

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.
Petitioner,

v.

CLEVELAND MEDICAL DEVICES, INC.,
Patent Owner.

Case IPR2025-00247
U.S. Patent No. 11,872,029

**DECLARATION OF DR. DAVID A. BORKHOLDER
IN SUPPORT OF PATENT OWNER'S RESPONSE**

I. INTRODUCTION

I, David Borkholder, declare as follows:

1. I have been asked by Patent Owner Cleveland Medical Devices Inc. (“Patent Owner” or “CleveMed”) to submit this declaration in the matter referenced above. I have reviewed U.S. Patent No. 11,872,029 (“the ’029 Patent”), its prosecution history, the *inter partes* review petition that Petitioner ResMed Corp. (“Petitioner” or “ResMed”) submitted regarding the ’029 Patent, the decision to institute by the Patent Trial and Appeal Board (“PTAB”), and the art cited in those documents. I am familiar with the technology at issue and what was known in the art at the time of the earliest priority date for the ’029 Patent which is November 4, 2005.

II. EXPERIENCE AND QUALIFICATIONS

2. The details of my education, work experience, and research are summarized in my curriculum vitae (“CV”) attached to this Report as Appendix A. I have summarized some of the relevant information which is on my CV herein.

3. I hold a Ph.D and M.S. in Electrical Engineering from Stanford University, Stanford, California, and a B.S. in Microelectronic Engineering from the Rochester Institute of Technology (RIT), Rochester, New York. I have over 30 years of professional engineering experience in industry and academia.

4. Since 2004 I have taught as a professor at RIT, including as an Assistant Professor of Electrical Engineering and Microsystems Engineering, Associate Professor of Electrical and Microelectronic Engineering, and Bausch + Lomb Associate Professor and later Bausch + Lomb Professor of Microsystems Engineering. From 2016 to 2020, I also served as Director of Personalized Healthcare Technology at RIT. I oversaw undergraduate and graduate education and research in the areas of electronics, sensors, MEMs, and biomedical engineering. Courses I taught included Electronics I and II, Fundamental Electrophysiology, Biomedical Sensors and Transducers, Biomedical Instrumentation, Introduction to Nanotechnology and Microsystems, Introduction to Product Development (Honors), Reverse Engineering (Honors), and The Design Process (Honors). I co-founded the biomedical option in electrical engineering in 2004 and defined key elements of the curriculum. My research focused on Microsystems for inner ear drug delivery and fundamental studies of auditory function; non-invasive physiological monitoring; and personnel borne sensors for blast dosimetry and traumatic brain injury. During this time, I also had an appointment at the University of Rochester as an Adjunct Assistant and then Associate Professor of Otolaryngology and an Adjunct Associate Professor of Biomedical Engineering. I retired in 2024 and now hold the title of Professor Emeritus.

5. While at RIT, I became Co-Founder and Chairman of the Board of Casana (formerly Heart Health Intelligence, Inc.) (Rochester, NY), which is a technology spin-out company based on in-home cardiovascular monitoring systems developed in the Borkholder Biomedical Microsystems Laboratory at RIT and exclusively licensed to Casana. I worked with the founder to define the company's business strategy and fundraising pitch. The company closed its first round of financing in September 2019, a Series A financing in August 2020, and a Series B financing in January 2022, for a total investment of \$46 million. From 2020 to March 2024, I worked at Casana full-time as its Chief Research Officer. Casana provides innovative healthcare delivery with a smart toilet seat that enables in-home health monitoring that is self-powered and easily accessible for the patient and provides clinically reliable data to health providers to respond to health changes in near real time. Casana's Heart Seat, which has been cleared by the FDA, uses proprietary algorithms to detect changes in heart rate and blood oxygenation to help care teams monitor patients' health trends. Casana's mission is to improve health and wellness through in-home health monitoring.

6. Also, while at RIT, from 2011 to 2021, I was Founder, Executive Chairman, and Chief Technology Officer of BlackBox Biometrics, Inc. (B3), which is the industry leader in sensor technology that instantly assesses forces that can cause traumatic brain injury. B3 formed as a technology spin-out company

based on the Blast Gauge Technology (www.blastgauge.com) developed in the Borkholder Biomedical Microsystems Laboratory at RIT and licensed exclusively to B3. As part of B3, I established the leadership team, and engineering, manufacturing, and customer service capabilities for commercialization of the Blast Gauge system. I championed efforts to treat blast overpressure exposure as an occupational hazard, which influenced congressional legislation in the FY18 and FY19 National Defense Authorization Acts, and specific brain health policies for the Department of Defense and Special Operations Command. As part of this work, I was interviewed for a November 27, 2023 front page New York Times article entitled “U.S. Troops Still Train on Weapons with Known Risk of Brain Injury.” One of my statements was selected as the New York Times Quotation of the Day. B3 was acquired by Airboss Defense Group in 2021.

7. Prior to becoming a professor at RIT, from 2001 to 2004, I served as Director of Hardware Engineering at ZONARE Medical Systems, Inc. (Mountain View, CA). In this role, I directed the Hardware Engineering group in the development of a portable ultrasound system utilizing non-traditional imaging techniques. My group developed three application-specific integrated circuits (ASICs), specifically analog, mixed signal, and high voltage, from concept to design, packaging and qualification, and successfully engineered a full-featured

medical diagnostic imaging system following requirements of the Food and Drug Administration (FDA) and International Organization for Standards (ISO).

