification would have been routine and straightforward to a POSITA, and it would have been clear that such a combination would predictably work and provide the expected functionality, because Utter describes a physiological monitoring system that operated in the proposed manner.

3. Application of the combination of Iwamiya with Sarantos and Utter to the claims

(a) Claim 14

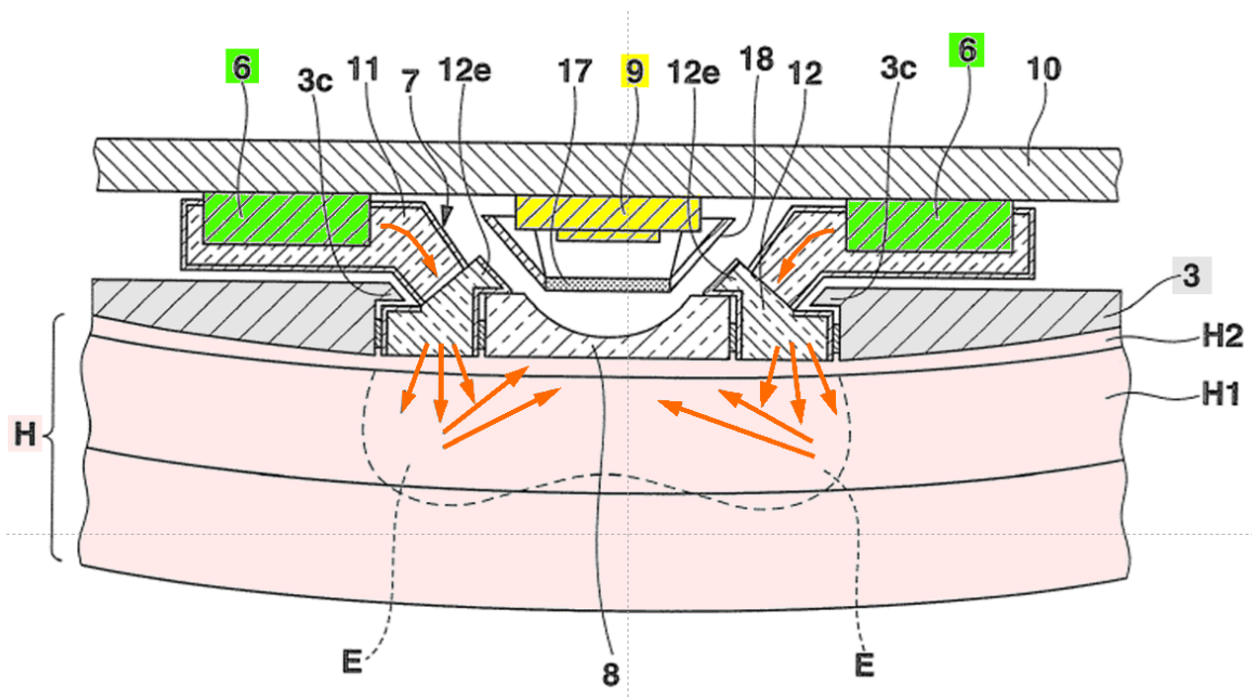
[14.0] A physiological monitoring device comprising:

148. The combination of Iwamiya with Sarantos and Utter provides a physiological monitoring device for the reasons discussed with respect to element [1.0], above.

(b)

[14.1] a plurality of optical sources configured to emit light proximate a wrist of a user;

149. The combination of Iwamiya with Sarantos and Utter provides a plurality of optical sources configured to emit light proximate a wrist of a user for the reasons discussed with respect to elements [1.0] and [1.1], above. For example, Iwamiya describes that the “optical biological information detecting apparatus” is provided in “a central portion of the back cover” of “a wristwatch” (*i.e.*, facing the wearer’s wrist). APPLE-1004, 5:54-66, FIG. 1. As shown in the following annotated FIG. 4 from Iwamiya, the device includes LEDs 6 (shown in green) that emit light (orange) that is reflected by the tissue of the wearer’s wrist (pink) and detected by photodiodes 9 (yellow).



[14.2] a diffuser configured to be positioned between the plurality of optical sources and a tissue measurement site on the wrist of the user when the physiological monitoring device is in use;

150. The combination of Iwamiya with Sarantos and Utter provides a diffuser configured to be positioned between the plurality of optical sources and a tissue measurement site on the wrist of the user when the physiological monitoring device is in use for the reasons discussed with respect to element [1.2], above. As I previously discussed, Iwamiya's "light guide unit 7 comprises a light guiding ring portion 11 and a ***diffusion/irradiation ring portion 12***" and functions to "guide[] the observation light emitted from the light emitting units 6 and ***annularly diffuse[]*** and irradiate[] the observation light with respect to a skin H." APPLE-1004, 6:7-14, 6:40-42, 7:14-24, 11:55-12:2, 12:18-36, 13:51-64. Based on this description, a POSITA would have recognized that the irradiation ring portion 12 is a diffuser. In another example, Iwamiya describes that "[t]he discharged observation light is ***annularly diffused*** and discharged from the emission surface 12d of the ***diffusion/irradiation ring portion 12*** contacting the skin H while being incident in the ***diffusion/irradiation ring portion 12*** of the light guide unit 7 from the ***incident surface 12c and being diffused***, and the discharged observation light is uniformly irradiated onto the skin H of the arm over a wide range of a ring shape." *Id.*, 10:25-31. In another example, Iwamiya describes that "the

observation light can be annularly diffused and irradiated onto the skin H by the light guide unit 7.” *Id.*, 11:19-23.

[14.3] a light block having a circular shape;

151. The combination of Iwamiya with Sarantos and Utter provides a light block having a circular shape for the reasons discussed with respect to element [1.6] and claim 6, above.

[14.4] a plurality of detectors configured to detect at least a portion of the light after the light passes through a portion of the tissue measurement site bounded by the light block, wherein the plurality of detectors are arranged in an array having a spatial configuration corresponding to a shape of the portion of the tissue measurement site bounded by the circular shaped light block, wherein the plurality of detectors are further configured to output at least one signal responsive to the detected light, and wherein the plurality of optical sources and the plurality of detectors are arranged in a reflectance measurement configuration;

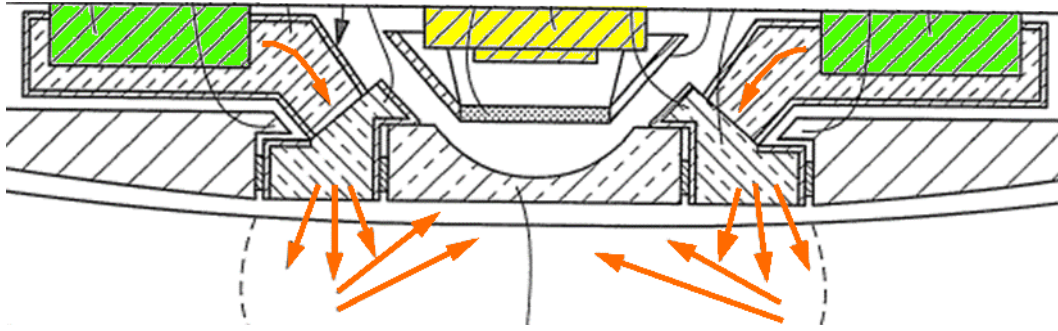
152. The combination of Iwamiya with Sarantos and Utter provides a plurality of detectors configured to detect at least a portion of the light after the light passes through a portion of the tissue measurement site bounded by the light block, wherein the plurality of detectors are arranged in an array having a spatial configuration corresponding to a shape of the portion of the tissue measurement site bounded by the circular shaped light block, wherein the plurality of detectors are further configured to output at least one signal responsive to the detected light, and wherein the plurality of optical sources and the plurality of detectors are

arranged in a reflectance measurement configuration for the reasons discussed with respect to at least elements [1.3] and [1.6] and claims 4, 5, and 6, above.

153. As I previously described, in the combination, Iwamiya describes that light emitted from light emitting units 6 travels through light diffusing material (annular light guide unit 7) and then passes into skin tissue that is encircled by the light block (reflection layers 13 and 15). APPLE-1004, 6:7-14, 12:3-17, FIGS. 3-4. Reflection layers 13 and 15, which form the light block, encircle a portion of patient tissue, shown in Iwamiya FIG. 4 as irradiation area E. APPLE-1004, FIGS. 3-4.

154. Iwamiya describes that the physiological monitoring device includes a plurality of photodiodes configured to detect light reflected by the encircled tissue. APPLE-1004, 6:7-14, 8:20-23, 12:3-17, 14:36-41, FIGS. 3-4. The photodiodes “may be two-dimensionally disposed in the places positioned at the side opposite to the skin H in the scattered light taking unit 8.” APPLE-1004, 14:36-39. “In this case, the plural light receiving units 9 are preferably disposed on the same circumference centered on an optical axis of the scattered light taking unit 8.” APPLE-1004, 14:39-41. A POSITA would thus have understood that the photodiodes described in Iwamiya are arranged in an array having a spatial configuration corresponding to a shape of the portion of the tissue measurement site encircled by the light block. *See, e.g.*, APPLE-1004, 14:36-41, FIGS. 2-4.

155. As shown in FIG. 4 of Iwamiya, the LEDs (green) emit light (orange) that is reflected through the tissue measurement site bounded by the light block which is then detected by the photodiodes (yellow):



APPLE-1004, Detail of FIG. 4 (annotated)

156. A POSITA would have understood the configuration shown in FIG. 4 of Iwamiya to be a reflectance measurement configuration, as discussed with respect to claim 4, above. APPLE-1009, 87-88, Figure 7.2.

[14.5] wherein the light block is configured to prevent at least a portion of light emitted from the plurality of optical sources from reaching the plurality of detectors without first reaching tissue;

157. The combination of Iwamiya with Sarantos and Utter provides that the light block is configured to prevent at least a portion of light emitted from the plurality of optical sources from reaching the plurality of detectors without first reaching tissue for the reasons discussed with respect to element [1.6], above.

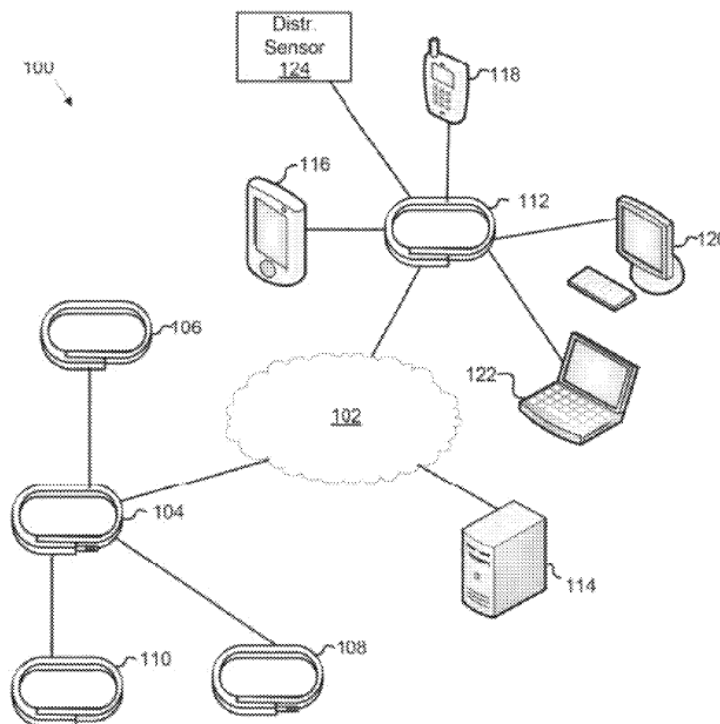
[14.6] a processor configured to receive and process one or more signals responsive to the at least one outputted signal and determine a physiological parameter of the user responsive to the one or more signals; and

158. The combination of Iwamiya with Sarantos and Utter provides a processor configured to receive and process one or more signals responsive to the at least one outputted signal and determine a physiological parameter of the user responsive to the one or more signals for the reasons discussed with respect to element [1.7], above.

