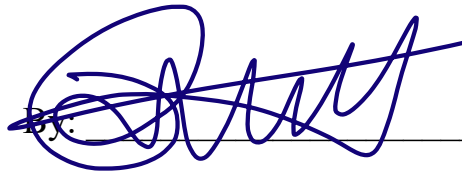


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Ammar Al-Ali
U.S. Patent No.: 10,687,743 Attorney Docket No.: 50095-0133IP2
Issue Date: June 23, 2020
Appl. Serial No.: 16/791,955
Filing Date: February 14, 2020
Title: PHYSIOLOGICAL MEASUREMENT DEVICES, SYSTEMS,
AND METHODS

DECLARATION OF DR. BRIAN W. ANTHONY

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

 12/9/2023

Brian W. Anthony, Ph.D.

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I. QUALIFICATIONS AND BACKGROUND INFORMATION

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. 10,687,743 (“the ’743 Patent,” APPLE-1001) and prior art references relating to its subject matter. I have reviewed the ’743 Patent and relevant excerpts of the prosecution history of the ’743 Patent (APPLE-1002). I have also reviewed the following prior art references and materials, in addition to other materials I cite in this declaration:

Prior Art Reference
US 9,392,946 (“Sarantos”)
U.S. Pat. No. 6,483,976 (“Shie”)
U.S. Pat. No. 8,446,275 (“Utter”)
U.S. Pat. Pub. No. 2016/0058312 (“Han”)

12. I have also reviewed various supporting references and other documentation as further noted in my opinions below.

13. Counsel (Fish & Richardson) has informed me that I should consider these materials through the lens of one of ordinary skill in the art related to the ’743 Patent at the time of the earliest possible priority date of the ’743 Patent, and I have done so during my review of these materials. The application leading to the ’743 Patent was filed on February 14, 2020 and claims the benefit of priority to a

provisional application filed July 2, 2015 (“the Critical Date”). I have therefore used that Critical Date in my analysis below.

14. I have no financial interest 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.

15. 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.

16. My opinions, as explained below, are based on my education, experience, and expertise in the fields relating to the '743 Patent. Unless otherwise stated, my testimony below refers to the knowledge of one of ordinary skill in the art 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 '743 Patent and the prior art discussed below.

II. OVERVIEW OF CONCLUSIONS FORMED

17. This declaration explains the conclusions that I have formed based on my analysis. To summarize those conclusions, based upon my knowledge and experience and my review of the prior art publications listed above, I believe that:

- Claims 1, 3-6, 9-13, 22-25 are obvious over Sarantos in view of Shie.
- Claim 7 is obvious over Sarantos in view of Shie and Utter.
- Claim 8 is obvious over Sarantos in view of Shie and Han.
- Claims 14 and 16-21 are obvious over Sarantos in view of Shie, Utter, and Han.

III. LEVEL OF ORDINARY SKILL IN THE ART

18. Based on the foregoing and upon my experience in this area, a person of ordinary skill in the relevant art relating to the subject matter of the '743 Patent ("POSITA") would have been a person of ordinary skill in the art relating to the subject matter of the '743 patent, and would have had a working knowledge of physiological monitoring technologies. A POSITA 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 had a Master of Science degree in a relevant academic discipline with less than a year of related work experience in the same discipline.

19. 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.

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

IV. LEGAL STANDARDS

A. Anticipation

21. 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.

22. 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

23. 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.

24. 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.

V. THE '743 PATENT

A. Overview of the '743 Patent

25. Prior to the Critical Date of the '743 Patent, numerous products, publications, and patents existed that implemented or described the functionality claimed in the '743 patent. The methodology of the '743 patent was therefore well known in the prior art as of the Critical Date. Further, to the extent there was any problem to be solved in the '743 patent, it had already been solved in the prior art systems before the Critical Date of the '743 patent as I discuss below.

26. The '743 patent, entitled “Physiological Measurement Devices, Systems, and Methods,” describes a “non-invasive, optical-based physiological monitoring system.” APPLE-1001, Face, Abstract.

27. In its background section, the '743 patent explains that “[s]pectroscopy is a common technique for measuring the concentration of organic and some inorganic constituents of a solution” and “[a] practical application of this technique is pulse oximetry, which utilizes a noninvasive sensor to measure oxygen saturation and pulse rate, among other physiological parameters.” *Id.*, 1:29-31, 1:53-56. “A pulse oximetry system generally includes a patient monitor, a communications medium such as a cable, and/or a physiological sensor having one or more light emitters and a detector, such as one or more light-emitting diodes (LEDs) and a photodetector. The sensor is attached to a tissue site” and “[t]he detector is responsive to the emitted light after attenuation or reflection by pulsatile blood flowing in the tissue site.” *Id.*, 2:4-13. “The monitor ... provide[s] a numerical readout of physiological parameters such as oxygen saturation (SpO₂) and/or pulse rate.” *Id.*, 2:15-17.

28. In this way, the '743 patent confirms that prior art “pulse oximetry systems” generally included one or more light emitters configured to emit light, a plurality of detectors configured to detect at least a portion of the light after passing through tissue and to output at least one signal responsive to the detected light, and a processor configured to receive and process one or more signals

responsive to the outputted at least one signal and determine a physiological parameter. *Id.*, 2:4-27.

29. The '743 patent discloses, in one embodiment, “an optical physiological measurement system [that] includes an emitter configured to emit light of one or more wavelengths” and “a diffuser configured to ... emit the spread light over a larger tissue area.” *Id.*, 2:50-55. “[A] detector is configured to detect the concentrated light and to transmit a signal indicative of the detected light ... to determine, based on an amount of absorption, an analyte of interest, such as, for example, arterial oxygen saturation or other parameter, in the tissue measurement site.” *Id.*, 2:63-3:3.

30. An exemplary light-absorbing detector filter 306 shown in the '743 patent's FIG. 4A (reproduced below) includes “a rectangular opening 402 [] positioned relative to the light concentrator 308 (shown in phantom) and the detector 310 such that light may pass through the rectangular opening 402, into the light concentrator 308, and to the detector 310.” APPLE-1001, 3:36-40.

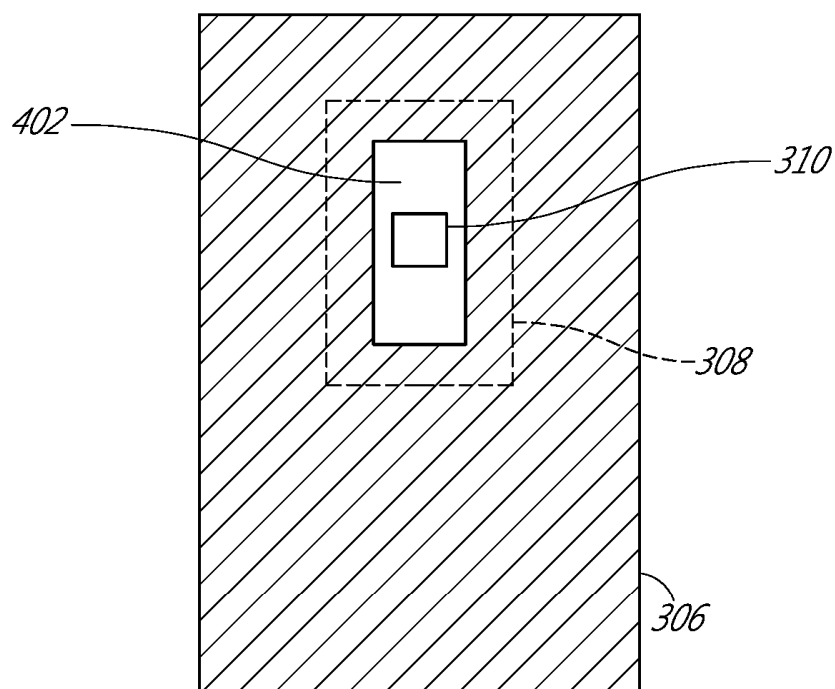


FIG. 4A

APPLE-1001, FIG. 4A.

31. The '743 patent's FIGS. 7A and 7B depict side and top views, respectively, of another embodiment of a 3D pulse oximetry sensor 700. APPLE-1001, 5:28-33. Sensor 700 includes emitter 702, light diffuser 704, light block (or blocker) 706, light concentrator 708, and detector 710. *Id.*, 10:49-51. The sensor

functions to irradiate tissue measurement site 102, e.g., a patient's wrist, and detects emitted light that is reflected by the tissue measurement site. *Id.*, 10:43-49. “[L]ight blocker 706 includes an annular ring having a cover portion 707 sized and shaped to form a light isolation chamber for the light concentrator 708 and the detector 710.” *Id.*, 11:10-12. “[L]ight blocker 706 and cover 707 ensures that the only light detected by the detector 710 is light that is reflected from the tissue measurement site.” *Id.*, 11:16-19.

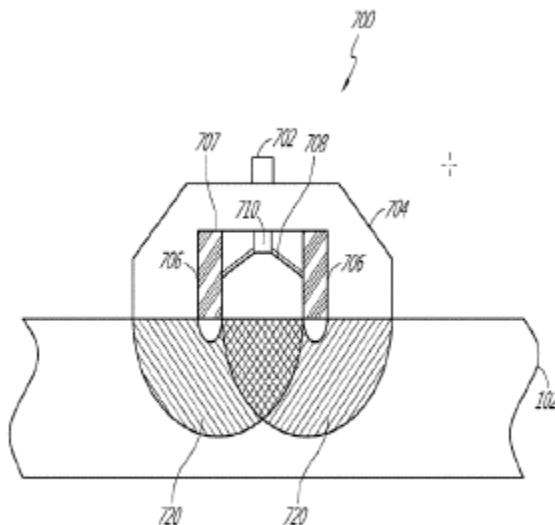


FIG. 7A

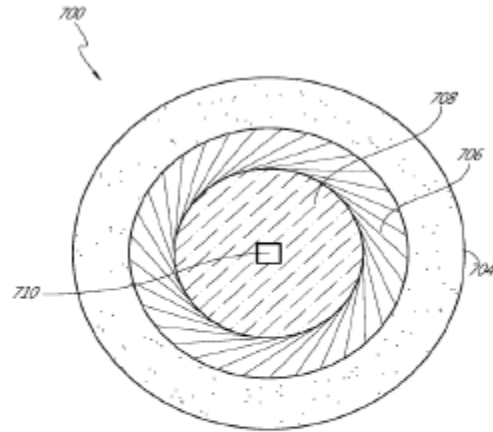


FIG. 7B

APPLE-1001, FIG. 7A (left), FIG. 7B (right).

32. FIG. 8 of the '743 patent is reproduced below:

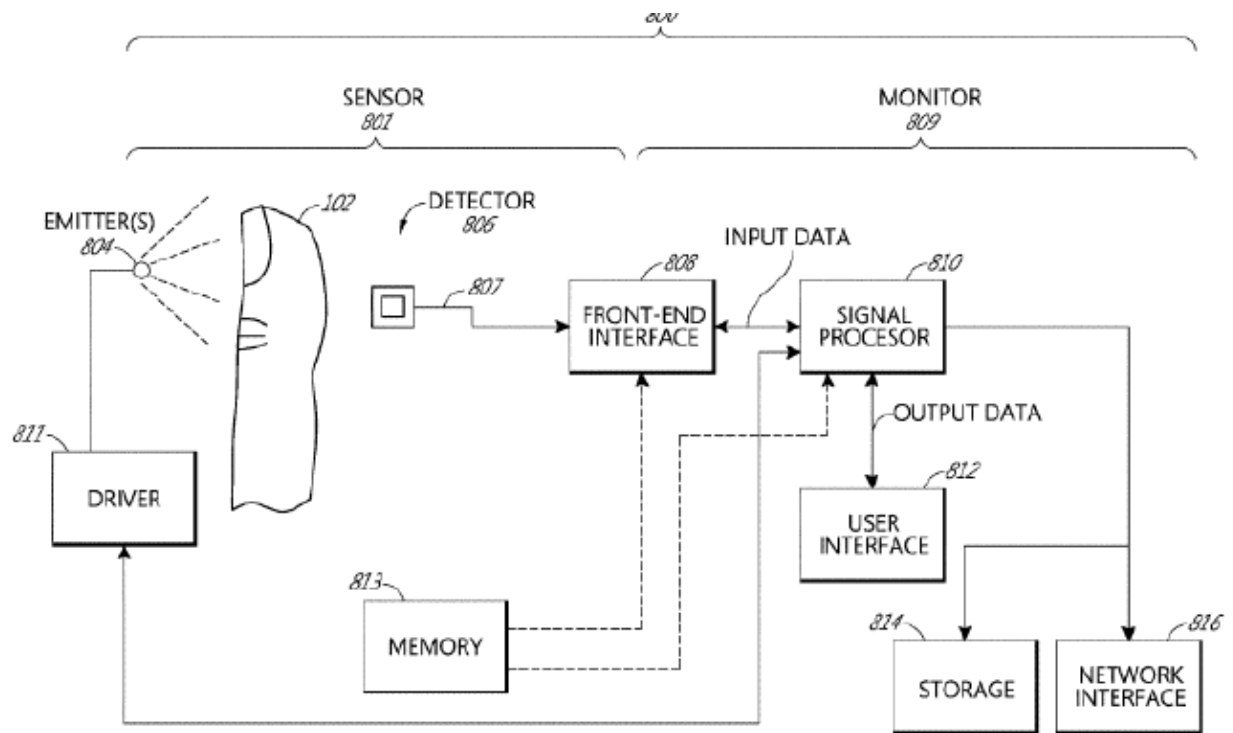


FIG. 8

APPLE-1001, FIG. 8.