8. From 1998 to 2001, I worked at Cepheid (Sunnyvale, CA), which was publicly traded (on NASDAQ) from 2000 to 2016, achieving a peak market cap in excess of \$4.5 billion. In 2016, Cepheid was acquired off the public market by Danaher Corp for \$4 billion. At Cepheid, I worked on programs for DNA analysis that were funded by the Defense Advanced Research Projects Agency (DARPA), a research and development agency of the United States Department of Defense responsible for the development of emerging technologies for use by the military. Additionally, I managed development of a ruggedized, battery powered thermal cycler to the United States Army Medical Research Institute for Infectious Diseases (USAMRI-ID). As Director of Electronic Systems at Cepheid, I directed the development of GeneXpert, a fully automated sample processing system capable of extracting DNA from raw samples and performing DNA analysis. This platform was chosen by the United States Postal Service for screening the mail for the bioterrorism agent *Bacillus Anthracis* (Anthrax).

9. From 1989 to 1992, while obtaining my B.S. at RIT, I worked at Eastman Kodak Company on a variety of projects within the Microelectronics Technology Division involving the manufacture and characterization of charge-

coupled device (CCD) image sensors. The results of this work were used to design production changes for enhanced imager sensitivity.

10. My Ph.D. dissertation at Stanford is entitled “Cell-Based Biosensors Using Microelectrodes.” For this dissertation, I designed and built microelectrode based sensors to monitor the morphology and electrophysiological activity of cultured cells as a means for toxin detection and pharmaceutical screening. I developed microelectrode arrays, novel packaging techniques, and fluidic systems for interfacing to, and maintenance of the cultured cell systems. I created interface electronics and software for signal detection and interpretation for both action potential and impedance measurements. I also developed new signal processing techniques to improve measurement specificity and allow classification of unknown biologically active agents. While teaching at RIT, I have also advised a number of students in obtaining their Ph.D. and M.S. degrees and served as a member of dissertation panels.

11. I have also conducted extensive funded research. I have been the principal investigator on over \$21 million in research funding from federal government and industry sponsors, \$10.8 million of that in my role as a professor at RIT. As co-investigator, I have contributed to additional total research awards of \$5.4 million at RIT. The funding I have received has been provided through government agencies, such as the National Institute of Health (NIH) and National

Institute on Deafness and Other Communication Disorders (NIDCD), as well as industry, such as Google.

12. I have served on numerous committees, review panels, and professional organizations. For instance, I have served on study sections for the NIH, for which I reviewed NIH grant applications as a scientific expert, including as Chair of the NIH Bioengineering of Neuroscience, Vision and Low Vision Technologies (BNVT) study section from 2014 to 2016. I served as the Director of the Personalized Healthcare Technology Initiative at RIT from 2016 to 2020. I have been an Associate Editor of the Institute of Electrical and Electronics Engineers (IEEE) Journal of Translational Engineering in Health and Medicine from 2019 to the present and an Editorial Section Board member of the journal Micromachines from 2020 to the present. I am currently a Senior Member of the IEEE, and belong to the IEEE Engineering in Medicine and Biology Society. In 2023 I was named to the Rochester board of the American Heart Association.

13. I have received various honors in my field, including Fellow of the American Institute for Medical and Biological Engineering (2020); Distinguished Inventor of the Year - Rochester Intellectual Property Law Association (2016); and Rochester Business Journal Health Care Achievement Award: Innovation (2014) for research leading to the successful commercialization and fielding of the Blast Gauge System. I am named as an inventor on 29 issued patents.

14. I have published numerous articles and papers and spoken at various conferences and invited talks. Since March 2021, I have been serving on research task group for the North Atlantic Treaty Organization (NATO) for the Human Factors and Medicine (HFM) panel on “Guidelines to mitigate military occupational brain health risks from repetitive blast exposure,” and the NATO HFM panel on “Blast Exposure Monitoring in Military Training and Operations.” I have also served for a number of years on the DARPA Defense Sciences Research Council, which has run studies for DARPA to identify white space opportunities for the agency, frequently leading to new DARPA programs. I led biomedical studies such as New Tools for Neuroscience, Information in the Brain, and Towards Non-Invasive Measurement of Neural Activity in Humans.

15. My work as described above has focused on the biomedical aspect of electrical engineering. All of my research has been biomedical, and I taught courses for the biomedical option in electrical engineering at RIT. Also, Cepheid, Zonare, and Casana are all medical device companies: Cepheid is DNA diagnostics, Zonare is ultrasound, and Casana is non-invasive in-home cardiovascular monitoring. At Casana, the system is installed in the home to automatically collect physiological data. The data is captured, wirelessly transmitted to a remote cloud database, and then analyzed by cloud-based algorithms to extract key parameters from the collected sensor waveforms. These

parameters are then presented to medical personnel to monitor the health of the patient.

III. COMPENSATION

16. My time is being billed at a rate of \$645 per hour, plus any direct expenses incurred. My compensation is based solely on the amount of time that I devote to activity related to this case and is in no way affected by any opinions that I render. I receive no other compensation from work on this action. My compensation is not dependent on the outcome of this matter.

IV. LEGAL STANDARDS

17. I understand that if a patent has an effective filing date that is before March 16, 2013, the “pre-AIA” (America Invents Act) versions of 35 U.S.C. §§ 102 and 103 apply. Each of the Asserted Patents was filed before March 16, 2013, or claims priority to an application filed before March 16, 2013. § 102(a). I understand that a patent is valid under pre-AIA 35 U.S.C. § 102(a) unless the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

18. I understand that the requirement of “known or used by others in this country”, means knowledge or use which is accessible to the public. The knowledge or use relied on in a pre-AIA 35 U.S.C. § 102(a) must be knowledge or

use “in this country.” Prior knowledge or use which is not present in the United States, even if widespread in a foreign country, cannot be the basis of a prior art under pre-AIA 35 U.S.C. § 102(a).