[14.7] wherein the physiological monitoring device is configured to transmit physiological parameter data to a separate processor.

159. Utter demonstrates that the physiological monitoring device resulting from the combination of Iwamiya with Sarantos and Utter is configured to transmit physiological parameter data to a separate processor. Utter discloses a non-invasive light-based wrist-worn physiological monitoring device, like Iwamiya's, that wirelessly transmits physiological parameter data to a separate processor, such as a smartphone. APPLE-1006, 14:42-15:3, 24:18-25, 36:21-30, 13:57-65, FIG. 1, FIG. 14. For example, Utter describes that "bands 104-112 may be implemented as wearable personal data or data capture devices (e.g., data-capable devices) that are worn by a user around a wrist, ankle, arm, ear, or other appendage, or attached to the body or affixed to clothing." APPLE-1006, 12:34-67. Utter describes that "one or more facilities, sensing elements, or sensors, both active and passive, may be implemented as part of bands 104-112 in order to capture various types of data

from different sources.” *Id.* Utter also describes a wireless network that allows for “transfer[ing] data from one or more bands 104-112 to various destinations” including “mobile computing device 116, mobile communications device 118, [or] computer 120.” APPLE-1006, 14:42-15:3, 24:59-25:4. For example, Utter describes “transfer[ing] data from one or more bands 104-112 to various destinations (e.g., another of bands 104-112, server 114, mobile computing device 116, mobile communications device 118, computer 120, laptop 122, and distributed sensor 124” and that “[t]he exchanged data may include personal physiological data and data derived from sensory-based user interfaces (‘UI’).” APPLE-1006, 14:4-15, 14:53-57. This communication can occur via “wireless communication facilities.” *Id.*, 14:42-15:3.



APPLE-1006, FIG. 1

160. As I previously discussed, a POSITA would have been motivated to transmit information from Iwamiya's wrist-worn wearable device, which has limited display space and processing power, to a secondary device like a smart phone, as taught by Utter in order to increase the functionality of the system without significantly increasing the power consumption of Iwamiya's sensor. *See, e.g.,* APPLE-1004, 5:54-66, FIG. 1; APPLE-1006, 14:42-15:3, 24:18-25, FIG. 1, FIG. 14.

(c) Claim 15

[15.0] The physiological monitoring device of claim 14, wherein the plurality of optical sources are positioned outside the light block and the plurality of detectors are positioned inside the light block.

161. The combination of Iwamiya with Sarantos and Utter provides that the plurality of optical sources are positioned outside the light block and the plurality of detectors are positioned inside the light block for the reasons discussed with respect to claim 6, above.

(d) Claim 16

[16.0] The physiological monitoring device of claim 14, wherein the physiological parameter comprises pulse rate.

162. The combination of Iwamiya with Sarantos and Utter provides that the physiological parameter comprises pulse rate for the reasons discussed with respect to claim 7, above.

(e) Claim 17

[17.0] The physiological monitoring device of claim 14, wherein the physiological parameter comprises oxygen saturation.

163. The combination of Iwamiya with Sarantos and Utter provides that the physiological parameter comprises oxygen saturation for the reasons discussed with respect to claim 8, above.

(f) Claim 18

[18.0] The physiological monitoring device of claim 14, wherein the plurality of optical sources are configured to emit light in a first shape, and wherein the diffuser comprises a material configured to change the first shape into a second shape by which the light emitted from one or more of the plurality of optical sources is projected towards the tissue measurement site.

164. The combination of Iwamiya with Sarantos and Utter provides that the plurality of optical sources are configured to emit light in a first shape, and that the diffuser comprises a material configured to change the first shape into a second shape by which the light emitted from one or more of the plurality of optical sources is projected towards the tissue measurement site for the reasons discussed with respect to elements [1.1] and [1.2], above.

(g) Claim 19

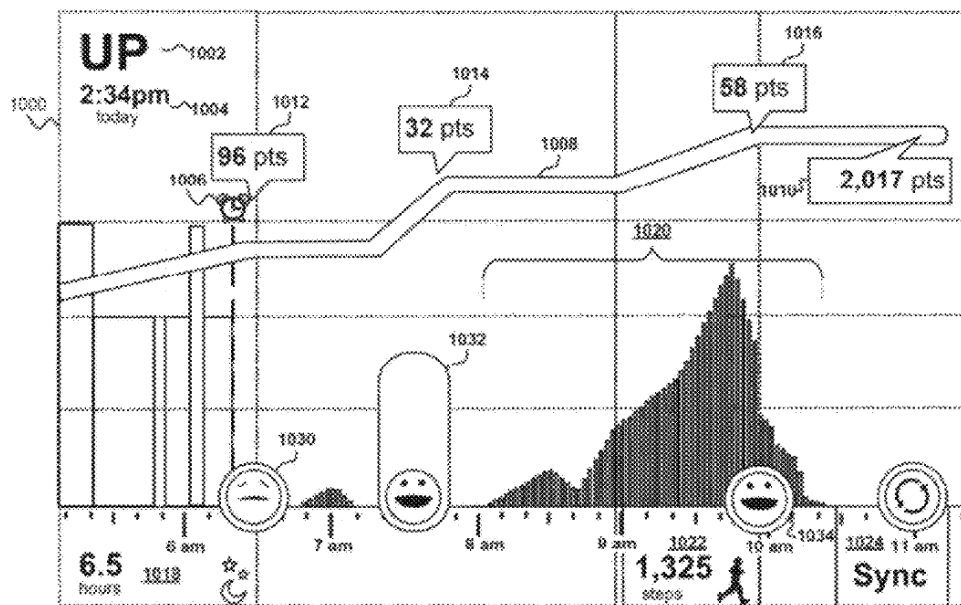
[19.0] A system configured to measure one or more physiological parameters of a user, the system comprising:

165. The combination of Iwamiya with Sarantos and Utter provides a system configured to measure one or more physiological parameters of a user. As I discussed above, Iwamiya describes an “optical biological information detecting

apparatus [that] includes a light emitting unit which emits observation light of a specific wavelength band to optically observe a desired portion of a tissue of a skin of a human body, and an annular light guide unit which guides the observation light to a desired area of a surface of the skin corresponding to the desired portion of the tissue of the skin, and which annularly irradiates the observation light onto the desired area of the surface of the skin.” APPLE-1004, Abstract. A POSITA would have recognized such a device as a physiological monitoring device. Iwamiya describes that its device includes “a display unit 23 that displays a measurement result of biological information, such as a pulse wave” which a POSITA would have recognized as measurement of a physiological parameter. APPLE-1004, 8:61-9:7. Additionally, in the combination, Sarantos discloses that the resulting device measures both “heart rate measurement” and “blood oxygenation levels” based on “one or more light intensity measurements.” APPLE-1005, 2:5-14, 5:55-59, 7:12-14, 13:39-47.

166. As I discussed above, when Iwamiya is combined with both Sarantos and Utter, the physiological monitoring device of Iwamiya is part of a system configured to measure one or more physiological parameters of a user. For example, Utter describes implementing its health monitoring system to include a wireless network that allows for “transfer[ing] data from one or more bands 104-112 to various destinations” including “mobile computing device 116, mobile

communications device 118, [or] computer 120.” APPLE-1006, 14:42-15:3, 24:59-25:4. This allows the resulting system to evaluate overall wellness of a user, including physical, mental, and emotional health through collecting information about the user, including physiological information such as heart rate and blood oxygen saturation. *Id.*, 13:1-16, 13:41-43, 17:56-57, 21:6-17. For example, as shown in Utter’s exemplary FIG. 10 reproduced below, the system resulting from the combination of Iwamiya with Sarantos and Utter provides “a graphical representation of a user’s wellness” based on detected and received information. *Id.*, 25:38-55, 28:24-41.



APPLE-1006, FIG. 10.

167. Utter discloses various secondary computing devices that would have been recognized to a POSITA to include commonplace components and

functionality, including a touch screen user interface, a storage device, one or more processors, and a network interface configured to wirelessly communicate with the primary physiological monitoring device. APPLE-1006, 32:25-46, 36:21-23, 13:57-65, 14:42-15:3, 24:18-25, 24:59-25:4. Such devices disclosed by Utter include mobile computing devices, mobile communications devices, desktop computers, and laptop computers, as shown in FIG. 1, reproduced above. *Id.* For example, Utter describes “a touch-sensitive screen on a mobile phone 1472.” *Id.*, 36:21-23. In another example, Utter describes that “[b]ands 106 and 110 may communicate with mobile communications device 118 and laptop 122 using any number of wireless communication technologies.” *Id.*, 24:18-25. As previously discussed, a POSITA would have found it obvious and beneficial to modify the device of Iwamiya to wirelessly communicate with such secondary devices to communicate detected physiological parameter information for storage, analysis, and display by such devices, thus forming a system configured to measure one or more physiological parameters of a user.

[19.1] a physiological monitoring device comprising:

168. The combination of Iwamiya with Sarantos and Utter provides a physiological monitoring device for the reasons discussed with respect to element [1.0], above.

[19.2] a plurality of emitters configured to emit light in a first shape;

169. The combination of Iwamiya with Sarantos and Utter provides a plurality of emitters configured to emit light in a first shape for the reasons discussed with respect to element [1.1], above.

[19.3] a material positioned between the plurality of emitters and a tissue measurement site when the physiological monitoring device is in use, the material configured to change the first shape into a second shape by which the light emitted from one or more of the plurality of emitters is projected towards the tissue measurement site;

170. The combination of Iwamiya with Sarantos and Utter provides a material positioned between the plurality of emitters and a tissue measurement site when the physiological monitoring device is in use, the material configured to change the first shape into a second shape by which the light emitted from one or more of the plurality of emitters is projected towards the tissue measurement site for the reasons discussed with respect to element [1.2], above.

[19.4] a plurality of detectors configured to detect at least a portion of the light passing through tissue, the plurality of detectors further configured to output at least one signal responsive to the detected light;

171. The combination of Iwamiya with Sarantos and Utter provides a plurality of detectors configured to detect at least a portion of the light passing through tissue, the plurality of detectors further configured to output at least one signal responsive to the detected light for the reasons discussed with respect to element [1.3], above.

[19.5] a surface comprising a dark-colored coating, the surface positioned between the plurality of detectors and the tissue when the physiological monitoring device is in use, wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface;

172. The combination of Iwamiya with Sarantos and Utter provides a surface comprising a dark-colored coating, the surface positioned between the plurality of detectors and the tissue when the physiological monitoring device is in use, wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface for the reasons discussed with respect to elements [1.4]-[1.5], above.

[19.6] a light block configured to prevent at least a portion of light from the plurality of emitters from reaching the plurality of detectors without first reaching the tissue; and

173. The combination of Iwamiya with Sarantos and Utter provides a light block configured to prevent at least a portion of light from the plurality of emitters from reaching the plurality of detectors without first reaching the tissue for the reasons discussed with respect to element [1.6], above.

[19.7] a processor configured to receive and process one or more signals responsive to the outputted at least one signal and determine a physiological parameter of the user responsive to the one or more signals; and

174. The combination of Iwamiya with Sarantos and Utter provides a processor configured to receive and process one or more signals responsive to the outputted at least one signal and determine a physiological parameter of the user

responsive to the one or more signals for the reasons discussed with respect to element [1.7], above.

[19.8] a processing device configured to wirelessly receive physiological parameter data from the physiological monitoring device, wherein the processing device comprises a user interface, a storage device, and a network interface configured to wirelessly communicate with the physiological monitoring device, and wherein the user interface includes a touch-screen display configured to present visual feedback responsive to the physiological parameter data.