33. FIG. 8 above illustrates “a block diagram of an example pulse oximetry system capable of noninvasively measuring one or more blood analytes in a monitored patient.” APPLE-1001, 5:34–37. Pulse oximetry system 800 includes sensor 801 (or multiple sensors) coupled to physiological monitor 809. *Id.*, 12:21–23. Sensor 801 includes emitter 804 and detector 806. *Id.*, 12:32–34. Monitor 809 includes signal processor 810, which “includes processing logic that determines measurements for desired analytes based on the signals received from the detector 806.” *Id.*, 13:33–40. Monitor 809 also includes user interface 812 that

provides “an output, e.g., on a display, for presentation to a user of pulse oximetry system 800.” *Id.*, 13:33–35, 13:64–66.

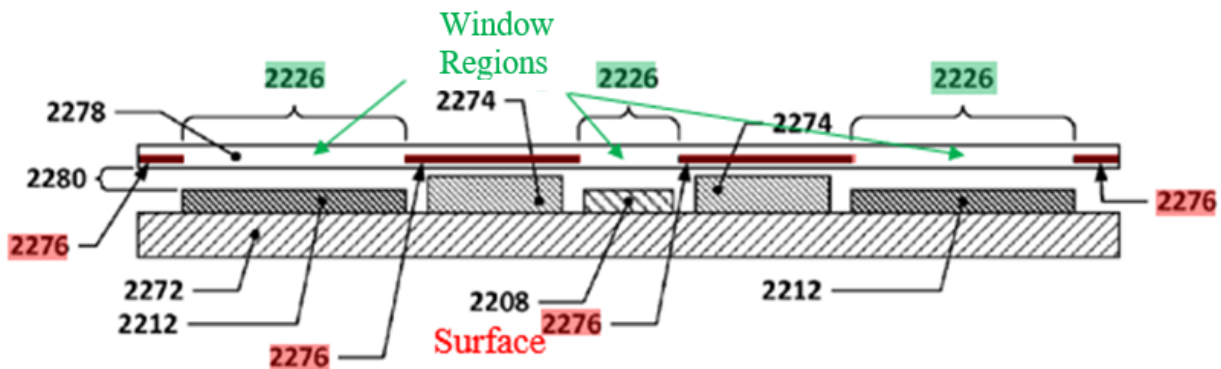
VI. SUMMARY OF THE PRIOR ART

A. Overview of Sarantos

34. Sarantos describes a “wristband-type wearable fitness monitor” that measures “physiological parameters” of the wearer, such as the person’s “heart rate” and “blood oxygenation levels.” APPLE-1005, 2:5-14, 5:55-59, 7:12-14, 13:39-47. 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. The light “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 measurement device. APPLE-1005, 2:5-14, 7:12-23, 13:39-47. The control

logic can then calculate different 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.

35. Sarantos's FIG. 22 depicts an example cross-section of a simplified representation of a PPG sensor used in its wrist-worn reflectance-based physiological monitor device. APPLE-1005, 16:60-67. The PPG sensor has a *dark-colored coating* or in-mold label 2276 (highlighted in red) to block light. APPLE-1005, 5:55-58.



APPLE-1005, FIG. 22.

36. In Sarantos, light source 2208 emits light through a window onto a user's skin, wherein the light is reflected back to and detected by photodetector elements 2212. APPLE-1005, 17:16-25. The light travels through

transparent/translucent windows regions 2226 (annotated in green above) ***defined in the dark-colored coating*** 2276 (also referred to as in-mold label 2276) applied to window 2278. *Id.* 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.*

B. Overview of Shie

37. Shie describes a diffuser that has a “light diffusing and shaping advantages” and changes a first shape of light into a second shape. APPLE-1007, 6:61-7:7. The diffuser includes a “plurality of surface micro-structures” that “are designed to homogenize light passing through” the diffuser “to produce a predetermined pattern of smoothly varying, non-discontinuous light exiting the” diffuser. APPLE-1007, Abstract. Shie describes that the exiting light “is therefore altered according to both the macro-optical characteristic of the” diffuser “as well as the homogenizing characteristics of the micro-structures.” *Id.*

C. Overview of Utter

38. Utter describes “[g]eneral health and wellness management techniques and devices...configured for use with a data-capable personal worn or

carried device. APPLE-1006, Abstract. In particular, Utter describes wrist-worn bands “that are configured to gather large amounts of personally relevant data that can be used to improve user health, fitness levels, medical conditions, athletic performance, sleeping physiology, and physiological conditions.” APPLE-1006, 12:56-64. Utter’s system can 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 (describing “light/infrared (‘IR’) sensor” and “pulse/heart rate (‘HR’) monitor”), 21:6-17. 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.

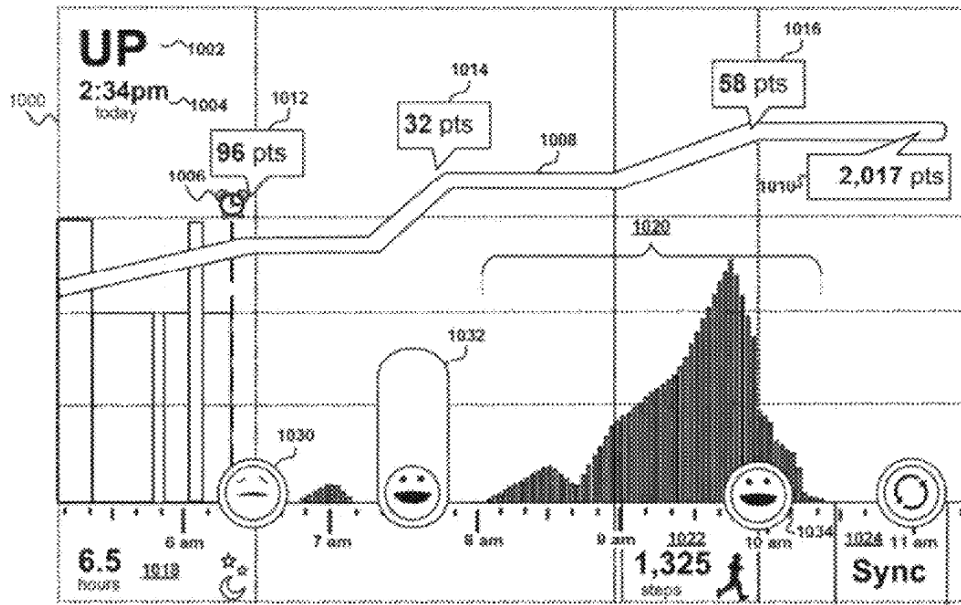
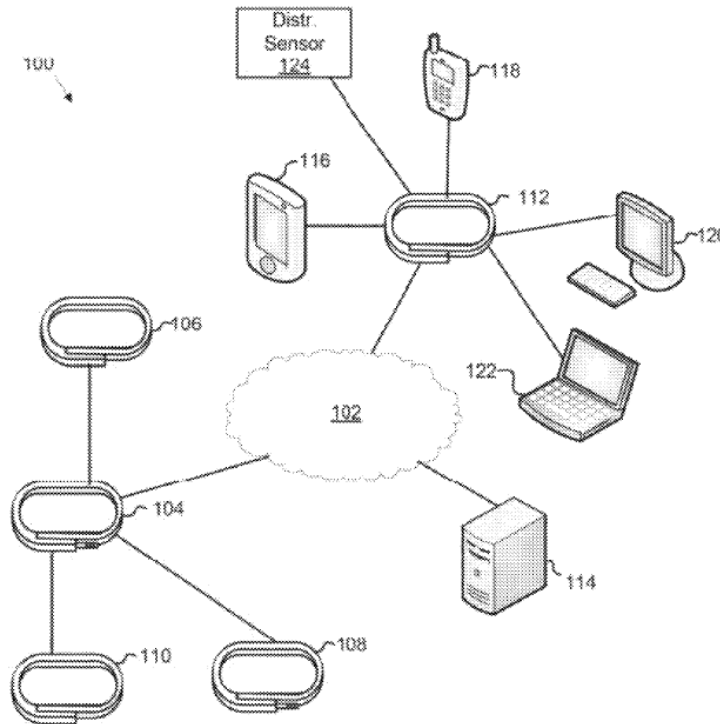


FIG. 10

APPLE-1006, FIG. 10.

39. 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.

40. Utter describes using “wireless communication” to “transfer 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, 24:18-25 (“Bands 106 and 110 may communicate with mobile communications device 118 and laptop 122 using any number of wireless communication technologies”).



APPLE-1006, FIG. 1.

41. 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.” *Id.*, 21:45-65, 36:15-30 (“Display engine 1454 can be configured to generate a graphical representation on an interface such as a touch-sensitive screen on a mobile phone 1472”). 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.

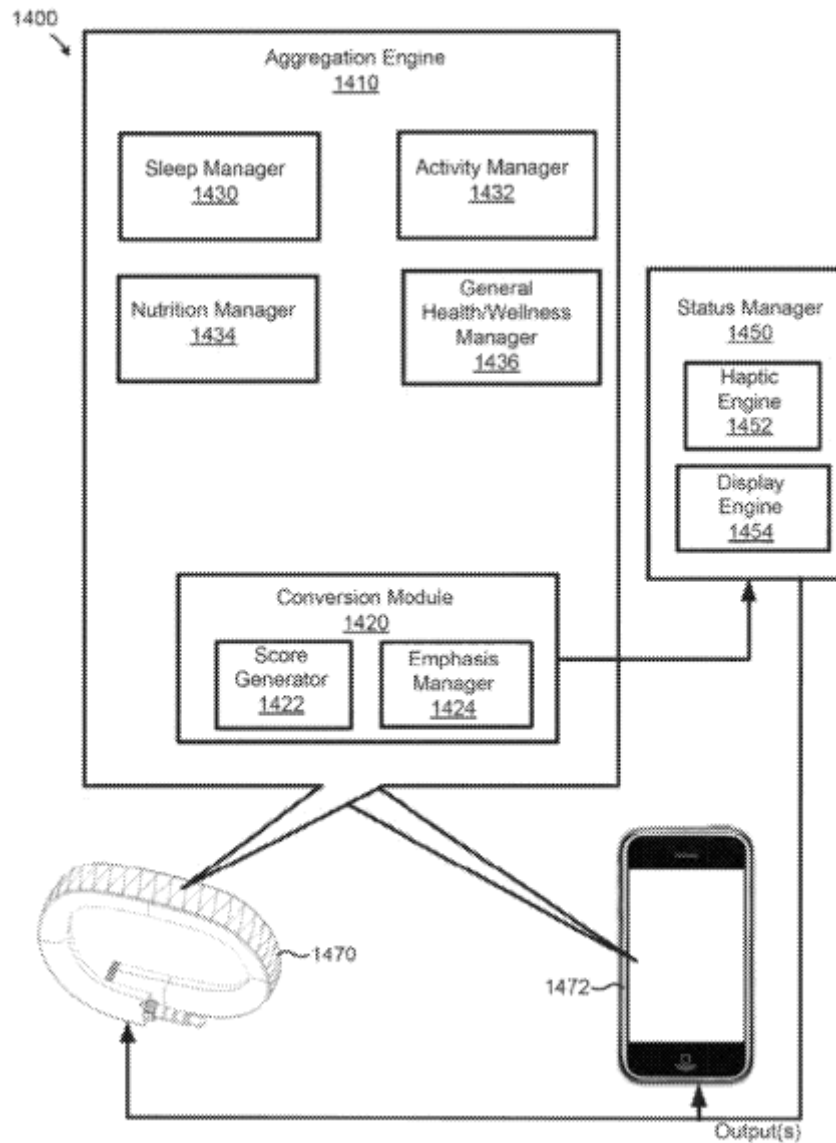


FIG. 14

APPLE-1006, FIG. 14.

D. Overview of Han

42. Han describes various embodiments of a “photoplethysmographic (PPG) device” that “include[s] 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. The PPG sensor can detect information that can be used to determine, e.g., a pulse rate or blood oxygen saturation for a user. *Id.*, ¶[0026]. 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.” *Id.*, ¶[0029].

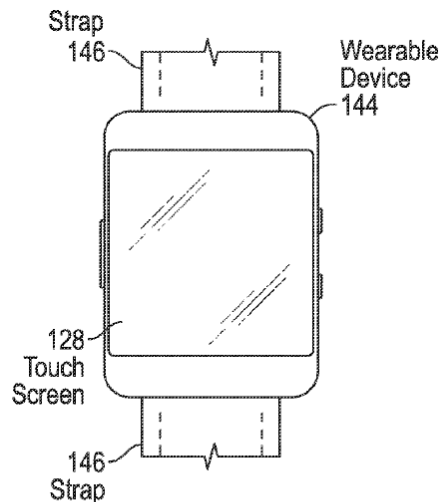


FIG. 1C

APPLE-1008, FIG. 1C.