19. I understand that a patent is valid under pre-AIA 35 U.S.C. § 102(b) unless the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States. I understand that § 102(b) (pre-AIA) includes several distinct bars regarding the prior art status, each of which relates to activity or disclosure more than one year prior to the date of the application.

20. An invention is in “public use” under pre-AIA § 102(b) where the invention is in public use before the critical date of the application and is ready for patenting. The test for public use is whether the purported use: (1) was accessible to the public; or (2) was commercially exploited. I understand that commercial exploitation will likely require more than, for example, a secret offer for sale. I also understand that mere knowledge of the invention by the public does not necessarily constitute a bar under pre-AIA § 102(b) as the pre-AIA § 102(b) requires public use or sale, not public knowledge. An invention is “on sale” under pre-AIA § 102(b) if the invention is both (1) the subject of a commercial offer for sale not primarily for experimental purposes and (2) ready for patenting.

21. I understand that if a reference is only distributed internally within an organization and is intended to be confidential, it is not considered a “printed publication.” Further, I understand that where indexing is concerned, the reference must have been available in such a way that a person of ordinary skill in the art would be able to locate it.

22. For example, the presence of a document on the Internet does not necessarily mean that the document is a printed publication because it may not be catalogued or indexed in a meaningful way or available. Rather, it must be available in a meaningful way (e.g., indexing by subject matter) such that a person interested in the art may be able to locate it.

A. Obviousness

23. I have been informed that if a single reference does not contain every limitation of a patent claim, it can only invalidate that claim if it would be obvious when considered in light of other prior art references or devices without viewing the combination with hindsight bias. Only if the differences between the claimed invention and the prior art are such that the claimed invention, as a whole, would have been obvious to a person having ordinary skill in the art at the time the invention was made without the benefit of hindsight is the claim invalid. I have been informed that the types of 35 U.S.C. § 102 prior art described above can individually be a basis for invalidating a patent, or these references can be

combined to show a patent is invalid as obvious under 35 U.S.C. § 103. I have been informed that the analysis of obviousness involves several factual inquiries including the scope and content of the prior art, the differences between the prior art and the claim, and the level of ordinary skill in the art at the time of the invention.

24. I have been informed that the test for analogous art is very specific. I have been informed that art is non-analogous unless it is: (1) from the same field of endeavor as the claimed invention; or (2) reasonably pertinent to the particular problem faced by the inventor. I have been informed that an art citation that is not from the same field of endeavor as a claimed invention must be “reasonably pertinent” to the problem addressed by the inventor. I have been informed that art is “reasonably pertinent” when it would “logically commend itself” to an inventor’s attention in considering his problem. Conversely, I have been informed that when art is directed to a different purpose than a claimed invention, an inventor would have less motivation or occasion to consider it. I have been informed that the fact that prior art references all concern the same field of endeavor is not in itself sufficient rationale for making the combination. Many types of techniques and systems exist in the same field of endeavor. That fact alone would not make it obvious to combine their features. I have been informed that a proper obviousness determination must show why a person of ordinary skill in the

art would have thought to combine particular available elements of knowledge, as evidenced by the prior art, to reach the claimed invention.

25. I have been informed that a party seeking to invalidate a patent on obviousness grounds must demonstrate by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.

26. I have been informed that the party seeking to invalidate a patent on obviousness bears the burden of particularly explaining (1) the primary and secondary references, (2) the missing elements supplied by the secondary references, (3) why a POSITA would have looked to the secondary reference to fill gaps in the primary reference, and (4) why adding the secondary reference's teaching would yield predictable results.

27. I have been informed that to establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. I have been informed that if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious.

28. Additionally, I understand that a patent is likely to be invalid for obviousness if a person of ordinary skill in the art can implement a predictable variation or if there existed at the time of the invention a known problem for which there was an obvious solution encompassed by the patent's claims. A combination is not obvious, however, where the combination cannot be implemented without undue experimentation or when the motivation to create the combination comes from hindsight.

29. I have been informed that, even when all claim limitations can be found in a combination of prior art references, the fact-finder must consider as part of the obviousness determination not only what the prior art teaches, but whether the prior art teaches away from the claimed invention and whether there is a motivation to combine teachings from separate references in the manner claimed. I have been informed that, in assessing whether a claimed invention is obvious, secondary considerations that may weigh towards the non-obviousness of the invention, including the following, should be considered:

- a. Whether the claimed invention satisfied a long-felt need;
- b. Whether the claimed invention was preceded by a history of failures by others to solve a problem or problems solved by such invention;

- c. Whether the claimed invention achieved a surprising or unexpected result;
- d. Whether the claimed invention exhibited performance superior to prior art devices and/or methods;
- e. Whether the claimed invention has achieved commercial success;
- f. Evidence of industry acquiescence;
- g. Licenses;
- h. Whether the claimed invention has been copied;
- i. Whether the claimed invention was the subject of skepticism by the industry; and
- j. Whether the prior art taught away from the claimed invention

30. I have been informed that there must be a nexus tying the evidence of secondary considerations to the unique characteristics of the claimed invention. Nexus can be established via a presumption when the evidence is tied to a product that embodies and is coextensive with the claims. Even without a presumption, nexus can be shown by tying the evidence to the unique characteristics of the claimed invention. I have also been informed that nexus is not limited to only novel features, but considers the invention as a whole.