175. As I discussed in Section IV.C.2, above, the combination of Iwamiya with Sarantos and Utter provides a processing device configured to wirelessly receive physiological parameter data from the physiological monitoring device, wherein the processing device comprises a user interface, a storage device, and a network interface configured to wirelessly communicate with the physiological monitoring device, and wherein the user interface includes a touch-screen display configured to present visual feedback responsive to the physiological parameter data.

176. As I previously discussed, Utter describes a non-invasive light-based wrist-worn physiological monitoring device similar to those described by both Iwamiya and Sarantos in the form of “bands 104-112 [that] may be implemented as wearable personal data or data capture devices (e.g., data-capable devices) that are worn by a user around a wrist, ankle, arm, ear, or other appendage, or attached to the body or affixed to clothing.” APPLE-1006, 12:34-67. Utter describes that “one or more facilities, sensing elements, or sensors, both active and passive, may be

implemented as part of bands 104-112 in order to capture various types of data from different sources.” *Id.* As shown in FIG. 6, the wrist-worn physiological monitoring devices described by Utter can wirelessly communicate with other computing devices to exchange information including measured physiological parameter information. APPLE-1006, 13:57-65, 14:43-57.

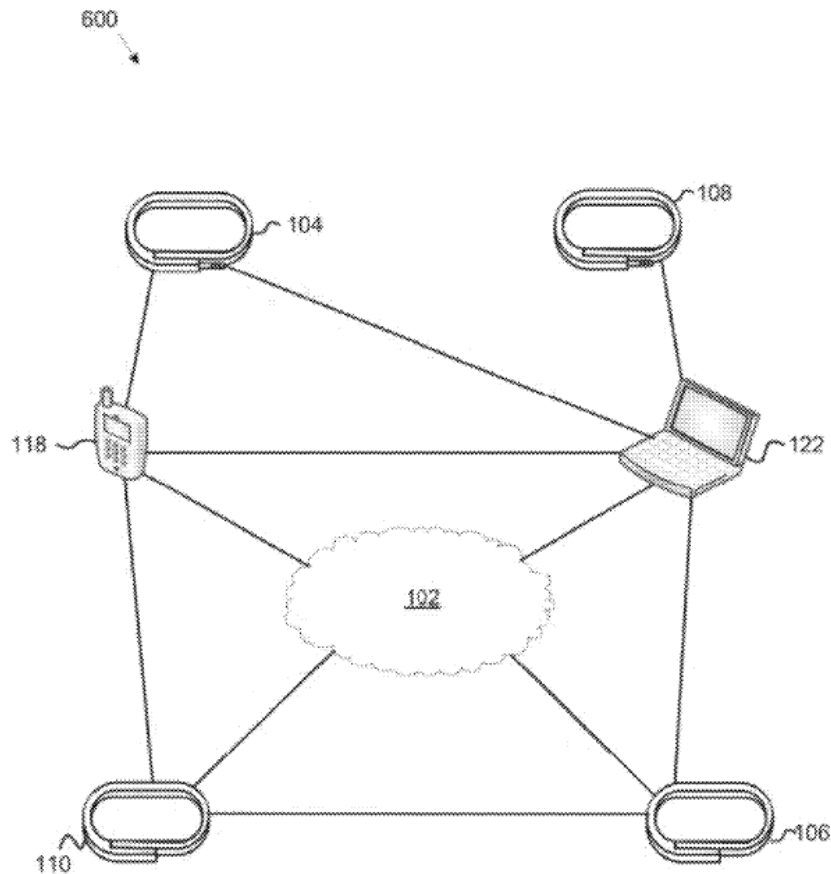


FIG. 6

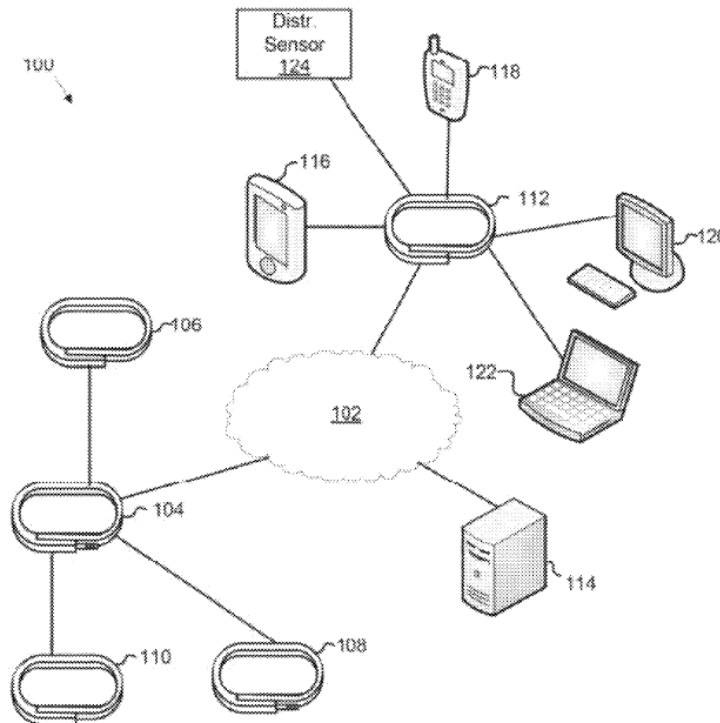
APPLE-1006, FIG. 6

177. In the predictable combination, the wrist-worn physiological monitoring device of Iwamiya (as predictably modified by Sarantos) is further

configured to include additional functionality, as taught by Utter, to transmit physiological data wirelessly to a secondary device such as a mobile computing device, mobile phone, or computer, in the same manner as Utter's wrist-worn wearable physiological monitoring device transmits information wirelessly from that device to a secondary device such as a mobile device or computer. APPLE-1006, 12:56-64, 13:1-16, 14:42-15:3, 24:18-25. For example, as discussed by Utter, the resulting device includes wireless communication functionality that allows for "transfer[ing] data from one or more bands 104-112 to various destinations" including "mobile computing device 116, mobile communications device 118, [or] computer 120." APPLE-1006, 14:42-15:3, 24:59-25:4. For example, Utter describes "transfer[ing] data from one or more bands 104-112 to various destinations (e.g., another of bands 104-112, server 114, mobile computing device 116, mobile communications device 118, computer 120, laptop 122, and distributed sensor 124" and that "[t]he exchanged data may include personal physiological data and data derived from sensory-based user interfaces ('UI')." APPLE-1006, 14:4-15, 14:53-57. As shown in FIG. 1 of Utter (reproduced below), the wrist-worn physiological monitoring devices of the resulting combination "may communicate with mobile communications device 118 and laptop 122 using any number of wireless communication technologies." *Id.*, 24:18-25. A POSITA would have recognized from Utter's descriptions of using WiFi,

Bluetooth, NFC, and other wireless communications protocols between the various devices that the secondary devices include a network interface configured to wirelessly communicate with the wrist-worn physiological monitoring device.

APPLE-1006, 14:42-15:3, 17:32-37, 24:18-25.



APPLE-1006, FIG. 1

178. Utter describes that all of the computing devices in the system, which includes the wrist-worn sensors and the other peripheral computing devices such as mobile devices, smart phones, desktop and laptop computers, etc., are configured to download and execute applications to conduct “[a]nalysis, evaluation, or other operations...on data gathered by an application” which can be displayed as part of a “graphical user interface” on “mobile computing device 116 or any other type of

client.” *Id.*, 21:45-65. For example, Utter describes that “[d]isplay engine 1454 can be configured to generate a graphical representation on an interface such as a touch-sensitive screen on a mobile phone 1472.” APPLE-1006, 36:15-30.

179. As I previously discussed, a POSITA would have been motivated to transmit information from Iwamiya’s wrist-worn wearable device, which has limited display space and processing power, to a secondary device like a smart phone, as taught by Utter in order to increase the functionality of the system without significantly increasing the power consumption of Iwamiya’s sensor. *See, e.g.*, APPLE-1004, 5:54-66, FIG. 1; APPLE-1006, 14:42-15:3, 24:18-25, FIG. 1, FIG. 14.

180. As I also described above, a POSITA would have been motivated to modify the device resulting from the combination of Iwamiya with Sarantos to further include functionality for performing data analysis and displaying information indicative of wellness trends. This modification allows the secondary device to act as an improved display for the wrist-worn wearable physiological device, describing that both the wrist worn sensor devices and peripheral computing devices (such as mobile computing devices) can download and execute applications to conduct “[a]nalysis, evaluation, or other operations...on data gathered by an application” which can be displayed as part of a “graphical user interface” on “mobile computing device 116 or any other type of client.” APPLE-

1006, 21:45-65. Utter describes that the secondary device also includes storage such as “system memory 1306 (e.g., RAM), storage device 1308 (e.g., ROM).” APPLE-1006, 32:30-38. Utter further discloses that the secondary device (i.e., mobile computing device) can show various metrics regarding the user’s health, and receive inputs through a touch-screen display user interface. APPLE-1006, 36:15-30 (“...a graphical representation on an interface such as a touch-sensitive screen on a mobile phone”), 13:1-16, 25:38-41, 28:24-29:8, 33:14-35, FIG. 10. Additionally, Utter describes a configuration in which an “iPhone” is used as a user interface for both receiving input and displaying information and POSITA would have known that iPhones at the time included a touch-screen user interface, a storage device, and a wireless network interface. APPLE-1006, 24:52-25:13.

181. As shown in Utter’s exemplary FIG. 10 reproduced below, the predictable combination provides “a graphical representation of a user’s wellness” based on detected and received information. *Id.*, 25:38-55, 28:24-41.

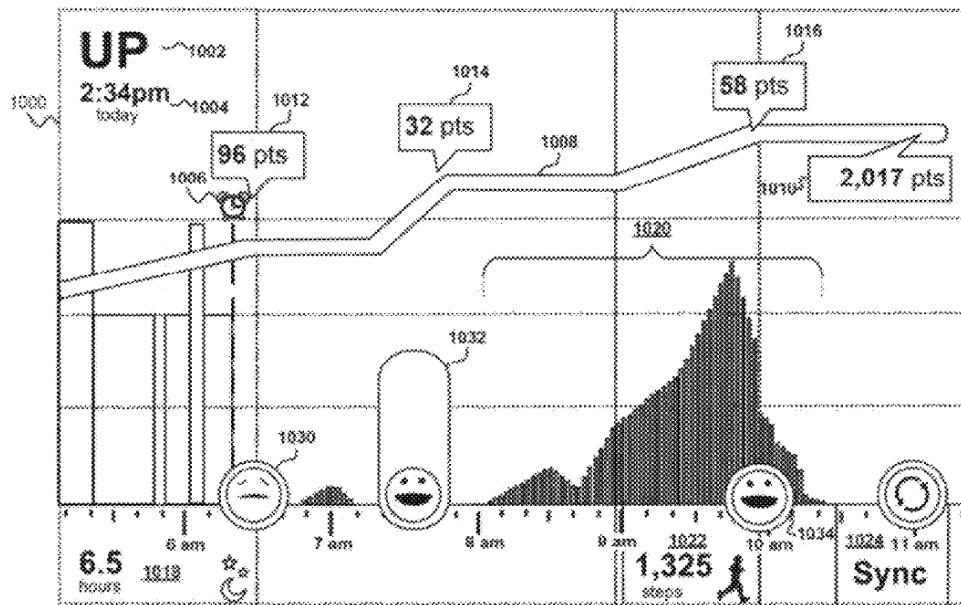


FIG. 10

APPLE-1006, FIG. 10.