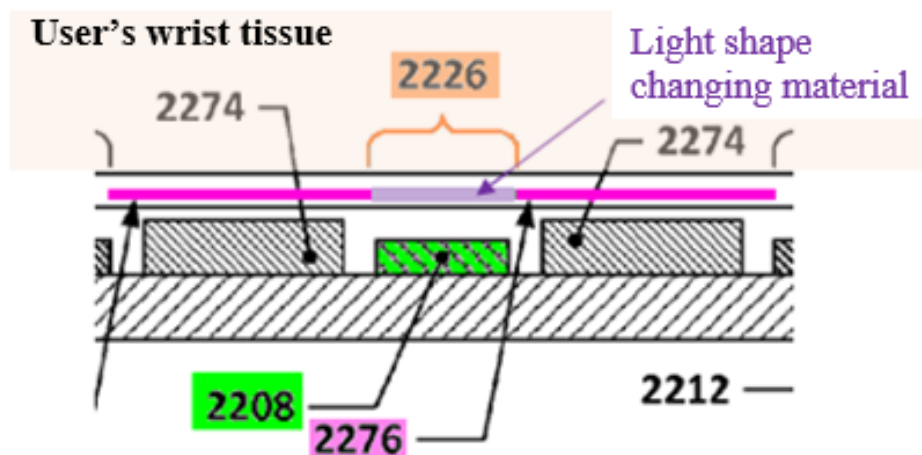
43. The wearable device includes a processor that “together with an operating system can operate to execute computer code and produce and use data.”

APPLE-1008, ¶[0068]. The touchscreen display can display determined physiological parameter data for the user. *Id.*, ¶¶[0070]-[0071].

VII. GROUND 2A: Claims 1, 3-6, 9-13, and 22-25 are obvious over Sarantos in view of Shie

A. Combination of Sarantos and Shie

44. It would have been obvious to a POSITA to use the light shape changing material (shown in light purple) of Shie in the window region 2226 (indicated in orange) between light source 2208 (highlighted in green) of Sarantos's wristwatch sensor and the user's wrist tissue, shown in FIG. 22 below, to change the shape of light emitted by light emitting devices included in light source 2208 into a second shape projected onto the tissue. APPLE-1005, 7:12-16, FIG. 22. The in-mold labels 2276 are shown in pink in FIG. 22 below.



APPLE-1005, FIG. 22 (modified and zoomed in).

45. Shie describes that “optical elements [that] receive[] light from a light source having particular characteristics defined by the properties of the light source and then alter the light propagating through the optical element” were known in the art. APPLE-1007, 1:42-45. This includes “[d]iffusers [that] have been applied as a separate layer to optical elements in order to add both light diffusing and directing characteristics.” *Id.*, 2:13-15. Shei provides numerous examples of various lens shapes and structures that provide the disclosed light shaping functionality. As Shei describes, each disclosed light shaping element includes “micro-structures” that function “to control the direction of light output from a light source so as to shape the light output into a desired distribution pattern or envelope.” *Id.*, 5:35-45. A POSITA would have recognized that, for example, the circular light shaping elements depicted described with respect to Shie’s FIGs. 1a, 1b, 3a, 3b, 8a, and 8b (reproduced below) would have been beneficially applied to the circular arrangements described in Sarantos. Similarly, the light shaping elements depicted with respect to Shie’s FIGs. 5a, 5b, 6a, and 6b (reproduced below) would have been beneficially applied to the square or rectangular arrangements described by Sarantos. Other embodiments/examples described in Shie would have been beneficially applied to those or other arrangements described by Sarantos depending on desired design characteristics.

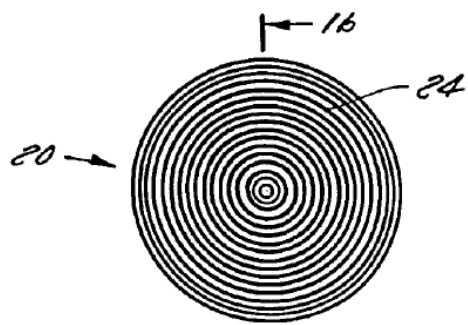


FIG. 1a

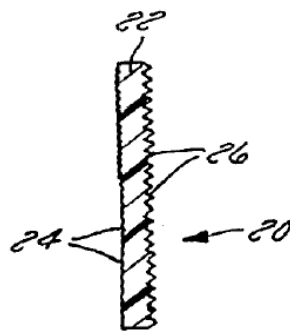


FIG. 1b

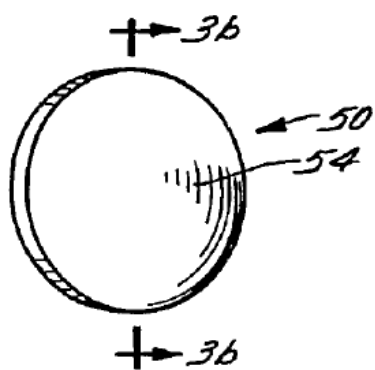


FIG. 3a

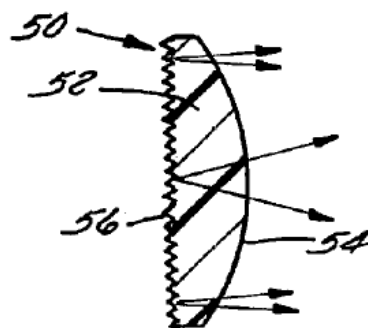


FIG. 3b

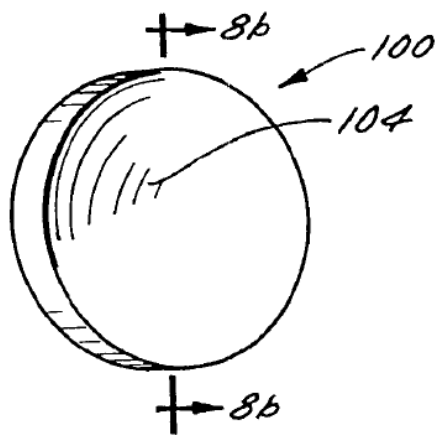


FIG. 8a

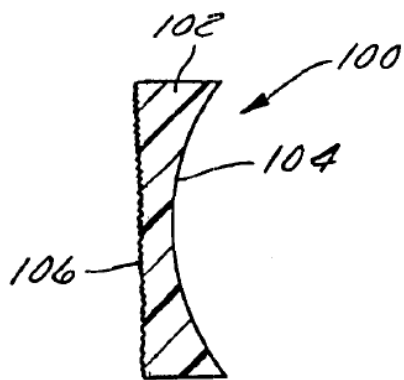


FIG. 8b

APPLE-1007, FIGS. 1a, 1b, 3a, 3b, 8a, 8b.

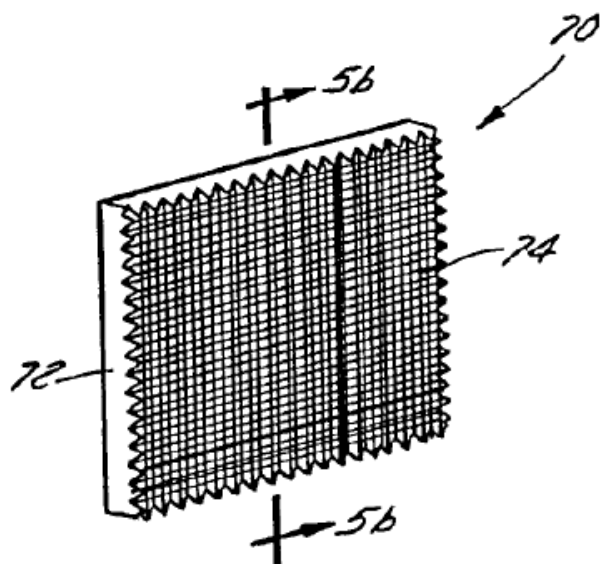


FIG. 5a

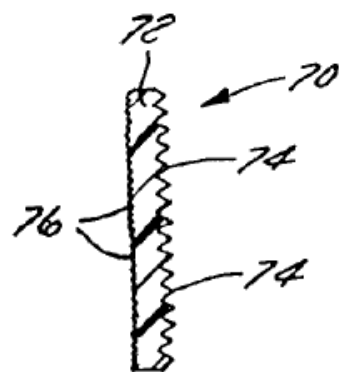


FIG. 5b

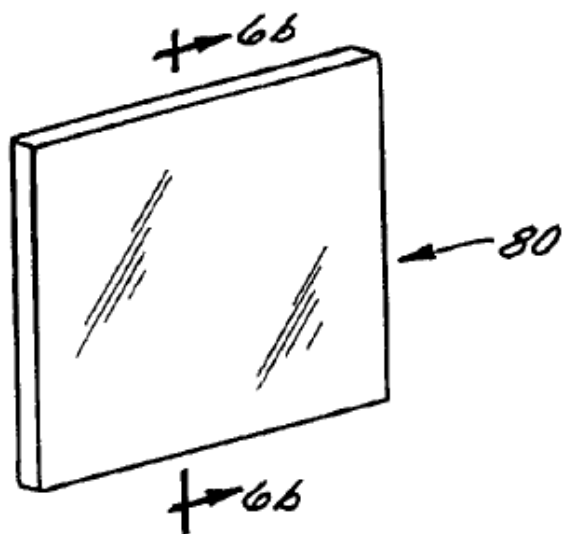


FIG. 6a

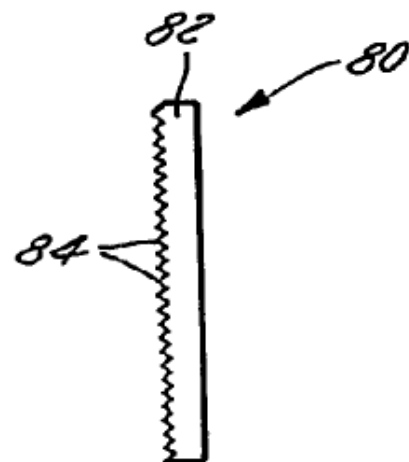


FIG. 6b

APPLE-1007, FIGS. 5a, 5b, 6a, 6b.

46. A POSITA would have been motivated to implement the window region 2226 between LEDs 2208 and the user's wrist tissue in the device of Sarantos using a light shape changing material (as taught by Shie), to direct more of the emitted light toward the tissue so as to increase power efficiency by shining light closer to photodiodes, as light not then reflected and incident on the photodiodes represents wasted power. For example, a POSITA would have understood that the "pulsatile component of absorption... is a small fraction of the received signal... used by the pulse oximeter instrument to perform its measurements," and thus, "it is important that the incident light be of significant magnitude to result in transmitted signals that have sufficient amplitude to provide accurate readings." APPLE-1016, 3:40-48. A POSITA knew that directing the light emitted toward the tissue to shine light closer to the photodiodes is one way of increasing the signal level of the light detected by the photodiodes that minimizes power consumption while still providing adequate radiated power for pulse oximetry. APPLE-1009, 76, 105; APPLE-1006, [0223] ("focus emitted light to a certain depth and location... so that the photodetector receives the maximum possible amount of scattered light"). Applying Shie's teachings to Sarantos would have furthered Sarantos' express goal of providing "a significant improvement in

the amount of AC light measurable by a photodetector without incurring a significant power consumption penalty” by configuring the resulting device to capture more of the light signal. APPLE-1005, 9:51-57.

47. Applying Shie’s teachings regarding light shaping elements to Sarantos’ device would have also allowed for the resulting device to increase accuracy of measurements by directing light towards a sufficient spatial area to decrease the likelihood of irregular readings caused by moles or other small or local aberrations on the skin. For example, a POSITA would have understood that “the skin surface, tissue, muscle, bone and especially blood cause light scattering which increases the absorbance of light” (APPLE-1009, 68-70), and “most of the total attenuation is due to the scattering of light away from the detector by the highly heterogeneous tissue.” APPLE-1033, 62. “The problem has been to contend with the wide variation in scattering and nonspecific absorption properties of very complex heterogeneous tissue” (APPLE-1033, 60) and “[l]ight scattering is still a source of inaccuracy in pulse oximeters.” APPLE-1009, 51. “The intensity of back scattered light from the skin depends... also on the structure and pigmentation of the skin.” APPLE-1009, 105. A POSITA would have understood that pigments and dyes present on the skin can cause measurement errors. APPLE-1009, 36; APPLE-1034, 10 (“pigment may cause error”). Thus, a POSITA would

have understood that illuminating a larger pulsatile vascular bed would reduce the likelihood of high measurement variation resulting from the local effect of moles and skin aberrations and enhance the quality of the measurement. APPLE-1009, 105.

48. Moreover, by implementing the window region 2226 between LEDs 2208 and the user's wrist tissue in Saranto's device using Shie's light shape changing material, a POSITA would have understood that light diffusion would have allowed the designers of the resulting device to match the light intensity to the general shape of the body, or to provide sufficient illumination over a heterogeneous region of tissue, so as to be insensitive to local tissue variations, and provide the most accurate physiological parameter detection.

49. Applying Shei's teachings regarding shaping elements to Sarantos would have also allowed the resulting device to be designed to obscure appearance of the light source from a user. A POSITA would have understood that users purchasing wrist-worn devices made decisions based partly on a device's appearance and would look at the front as well as the back of the device. Typically, the back of a watch has an opaque cover to conceal the electronic components from a user's view. APPLE-1004, 5:66-67 ("the back cover 3 is formed of a metal, such as stainless steel"); APPLE-1006, [0236], FIG. 2B;

APPLE-1035, 1. An optical element with diffusing microstructures (as taught by Shie), which forms a portion of the back cover, would obscure the light source's appearance from the user while allowing light transmission toward the tissue.

50. Light shape changing materials were known in the art to be used for such purposes, so a POSITA would have reasonably expected Shie's light shape changing material (e.g., diffuser) to work successfully in Sarantos's sensor.

APPLE-1033, 60-62.