V. PERSON OF ORDINARY SKILL IN THE ART

31. I understand that for purposes of this IPR, a person of ordinary skill in the art (“POSITA”) in 2005, is someone who “had at least a bachelor’s degree in mechanical engineering, electrical engineering, computer science, biomedical engineering, or a similar technical field, with at least two years of relevant product design experience working with diagnostic sensor systems and network data systems, such as networked PAP machines.” Pet. at 4. “Additional experience could substitute for less education, and additional education could likewise substitute for less experience.” *Id.* I use this POSITA for my opinions.

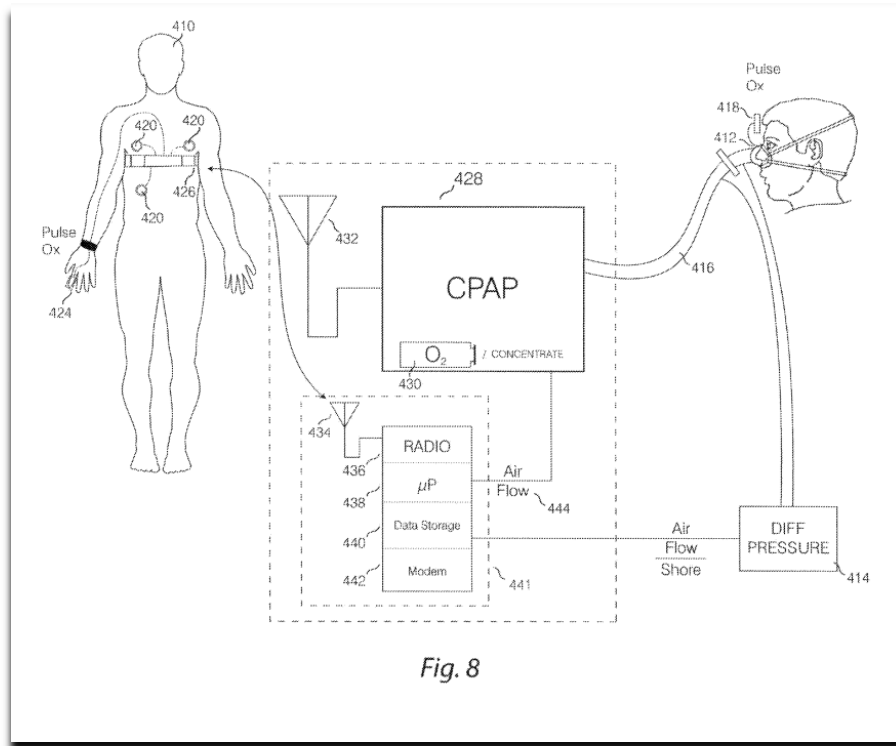
VI. OVERVIEW OF THE ’029 PATENT

32. The ’029 Patent relates to a novel integrated sleep diagnosis and treatment device for patients suffering from sleep apnea. ’029 Patent at Abstract, 1:31-35. The device (1) analyzes the patient’s breathing metrics, including parameters related to a patient’s breath, such as respiratory airflow and effort, and blood oxygenation levels, and (2) adjusts the treatment based, at least in part, on this analysis. *Id.* at 2:49-56, 3:21-56.

33. The claimed invention uses a positive airway pressure (“PAP”) device with internal airflow sensors that detect the patient’s respiratory airflow data. *Id.* at 7:36-8:41. The readings from airflow sensors are collected and processed by the PAP’s device processor(s) to indicate the data of severity of a patient’s sleep

disorder symptoms that is used along with the usage of the PAP device to generate an index (*e.g.*, respiratory disturbance index (RDI), apnea-hypopnea-index (AHI)), related to the patient's treatment and the treatment's efficacy, which are transferred to a remote internet site and a cell phone for display. *See id.* at Claim 1. The PAP device may distinguish between, and calculate the severity of, obstructive and central apneas and then be adjusted remotely based on the data sent to the remote internet site. *See id.* at Claims 12, 18.

34. An exemplary embodiment of the PAP device, shown below, includes a pressure generator, a blower with an air output, a mask or nasal cannula, a flow sensor, and a pressure sensor, with a microprocessor 438 for processing the data or signals from the flow sensor to determine the data of severity of the patient's sleep disorder symptoms and/or index related to the treatment's efficacy:



'029 Patent at FIG. 8, 23:31-54.

35. The calculated information is used to control the pressure or flow of gas provided to the subject, initiate a medicinal intervention, monitor the condition of the subject, and/or monitor the usage of the pressure support device. *Id.* at 22:22-25, 23:20-30, Claims 6, 12, 14, 18.

VII. OVERVIEW OF THE ASSERTED REFERENCES

A. Truitt (Ex. 1007)

36. Truitt discloses a conventional PAP device with no disclosed ability to integrate the PAP device with other devices. The Truitt invention “pertains to a technique for measuring gas flow and/or volume in a pressure support system” so

that its signal “can be used in the same manner” as those sensors used in conventional PAP devices. Truitt at 1:12-13, 3:41-46, 3:66-4:1.

37. The claims of the '029 Patent require a PAP device that measures a subject's respiratory airflow and calculates symptom severity data. '029 Patent at Claim 1. On the other hand, Truitt's invention seeks to measure the airflow provided to the patient, like conventional PAP devices, but without the flow sensors found on those conventional PAP devices. Truitt at 3:66-4:3, 5:35-38, 6:38-60. Thus, rather than disclose any new functionalities, Truitt discloses conventional functions, such as monitoring the pressure or flow of gas delivered to the patient, adjusting the pressure or flow in a feedback fashion to meet the desired prescription pressure level, and adjusting pressure based on the breathing cycle. *Id.* at 2:60-3:4. Measurements of the airflow delivered to the patient do not represent the patient's respiratory airflow; they represent the airflow provided to the patient.