182. Utter describes that its system “is configured to process data, such as data representing parameters based on sensor measurements or the like, as well as derived parameters that can be derived (e.g., mathematically) based on data generated by one or more sensors.” APPLE-1006, 33:14-35. Configuring Iwamiya’s wrist-worn physiological monitoring device to transmit the physiological parameter data calculated at the wrist-worn sensor device to a secondary device to allow for combination with additional data to generate overall wellness data and trends (along with other applicable teachings of Utter) “can be used to improve user health, fitness levels, medical conditions, athletic performance, sleeping physiology, and physiological conditions.” APPLE-1006, 12:56-64, 33:50-60 (“improve the user’s health and wellness”), 34:15-27.

183. Utter describes that in the resulting combination, the “graphical representation may include graphical representations of various aspects of a user’s exercise level for a particular workout, including...the user’s heart rate during the workout (not shown).” APPLE-1006, 27:41-52. Furthermore, the “[a]nalysis, evaluation, or other operations performed on data gathered by an application downloaded from server 114 may be presented (i.e., displayed) on a graphical user interface...on mobile computing device 116.” *Id.*, 21:59-65.

184. Utter further discloses that various data analysis can be performed by any of the devices in the system, including implementing the system such that such data analysis is spread between multiple devices. In one example, Utter describes that the secondary devices (*i.e.*, a mobile computing device or computer) can “perform various analyses and evaluations that can generate information as to a person’s physical (e.g., healthy, sick, weakened, or other states, or activity level), emotional, or mental state” and “determine an aggregate value for producing a graphical representation of a user’s wellness.” APPLE-1006, 13:1-16, 25:38-41, 28:24-29:8.

185. The data collection, processing, and displaying functions can be performed on the wrist-worn device, the mobile device, or distributed between the wrist-worn device, the mobile device “or any other device.” *Id.*, 36:23-30.

Therefore, a POSITA would have recognized, based on the express disclosures of

Utter, that in at least some configurations of the combination of Iwamiya with Sarantos and Utter, processing of the received signals to determine physiological parameters such as heart rate and blood oxygen saturation is conducted on the wrist-worn device while the mobile computing device (or other secondary device) is “configured to generate a graphical representation on an interface, such as a touch-sensitive screen on a mobile phone” which would have been beneficially applied to the Iwamiya-Sarantos combination as described above. *Id.* 36:21-24, 14:4-15, 14:53-57, 13:1-16, 13:41-43, 17:56-57, 21:6-17.

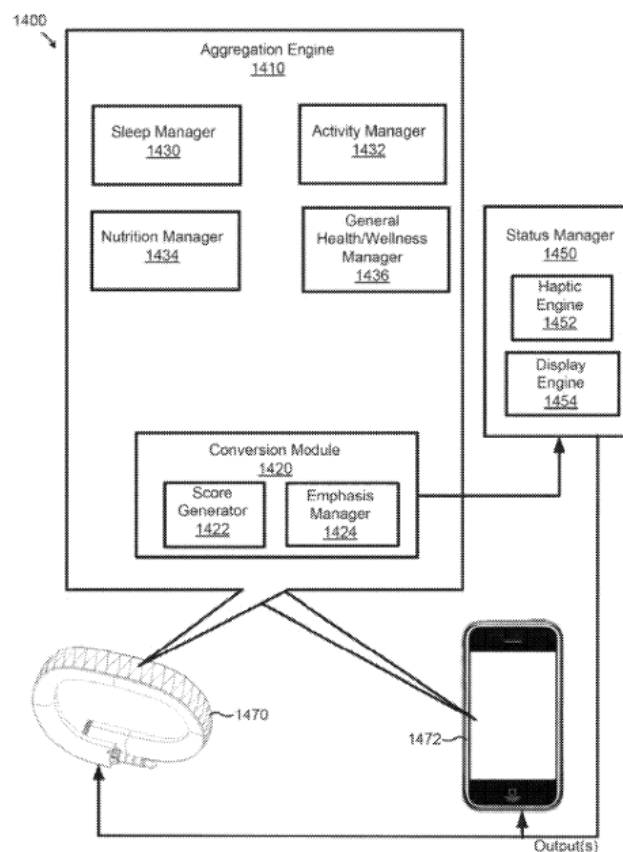


FIG. 14

APPLE-1006, FIG. 14

Such a configuration of distributing the processing of such data would have allowed for a faster, more responsive system that would allow for quick viewing of some physiological parameter data on the wrist-worn device while allowing for more detailed analysis (including the wellness trend analysis described by Utter) to be conducted at the secondary device having the greater processing capability.

(h) Claim 20

[20.0] The system of claim 19, wherein the system is configured to determine a state of wellness of the user based on the determined physiological parameter.

186. The combination of Iwamiya with Sarantos and Utter provides that the system is configured to determine a state of wellness of the user based on the determined physiological parameter. As shown in Utter's exemplary FIG. 10 reproduced below, the predictable combination provides "a graphical representation of a user's wellness" based on detected and received information.

Id., 25:38-55, 28:24-41.

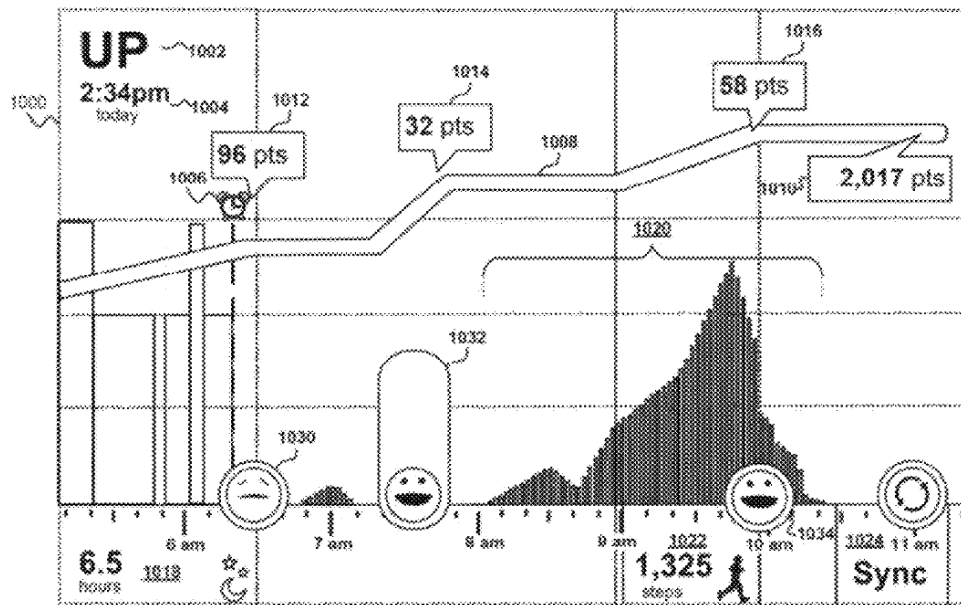


FIG. 10

APPLE-1006, FIG. 10.

187. Utter describes that its system “is configured to process data, such as data representing parameters based on sensor measurements or the like, as well as derived parameters that can be derived (e.g., mathematically) based on data generated by one or more sensors.” APPLE-1006, 33:14-35. Configuring Iwamiya’s wrist-worn physiological monitoring device to transmit the physiological parameter data calculated at the wrist-worn sensor device to a secondary device to allow for combination with additional data to generate overall wellness data and trends (along with other applicable teachings of Utter) “can be used to improve user health, fitness levels, medical conditions, athletic performance, sleeping physiology, and physiological conditions.” APPLE-1006, 12:56-64, 33:50-60 (“improve the user’s health and wellness”), 34:15-27.

188. Utter describes that in the resulting combination, the “graphical representation may include graphical representations of various aspects of a user’s exercise level for a particular workout, including...the user’s heart rate during the workout (not shown).” APPLE-1006, 27:41-52. Furthermore, the “[a]nalysis, evaluation, or other operations performed on data gathered by an application downloaded from server 114 may be presented (i.e., displayed) on a graphical user interface...on mobile computing device 116.” *Id.*, 21:59-65.

(a) Claim 21

[21.0] The system of claim 19, wherein the system is configured to determine a trend of wellness of the user based on the determined physiological parameter.

189. As discussed above, the combination of Iwamiya with Sarantos and Utter provides that the system is configured to determine a trend of wellness of the user based on the determined physiological parameter. Utter describes that in the predictable combination, the secondary devices (*i.e.*, a mobile computing device or computer) can “perform various analyses and evaluations that can generate information as to a person’s physical (e.g., healthy, sick, weakened, or other states, or activity level), emotional, or mental state” and “determine an aggregate value for producing a graphical representation of a ***user’s wellness***.” APPLE-1006, 13:1-16, 25:38-41, 28:24-29:8.

190. For example, “FIG. 10 illustrates an exemplary graphical representation of a user’s wellness ***over a time period***.” *Id.*, 27:3-16.

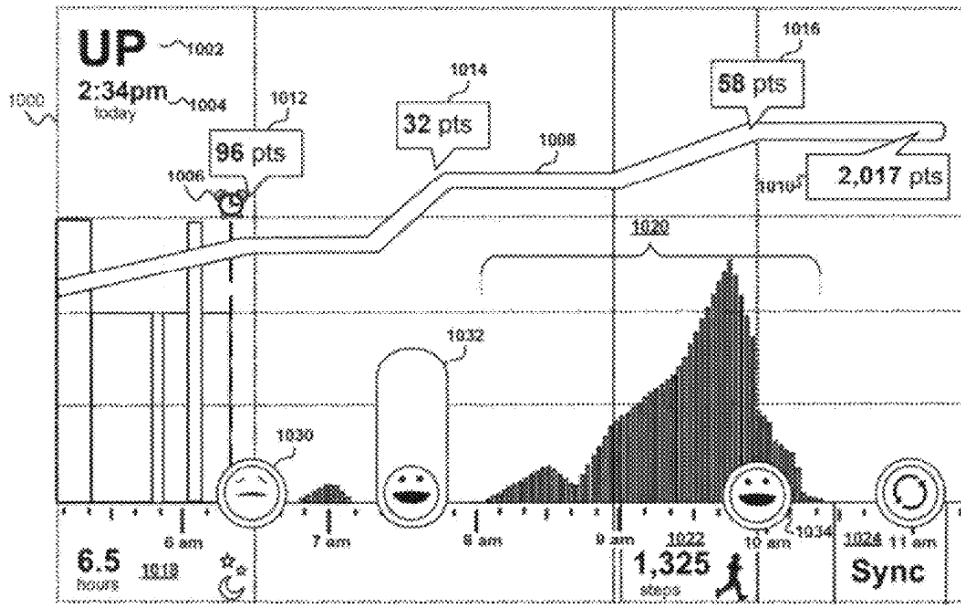


FIG. 10

APPLE-1006, FIG. 10.

191. As another example, FIG. 11 “shows a summary of a user’s wellness progress over the course of a week.” *Id.*, 28:24-29:8.