B. Manner in which Iwamiya and Sarantos render obvious Claims 1-6, 9-13, 24, and 25

i. Claim 1

[1pre] A physiological measurement device comprising:

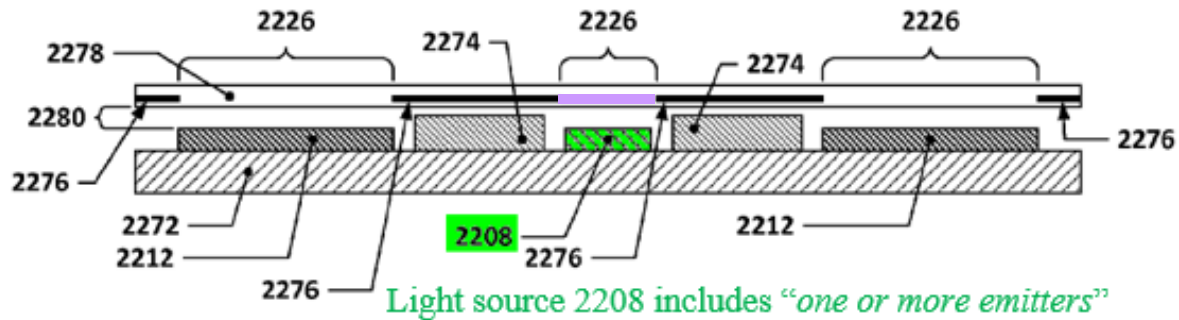
51. To the extent the preamble is limiting, the Sarantos-Shie Combination ("SSC") renders obvious [1pre]. In particular, Sarantos discloses a "wristband-type wearable fitness monitor" including a photoplethysmography (PPG) sensor, which is a "***physiological measurement device.***" APPLE-1005, 7:12-16.

[1a] one or more emitters configured to emit light in an initial light pattern;

52. SSC's physiological measurement device has a light source (e.g., 2208 shown in green in Sarantos's FIG. 22 below) that includes a plurality of LEDs ("***one or more emitters***"). APPLE-1005, 2:18-19, 13:34-53, 17:1-25.

Because light emitted from a LED has an initial light pattern, it would have been

obvious to a POSITA that light emitted from the Sarantos's LEDs would have been *“configured to emit light at an initial light pattern.”*



APPLE-1005, FIG. 22.

53. Although FIG. 22 does not explicitly depict a plurality of emitters, such an implementation is depicted in the example shown in Sarantos' FIG. 18. For instance, as shown below in FIG. 18, the light source 1808 includes a plurality of LEDs 1810. APPLE-1005, 15:24-43.

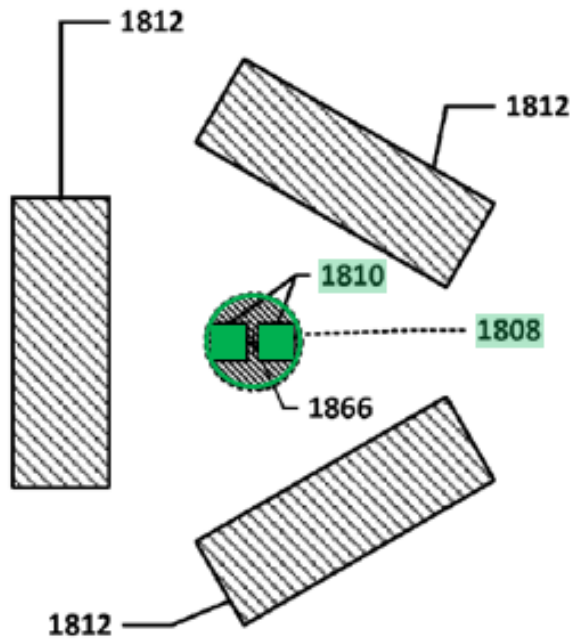
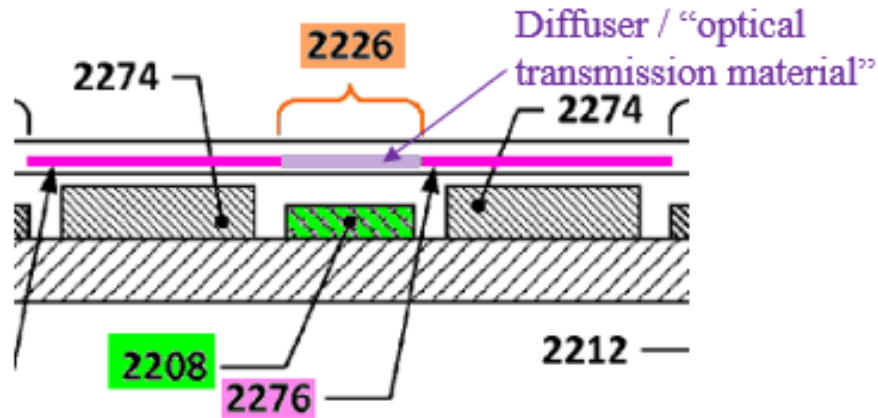


FIG. 18

APPLE-1005, FIG. 18.

[1b] an optical transmission material configured to be positioned between the one or more emitters and a tissue measurement site, wherein the optical transmission material is configured to alter a direction of at least a portion of the light emitted from the one or more emitters to shape an output light pattern by which the emitted light is directed toward a surface of the tissue measurement site, wherein the output light pattern comprises a different geometric shape than the initial light pattern;

54. As shown in the snapshot of Sarantos's FIG. 22 below, LEDs in SSC's light source 2208 (shown in green) emit light through a window 2226 (referenced in orange and colored in purple) defined by in-mold labels 2276 (shown in pink). APPLE-1005, 17:1-25, Fig. 22.



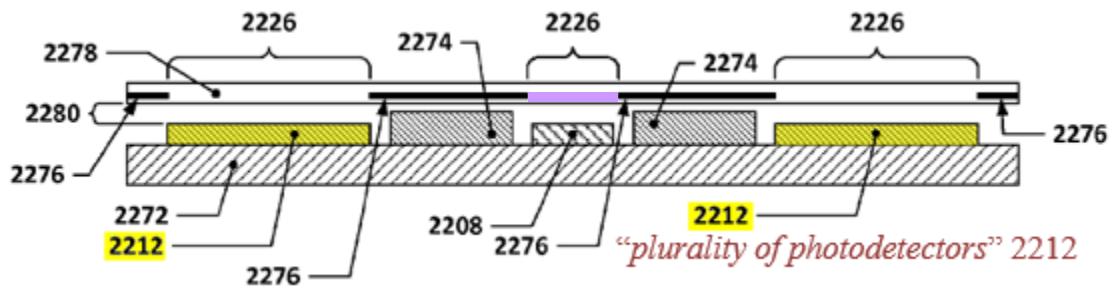
APPLE-1005, FIG. 22 (modified and zoomed in).

55. As noted above in §VII.A, in the SSC, the window 2226 includes Shie’s diffuser (“*optical transmission material*”), which has “light diffusing and shaping advantages” and can increase light transmission. APPLE-1007, 6:61-7:7. As indicated above in Sarantos’ FIG. 22, the diffuser (“*optical transmission material*”) is “configured to be positioned between the one or more emitters [2208] and a tissue measurement site,” which is on the top side (not shown) of the figure. And because the diffuser is light diffusing with shaping advantages, it would have been obvious to a POSITA that when light passes the diffuser/optical transmission material from the emitters 2208 towards the user’s skin, SSC’s “*optical transmission material is configured to alter a direction of at least a portion of the light emitted from the one or more emitters to shape an output light pattern by which the emitted light is directed toward a surface of the tissue measurement site.*”

56. As noted in [1a], light emitted from a LED has an initial light pattern. It would have been obvious to a POSITA that when light passes through a diffuser, the diffusion action generally causes the multiple directions of the light to increase or spread and alter and impact the shape of the output light pattern. *See infra* [9]. For this reason, SSC renders obvious [1b].

[1c] 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;

57. As shown in Sarantos' FIG. 22 below, "two HAR photodetector elements 2212" (highlighted in yellow) "are positioned on either side of a light source 2208." APPLE-1005, 17:1-3.



APPLE-1005, FIG. 22 (modified).

58. The "light from the light source 2208 [is allowed] to shine through its associated window region 2226 and into the person's skin, where the light then diffuses into the surrounding flesh and is then emitted back out of the person's skin and into the HAR photodetector elements 2212 through the respective window

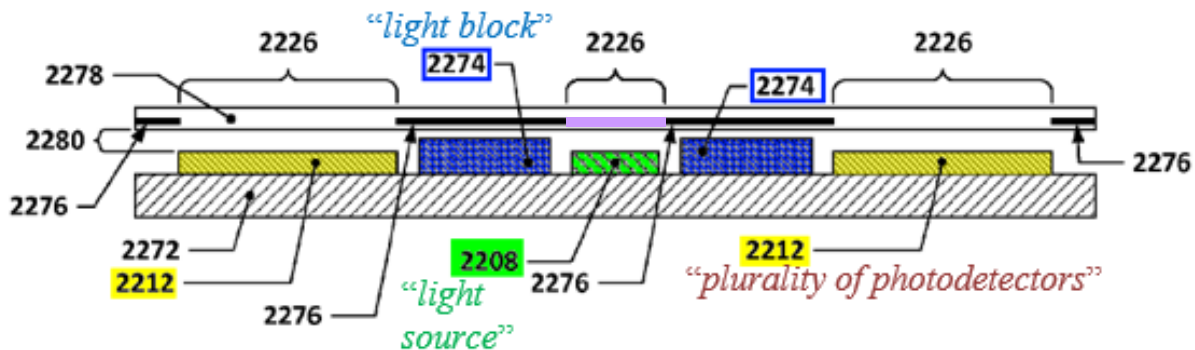
regions 2226 associated with the HAR photodetector elements 2212.” APPLE-1005, 17:19-25. Accordingly, SSC’s physiological measurement device includes photodetector elements 2212 (“*a plurality of detectors*”) that are “*configured to detect at least a portion of the light after passing through tissue.*” APPLE-1005, 17:1-3, FIG. 22.

59. The photodetectors can also provide a control logic unit “a signal indicative of an amount of detected light from the photodetector element.” APPLE-1005, 20:24-33. Thus, SSC’s “*the plurality of detectors [are] further configured to output at least one signal responsive to the detected light.*”

[1d] a light block configured to prevent at least a portion of the light emitted from the one or more emitters from reaching the plurality of detectors without first reaching the tissue;

60. Sarantos teaches that “to reduce the chance that light from the light source 2208 will reach either of the HAR photodetector elements 2212 *without first being diffused through the person's skin*, the light source 2208 may be separated from the HAR photodetector elements 2212 within the PPG sensor by walls 2274, which may extend to the window 2278 or may stop short of the window 2278.” APPLE-1005, 17:25-32. “The walls 2274 may prevent light from the light source 2208 from reaching the HAR photodetector elements 2212 by following paths completely within the housing of the PPG sensor.” APPLE-1005,

17:39-51. In this manner, SSC's walls 2274 (shown in dark blue below) are "*light block[s] configured to prevent at least a portion of the light emitted from the one or more emitters from reaching the plurality of detectors without first reaching the tissue.*"



APPLE-1005, FIG. 22 (modified).

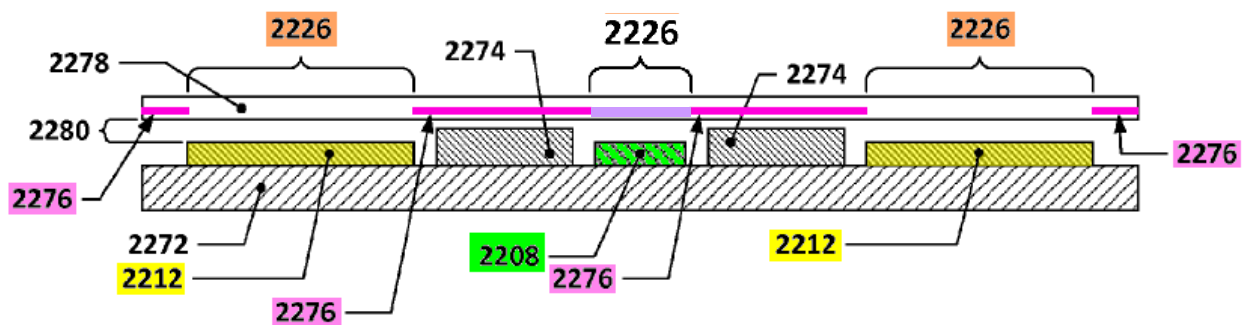
[1e] a surface comprising a dark-colored coating, the surface positioned between the plurality of detectors and the tissue, wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface; and

61. SSC's device includes a window 2278 that is "offset from the substrate 2272" and is described as follows:

[Window 2278] is made from a translucent or transparent material, such as transparent acrylic, with an *in-mold label 2276 embedded within it*. The *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. In other implementations, other masking techniques, such as a painted or silk-screened mask applied to the window 2278, may be used.

62. APPLE-1005, 17:1-12 (Emphasis added). As shown below in Sarantos' FIG. 22, SSC's device includes a window 2278 ("**surface**") that is "**positioned between the plurality of detectors and the tissue.**" Window 2278 "**compris[es] a dark-colored coating**" in the form of in-mold labels 2276 (shown in pink) that can be black or opaque to light to prevent light from entering or exiting. APPLE-1005, 17:1-25. Sarantos explains that various types of surfaces with dark-colored coatings 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.*



APPLE-1005, FIG. 22 (modified).