38. Further Truitt describes the conventional CPAP auto-titration mode distinguished in the '029 Patent “where the flow of breathing gas and the pressure level thereof is controlled based on the conditions of the patient, these pressure and flow sensors, or other sensors, such as a microphone, are used to detect snoring, apneas, hypopneas, etc.” Truitt at 3:4-9; *id.* at 1:35-43 (describing the same known CPAP therapy, which changes pressure based on the detection of snoring or upper

airway resistance); '029 Patent at 2:32-37 (“More advanced, but still very basic devices have been developed that adjust this continuous positive gas pressure through sensors built into the device for creating the positive gas pressure, which measure gas flow through the device. These basic adjustable devices have been found to be expensive and largely ineffective.”). However, the feedback loop is not based on physiological data or symptom severity data but rather just whether an abnormal pressure or flow level is detected within the device. '029 Patent at 2:38-40 (“None of the devices on the market can be used to adjust a patient's treatment, whether physical or chemical, based on the patient's current physiological state.”). That this event may be assigned as an apnea does not show that the subject's symptom severity is quantified and used to adjust the PAP device.

39. As was known at the time, the determinations made by Truitt were highly inaccurate and not suitable for patient monitoring because conventional PAP devices (1) were not controlled by physiological feedback and (2) supplied air at different periods that were not always beneficial to the patient. Truitt at 3:21-36; *see also* Ex. 1002 at 160 (quoting Geva ¶ [0299]: “[c]onventional CPAP systems . . . have several drawbacks: (1) apnea events may return whenever the CPAP is used improperly, which is normally the case because conventional CPAP systems are poorly controlled, or not controlled at all, by physiological feedback. Therefore,

these systems output a constant continuous pressure, or vary the pressure to coincide with the person's breathing pattern, or start with low pressure, after which the pressure is gradually increased From technical point of view conventional CPAP systems are inefficient, because they supply, at different periods, air that is not beneficial to the patient.”). As shown by the National Library of Medicine, “[p]hysiological feedback is mediated through extensive feedback mechanisms that use physiological cues as feedback loop signals to control other systems.” Ex. 2017 at 1.

B. Kumar (Ex. 1008)

40. Kumar discloses a system and method for network-based monitoring of physiological data. Kumar at Abstract. Kumar's patient-side device 102 transmits signal data to computing device 110, which forwards that data to central server 106, from which it is sent to a medical provider. *Id.* at FIG. 1A. The signal data transmitted from the patient-side device is received and analyzed using computing device 110's data interpretation and analysis module 114. *Id.* at ¶ [0075] (“data interpretation and analysis module 114 is used to interpret the data stream from the client-side device, perform mathematical analysis on the data using FFT, DFT, etc., and generate statistics”).

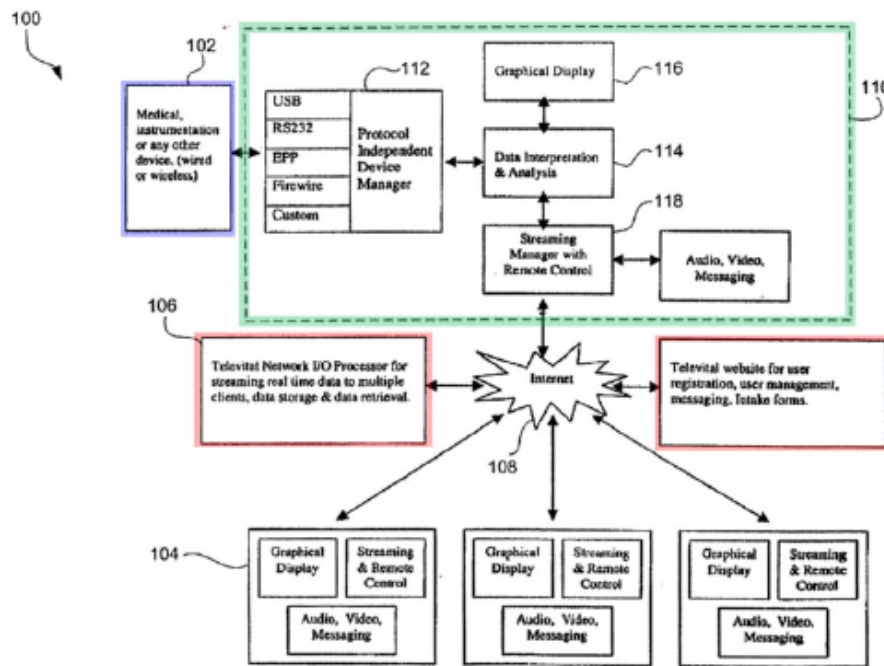


Fig. 1A

Pet. at 23 (citing Kumar, Fig. 1A) (annotated); *see also* Kumar at ¶ [0067] (“[T]he system includes one or more patient-side devices 102 for collecting data from a patient/client, one or more provider-side devices 104, and an engine implemented on a central server 106.”); Kumar at Fig. 5, ¶¶ [0078]-[0083], [0091]-[0092].

41. A POSITA would understand, that based on the type of sensors and devices described in Kumar, its implementation regarding its use for sleep apnea, its intended purpose is to replace attended, in-laboratory testing with “on-line live monitoring.” Kumar at ¶ [0240-241] (disclosing that its system is intended for monitoring devices used in traditional in-home sleep testing, using polysomnography and oximetry, and in standard in-laboratory polysomnography

and breathing monitoring, using thermocouples or thermistors, thoracic EMG or inductive plethysmography, and oximetry); *id.* at ¶ [0179] (“Data collected by the unit is processed by the system to provide real-time medical monitoring, summary reports, statistical calculations, and visual displays, which can further be tailored for the healthcare provider’s particular needs, and can each be tailored for a particular protocol.”).