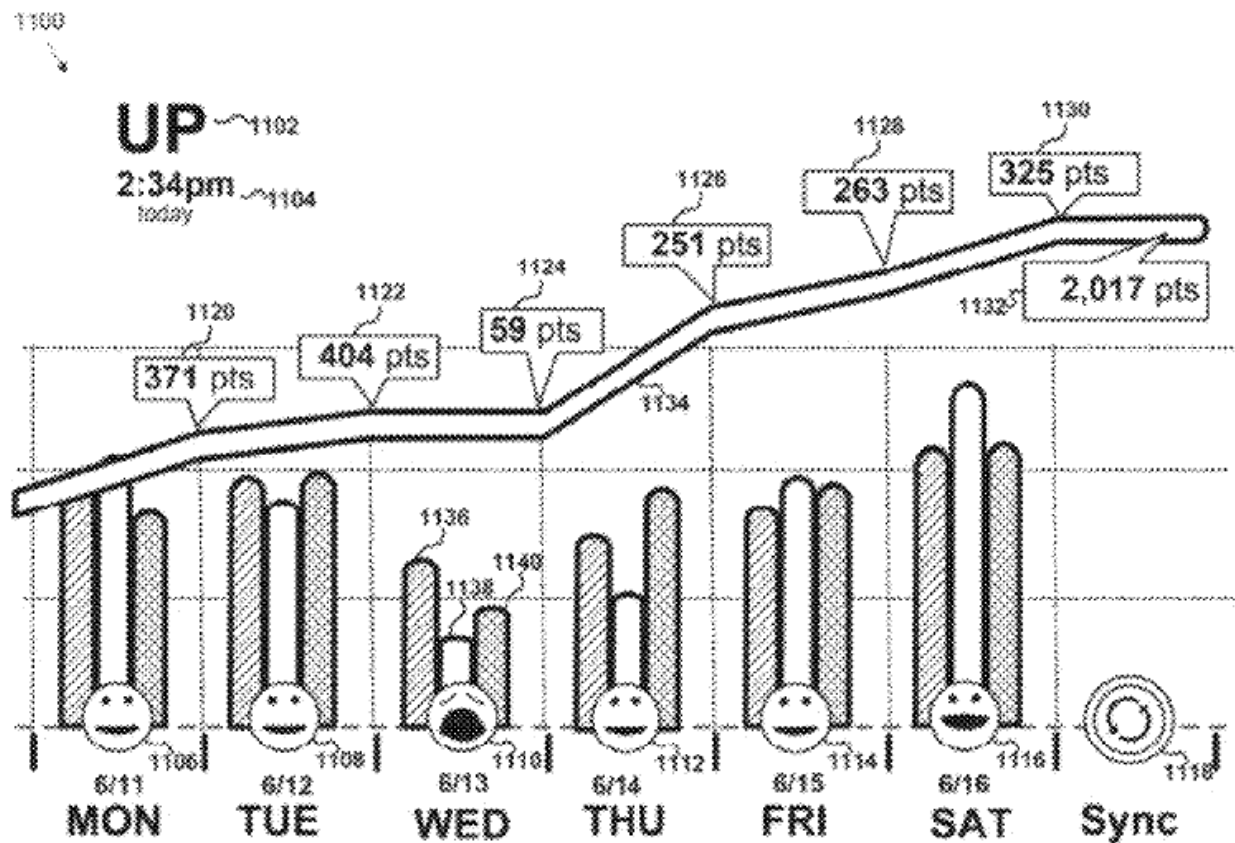


FIG. 11

APPLE-1006, FIG. 11.

192. In another example, Utter provides that in the predictable combination “data may be analyzed by sensor input evaluation module 420...to determine *trends, patterns, and other useful information.*” APPLE-1006, 20:8-16, 35:7-26, 41:4-29.

(i) Claim 22

[22.0] The system of claim 19, wherein the visual feedback presented by the touch-screen display is responsive to at least one of a pulse rate and an oxygen saturation of the user.

193. The combination of Iwamiya with Sarantos and Utter provides that the visual feedback presented by the touch-screen display is responsive to at least one of a pulse rate and an oxygen saturation of the user for the reasons discussed with respect to claims 2, 7, and 8, above.

(j) Claim 23

[23.0] The system of claim 19, wherein the material comprises at least one of glass and plastic.

194. The combination of Iwamiya with Sarantos and Utter provides that the material comprises at least one of glass and plastic for the reasons discussed with respect to claims 9 and 10, above.

(k) Claim 24

[24.0] The system of claim 19, wherein the second shape comprises a width and a length, and wherein the width is different from the length.

195. The combination of Iwamiya with Sarantos and Utter provides that the second shape comprises a width and a length, and wherein the width is different from the length for the reasons discussed with respect to claim 12, above.

(l) Claim 25

[25.0] The system of claim 19, wherein the plurality of detectors are arranged in an array having a spatial configuration corresponding to a shape of a portion of the tissue measurement site bounded by the light block.

196. The combination of Iwamiya with Sarantos and Utter provides that the plurality of detectors are arranged in an array having a spatial configuration corresponding to a shape of a portion of the tissue measurement site bounded by the light block for the reasons discussed with respect to claim 5, above.

V. Legal Principles

A. Anticipation

197. I have been informed that a patent claim is invalid as anticipated under 35 U.S.C. § 102 if each and every element of a claim, as properly construed, is found either explicitly or inherently in a single prior art reference. Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes the claimed limitations, it anticipates.

198. I have been informed that a claim is invalid under 35 U.S.C. § 102(a) if the claimed invention was known or used by others in the U.S., or was patented or published anywhere, before the applicant's invention. I further have been informed that a claim is invalid under 35 U.S.C. § 102(b) if the invention was patented or published anywhere, or was in public use, on sale, or offered for sale in this country, more than one year prior to the filing date of the patent application. And a claim is invalid, as I have been informed, under 35 U.S.C. § 102(e), if an

invention described by that claim was described in a U.S. patent granted on an application for a patent by another that was filed in the U.S. before the date of invention for such a claim.

B. Obviousness

199. I have been informed that a patent claim is invalid as “obvious” under 35 U.S.C. § 103 in light of one or more prior art references if it would have been obvious to a POSITA, taking into account (1) the scope and content of the prior art, (2) the differences between the prior art and the claims, (3) the level of ordinary skill in the art, and (4) any so called “secondary considerations” of non-obviousness, which include: (i) “long felt need” for the claimed invention, (ii) commercial success attributable to the claimed invention, (iii) unexpected results of the claimed invention, and (iv) “copying” of the claimed invention by others.

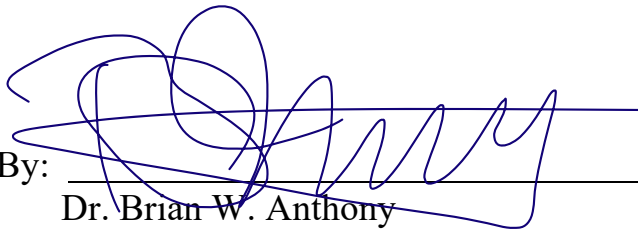
200. I have been informed that a claim can be obvious in light of a single prior art reference or multiple prior art references. To be obvious in light of a single prior art reference or multiple prior art references, there must be a reason to modify the single prior art reference, or combine two or more references, in order to achieve the claimed invention. This reason may come from a teaching, suggestion, or motivation to combine, or may come from the reference or references themselves, the knowledge or “common sense” of one skilled in the art, or from the nature of the problem to be solved, and may be explicit or implicit

from the prior art as a whole. I have been informed that the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. I also understand it is improper to rely on hindsight in making the obviousness determination.

I currently hold the opinions set expressed in this declaration. But my analysis may continue, and I may acquire additional information and/or attain supplemental insights that may result in added observations.

I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of the Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Dated: 11/30/2023

By: 
Dr. Brian W. Anthony

ATTACHMENT

MASSACHUSETTS INSTITUTE OF TECHNOLOGY
School of Engineering Faculty Personnel Record

Date: October 20, 2021

Name:

Brian W. Anthony

Department:

Mechanical Engineering / Institute of Medical Engineering and Science

1. Date of Birth: July 1972
2. Citizenship: USA
3. Education:

<u>School</u>	<u>Degree</u>	<u>Date</u>
Carnegie Mellon University	BS	1994
MIT	SM	1998
MIT	PhD	2006

4. Title of Thesis for Most Advanced Degree:
Video Based System Monitoring

5. Principal Fields of Interest:
Computational Instrumentation, Medical Device Design and Manufacturing, Innovation and Product Realization, Ultrasound Imaging and Novel uses of Ultrasound

6. Name and Rank of Other Department Faculty in the Same Field:
Harry Asada, Professor
Ian Hunter, Professor
Kamal Youcef-Toumi, Professor
Charlie Sodini, Professor (EECS)

7. Non-MIT Experience (including military service):

<u>Employer</u>	<u>Position</u>	<u>Beginning</u>	<u>Ending</u>
LANL	Scientist	1992	1994
Independent Consultant	Consultant	1994	1998
Xcitex	CoFounder / CTO	1998	2005
Cooper Perkins	CTO	2005	2007
dRNome	CoFounder	2011	2016

8. History of MIT Appointments:

<u>Rank</u>	<u>Beginning</u>	<u>Ending</u>
Lecturer, Sloan	2006	2009
Lecturer, MechE	2006	(present)
Research Scientist	2006	2013
Principal Research Scientist	2013	(present)
Director Singapore MIT Alliance – Manufacturing Systems and Technology		

Program (SMA-MST)	2006	2010
Director Master of Engineering in Manufacturing Program (MEngM)	2006	(present)
Faculty Lead for Education, MIT Skoltech Initiative	2011	2016
Deputy Director, MIT Skoltech Initiative	2014	2016
Associate Director, AIM Academy	2016	2017
Associate Director, MIT.nano	2017	
Faculty Lead for Industry Engagement, MechE	2018	

9. Consulting Record:

<u>Firm</u>	<u>Beginning</u>	<u>Ending</u>
Engagements greater than 3 months.		
Los Alamos National Labs		2000
Textron		2000
Federal Trade Commission		2000
FAA		2004
Kodak		2004
Redlake		2005
Olympus		2006
TIS	2009	2012
Photron	2009	2011
Cooper Perkins	2010	2012
IDEO	2012	---
Alcon	2012	---
Ximedica	2013	2014
Herman Miller	2014	2014
Novartis	2015	2015
Lenze	2015	2016
Apple	2017	

10. Professional Service

<u>Activity</u>	<u>Beginning</u>	<u>Ending</u>
MEngM Admissions Committee	2006	present
CDO Admissions Committee	2007	2008
Career Fair – SMA in Singapore, Org Chair	2007	2007
Career Fair – SMA/MIT in Singapore, Org Chair	2008	2008
Mfg. microFluidics Symp, Chair	2009	2010
SMART Proposal Lead on Med Devices	3/2010	9/2010
LMP Summit Co-Chair	2011	2011
MEDRC Workshop, Chair	2012	2012
Pilot IMI Proposal, MIT Lead	5/2012	6/2012
Additive mfg working group, Lead	6/2012	8/2012
MIT's role in reducing the cost of health care	2014	2015

<u>Activity</u>	<u>Beginning</u>	<u>Ending</u>
SPIE Conference Committee	2011	2018
SPIE Conference Committee	2012	2018
Co-Chair Education Workstream, AMP 2.0	2013	2014

11. Awards Received:

<u>Award</u>	<u>Date</u>
National Television Academy, Emmy for Innovative Technical Achievement. "Golf on CBS, SwingVision."	2005
BPLA Invented Here, Featured Honoree	2014

12. Current Organization Membership:

<u>Organization</u>	<u>Offices Held</u>
ASME	
IEEE	
SPIE	
AIUM (American Institute of Ultrasound in Medicine)	
Sigma Xi	

13. Patents and Patent Applications Pending:

1. US Patent 5606130 "Method for determining the octane rating of gasoline samples by observing corresponding acoustic resonances therein."
2. US Patent 6393384 "Apparatus and method for remote ultrasonic determination of thin material properties using signal correlation."
3. US Patent 6226081 "Optical height of fill detection system and associated methods."
4. US Patent 8,333,704, B. Anthony and M. Gilbertson, "Handheld Force-Controlled Ultrasound Probe," Dec 11, 2012
5. US Patent 8,328,725, B. Anthony and M. Gilbertson, "Ultrasound Probe," Dec 18, 2012
6. US Patent 8,382,671, B. Anthony and M. Gilbertson, "Handheld Ultrasound Probe," Feb 26, 2013
7. US Patent 9,121,705, B. Anthony and D. Ljubicic, "Sensor for Simultaneous Measurement of Thickness and Lateral Position of a transparent object," Sept 1, 2015
8. US Patent 9,456,800, Brian W. Anthony, Matthew W. Gilbertson, "Ultrasound scanning system", Oct 4, 2016
9. US Patent 10353191, Circular scanning technique for large area inspection, July 16, 2019.
10. MIT Case 14088, Force Controlled Ultrasound Probe, 16-Dec-09
11. MIT Case 14387, Deformation Estimation and Correction in Elastography with a Handheld Force Controlled Ultrasound Probe, 16-Jul-10
12. MIT Case 14422, High-Speed Profilometer for Manufacturing Inspection, 30-Jul-10
13. MIT Case 14966J, Force Measurement Ultrasound Probe for Sonographer Fatigue Monitoring, 10-Jun-11