63. Window regions 2226 shown in orange above the photodetector elements 2212, are defined in the in-mold labels 2276 ("**wherein an opening**

defined in the dark-colored coating”). As noted above, in the SSC device, light passes through these window regions 2226 (“an opening ... is configured to allow at least a portion of light reflected from the tissue to pass through the surface”).

APPLE-1005, 17:1-12.

[1f] 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 a user responsive to the one or more signals.

64. Sarantos’ FIG. 27 (reproduced below) is “a high-level block diagram” of SSC’s device and illustrates that the SSC device includes control logic 2706 that includes “a processor” 2768. APPLE-1005, 20:24-33.

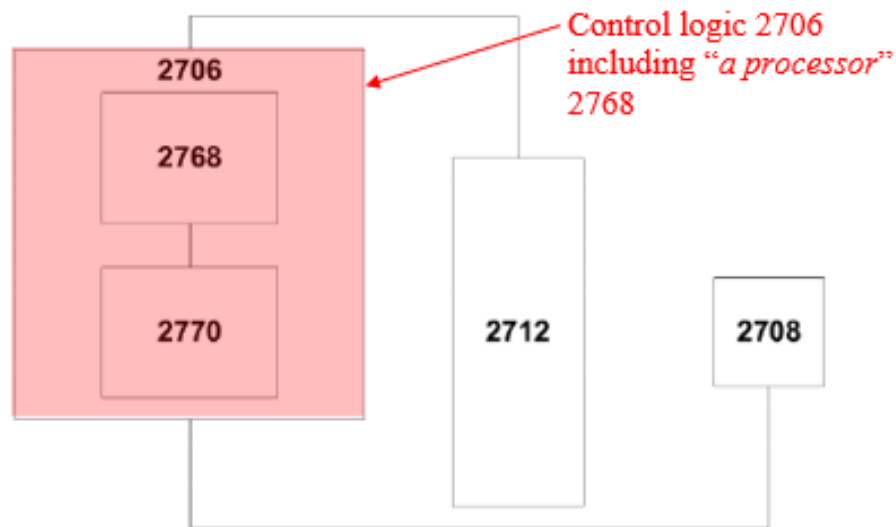


FIG. 27

APPLE-1005, FIG. 27.

65. “The control logic is operatively coupled with a light source 2708 and a photodetector element 2712. The control logic 2706 may thus cause the light

source 2708 to emit light at desired times, and may receive a signal indicative of an amount of detected light from the photodetector element 2712.” APPLE-1005, 20:24-33. In this manner, SSC renders obvious “*a processor configured to receive and process one or more signals responsive to the outputted at least one signal.*”

66. The control logic 2706 can then use the received and processed signals to determine a physiological parameter, such as the user’s heart rate (“*and to determine a physiological parameter of a user responsive to the one or more signals*”). APPLE-1005, 20:7-14.

ii. Claim 3

[3] The physiological measurement device of claim 1, wherein the optical transmission material comprises glass.

67. As described above in [1b], Shie describes a diffuser that has “light diffusing and shaping advantages” and changes a first shape of light into a second shape. APPLE-1007, 6:61-7:7. As explained in §VII.A, it would have been obvious to a POSITA to use Shie’s diffuser as a light-changing material in the wristwatch sensor of Sarantos in between LEDs 2208 and the user’s wrist tissue so as to change the shape of light emitted by LEDs 2208 into a second shape projected onto the tissue. APPLE-1005, 7:12-16, FIG. 22.

68. Shie further discloses a range of suitable materials for the diffuser, one such material being glass. APPLE-1007, 5:49-54 (“The present invention is not to be limited to forming these micro-structures in any particular material and therefore the optical elements described herein may be formed from such materials as *sol-gel glass*, *quartz glass*, polycarbonate and acrylic plastics, epoxies, and any other suitable plastic, *glass*, or other moldable materials.”). It would have been obvious to implement the light-shaping material using glass as taught in Shie due to its ability to be shaped into a suitable geometry for the application, its ability to support micro-structures that facilitate light diffusion, and its favorable temperature characteristics that allow glass to be used in a range of thermal environments.

69. The use of a glass diffuser in the combination also would have been obvious to a POSITA since it merely entails the use of a known solution to improve similar systems and methods in the same way. Here, applying Shie’s teaching of a glass diffuser to Sarantos’s sensor would have yielded a predictable result of a light-shaping diffuser that changes the shape of light emitted by LEDs 2208 into a second shape for projection onto the tissue. *See* [1b].

iii. Claim 4

[4] The physiological measurement device of claim 1, wherein the optical transmission material comprises plastic.

70. As noted above in [3], Shie discloses a range of suitable materials for the diffuser (“***optical transmission material***”), one such material being plastic.

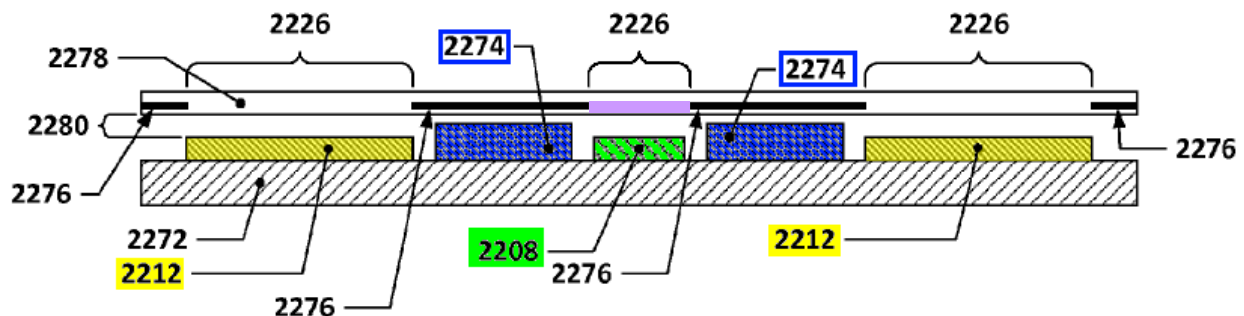
APPLE-1007, 5:49-54 (“The present invention is not to be limited to forming these micro-structures in any particular material and therefore the optical elements described herein may be formed from such materials as sol-gel glass, quartz glass, ***polycarbonate and acrylic plastics***, epoxies, and any other suitable ***plastic***, glass, or other moldable materials.”); *see supra* [1b], §VII.A. It would have been obvious to implement the diffuser in the combination using a plastic material, as taught in Shie, due to its ability to be shaped into a suitable geometry for the application and its ability to support micro-structures that facilitate light diffusion.

71. The use of a plastic diffuser in the combination also would have been obvious to a POSITA since it merely entails the use of a known solution to improve similar systems and methods in the same way. Here, applying Shie’s teaching of a plastic diffuser to Sarantos’s sensor would have yielded a predictable result of a light-shaping diffuser that changes the shape of light emitted by LEDs 2208 into a second shape for projection onto the tissue. *See* [1b].

iv. Claim 5

[5] The physiological measurement 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.

72. Sarantos discloses that “FIGS. 22 through 24 depict cross-sections of simplified representations of **various PPG sensors**, in accordance with **various example implementations**.” APPLE-1005, 16:60-62, 6:52-54. As discussed with respect to [1d], *supra*, Sarantos’ walls 2274 (blue) shown in FIG. 22 provide the claimed light block:



APPLE-1005, FIG. 22 (modified).

73. Sarantos provides multiple exemplary arrangements of photodetectors that can comport with the layout shown in this cross-sectional design, and that each individually satisfy this claim. As shown in FIG. 22, the light block 2274 is spaced equidistantly between the light source 2208 and photodetector elements 2212.

Sarantos describes FIG. 25 as “**an example implementation**” of a **PPG sensor** and therefore a POSITA would have recognized that FIG. 25 is one of the “**various**

PPG sensors, in accordance with **various example implementations**”

corresponding to the cross-section view of FIG. 22. APPLE-1005, 19:31-35, 16:60-32. A POSITA therefore would have viewed FIG. 25 and its corresponding disclosure as a natural extension of and incorporating the features of FIG. 22, including the light block 2274 spaced equidistantly between the light source and photodetector elements. Alternatively, it would have been obvious to implement the wall 2274 of FIG. 22 in the annular arrangement of FIG. 25 to beneficially prevent light that has not been attenuated through the user’s skin from reaching the photodetector elements. APPLE-1005, 17:26-42.

74. As shown below in FIG. 25, Sarantos discloses using annular photodetector elements. APPLE-1005, 19:22-35, Fig. 25 (showing annular photodetector element 2512 with a light source 2508 in the middle).

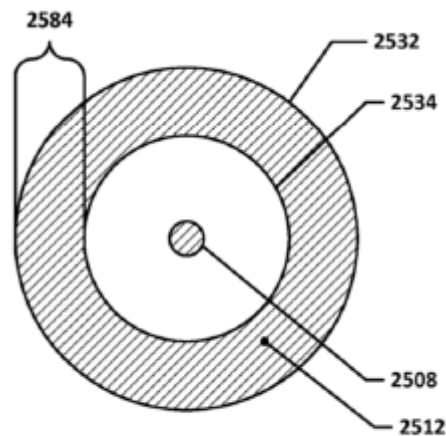


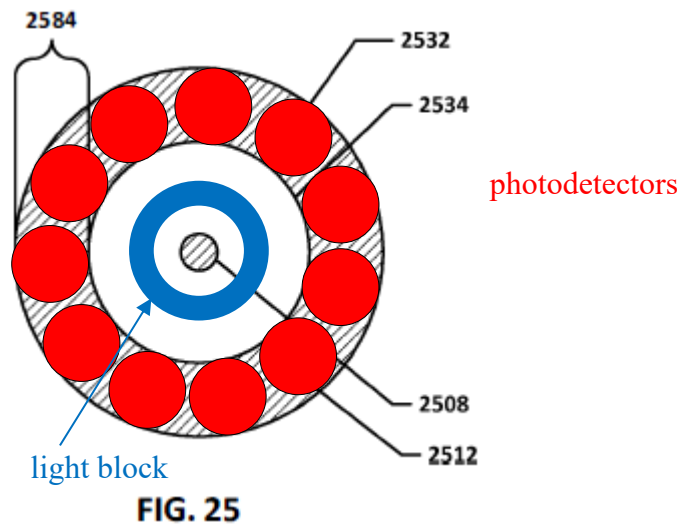
FIG. 25

APPLE-1005, FIG. 25.

75. A POSITA would have recognized that implementing the example annular arrangement of FIG. 25 to include the light block (wall 2274) expressly disclosed with respect to FIG. 22 (to beneficially prevent light that has not attenuated through the user's tissue from reaching the photodetector elements 2512), the light block would be arranged in a circular configuration. Alternatively, it would have been obvious to at least arrange the light block (wall 2274) in a circular arrangement in the annular configuration of FIG. 25 because both the light source 2508 and photodetector elements 2512 have a circular arrangement. This configuration in combination with FIG. 22's depiction of the wall 2274 being positioned equidistant between the light source and photodetector elements indicates that a circular arrangement for the wall 2274 in FIG. 25's configuration is the most obvious design choice. Given the annular configuration of detectors around a circular LED, the small form factor, and the limited space in Sarantos' PPG sensor described in FIGS. 22 and 25, a POSITA would have found a circular shape light block to be a reasonable and obvious design choice.

76. Furthermore, although photodetector element 2512 is described as a single photodetector element (APPLE-1005, 19:33-52), Sarantos is also clear that "it is to be understood that any of the implementations 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.” APPLE-1005, 20:52-57. From Sarantos’ disclosure, a POSITA would have understood that the annular photodetector element 2512 of FIG. 25 can be implemented using a plurality of photodetector elements (depicted by red circles) arranged about the light source in an annular configuration, as depicted below.



APPLE-1005, FIG. 25 (modified).

77. Therefore, Sarantos demonstrates that at least the configuration of FIG. 25 includes a plurality of detectors arranged in an array having an annular configuration corresponding to an annular a portion of the tissue measurement site bounded by the annular light block.

78. As further alternative examples of how Sarantos satisfies this claim, FIGs. 15-16 illustrate multiple photodetector elements (three and four respectively) arranged in an array corresponding to a circular shape about their respective light

sources. APPLE-1005, 14:56-15:8. FIG. 18 illustrates a similar circular configuration of photodetector elements surrounding a light source comprising two light-emitting devices. APPLE-1005, 15:24-43. A POSITA would have used any of these arrangements of photodetector elements in accordance with the layout taught in FIG. 22 by, *e.g.*, arranging the photodetector elements in a circular configuration (as illustrated in FIGs. 15-16 and 18) with an insulated light block between the light source and the photodetectors (as illustrated in FIG. 22). For instance, a POSITA, based on the teachings of Sarantos, would have implemented the circular configuration of the photodetectors shown in FIG. 18 based on FIG. 22's layout as follows:

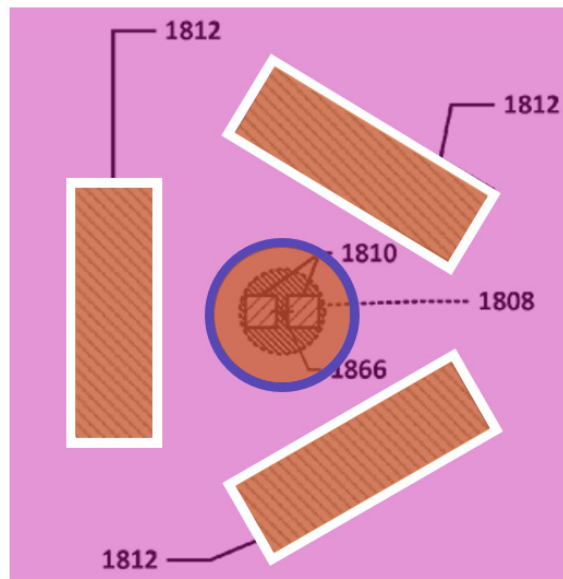


FIG. 18

APPLE-1005, FIG. 18 (annotated), with light block (blue), window with in-mold label (purple), window regions, photodetectors 1812, light source 1808.¹

79. As described above in [1d], the light block bounds the light emitted from the light source such that the light reaches the tissue measurement site without first reaching the photodetectors. A POSITA would have understood that the spatial configuration of the array of photodetectors would correspond to the

¹ The annotated Figure 18 illustrates an exemplary circular shape for the light block. A POSITA would have understood that differently shaped light blocks (e.g., rectangular, triangular, etc.) could be used with the circular configuration of the photodetectors shown above.

shape of the tissue bounded by the light block, as doing so would define a sufficiently large illumination of a region of heterogeneous tissue and re-radiant emittance of light into the tissue to the photodetectors. Accordingly, the photodetectors are arranged in an array having a spatial configuration corresponding to the tissue shape bound by the light block.

v. Claim 6

[6] The physiological measurement device of claim 1, wherein the dark-colored coating comprises black pigment.