C. Mumford (Ex. 1009)

42. Mumford’s sleep efficacy algorithm requires signals from a combination of electrodes integrated into its mask, as the primary inputs for its sleep efficacy algorithm. Mumford at 15:39-16:3 (the sleep efficacy algorithm uses “a frontal staging algorithm, ***based on at least the electrode signals***, to determine which stage of sleep the wearer 18 is in.”) (emphasis added); *id.* at 15:42-46. Without at least a combination of electrodes being used, Mumford’s sleep efficacy algorithm would be useless. *See id.* at Claims 1, 17-19, 24 (Mumford independent claims all claiming multiple sensors and electrodes used within the mask assembly).

43. Mumford discloses “a mask assembly with integrated sensors for sensing the efficacy of treatment of medical conditions.” Mumford at 1:20-22. “The mask assembly 12 further includes sensors (e.g., electrodes E1, E2, E3, E4 and E5 of FIGS. 2a and 2b) positioned on the nasal mask 12, the straps 24 and 26 .

...” *Id.* at FIGS. 2a-b, 7:22-25, 9:40-10:24. The mask sensors are connected to the monitoring unit and include electrodes for detecting EEG, EMG, EOG, and sensors for detecting blood oximetry, body position, and pressure. *Id.* at 7:25-33. The sensors are integrated directly into the inner surface of the mask so that the electrodes rest against the skin of the wearer. *Id.* at 7:58-60, 8:24-27, 8:40-45 (providing examples of the sensors that are preferable because they require minimal preparation of the skin of the CPAP wearer), 8:46-67 (discussing metal, saline, disk, and peel and stick electrodes that may directly integrated into the mask and require additional preparation prior to use), 9:2-6 (discussion how it is beneficial for the wearer to prepare their skin in the locations where the electrodes are used).

44. The locations of the various electrodes are chosen to be “on the face and head of the wearer 18 in order to obtain good signal quality and different types of physiological data with a minimal number of electrodes.” Mumford at 9:17-39 (discussing the physiological data collected from the electrodes providing data related to the CPAP wearer’s brainwaves, facial muscle tone and eye movements). Mumford also discloses the electrodes can be used in different combinations but in each instance, Mumford discloses using multiple sensors for gathering physiological information, never just a single sensor. *Id.* at 10:51-11:48. Thus, Mumford discloses that multiple sensor electrodes are necessary to supply the

multiple channels of physiological information necessary for its algorithm to function as intended *Id.* at 10:66-11:16.

45. Mumford has an alternative mask assembly embodiment with an integrated oximeter, pressure transducer, and position sensors. *Id.* at 11:66-12:21. In that embodiment, the pressure transducer is disposed within the nasal cavity of the mask so that it is near the gas inlet. *Id.* The pressure transducer is used to detect the pressure within the mask for deriving the breathing rate of the wearer to provide an indication of apnea and hypopnea events. *Id.* at 12:42-46. The electrodes and sensors are connected to a monitoring unit 16 with mask interface 602 module. *Id.* at 7:27-33, 14:65-66. The physiological information provided by the various sensors is processed by the monitoring unit according to a sleep efficacy algorithm that determines the sleep stage of the wearer and how many arousals they experienced. *Id.* at 7:34-42. Mumford also discloses using these parameters to control the CPAP. *Id.* at 7:46-51.

VIII. GROUND 1: THE CHALLENGED CLAIMS ARE PATENTABLE OVER TRUITT IN VIEW OF KUMAR

A. Grounds 1-3: The Challenged Claims are Patentable Over Truitt and Kumar

1. Truitt Does Not Disclose Measuring or Deriving the Respiratory Airflow of a Subject while using the PAP or Outputting Airflow Sensor Data

46. It is my opinion that the Petition fails to demonstrate that Truitt discloses “an airflow sensor internal to the enclosure of the PAP device adapted for measuring or deriving the respiratory airflow of a subject while using the PAP.” ’029 Patent at Claim 1; Pet. at 27-29. Neither Petitioner nor its experts explain how measuring the airflow provided to the patient is either a measurement or derivation of the *patient’s* respiratory airflow. Pet. at 28; Ex. 1003 (Kirkness Decl.) at ¶ 219 (opining that the airflow “signal that controller 38 uses to calculate gas flow and/or volume passing through conduit 56” is used to control “the operations of blower assembly 52 . . . and/or the operation of valve 40 that controls air flow and pressure provided to the patient”); Ex. 1005 (Chatterjee Decl.) at ¶ 106 (“flow sensing assembly 72 . . . measures the pressure differential that can be used for calculating the flow of gas”).

47. Truitt discloses that its conventional PAP device merely receives flow and/or pressure signals and adjusts the internal flow or pressure “in a feedback fashion,” but that does not disclose or imply that the system derives respiratory airflow:

Controller 38 receives the signals output from sensors 20 and 22 and controls the operation of valve 40, pressure generator 12, or a combination thereof in a feedback fashion based on these received signals. For example, in a simple CPAP device, controller 38 monitors the pressure

or flow of breathing gas delivered to the patient and adjusts the pressure or flow in a feedback fashion to meet the desired prescription pressure level.

Truitt at 2:57-64. Using this feedback technique, conventional PAP devices measured the airflow being provided **to the patient** within the device and (1) provide bi-level pressure support, “where the pressure is greater during inspiration than during expiration,” or (2) auto-titrate pressure to counteract or prevent “snoring, apneas, hypopneas, etc.” Truitt at 2:64-3:11.