14. MIT Case 15012, A 6-DOF Optical System for Freehand 3D Ultrasound, 05-Jul-11
15. MIT Case 15681J, Local Actuation and Control of Stamp Deformation in Microcontact Printing, 06-Jun-12
16. MIT Case 15782, Usability Improvements to a Handheld Force-Controlled Ultrasound Probe, 03-Aug-12
17. MIT Case 15884, Computer-Guided Restoration of Ultrasound Scan Poses by Optical Tracking, 01-Oct-12
18. MIT Case 16160, Quick-Release Mechanism for a Force-Measuring Ultrasound Probe, 22-Feb-13
19. MIT Case 16447, Force-correlated Quantitative Ultrasound Image Analysis, 02-Jul-13
20. MIT Case 17106J, Acoustic Characterization of Superficial Body Fluids, 07-May-14
21. MIT Case 17211J, Wireless Capsule Endoscopic Ultrasound, 24-Jun-14
22. MIT Case 17259K, A Concentric Circle Scanning Technique for Large Area Inspection, 09-Jul-14
23. MIT Case 17260K, Grid-Based Matching for Full-Field Large-Area Deformation Measurement, 09-Jul-14
24. MIT Case 17344, Recovery and Computer-Guided Restoration of Ultrasound Scan Poses Based on Human Skin Features, 21-Aug-14
25. MIT Case 17864J, Ultrasound-Based Individual Scatterer Detection Method Using Scatterer Motion Induced by Acoustic Radiation Force, 21-Apr-15
26. MIT Case 17865, Ultrasound-Based Absolute Scatterer Concentration Measurement Technique: Image Volume Estimation from Scatter Spread Function Extracted From the Image, 21-Apr-15
27. MIT Case 17990, Hydrogel Ultrasound Angle Wedge, 04-Jun-15
28. MIT Case 18074, Joint Camera-Ultrasound Data Acquisition for Limb Scanning, 13-Jul-15
29. MIT Case 18544, An Iterative RTM with a Priori Data to Estimate Bone Thickness Using a Cylindrically Scanning Ultrasound Tomography Scanner, 22-Feb-16
30. MIT Case 18545K, Block-Wise Inversion for the Soundspeed of Human Soft Tissue and Bone Using Ray Based Travel Time Tomographic Techniques, 22-Feb-16
31. MIT Case 18636, Concentric Ring-Based Point Pattern Matching of Skin Features, 05-Apr-16
32. MIT Case, Physical and Chemical Characterization of Aerosols with Photonic Waveguides, United States Patent Application 20190234850
33. (to be updated)

14. Professional Registration:

N/A.

15. Major New Products, Processes Designs, or Systems:

See next.

16. Major New Products, Processes Designs, or Systems:

The following is split between a) University Programs or Significant Initiatives, b) Products, and c) Companies.

A. Programs, Centers, or Significant Initiatives

MechE Alliance – Industry Immersion Project Program

The I2P Program provides MechE graduate students with an exclusive opportunity to gain real-world experience working on a 3-to-6 month industry project at a participating company while still enrolled at MIT. Project concepts are first proposed by the company, and then refined and improved by students and their faculty advisors to best suit their academic experience and career interests.

Living Lab in IMES

The Sekisui House at MIT will establish a multi-year and sustained collaboration around specific themes and needs, answer key questions—via targeted projects designed to collect clinically relevant evidence—and generate significant technology innovations. The program will be staffed and operated by clinicians, researchers, and technical instructors, while fostering educational and global exchange between disparate communities, all while highlighting efforts in medical and observational research. The broader MIT community will be engaged with annual workshops and calls for proposals, as well as nominations for faculty and students to join programs surrounding specific themes.

Immersion Lab – MIT.nano

The Immersion Lab is a two-story, state-of-the-art space for research in visualization, augmented and virtual reality (AR/VR), and the depiction and analysis of spatially related data. Housed in MIT.nano, the lab is an open-access research space. The Immersion Lab mission is to propel research and education at MIT by: Providing the community with an array of cutting-edge technologies to facilitate immersive experiences; Broadening interdisciplinary interest in immersive technologies at MIT and promoting collaborations in art, science, and technology; Supporting teaching in enhanced reality and mentoring MIT community members seeking to realize their projects using our facility; Bridging the domains of hardware and software—and encouraging cycles in which advances in one domain spark innovation in the other; Fueling experimentation and research in enhanced reality technologies through seed grants, shared equipment, symposia, and other resources.

MEngM

Former Director of the Master of Engineering in Manufacturing Program, and previously the director of the Singapore MIT Alliance - Manufacturing Systems and Technology Program since 2006. In these roles I have developed an education partnership program with small to multi-national corporations, defined and built the MEngM program and structure for the development and execution of company based projects. I place student groups into companies, teach professional engineering practice in the context of industry based group projects, and broadly define and execute the operations of the MEngM degree program. Between 2007 and 2010, I raised over \$900,000 from our partner companies to support program sponsored student fellowship and program operations.

MEDRC

Co-Founder, Co-Director of the Medical Electronic Device Realization Center (MEDRC). Along with Charlie Sodini, and Joel Voldman, I recruit large Medical Device manufacturing companies, lead research, and engage with the Med Tech community nationally and internationally.

The MEDRC establishes partnerships between the microelectronics industry, the medical devices industry, medical professionals, and MIT faculty, researchers and students to collaboratively achieve improvements in the cost and performance of medical electronic devices. The successful realization of such a vision also demands innovations in the usability and productivity of medical devices, and new technologies and approaches to manufacture devices. The MEDRC is a focal point for large business, for venture-funded startups, and for the medical community.

The unique research methodology of the MEDRC begins with the project definition. Research activities are jointly defined by faculty, physicians and clinicians, and industrial partners. Visiting scientists from microelectronic and medical device companies, physically resident at the Center, provide the industrial viewpoint in the project definitions and participate in the realization of the technology. Prototype systems are developed which are used in clinical tests early in the projects to help guide the research technology being developed in parallel.

To date we have raised significant funding and identified a visiting scientist from GE, Analog Devices, Maxim, Philips, Nihon Kohden, Novartis. Each company commits to \$900,000 over 3 years.

MIT Skoltech Initiative

Deputy Director, and Lead Education, MIT Skoltech Initiative. I served as the education faculty lead in the development of high level curriculum concept for SkolTech Master's degree programs, spanning across domains (space, nuclear, biomedicine, IT, and energy). We develop the education-team collaboration, build consensus on vision, objectives, and plans, and to create education programs for each domain.

AIM Academy

Associate Director of AIM Advance Integrated Photonics Manufacturing Academy. The AIM Photonics manufacturing institute is a public-private partnership that focuses the nation's premiere capabilities and expertise to capture critical global manufacturing leadership in Integrated Photonics technology that is essential to the U.S. economy. In this role I supported community, careers and investment for US world leadership in Integrated Photonics manufacturing. I lead development of a Masters program in Integrated Photonics Manufacturing and development of an Education Factory practice facility.

MIT.nano / SENSE.nano

Associated Director, MIT.nano.

Founding director of first center of excellence at MIT.nano, SENSE.nano. New sensors and sensing systems can provide previously unimaginable insight into the condition of the built and natural world and to positively impact man, machine, and environment. For example, new sensors can provide accessible sensing capabilities important to individual's health and wellness, such as recently-developed nanoparticle-embedded paper strips that can rapidly diagnose Zika, Ebola, and other diseases in a simple color-coded test. Massively distributed networks of sensors enable large-scale, global data collection important to agriculture and water distribution, environment monitoring, disaster recovery, disease outbreak detection and intervention, supply chain operations, and the operations of cities. Nano sciences and technologies offer unprecedented opportunities to realize designs for, and scale manufacturing of, the sensors and sensing technologies required to fundamentally understand and fight diverse challenges. MIT—with comprehensive excellence in engineering, business, earth science, electronics, computation, nanoscience, materials science, neuroscience, chemistry, physics, manufacturing, and biology—is poised

to address the engineering, science, policy, and commercial challenges required to realize these grand, but nano, visions, to translate them to scale, and to positively impact society. MIT.nano is a world-class, nano-capable, shared laboratory facility and provides an open collaborative and cross-disciplinary nexus for advanced research, innovation, and education.

MIT Center for Clinical and Translation Research

Director of Clinical Technology.

The CCTR provides the facilities needed to conduct safe human research - in concert with colleagues in MIT Medical, the VPR Office of Research Compliance, and the Committee on the Use of Humans as Experimental Subjects (COUHES). The Center embodies a three-part mission: addressing critical needs in translational research within medicine, expanding central resources essential to MIT, and enabling external links to outside schools (Tufts University, Harvard University, Harvard Medical School), hospitals, and agencies (e.g. FDA).

Other Significant, formative, Initiatives

SMART Center - March through September 2010

I developed consensus around a theme, built the team of 10 investigators in Singapore and 10 investigators at MIT for a whitepaper and requested full center-proposal for SMART, entitled “*Realization (Design, Manufacturing, and Use) of Injectable Physiological Monitors – Enabling a Patient Centric Information Driven Healthcare Future.*” The research was motivated by addressing the need for unobtrusive, continuous, ambulatory, physiological monitoring of Congestive Heart Failure and Chronic Obstructive Pulmonary Disease patients. The 'state of health' information generated from these sensors can help reduce societal health care costs, improve quality of health care, increase quality lifespan, and lead to new understanding of the human physiology. Our proposal made it to the final round but was not selected. However these efforts lead to the creation of the MEDRC.

Pilot Innovation Manufacturing Institute (IMI) Proposal – May, June 2012

A team (University of Massachusetts Amherst, University of Connecticut, Massachusetts Institute of Technology, the Connecticut Center for Advanced Technology, the Pennsylvania State University, UMass Lowell, United Technologies Corporation, and the National Center for Manufacturing Sciences) proposed to form an independent, non-profit technical center of excellence to accelerate technological progress and innovation in additive manufacturing (AM), in response to the May 8, 2012 Air Force Research Laboratory Broad Agency Announcement (BAA-122-17-PKM) for the NNMI pilot. The NNMI Pilot Institute will demonstrate the value of the kind of collaborative problem-solving and asset-building that could occur on a broader scale with a nation-wide network of Institutes for Manufacturing Innovation. Federal government funding for the 2.5-year pilot program is \$30M with a minimum of \$30M in required cost sharing from industry, state government and universities.

In our center, The Advanced Direct Additive Manufacturing Institute (ADAM-I), we proposed to address key gap-bridging challenges in AM, including: rapid net shape production of structural metal, ceramic and polymer parts, and cost-effective manufacturing of large-area functional materials, components and devices.

Marty Schmidt and I spearheaded the MIT collaboration. We developed the business plan and financial sustainability model for the proposed center. I raised \$3 million in matching fund commitments (10% of the total match commitment).

Flexible Hybrid Electronics Manufacturing Innovation Institute (NextFlex) – October 2015

MIT PI on winning proposal, including a team of : Marc Baldo, Duane Boning, Vladimir Bulovic, Karen K Gleason, David E Hardt, Anastasios John Hart, Sang-Gook Kim.