80. See *supra* [1e]. For example, 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.

vi. Claim 9

[9] The physiological measurement device of claim 1, wherein the output light pattern comprises a width and a length, and wherein the width is different than the length.

81. Shie discloses “cylindrical” optical elements configured such that “a beam of light entering the lens remains unaffected in its width and is spread by the cylindrical lens contour in a direction perpendicular to its width.” APPLE-1007,

1:15-23; *see also id.*, FIGS. 2a-2b & 6:44-64 (describing a cylindrical lens 30 for “the curvature and contour of the cylindrical lens surfaces 34, 40 and 44 define the macro-optical characteristic of the lens 30”). Thus, a cylindrical lens, as taught in Shie, changes light that enters the lens from a first shape to a second shape having a length different from its width, due at least in part to the lens’s spreading in the length dimension without corresponding spreading in the width dimension.

82. As discussed above in §VII.A, it would have been obvious to incorporate a light-shaping material as taught in Shie in the wristwatch sensor of Sarantos between LEDs 2208 and the user’s wrist tissue, e.g., to change the shape of light emitted by LEDs 2208 into a second shape projected onto the tissue. APPLE-1005, 7:12-16, FIG. 22. In this context, it also would have been obvious to use a cylindrical optical element as the light-shaping material in the combination to spread light in a length dimension but not the width as taught in Shie.

83. A POSITA would have been motivated to implement a cylindrical light-shaping material in the combination to better project light toward portions of the wrist tissue nearest the high-aspect ratio (HAR) photodiodes (or otherwise to project the light toward portions of the wrist tissue that would optimize the ability of light after attenuation by the wrist tissue to be re-emitted toward the HAR photodiodes). By directing the light in this manner, the photodiodes would have

captured more of the light signal and better produce reliable measurement information without requiring overly expensive, highly-sensitive detector elements.

84. In some cases, the cylindrical light-shaping material would be particularly advantageous to spread the light toward photodiodes that are not arranged in a circular configuration but are instead positioned opposite each other on opposite sides of the sensor. For instance, in Sarantos' FIG. 14 (reproduced below), "two HAR photodetector elements 1412 are shown with a light source 1408 interposed midway between them." APPLE-1005, 14:58-60. A cylindrical light-shaping material would have been advantageous to extend the light in one dimension toward portions of the tissue corresponding to the oppositely positioned photodiodes 1412.

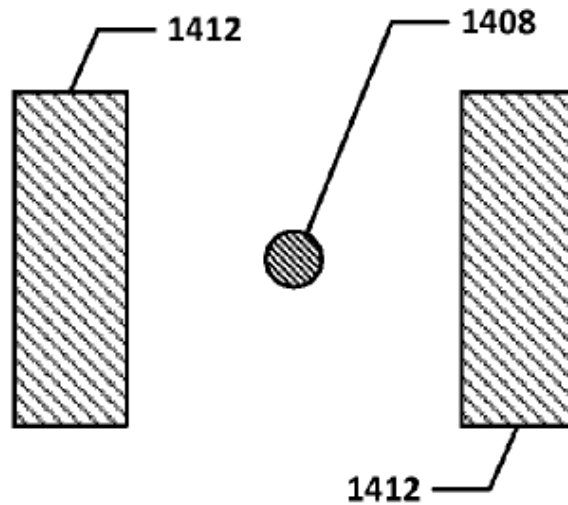


FIG. 14

APPLE-1005, FIG. 14.

vii. Claim 10

[10] The physiological measurement device of claim 1, wherein the output light pattern comprises an oval shape.

85. Further to the discussion in [9], in some cases, it would have been beneficial and obvious that the cylindrical light-shaping material would yield an output light pattern that comprises an oval shape, useful on body regions that are long and narrow (fingers, arms along length instead of around the curve of arm, etc) (instead of a large flat region of the body), or to be aligned with a domination arterial direction. For example, as discussed above in [5] and shown in Sarantos'

FIG. 25 below, the SSC device can include an annular arrangement in which a light source 2508 is surrounded by an annular photodetector element 2512 and a light block (not shown). APPLE-1005, 19:22-35.

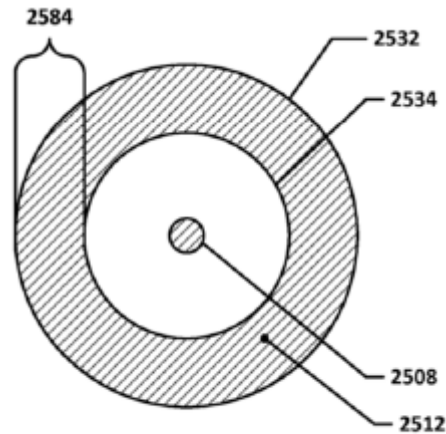


FIG. 25

APPLE-1005, FIG. 25.

86. It would have been obvious to a POSITA that such an arrangement would have been used when the output light pattern comprises an oval shape. In particular, the annular arrangement shown in FIG. 25 would have been effective to detect light in an oval pattern. A POSITA would be motivated to do so, to capture a greater amount of light from the tissue measurement site (user's skin).

87. Notwithstanding the above, due to the language ("comprising") used in claim 10, **any** portion of the output light pattern that has an oval shape would satisfy this claim. And it would have been obvious to a POSITA that the output light pattern would have included at least one portion that has an oval shape.

viii. Claim 11

[11] The physiological measurement device of claim 1, wherein the physiological parameter is oxygen saturation.

88. Sarantos also discloses that its sensor measures oxygen saturation.

APPLE-1005, 13:40-53 (disclosing measuring “blood oxygenation levels”).

ix. Claim 12

[12] The physiological measurement device of claim 1, wherein the physiological parameter is pulse rate.

89. In the combination, Sarantos discloses that the sensor measurements can be used to determine a person’s heart or pulse rate:

As a person's heart beats, the person’s blood vessels expand and contract in synch with the heart as the pumping of the heart exerts pressure on the person's blood which, in turn, results in cyclic pressure increases in the person's blood vessels. When a blood vessel expands, it allows more blood to flow into the vessel, which results in the amount of blood present in a given region of the person's flesh fluctuating in rhythm with the person's heart rate. This, in turn, results in fluctuations in the amount of light from the light source that is emanated back out of the flesh. The heart rate may then be determined by measuring the amount of light that emanates back out of the

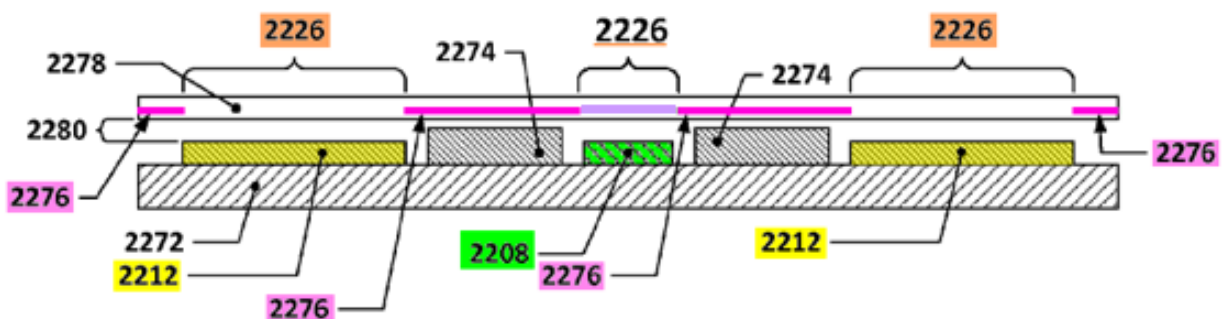
person's flesh via the above-described diffusion mechanism.

90. APPLE-1005, 7:36-48; *see also id.*, 3:15, 13:39-43, 17:16, 18:35-44.

x. Claim 13

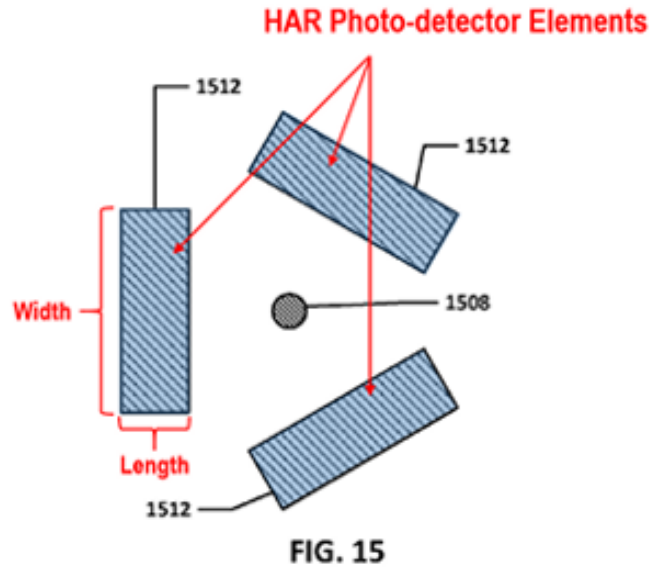
[13] The physiological measurement device of claim 1, wherein the opening defined in the dark-colored coating comprises a width and a length, and wherein the width is larger than the length.

91. As discussed above with respect to [1e], Sarantos discloses a respective window for each photodiode in the sensor that permits diffuse light reflected from the tissue measurement site to reach the photodiode for detection and measurement. *See* [1e]. For example, Sarantos' FIG. 22 depicts a surface with a dark-colored coating (window 2226 with in-mold label 2276 above the photodiodes 2212) positioned between the photodiodes 2212 and tissue of user's wrist, wherein windows 2226 above the photodiodes 2212 in the dark-colored coating allow light reflected from the tissue to reach photodiodes 2212. APPLE-1005, FIG. 22. In the annotated version of FIG. 22 below, windows 2226 are shown in orange, in-mold labels 2276 are shown in pink, and photodiodes 2212 are shown in yellow.



APPLE-1005, FIG. 22 (modified).

92. Sarantos discloses that the photodiodes have a “high-aspect ratio” (“HAR”), such that “at least 90% of the photodetector element active area[] ... has a maximum first dimension along a first axis that is at least twice as large as a maximum second dimension of the photodetector element along a second axis that is perpendicular or orthogonal to the first axis.” APPLE-1005, 9:47-65; *generally id.*, 9:48-10:26, FIGS. 15-16, 18. For instance, Sarantos’ FIG. 15 (reproduced below) shows that the HAR photodiodes can have a width larger than their length.



APPLE-1005, FIG. 15.

93. Sarantos further discloses 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.” APPLE-1005, 17:42-47. Thus, it would have been obvious to a POSITA that the window regions defined in the dark-colored coating each include a width and a length corresponding to the width and length of their respective HAR photodiodes, and the width is larger than the length.

xi. Claim 22

[22pre] A physiological measurement device comprising:

94. See [1pre].

[22a] one or more emitters configured to emit light;

95. See [1a].

[22b] a diffuser configured to be positioned between the one or more emitters and a tissue measurement site;

96. See [1b]².

[22c] a circular shaped light block;

97. See [1d], [5].

[22d] 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;

98. See [1c], [5].

[22e] wherein the light block is configured to prevent at least a portion of light emitted from the one or more emitters from reaching the plurality of detectors without first reaching tissue; and

99. See [1d].

² The “diffuser” in [22b] corresponds to the “optical transmission material” in [1b].

[22f] 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.

100. See [1f].

xii. Claim 23

[23] The physiological measurement device of claim 22, wherein the one or more emitters are configured to emit the light in an initial light pattern, and wherein the diffuser comprises an optical transmission material configured to alter a direction of at least a portion of the light emitted from the one or more emitters to shape an output light pattern by which the emitted light is directed toward a surface of the tissue measurement site, and wherein the output light pattern comprises a different geometric shape than the initial light pattern.

101. See [1a], [1b], [22].

xiii. Claim 24

[24] The physiological measurement device of claim 22, wherein the physiological parameter is oxygen saturation.

102. See [11], [22].

xiv. Claim 25

[25] The physiological measurement device of claim 22, wherein the physiological parameter is pulse rate.