48. Determining whether a patient may be inhaling or exhaling so that a bi-level system can change its programmed pressure level, does not provide the necessary airflow sensor data of the subject needed to “derive the [subject’s] respiratory airflow” and calculate “data of a severity of the [subject’s] sleep disorder systems” in Claim 1. Paper 12 (Institution Decision) at 24-26; Truitt, 6:49-60.

49. The ’029 Patent describes that a subject’s respiratory airflow can be derived using a “pneumotachograph” “connected to a pressure transducer,” or through “nasal or oral airway pressure” fluctuations. ’029 Patent at 8:12-22. Using either method, a POSITA would recognize that just providing for the “flow and/or volume passing through the conduit” to the patient does not provide a

measurement or derivation of the subject's respiratory airflow without more processing of the airflow signal. Ex. 1003, ¶219.

50. Although Truitt's system may detect certain symptoms, like snores, apneas, and hypopneas, it does not disclose detecting these symptoms as a function of the patient's respiratory airflow *or* how to derive the patient's respiratory airflow from the measurements that its system does take. Truitt at 2:57-60, 6:39-48. Also, Truitt does not disclose how its airflow sensor data can be used in calculating the data of a severity of the sleep disorder symptoms.

51. Therefore, it is my opinion that Truitt does not disclose "an airflow sensor internal to the enclosure of the PAP device adapted for measuring or deriving the respiratory airflow of a subject while using the PAP."

2. Truitt and Kumar Do Not Disclose a Processor Within the PAP Device that Receives Airflow Sensor Data and Calculates Data Indicative of the Severity of the Patient's Symptoms

52. It is my opinion that Truitt does not disclose a PAP device with a processor that receives airflow sensor data and calculates data indicative of the severity of the patient's symptoms, and Petitioner does not suggest that Kumar cures Truitt's deficiencies. Pet. at 17-21, 28-29.

53. I agree with the litigation claim construction opinions of Dr. Jafari that a POSITA would readily understand that "data of a severity" for the subject's symptoms indicates "the degree of deviation from the baseline characteristics of a

patient without sleep disorder symptoms.” Ex. 2020 (Jafari Decl.) at ¶¶ 41-42, 46.

In the context of the ’029 Patent the terms “data of a severity” and “sleep disorder symptoms” are terms of art that are readily understood by POSITAs. They have known algorithms to identify different categories of respiratory events (such as central or obstructive apneas, hypopneas, Cheyne-stokes breathing) and determine the level of severity of the patient’s sleep breathing disorder symptoms associated with those events. *See also* Ex. 2020 (Jafari Decl.) at ¶¶ 39-40, 46.

54. Petitioner’s suggestion that Truitt discloses this limitation “because it discloses monitoring the patient’s condition, and specifically detecting snoring, apneas, and hypopneas,” relies on an unsupported and overly broad interpretation of the term “data of a severity of the symptoms of the subject.” Pet. at 17-18; Paper 12 at 27-28. As the Board previously determined for a parent of the ’029 Patent:

Based on the above disclosures in the specification, we agree with Patent Owner that the specification discloses that the gathered information is processed to monitor the condition of the subject (i.e., the system quantitatively estimates or determines the “severity of sleep disorder symptoms”) and how much pressure / flow of gas is to be provided to the subject (i.e., the system calculates the “usage of the PAP device by the subject”).

ResMed Corp. v. Cleveland Med. Devices, Inc., No. PGR2024-00012, Paper 7 at 16 (P.T.A.B. June 24, 2024) (finding written description support for the term, “data of severity of sleep disorder symptoms of the subject and the data of usage of the PAP device by the subject both calculated by the PAP device”). The Board’s findings were supported from the specification’s discussion of the ’029 Patent processor’s analytical functionality upon the received sensor signals. *See id.* at 14-16 (citing ’284 Patent¹ at 3:21–23, 8:37–41, 19:3–17, 23:20–25). It is my opinion that this interpretation by the Board of what constitutes usage and severity data is fatal to Petitioner’s reliance upon Truitt.

55. *First*, the Board’s determination that “monitor[ing] the condition of the subject” means to “quantitatively” calculate “severity of sleep disorder symptoms” not merely to detect symptoms. *ResMed Corp.*, No. PGR2024-00012, Paper 7 at 14-16; ’029 Patent at Claim 1. Accordingly, merely identifying symptoms, like snores, apneas, and hypopneas is not tantamount to calculating “data of a *severity* of the symptoms of the subject.” Pet. at 17-18. Indeed, Truitt

¹ The same disclosures are found in the ’029 Patent at 3:25-27, 8:43-46, 19:8-22, 23:23-30.

gives no guidance as to how one would quantitatively determine the severity of the subject's symptoms once they were detected. *Id.*

56. Truitt represents the type of “more advanced” CPAP machines distinguished in the '029 Patent, which could “adjust this continuous positive gas pressure through sensors built into the device,” but which were unable “to adjust a patient's treatment, whether physical or chemical, based on the patient's current physiological state.” '029 Patent at 2:32-42. These systems, which “measure[ed] gas flow through the device,” were found to be “expensive and largely ineffective.” *Id.* Notably, Petitioner does not attempt to distinguish Truitt's machine from the “basic adjustable devices” distinguished in the '029 Patent.

57. This is further confirmation that the basic adjustable CPAPs, like Truitt were unable to monitor the physiological condition of the patient through the generic identification of snores apneas, and hypopneas via “measur[ing] gas flow through the device.” '029 Patent at 2:28-48. This is because accounting for just the flow of gas within the device to register a generic event count from abnormal sensor readings fails, those readings are prone to inaccurate data generation caused by patient misuse or a leak in system rendering it not indicative of the subject's physiological condition. *See* Ex. 1002 at 160 (citing Geva ¶ [0299]).