\$150M national center with a mission to catalyze the development of an ecosystem for manufacturing new forms of electronics that integrate bulk ICs and printed devices with functions such as power, communications, fluidics, and bio-sensing in flexible systems that can bend, fold, stretch, and conform.

B. Products

Fuselage Crack Inspection System for FAA

In support of the Federal Aviation Administration National Aging Aircraft Research Program (NAARP) the state-of-the-art Full-Scale Aircraft Structural Test Evaluation and Research (FASTER) Facility was established at the FAA William J. Hughes Technical Center. A fixture was designed to simulate the actual loads to which an aircraft fuselage structure is subjected while in flight. Data from tests using this fixture was used to experimentally validate analytical theories and methodologies to evaluate and predict the onset of Widespread Fatigue Damage (WFD). Crack growth data from testing was gathered from the Remote Control Crack Monitoring System.

I designed, built, and delivered The Remote Control Crack Monitoring System consisting of a pair of cameras with two different fields of view manipulative by with a large gantry robot. The cameras ‘fly’ over the fuselage surface to identify and track cracks using processed camera images to generate the feedback signal

Laser Wave for Textron

Textron Inc.’s LaserWave[®] products integrated advanced signal processing techniques, robust software algorithms, lasers, optics and ultrasonic technology. The LaserWave Instrument could measure material characteristics such as density, hardness, temperature, thickness, elastic constants and more. LaserWave was developed to measure the temperature of Silicon Wafers undergoing rapid thermal processing and evolved to become a general system for material characterization.

A pulse laser system is used to initiate a circular thermo-elastic Lamb wave. I developed propagation models describing the propagation of the collapsing circular, thermo-elastic, transient Lamb waves. I developed real-time inversion routines using a time-frequency wavelet decomposition to extract and identify group velocity mode shapes. The LaserWave products use models and algorithms that I developed to invert the measured temporal signals in order to estimate elastic constants and material thickness of thin layers.

This product line didn’t fit Textron’s business mode. They transferred the technology to Brown University.

<http://investor.texttron.com/newsroom/news-releases/press-release-details/2003/Texttron-Donates-Laser-Technology-to-Brown-University-Research-Foundation/default.aspx>

Motion Tools for Photron Inc

I designed Photron Motion Tools to operate high-speed PCI cameras. Photron Motion Tools provides users with manual and automatic tracking capabilities. By simply selecting the point of interest within the recorded image sequence, Motion Tools automatically tracks the points-motion within the sequence.

http://www.photron.com/index.php?cmd=product_general&product_id=17

i-Speed for Olympus

Capable of capturing images at speeds from 60 to 150,000 frames per second in 'normal' mode (down to 1 second/frame in 'timelapse' mode) i-SPEED cameras are an effective method of locating problems quickly and easily. The user can evaluate designs, increase productivity and reduce maintenance costs. Video images are digitally captured onto its onboard memory, where they can be written to compact flash card or downloaded via Ethernet connection to a laptop or PC.

I designed custom software to provide the operator with the ability to analyze and enhance images. Velocity and distance measurement can also be calculated. The i-SPEED Software Suite was designed to mirror the ease-of-use and high specification power of the camera range.

<http://www.olympus-ims.com/en/ispeed-software/>

Swing Vision for CBS

I designed and built the Swing Vision camera system, camera control system, camera mounts, the server architecture, and the analysis software. Two high-speed cameras record a golfer t-shot. A 2000 fps camera records the full view of the golfer. A 12500 frame per second camera is used to record the ball-club interaction. As the 2000 fps video is broadcast in slow motion, the 12500 fps video (gigabytes of raw video data) is **automatically** analyzed (in under 20 seconds). The ball is located, used for calibration, and tracked, the club is identified and tracked – all under highly variable condition (variable lighting from shadows, grass, occlusions, etc). The calculated speeds, back spin, and launch angle are sent to the broadcast truck. The results are broadcast in a graphic.

I won an Emmy for this system in 2005.

MiDAS - Xcitex

As Xcitex's first engineer, I developed the core of the flagship products - MiDAS and ProAnalyst. And as CTO and Vice-President of Xcitex, I developed and directed the development of products and solutions for the industrial and scientific video markets.

MiDAS is now the the standard for controlling, synchronizing, and automating digital high-speed and industrial video cameras. With thousands of installations worldwide, MiDAS software is used by researchers, production line engineers, scientists, doctors, and military range operators to convert their video cameras into easy-to-use motion capture systems.

MiDAS includes intelligent triggering, autonomous recording, synchronized video/data collection, large file organization tools. Features such as distance and velocity measurement calipers, auto-tracking, and video triggering are included.
http://xcitex.com/html/midas_description.php

ProAnalyst - Xcitex

As Xcitex's first engineer, I developed the core of the flagship products - MiDAS and ProAnalyst. And as CTO and Vice-President of Xcitex, I developed and directed the development of products and solutions for the industrial and scientific video markets.

ProAnalyst is a software package for automatically measuring moving objects with video. It is used extensively by NASA, engineers, broadcasters, researchers and athletes. ProAnalyst allows users to measure and track velocity, position, size, acceleration, location and other characteristics. Results can be instantly graphed and reviewed, compared against external data, and exported to a variety of output formats for further analysis or presentation purposes.

http://xcitex.com/html/proanalyst_description.php

C. Companies

Xcitex – CoFounder, formerly CTO, formerly Vice-President, Board of Directors

Xcitex was self-funded and grew through solid product development and consistent execution of our business strategy. As Xcitex's first engineer, I developed the core of the flagship products - MiDAS and Pro Analyst. I also describe these products in a document that I include as supplemental material. As CTO and Vice-President of Xcitex, I built the technical team, architected and directed the development of products and solutions for the industrial and scientific video markets. Our products alone fueled our growth from startup to dominant market leader.

dRNOME – CoFounder, Investor, Board of Director

CueVue is a cloud computing and storage service for the scientific video industry - enabling video content query and generalized motion analysis in video content management systems. We provide tools for managing, manipulating, archiving, and searching your scientific video. It removes the necessity for its customers to make heavy investments in expensive hardware and software solutions, removes the overhead required to manage high-volume video needs, and we back this with a service level guarantee.

Dynamic Time and Space Warping (DTSW), an algorithm that I developed for part of my doctoral work is core technology for CueVue - enabling video content query and generalized motion analysis in video content management systems.

dRNOME Inc. (CueVue.com – Launched in February 2011, sold technology in 2014). Our core technologies can be used to perform automated feature recognition of multiple streaming telemetry sources and to extract metadata and make this information available for ongoing operations, forensics, and security. Our products enable multi-camera real-time feature recognition, extraction & tagging automation.

Enumage – CoFounder, Investor, Board of Director

Specializing in Laser Ultrasound.

1. Books:

Smart Manufacturing On-line course, deployed 2019 and 2020

2. Papers in Referred Journals:

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- 3.47. Kundu, I., Du, X., & Anthony, B. W. (2018). "Imaging platforms for registering and analyzing the skin microrelief structure." Presented at the SPIE Smart Structures and Materials + Nondestructive Evaluation and Health Monitoring, Denver, Colorado. (2018)
- 3.48. Zakrzewski, A. M., & Anthony, B. W. (2018). Pre-and-Post Exercise Blood Pressure Estimation from Force-Measured Ultrasound: First Results. Presented at the 2018 40th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC), Honolulu, HI.
- 3.49. Donk, F., Yang, H., & Anthony, B. W. (2018). Miniaturization of External Mechanical Vibration for Shear Wave Elastography Imaging. Presented at the 2018 40th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC), Honolulu, HI.
- 3.50. Chen, M., Li, Q., Karimian, N., Yeh, H., Duan, Y., Fontan, F., ... Samir, A. E. (2018). Contrast-Enhanced Ultrasound to Quantify Perfusion in a Machine-Perfused Pig Liver. Presented at the 2018

40th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC), Honolulu, HI.

- 3.51. Wang, Y. J., & Anthony, B. W. (2018). Characterization of wave fields using transient motion of microspheres under acoustic radiation force. Presented at the 21st International Symposium on Nonlinear Acoustics, Santa Fe, NM.
- 3.52. Yang, H., Carrascal, C., Xie, H., Shamdasani, V., Anthony, B.W., “Design and Experimental Validation of Miniature External Mechanical Vibrators towards Clinical Ultrasound Shear Wave Elastography”, IUS, 2018.
- 3.53. Singh, Robin; Ma, Danhao; Kimerling, Lionel; Agarwal, Anuradha; Anthony, Brian, “Microscale photoacoustic spectroscopy using integrated photonics for lab-on-chip applications”, Spie BIOS, (accepted), 2018.
- 3.54. J. B. Frontin and B. W. Anthony, “Quantifying Dermatology: Method and Device for User-Independent Ultrasound Measurement of Skin Thickness,” in 2019 41st Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC), 2019, pp. 5743–5748.
- 3.55. A. Benjamin et al., “Renal volume reconstruction using free-hand ultrasound scans,” J. Acoust. Soc. Am., vol. 145, no. 3, pp. 1922–1922, Mar. 2019.
- 3.56. A. Y. Huang and B. W. Anthony, “An Instrumented Ultrasound Probe for Shear Wave Elastography With Uneven Force Distribution,” in 2019 41st Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC), 2019, pp. 6208–6211.

4. Other Major Publications:

- 4.1. Anthony, B.W.; Zarrouati, N.; Ljubicic, D. “Photogrammetric Based Inspection of Polymer Devices”, Singapore MIT Alliance (SMA) Symposium January 2008.
- 4.2. Fitriani, Brian W. Anthony, "Multiscale Dynamic Time and Space Warping" SMA Symposium, January 21-22, 2009.
- 4.3 Anthony, B.W., "Video Analytics – Future is Fast and Distributed", Government Security News (GSN) Guide to Video Surveillance, September 2011. Invited guest column.

4b. Articles in Preparation:

- 4.4 Du, X., Anthony, B., "Rotational Manufacturing Inspection System: Design for Vibration Reduction", target:
- 4.5 Du, X., Anthony, B., "Local-Active-Rotational-Based Super Resolution", target: IEEE Transactions on Pattern Analysis and Machine Intelligence
- 4.6 Ljubicic, D., Anthony, B., "Sensor for Thickness and Lateral Position of a Transparent Web in a Roll-to-Roll Process", target: IEEE Sensors
- 4.7 Feigin M., Ranger B., Anthony B., “Statistical Maximal Consensus Framework for Image Registration with Application to Medical Ultrasound Imaging”, pending submission to IEEE Transactions on Medical Imaging

5. Internal Memoranda and Progress Reports: List chronologically; number each item.

N/A

6. Invited Lectures (as of 2015):

June 2002, “High-speed software synchronizes images and data”, Technology Interview. Vision Systems Design.

June 2003, 2003 “Highspeed Video and Data”, Brian W. Anthony, MIT High-Speed Photography and Videography for Motion Analysis: Systems and Techniques.

June 2003, 2004, 2005, 2006, “Overview of Machine Vision”, Brian W. Anthony, MIT High-Speed Photography and Videography for Motion Analysis: Systems and Techniques.

June 2006, “Video Event Analysis and Video Event Detection - Video Based System Monitoring”. Brian W. Anthony. CSAIL Machine Vision Colloquium.

July 24, 2008, "Computational Imaging Systems," Samsung Electro Mechanical Research, Korea.

May 5, 2009, "Video Instrumentation," LMP Seminar, MIT

January 5-7, 2011, "Automation of a Work Cell for Polymer Microdevice Production: Precise Alignment and Visual Quality Inspection ", The Second Conference on Advances in Microfluidics and Nanofluidics and Asian-Pacific International Symposium on Lab on Chip (AMN-APLOC 2011). Singapore.

February 11, 2011, "The MEDRC," MassMEDIC Board of Directors Meeting. Greenberg Traurig, International Place, Boston.