103. See [12], [22].

VIII. GROUND 2B – Claim 7 is obvious over Sarantos, Shie, and Utter

A. Combination of Sarantos, Shie, and Utter

104. A POSITA would have been motivated, would have found obvious, and would have reasonably expected success in beneficially applying the teachings of Utter to the Sarantos-Shie combination such that the resulting wrist-worn optical biological information detecting apparatus would 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 measurement 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. A POSITA would have understood that the secondary devices that Utter discloses, such a mobile computing device 116, mobile communications device, desktop computer, and laptop computer, all conventionally comprise, among many other components, a touch screen user interface, a storage device, one or more processors, and a network interface configured to wirelessly communicate with the primary physiological measurement device. APPLE-1006, 32:25-46, 36:21-23 (...a touch-sensitive screen on a mobile phone 1472), 13:57-65, 14:42-15:3, 24:18-25 ("Bands 106 and 110 may communicate with mobile communications

device 118 and laptop 122 using any number of wireless communication technologies”), 24:59-4.

105. Indeed, Utter discloses that its configuration allows the secondary device to act as a user interface to the physiological measurement 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 (“Display engine 1454 can be configured to generate a graphical representation on an interface such as a touch-sensitive screen on a mobile phone 1472”).

106. Utter further discloses that the secondary device (*i.e.*, 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. A POSITA would have been motivated to wirelessly connect the wristband-type wearable optical biological information detecting apparatus of Sarantos to a secondary processing device 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.

107. A POSITA would have been motivated to transmit the physiological parameter data determined by Sarantos' wrist-worn wearable device, to a secondary device like a smart phone, as taught by Utter, to increase the functionality of the system without significantly increasing the power consumption of Sarantos' sensor. APPLE-1006, 14:42-15:3, 24:18-25, FIG. 1, FIG. 14.

108. For example, a POSITA would have understood that it is important for wearable sensors, such as that described in Sarantos, 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. *See, e.g.*, APPLE-1004, 5:54-66, FIG. 1. By wirelessly transmitting information to a mobile computing device or laptop "using any number of wireless communication technologies," additional features can 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 Sarantos' sensor. 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;

APPLE-1009, 199 (describing that physiological measurement devices must “solve a need for the customer” and “meet the user’s expectations” such as through “design of an optimal user interface”).

109. Further, a POSITA would have found it obvious to modify Sarantos based on Utter, and would have reasonably expected success in doing so, because doing so entails the use of known solutions to improve similar systems and methods in the same way. A POSITA would have recognized that applying Utter’s teachings of transmitting physiological parameters wirelessly to a secondary computing device to Sarantos would have led to the predictable result, taught by Utter, of a mobile computing device, computer, or other computing device displaying information based on the received physiological parameters. APPLE-1006, 14:42-15:3, 24:18-25, 21:45-65, 36:15-30.

110. Transmitting the physiological parameter data calculated by Sarantos’ 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 allow for sharing of information with other users. APPLE-1006, 14:23-42, 21:25-43.

111. For at least these reasons, a POSITA would have been motivated and found it obvious to implement the combination of Sarantos and 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 measurement system that operated in the proposed manner.

B. Manner in which Iwamiya, Sarantos, and Utter render obvious Claim 7

i. Claim 7

[7] The physiological measurement device of claim 1, wherein the device is configured to wirelessly transmit physiological parameter data to a separate device.

112. As described above in §VIII.A, the Sarantos-Shie-Utter combination renders obvious a physiological measurement device wirelessly transmitting physiological parameter data to a separate device, such as a smart phone. APPLE-1005, 7:12-16, FIG. 22; APPLE-1006, 31:1-16, 37:41-63, 55:29-51, 57:20-58:9.

IX. GROUND 2C – Claim 8 is obvious over Sarantos, Shie, and Han

A. Combination of Sarantos, Shie, and Han

113. A POSITA would have been motivated, would have found obvious, and would have reasonably expected success in beneficially applying the teachings of Han to the Sarantos-Shie combination such that the resulting wrist-worn measurement device would have been implemented with a touch-screen display. A POSITA would have recognized that Han's touchscreen would have increased the utility of the Sarantos-Shie device by allowing for an easy and intuitive way to provide user input to the wrist-worn device, including to parse tap and event gesture and make user selections. APPLE-1008, [0029], [0072]-[0077]. A POSITA would have recognized that touchscreen user interfaces for mobile devices, including wrist-worn watch devices, were ubiquitous by 2015 and therefore implementing the Sarantos-Shie device to include a touchscreen interface on the display would have provided users with a familiar interface that they would have readily known how to use. Furthermore, use of a touchscreen interface would have eliminated or reduced the need to provide other physical interface components such as buttons or keys, thereby contributing to a sleek, user-friendly design for the resulting device.

114. Further, a POSITA would have found it obvious to enhance the Sarantos-Shie combination based on Han because doing so entails the use of

known solutions to improve similar systems and methods in the same way. A POSITA would have recognized that applying Han's teachings of a wrist-worn physiological monitor having a touchscreen to Sarantos-Shie would have led to the predictable result of a measurement device with a touch screen. APPLE-1008, [0029], [0072]-[0077].

115. Accordingly, for at least these reasons, a POSITA would have been motivated and found it obvious to implement the combination of Sarantos, Shie, 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 measurement device that operated in the proposed manner. *See, e.g.*, APPLE-1008, [0029], [0072]-[0077].

B. Manner in which Sarantos, Shie, and Han render obvious Claim 8

i. Claim 8

[8] The physiological measurement device of claim 1, further comprising a touch-screen display configured to present information related to the determined physiological parameter.

116. For the reasons noted above in §IX.A, Sarantos-Shie-Han render obvious a physiological measurement device that comprises a touch-screen display. Han discloses a touch-screen display 830, which “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.” APPLE-1008, FIG. 8, ¶¶[0070]-[0077]. The display device 824 can display various types of information including, e.g., a graphical user interface, images, and raw data. *Id.* Recall from §VI.A that Sarantos discloses a “wristband-type wearable fitness monitor” that measures “physiological parameters” of the wearer, such as the person’s “heart rate” and “blood oxygenation levels.” APPLE-1005, 2:5-14, 5:55-59, 7:12-14, 13:39-47, FIG. 2.

117. It would have been obvious to a POSITA that the touch-screen display in the Sarantos-Shie-Han device would have been “*configured to present information related to the determined physiological parameter.*” In particular, a POSITA would have immediately recognized that displays are commonly used to display information, such as measured physiological parameter data, such as heart rate or blood oxygenation levels, so that the user can be informed of the user’s health indicators. APPLE-1014, ¶¶[0002]-[0010]; APPLE-1015, 14:1-40, 1:35-2:35. The provision of a display, as taught in Han, would have promoted user interaction with the device, and would have permitted a user to access data indicative of the user’s health more readily. The use of such a display in the combination would have entailed no more than the use of a known technique to improve similar devices in the same way and combining prior art elements

according to known methods to yield predictable results. The combination would have been predictable and had a reasonable expectation of success, particularly given that the elements of the combined system would each perform the same or similar functions as they had been known to perform in their respective individual systems.

118. It would have been obvious to apply Han's suggestion for a touchscreen display in the combination to provide an intuitive and convenient method for a user to view information and provide inputs to the measurement device using touch technologies that were widely available by the Critical Date of the '743 patent. Additionally, by providing a touch-screen display, separate input devices such as mechanical buttons could be eliminated, thereby streamlining the design of the device and providing room to maximize the display size without significantly increasing the overall size of the wristworn device.

X. GROUND 2D – Claims 14 and 16-21 are obvious over Sarantos, Shie, Utter, and Han

A. Combination of Sarantos, Shie, Utter, and Han (SSUH)

119. A POSITA would have been motivated, would have found obvious, and would have reasonably expected success in combining the teachings of Han with the Sarantos-Shie-Utter combination for the same reasons noted above in

Section IX.A or combine the teachings of Utter with the Sarantos-Shie-Han combination for the same reasons noted above in Section VIII.A. Regardless of how either combination is made, the outcome would be a SSUH device that is the same in both combinations. For instance, such a device would have a touch screen display to display information and receive touch inputs and would also include a wireless device for wirelessly transmitting information from the device to another device, as explained above in Section VIII.A

B. Manner in which Sarantos, Shie, Utter, and Han render obvious claims 14 and 16-21

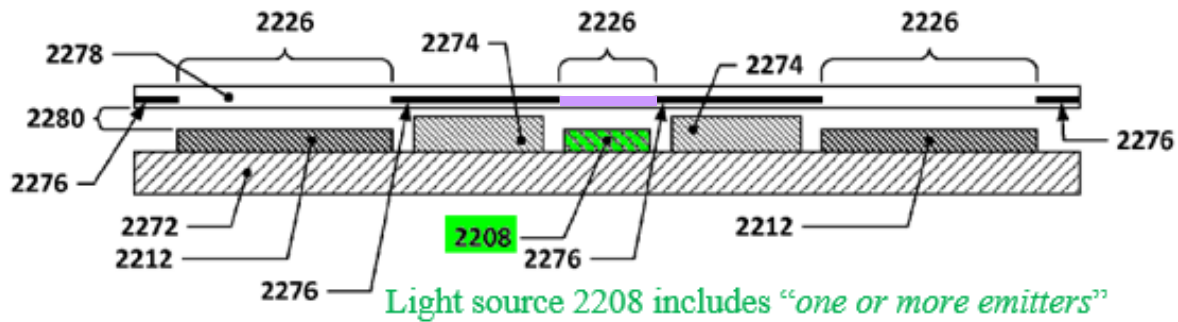
i. Claim 14

[14pre] A physiological measurement device comprising:

120. *See* [1pre].

[14a] one or more optical sources configured to emit light of one or more wavelengths in an initial light pattern proximate a wrist of a user;

121. *See* [1a]. The SSUH device has a light source (e.g., 2208 shown in green in Sarantos’s FIG. 22 below) that includes a plurality of LEDs (“***one or more optical sources***”). APPLE-1005, 2:18-19, 13:34-53, 17:1-25. Because light emitted from a LED has a wavelength and an initial light pattern, it would have been obvious to a POSITA that light emitted from the Sarantos’s LEDs would have been “***configured to emit light of one or more wavelengths in an initial light pattern.***”



APPLE-1005, FIG. 22 (modified).

122. In addition, because Sarantos’s physiological sensor is a wristwatch, the LEDs emit light “proximate a wrist of a user.” APPLE-1005, 7:12-25.

[14b] an optical transmission material configured to be positioned between the one or more optical sources and a tissue measurement site, wherein the optical transmission material is configured to alter a direction of at least a portion of the light emitted from the one or more optical sources to shape an output light pattern by which the emitted light is projected toward a surface of the tissue measurement site, the output light pattern comprising a different geometric shape than the initial light pattern;

123. See [1b].

[14c] 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, wherein the one or more optical sources and the plurality of detectors are arranged in a reflectance measurement configuration;

124. See [1c].

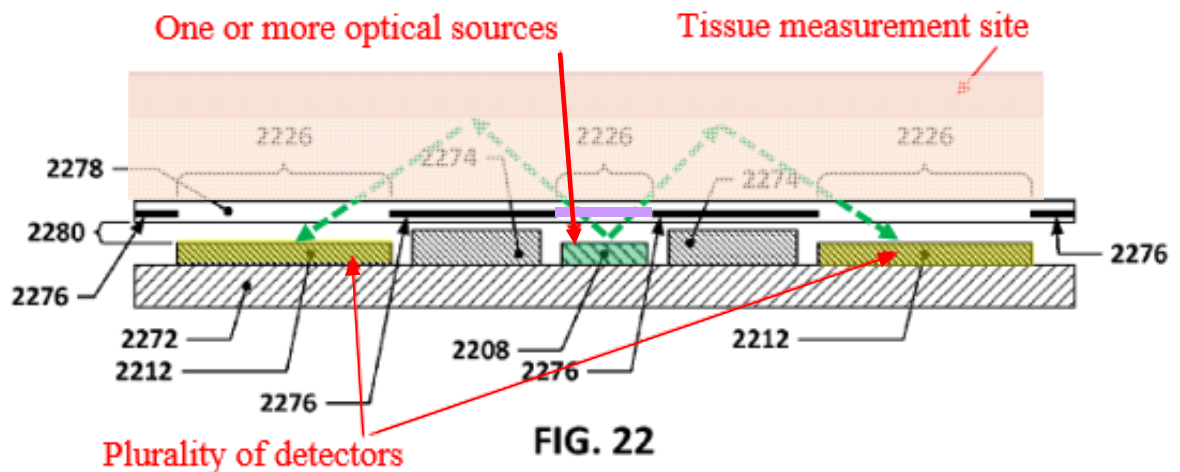
125. In addition, a POSITA would have been motivated to incorporate Shie’s diffuser between LEDs 2208 and a user’s tissue such that light emitted from LEDs 2208 travels through the light diffusing material of the diffuser and then

passes into tissue that is encircled by the light block (walls 2274). APPLE-1005, 17:1-25; APPLE-1007, 6:61-7:7. Photodetector elements 2212 are positioned just outside of walls 2274. APPLE-1005, FIG. 22.

126. Sarantos discloses multiple LEDs and a plurality of photodiodes wherein light is shone from the multiple LEDs into tissue and reflected back to the photodiodes. APPLE-1005, 17:1-4, 17:16-25, FIG. 22. This is a reflectance measurement configuration.

127. According to the '743 Patent, “[r]eflective pulse oximetry is a method by which the emitter and detector are located on the same side of the tissue measurement site 102.” APPLE-1001, 10:14-16; *see also id.*, FIGS. 6, 7A-7B. This contrasts with transmissive pulse oximetry in which the emitter and detector are located on opposite sides of the measurement site. *See id.*, FIG. 3.