March 23-25 2011, "New Perspectives – similar problems", S2I2 Workshop on Collection Digitization, Field Museum, Chicago

June 20-22, 2011, "Design, Manufacturing, Information Technology, and Healthcare – enabling an information-driven healthcare future – industry, academia collaborations", Medical Device Manufacturing Summit, Red Rock Casino Resort & Spa, Las Vegas, NV.

July 6, 2011, “Design, Manufacturing, Information Technology, and Healthcare - enabling an information-driven healthcare future – industry, academia collaborations” Korean Institute of Science and Technology.

Nov 13-15, 2011, Invited Keynote Talk, "Medical Device Manufacturing - Helping to revitalize US manufacturing to capitalize on innovation," Medical Device Manufacturing Summit, Amelia Island, Florida

November 18, 2011, Invited Keynote Talk, "Computational Videography in Manufacturing," MIT Center for Biomedical Innovation’s Biomanufacturing Summit: Implementing Innovation in Biomanufacturing: The Hurdles and Opportunities, Bartos Theater, Building E15 MIT.

January 27, 2012, "The MEngM and MEDRC Models and Experiences," MassMEDIC's Workshop on Catalyzing Innovation through Industry/Academic Collaborations.

March 9, 2012, “Computational Enhanced Manufacturing Inspection Systems” Department of Manufacturing Engineering, Ann Arbor, Michigan

March 13, 2012, "Computational Instrumentation - designing systems at the intersection of mechanical engineering, electrical engineering, and computer science," LMP Seminar, MIT

March 15-16, 2012, "Industry, innovation, and entrepreneurship, in graduate education and research," SKTech Education Workshop, Moscow, Russia.

March 27-28 2012, Invited Keynote Talk, "The Inner Beauty of Computational Enhanced Systems,"
Technology Review EmTech India Conference, Bengaluru, India.

June 9, 2012, Invited Moderator, "American Transformations: the Next Industrial Revolution", MIT Graduate
Alumni - Tech Reunions, MIT, Cambridge, MA.

May 22 2013, Invited Speaker, MIT Vienna Conference

June 16, 2013 , Invited Keynote Talk, "Lessons Learned from the MEDRC," EmTech China Conference,
Shanghai, China.

November 13 2013, Invited Speaker, "Microfluidic Devices Manufacturing - Sensing and Instrumentation
Challenges and Opportunities", Lab-on-a-chip Asia, Singapore

October 2013, Invited Speaker, "Have Russia's Innovation Prospects Stalled or Are You Just Not Looking Hard
Enough?", US Russian Business Council (USRBC) Annual Meeting,

January 2015, Keynote, "Limb Imaging" Wayne State University and Karmanos

October 2015, "Medical Device Innovation", Novartis Innovation Summit

(to be updated)

Summary:

	<u>Total</u>	<u>Completed</u>	<u>In Progress</u>
Bachelor's	4	4	0
Master's	32	27	5
MEngM	16	16	0
Engineer's			
<u>Doctoral</u>			
As Supervisor	20	10	10
As Reader	4	3	1

Bachelor's Theses

Johnson, Michael B., "Design of a precise X-Y-Theta nanopositioning optical sensor", June 2009.

Syverud, Brian, "Robotic ultrasound manipulator: calibration of position and orientation measurement system", June 2009.

Chai, Lauren, "Design and Manufacture of arterial phantoms for ultrasound imaging", expected June 2012

Ramos, Javier, "Design of Force Measurement Probe", June 2012

Master's Theses

Fitriani, "Multiscale Dynamic Time and Space Warping", 2008

Zarrouati, Nadège, "A precision manipulation system for polymer microdevice production", 2010

Gilbertson, Matthew Wright, "Handheld force-controlled ultrasound probe", 2010

Sun, Shih-Yu, "Deformation correction in ultrasound imaging in an elastography framework", 2010

Zakrzewski, Aaron, "Multi-scale elastography with application to real-time blood pressure estimation", 2013

Koppaka, Sisir, "Quantitative Ultrasound for DMD progression tracking", (in CDO) 2015

Zhang, Xiang (Shawn), "3D Ultrasound scanning system for muscle deterioration monitoring, prosthetic fitting, and bone density monitoring", 2015

Primack, Willow. "Capacity Optimization of a Warehouse Flow Sortation System", LGO, 2015

Churchill, Hugh E., II, "Impact of lean implementation on cycle-time and efficiencies within Amazon soft-lines fulfilment", LGO, 2015.

Sazdanoff, Nicholas, "Evaluation of Postponement for Improved Drug Product Supply Chain Stability", LGO, 2015.

Kojimoto, Nigel Costello, "Ultrasonic Inspection Methods for Defect Detection and Process Control in Roll-to-Roll Flexible Electronics Manufacturing", 2015

Kundu, Ina Annesha, "Imaging platforms for detecting and analyzing skin features and Its stability: with applications in skin health and in using the skin as a body-relative position-encoding system", 2015

Conover Susan, "Prime Areas for Improvement in Skin Cancer Detection and How Technology Can Help", SDM, 2015

Hess, Tylor, "System for small-volume high-frequency ultrasound, and quantitative optical molecular imaging assessment of biopsy samples", 2016

Kang Qi Ian Lee, "Skin Feature Analysis", CDO, 2016

Athena Yeh Huang, "New US Probes", 2017

Alex Benjamin, "US Education Hardware", CDO, 2017

Heng Yang, "Pulsed Elastography", 2017

Rebecca Zubajlo, "US Clamp Probe", 2017

Rishon Robert Benjamin, "Roll to roll polymer web inspection", CDO, 2017

Samer Haidar, "Consumer Medical Device Supply Chain Strategy", LGO, 2016

Mariam A Al-Meer, "Reducing Heart Failure Admissions through Improved Care Systems and Processes", LGO, 2017

Michael Sandford, "Improving Speed-to-Market through 3D Printing", LGO, 2017

Moritz Alexander Graule, "Dynamic SLAM", 2017

Mingxiu Sun, "Education and Practice Factory", 2018

Robin Singh. "Integrated Photonics", 2018

Judy Beaudoin, "Quantifying Dermatology: User-Independent Ultrasound Measurement of Skin Thickness, 2018

Andrew Farenheit, "Manufacturing Fleet Flexibility" 2019

Chris DiAndreth, "Product Flow Optimization within the Downstream Supply Chain" 2019.

Manuel Martínez Puppo, “Replenishment in an Integrated Stock World”, 2019.

Shirley Lu, “Fiber Manufacturing”, expected 2020

Sangwoon Kim, “Deep learning in manufacturing”, expected 2020.

MEng Theses

Su, Xiangyong, “Optimization of labor allocation at a syringe production facility: design proposals”, September 2008.

Liaw, Sze Sen, “Optimization of labor allocation at a syringe production facility using computer simulation”, September 2008.

Ng, Gar Yan, “Optimization of labor allocation at a syringe production facility: work study”, September 2008.

Linares, Rodrigo, “Manufacturability of lab on a chip devices: tolerance analysis and requirements establishment”, September 2010.

Selvakumar, Sivesh, “Manufacturing of Lab-On-a-Chip devices: variation analysis of liquid delivery using blister packs”, September 2010.

Namvari, Kasra, “Manufacturability of lab-on-chip devices: dimensional variation analysis of electrode foils using visual technology”, September 2011.

Donoghue, Linda, “Design of a micro-interdigitated electrode for impedance measurement performance in a biochemical assay”, September 2011.

Holmes, Jacklyn, “Robustness and repeatability of interdigitated electrodes on a substrate tested in an aqueous environment”, September 2011

Judge, Benjamin, “Electrode manufacturing for micro-fluidic devices”, September 2012

Jain, Nikhil, “Blister pack manufacturing for micro-fluidic devices”, September 2012

Inamdar, Tejas Satish, “Blister pack modeling for micro-fluidic devices”, January 2013

Saber, Aabed Saud, “Electrode modeling for micro-fluidic devices”, January 2013

Nguyen, Khanh Huy, “Microfluidic device manufacturing - tools”, September 2013

Ragosta, Nicholas Hiroshi, “Microfluidic device manufacturing - inspection”, September 2013

Kalsekar, Viren Sunil, “Microfluidic device manufacturing - process”, September 2013

Elise Xue, “Deep-learning in ultrasound”, June 2018

Engineer’s Theses

N/A

Doctoral Theses, Supervisor

Ljubicic, Dean, “Design of high-speed inspection system for micro-fluidic device manufacturing”, MechE, January 2013

Gilbertson, Matthew Wright, “Human in the loop design and modeling of force controlled ultrasound probes”, MechE, May 2014

Sun, Shih-Yu, “Real-time visual and ultrasound simultaneous localization and mapping (SLAM)”, EECS, August 2014

Zakrzewski, Aaron, “Real-time multi-scale pressure enhanced elastography”, MechE, 2017.

Roberts, Megan, “Advance manufacturing of flexible arrays for ultrasound probes”, MechE, 2018.

Lee, John, “Cell tracking and non-invasive ultrasound-based methods to diagnose neonatal and young infant meningitis”, EECS, 2015

Fincke, Jonathan Randall, "Ultrasonic quantification of human limbs (bone and tissue) using tomographic inversion techniques", 2018

Ranger, Bryan, “Prosthetic fitting”, HST, 2018

Ina Annesha Kundu, “Skin Imaging”, 2018

Rebecca Zubajlo, “Physical Measurement of Cells”, expected 2021

David Donghyun Kim, “Fiber Manufacturing Equipment”, expected 2020

Lauren Chai, “Radiation Force Manufacturing”, expected 2020

Jenny Wang, “Particle motion for acoustic radiation force characterization”, expected 2020

Anne Pigula, HST, “Image Based Biomarkers for Duchene Muscular Dystrophy”, expected 2020

Xiang Zhang, “Precision Tomography Platforms”, 2019

Alex Benjamin. “Volume Freehand Tomography”, expected 2020

Melinda Chen, “Liver Vascular Health Imaging”, expected 2020

Robin Singh, “Integrated Photonics Medical Sensors”, expected 2021

Alex Jaffe. EECS, “Venous and Blood Pressure in the extremities”, expected 2021

Yuwei Li, “Techniques for using AR/VR to measure physiological response”, expected 2022

Arjun Chandar, “Smart Manufacturing”, expected 2021

Doctoral Theses, Reader / Committee

Shi, Chuan, “Efficient Buffer Design Algorithms for Production Line Profit Maximization”, September 2011

Petrzelka, Joe, “On the contact fidelity and sensitivity of roll-based soft lithography”, June 2012

Smyth, Katherine, “Piezoelectric Micro-machined Ultrasonic Transducers for Medical Imaging”, October 2016

Athanasios G. Athanassiadis, “Optoacoustic Imaging”, 2019

Current Postdocs

<i>Name</i>	<i>Dates of Appointment</i>	<i>PhD Granting Institution</i>
Greg Ely	2019 -	MIT
Megan Roberts	2018 -	MIT
Shawn Zhang	2019 -	MIT

Previous Postdocs

<i>Name</i>	<i>Current Title</i>	<i>Current Employer</i>
Vannah, Bill	Scientist	Mary Free Bed Rehabilitation Hospital
Victor Lempitsky	Head of AI	Samsung
Javier J. Gonzalez	May 2013 – 2015	University of Madrid
Matthew Gilbertson	Senior Electro-Optical Engineer	Lockheed Martin
Xian, Du	Professor	UMass (2018)
David Ibarra	Professor	Monterery Tec
Micha Feigin	Research Scientist	MIT
Ian Butterworth	Biomedical Research Engineer	MIT
Carlos Castro-Gonzalez		
	Co-Founder and CEO	Leuko
Berta Martí Fuster	Head of Communications	Oncoheroes Biosciences
Bonghun (Bruce) Shin	Senior Scientist	University Waterloo