128. In the combination, Sarantos discloses that the LEDs and photodetectors (i.e., photodiodes) are located on the same side of the a tissue measurement site, and are therefore arranged in a reflectance measurement configuration. *See* [1a], [1c]; APPLE-1005, 17:1-51, 15:23-44, FIG. 22 (reproduced below).



APPLE-1005, FIG. 22 (modified).

129. Therefore, SSUH renders obvious *“wherein the one or more optical sources and the plurality of detectors are arranged in a reflectance measurement configuration.”*

[14d] a light block configured to prevent at least a portion of light emitted from the one or more optical sources from reaching the plurality of detectors without first reaching the tissue;

130. See [1d].

[14e] a surface comprising a dark-colored coating, the surface positioned between the plurality of detectors and the tissue, 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;

131. See [1e].

[14f] 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

132. See [1f].

[14g] a touch-screen display configured to present information responsive to the determined physiological parameter;

133. See [8].

[14h] wherein the physiological measurement device is configured to wirelessly transmit physiological parameter data to a separate device.

134. See [7].

iii. Claim 16

[16] The physiological measurement device of claim 14, wherein the optical transmission material comprises at least one of glass and plastic.

135. See [3], [4], [14].

iv. Claim 17

[17] The physiological measurement device of claim 14, wherein the output light pattern comprises a width and a length, and wherein the width is different than the length.

136. See [9], [14].

v. Claim 18

[18] The physiological measurement device of claim 14, wherein the physiological parameter is oxygen saturation.

137. See [11], [14].

vi. Claim 19

[19] The physiological measurement device of claim 14, wherein the physiological parameter is pulse rate.

138. See [12], [14].

vii. Claim 20

[20] The physiological measurement device of claim 14, wherein the opening defined in the dark-colored coating comprises a width and a length, and wherein the width is larger than the length.

139. See [13], [14].

viii. Claim 21

[21] The physiological measurement device of claim 14, 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.

140. See [5], [14].

XI. CONCLUSION

141. For all the reasons I have noted in the foregoing paragraphs, claims 1, 3-14, and 16-25 of the '743 patent are obvious in view of the references discussed above.

142. I declare under penalty of perjury that the foregoing is true and accurate to the best of my ability. The findings and opinions set forth in this declaration are based on my work and examinations to date.

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

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

Curriculum Vitae

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
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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

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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
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31. MIT Case 18636, Concentric Ring-Based Point Pattern Matching of Skin Features, 05-Apr-16
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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 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:

- 2.1. B. Anthony, A. Abbate, D. Klimek, P. Kotidis., "Analysis of Ultrasonic Waves in Arbitrarily Oriented or Rotating Anisotropic Thin Materials", Quantitative Nondestructive Evaluation. Vol 18. pgs 215 - 222. (1999).
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- 2.14. Lee, J., Boning, D., Anthony, B., "Measuring the Absolute Concentration of Microparticles in Suspension using High Frequency B-mode Ultrasound Imaging", Ultrasound in Medicine and Biology, 2018.
- 2.15. Correa-de-Araujo, R., Harris-Love, M., Miljkovic, I., Fragala, M.S., Anthony, B.W., Manini, T., Newman, A.B., "The Need for Standardized Assessment of Muscle Quality in Skeletal Muscle

- Function Deficit and Other Aging-Related Muscle Dysfunctions: A Symposium Report", *Frontiers in Physiology*, Section on Striated Muscle Physiology, 2017
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 - 2.34 M. Feigin-Almon, D. Freedman, and B. W. Anthony, "A Deep Learning Framework for Single-Sided Sound Speed Inversion in Medical Ultrasound," *IEEE Trans. Biomed. Eng.*, pp. 1–1, 2019.

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- 3.2. David E. Hardt, Brian W. Anthony and Shu Beng Tor, "A Teaching Factory for Polymer Microfabrication – muFac", *Proc. 5th International Symposium on Nano-Manufacturing (ISNM)*, Athens, November 12-15, 2008.
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- 3.12. Donoghue, L., Anthony, B. W., "Design for manufacture of a micro-interdigitated electrode for impedance measurement in a biochemical assay," *Proceedings of SPIE Vol. 8251, 82510Y* (2012).
- 3.13. Holmes, J., Anthony, B. W., "Robustness and repeatability test of interdigitated electrodes on a polymer substrate in an aqueous environment," *Proceedings of SPIE Vol. 8251, 825110* (2012).
- 3.14. Sun, S.-Y, Anthony, B. W. "Freehand 3D ultrasound volume imaging using a miniature-mobile 6-DOF camera tracking system". 2012 IEEE International Symposium on Biomedical Imaging (ISBI), 2-5 May, (2012).

- 3.15. Gilbertson, M.W., Anthony, B.A., 2012. "Ergonomic Controls Strategies for a Handheld Force-Controlled Ultrasound Probe," 2012 IEEE/RSJ Intelligent Robots and Systems (IROS) Conference. Vilamoura, Portugal. (2012)
- 3.16. Sun, S.-Y, Gilbertson, M., Anthony, B. W. "6-DoF Probe Tracking via Skin Mapping for Freehand 3D Ultrasound". 2013 IEEE International Symposium on Biomedical Imaging (ISBI), (2013).
- 3.17. Sun, S.-Y, Gilbertson, M., Anthony, B. W. "Computer-Guided Ultrasound Probe Realignment by Optical Tracking". 2013 IEEE International Symposium on Biomedical Imaging (ISBI), (2013).
- 3.18. Inamdar, T., Anthony, B. W., "Characterizing fluidic seals for on-board reagent delivery," Proceedings of SPIE (2013).
- 3.19. Zakrzewski, A., Anthony, B. W. "Quantitative Elastography and its Application to Blood Pressure Estimation: Theoretical and Experimental Results". 2013 IEEE Engineering in Medicine and Biology Society (EMBS), (2013).
- 3.20. Gilbertson, M. Anthony, B.W., "An Ergonomic, Instrumented Ultrasound Probe for 6-Axis Force/Torque Measurement". 2013 IEEE Engineering in Medicine and Biology Society (EMBS), (2013).
- 3.21. Dhyani, M, Gilbertson, M., Samir, A., Anthony, B.W., "Precise Quantification of Sonographic Forces: A First Step Toward Reducing Ergonomic Injury", 2014 AIUM Annual Convention, (2014).
- 3.22. Koppaka, S., Gilbertson, M., Wu, J., Rutkove, S., Anthony, B. W. "Assessing Duchenne Muscular Dystrophy With Force-controlled Ultrasound". 2014 IEEE International Symposium on Biomedical Imaging (ISBI), (2014).
- 3.23. Koppaka, S., Gilbertson, M., Rutkove, S., Anthony, B. W. "Evaluating the Clinical Relevance of Force-correlated Ultrasound". 2014 IEEE International Symposium on Biomedical Imaging (ISBI), (2014).
- 3.24. J. H. Lee, C. M. Schoellhammer, G. Traverso, D. Blankschtein, R. Langer, K. E. Thomenius, D. S. Boning, B. Anthony, "Towards Wireless Capsule Endoscopic Ultrasound (WCEU)," IEEE International Ultrasonics Symposium (IUS), Chicago, IL, 2014, pp. 734-7.
- 3.25. Zhang, Xiang; Fincke, Jonathan; Kuzmin, Andrey; Lempitsky, Victor; Anthony, Brian, "A single element 3D ultrasound tomography system," in Engineering in Medicine and Biology Society (EMBC), 2015 37th Annual International Conference of the IEEE , vol., no., pp.5541-5544, 25-29 Aug. 2015.
- 3.26. Ranger, Bryan J.; Feigin, Micha; Pestrov, Nikita; Zhang, Xiang; Lempitsky, Victor; Herr, Hugh M.; Anthony, Brian W., "Motion compensation in a tomographic ultrasound imaging system: Toward volumetric scans of a limb for prosthetic socket design," in Engineering in Medicine and Biology Society (EMBC), 2015 37th Annual International Conference of the IEEE , vol., no., pp.7204-7207, 25-29 Aug. 2015.
- 3.27. Lee, John H.; Jimenez, Javier; Xiang Zhang; Boning, Duane S.; Anthony, Brian W., "Ultrasound image-based absolute concentration measurement technique for materials with low scatterer concentration", IEEE International Ultrasonics Symposium (IUS), 2015.
- 3.28. Lee, John H.; Jimenez, Javier; Butterworth, Ian R.; Castro-Gonzalez, Carlos; Shukla, Shiva K.; Marti-Fuster, Berta; Elvira, Luis; Boning, Duane S.; Anthony, Brian W., "Measurement of very low concentration of microparticles in fluid by single particle detection using acoustic radiation force induced particle motion", IEEE International, Ultrasonics Symposium (IUS), 2015.
- 3.29. Anthony, B. W., "Enhanced ultrasound for advanced diagnostics, ultrasound tomography for volume limb imaging and prosthetic fitting," Proc. SPIE 9790, N. Duric and B. Heyde, Eds., 97900Q (2016).
- 3.30. Fincke, J. R., Feigin, M., Prieto, G. A., Zhang, X., Anthony, B., "Towards ultrasound travel time tomography for quantifying human limb geometry and material properties," Proc. SPIE 9790, N. Duric and B. Heyde, Eds., 97901S (2016).
- 3.31. Kuzmin, A., Zhang, X., Fincke, J., Feigin, M., Anthony, B. W., Lempitsky, V., "Fast low-cost single element ultrasound reflectivity tomography using angular distribution analysis," 2016 IEEE 13th Int. Symp. Biomed. Imaging, 1021–1024, IEEE (2016).

- 3.32. Pigula, A. J., Wu, J. S., Gilbertson, M. W., Darras, B. T., Rutkove, S. B., Anthony, B. W., "Force-controlled ultrasound to measure passive mechanical properties of muscle in Duchenne muscular dystrophy," 2016 38th Annu. Int. Conf. IEEE Eng. Med. Biol. Soc., 2865–2868, IEEE (2016).
- 3.33. Ranger, B. J., Feigin, M., Zhang, X., Mireault, A., Raskar, R., Herr, H. M., Anthony, B. W., "3D optical imagery for motion compensation in a limb ultrasound system," Proc. SPIE 9790, N. Duric and B. Heyde, Eds., 97900R (2016).
- 3.34. Zhang, X., Fincke, J. R., Anthony, B. W., "Single element ultrasonic imaging of limb geometry: an in-vivo study with comparison to MRI," Proc. SPIE 9790, 97901R–97901R–7 (2016).
- 3.35. Nguyen, M.M, Graule, M.A., Huang, A.Y, Shamdasani, V., Anthony, B.W., Xie, H., "Ultrasound shearwave elastography with force sensing – integration design and preliminary ex-vivo results.," Proc. Int. Tissue Elast. Conf. 2016 (2016).
- 3.36. Feigin M., Ranger, B., Anthony, B., "Statistical Consensus Matching Framework for Image Registration," IEEE Int. Conf. Pattern Recognition, (2016).
- 3.37. Zakrzewski, A. M., Dhyani, M., Samir, A. E., Anthony, B. W., "Non-Invasive, Non-Occlusive Blood Pressure Estimation Using Ultrasound: Clinical Results (I)," 38th Annu. Int. Conf. IEEE Eng. Med. Biol. Soc. (2016).
- 3.38. Anthony, et al, "Arterial Blood Pressure Estimation Using Ultrasound: Results on Healthy Volunteers and a Medicated Hypertensive Volunteer", 2017 39th Annu. Int. Conf. IEEE Eng. Med. Biol. Soc., accepted (2017).
- 3.39. Anthony, et al, "Non-Invasive Diagnosis of Non-Alcoholic Fatty Liver Disease (NAFLD) using Ultrasound Image Echogenicity", 2017 39th Annu. Int. Conf. IEEE Eng. Med. Biol. Soc., accepted (2017).
- 3.40. Anthony, et al, "Camera-tracking vs. image-based motion compensation in a tomographic limb ultrasound system", 2017 39th Annu. Int. Conf. IEEE Eng. Med. Biol. Soc., (2017).
- 3.41. Fincke JR. Imaging cortical bone using the level-set method to regularize travel-time and full waveform tomography techniques. J Acoust Soc Am. Acoustical Society of America; (2017)
- 3.42. Yang H, Nguyen MM, Huang S-W, Shamdasani V, Xie H, Anthony BW. "Simulation, design, and implementation of external mechanical vibration for ultrasound shear wave elastography.", IEEE International Ultrasonics Symposium (IUS) IEEE; 2017.
- 3.43. A. Benjamin et al., "Non-invasive diagnosis of non-alcoholic fatty liver disease (NAFLD) using ultrasound image echogenicity," 2017 39th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC), Seogwipo, 2017,
- 3.44. H. Yang, A.Benjamin, B. Anthony, "Simulation of multi-source external mechanical vibration for shear wave elastography," The Journal of the Acoustical Society of America, 142, 2017
- 3.45. Singh, R., Ma, D., Agarwal, A., & Anthony, B. W. (2018). On-chip photonic particle senso. Presented at the SPIE BiOS, San Francisco, CA.
- 3.46. Kundu, I., & Anthony, B. W. . "Imaging the superficial vascular structure for mapping and identification." |SPIE Smart Structures and Materials + Nondestructive Evaluation and Health Monitoring, Denver, Colorado. (2018)
- 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 Fahrenheit, "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