58. Petitioner’s reasoning on this point is also wrong because it assumes that all ways of monitoring a patient’s condition involve “calculating ‘data of severity of sleep disorder symptoms.’” Pet. at 17. While calculating severity data is one way to monitor a patient’s condition, the opposite is not true: there are boundless ways to monitor a patient’s condition (taking the patient’s temperature, pulse, blood pressure, etc.) that are entirely unrelated to calculating the severity of a patient’s symptoms. See Truitt at 3:4-9 (disclosing that in auto-titration mode, “other sensors, such as a microphone, are used to detect snoring, apneas, hypopneas, etc.” in addition to pressure and flow sensors). Accordingly, I find no basis for Petitioner’s conclusion that Truitt teaches calculating severity data from airflow sensor data merely because it discloses monitoring the patient’s condition. *Id.*

59. *Second*, although Truitt discloses detecting individual disordered breathing events, it does not disclose calculating indices like AHI, which represent the severity of the patient’s symptoms. Pet. at 18-21. Petitioner does not claim that Truitt expressly discloses calculating an index, like AHI, it argues that Truitt’s use of “data collected while using the PAP device” to “counteract or prevent” apneas and hypopneas satisfies the claimed “index.” *Id.* at 21. That is not correct: Like the PAP machines distinguished in the background of the ’029 Patent Truitt discloses using “auto-titration,” or a bi-level mode, which responds immediately to

changes in pressure detected at the CPAP machine. Truitt at 1:30-43, 6:49-60.

These interventions are made in real-time as the breathing event occurs and cannot be based on any *index* calculated over time.

60. Additionally, Petitioner's assertion that a POSITA ***could have*** calculated the patient's AHI using data generated at Truitt's CPAP machine does not establish that a POSITA ***would have*** been motivated to do so. Petitioner does not explain how calculating AHI at Truitt's CPAP machine would provide any known benefit or how or why a POSITA would use that value in the context of Truitt's real-time treatment device. *See* Pet. at 18-21.

61. Furthermore, the PAP device is responsible for transmitting more than just an index to the remote internet site. '029 Patent at Claim 1 ("a remote internet site, the remote internet site adapted for receiving i) and ii), or i), ii), and iii)")². In either data transmission scenario, the "data of a severity of the sleep disorder symptoms of the subject" is a required calculation that must be performed by the processor of the PAP device and sent to the remote internet site. Rather than

² In Claim 1, "i)" is the "data of severity of the sleep disorder symptoms of the subject;" ii) is the "data of usage of the PAP device by the subject;" and iii) is "the index based in whole or in part on either i) or ii) or both i) and ii)."

explain how simply noting an apnea or hypopnea event took place equates to the severity level of a subject's symptoms, the Petition conflates the Board's previous findings regarding an "index of treatment efficacy." Pet. at 18-20 (citing Ex. 1010 at 27 which is addressing the *Wands* factors for enablement of the "index of treatment efficacy"). However, the determination of an index of treatment efficacy is based upon the calculation of the severity of the patient's symptoms or usage.

62. The Petition attempts to draw support for its reading of Truitt by asserting that the '029 Patent equates "conditions" and "symptoms," ignores that the cited discussion concerns how the subject's physiological conditions or symptoms are determined as critical or not using an Auto-Regressive Moving Average (ARMA) model by the PAP processor on the airflow sensor signal. *Compare* Pet. at 18 (citing '029 Patent at 21:11-13) *with* '029 Patent at 20:56-21:29 (describing an embodiment of the invention using the ARMA model for determining a quantified level of severity of the subject's symptoms). Notably, the ARMA model is used to determine the physiological change occurring in the patient at the onset of a symptom "allowing precisely controlled treatments to be delivered to the subject or patient." '029 Patent at 21:1-15. No such disclosure is found anywhere in Truitt.

63. For at least the foregoing reasons, it is my opinion that Truitt does not disclose a “processor adapted for receiving the airflow sensor data, for calculating the data of a severity of the symptoms of the subject and/or the index.”

3. Motivation to Combine Truitt and Kumar

64. It is my opinion that a POSITA would not have been motivated to implement Truitt into “a networked PAP treatment system” as taught by Kumar. Pet., 7. Petitioner’s contention that a POSITA would need to “improve the PAP device of Truitt” in order to incorporate it into the “telemedicine system as taught by Kumar” (*id.*) simply creates a problem to be solved as the reason to combine the prior art.

65. *First*, the Petitioner and its expert allege that motivation is found in the need to obtain more representative data from monitoring a subject at their home. Pet., 7-8 (citing Ex. 1003 at ¶¶144-145). But this is not motivation at all because conventional CPAPs, like those described in Truitt, were already being used by patients in their home. A POSITA would obtain the Petition’s “representative data” simply by using a conventional CPAP, like in Truitt. *See e.g.*, Ex. 1013 at [0063](“the patient will be sent home with an AUTOSET TTM apparatus”). Additionally, the standard of care at this time was for patients to use the CPAP device for a period of time to allow the patient “to become more familiar with wearing the mask and breathing against the pressure.” *Id.* at [0069].

66. Further, Petitioner's expert appears to suggest that a medical professional would need this "representative data" so they can observe the subject in different situation such as after drinking alcohol or after being sick. Ex. 1003 at ¶ 145. As was known to POSITAs, conventional CPAPs included memory that could store and upload data through USB connection or SD Card and neither the Petition or any reference suggests that i) a physician would use at-home CPAP therapy in situations where the patient requires live monitoring, and ii) that the Truitt-Kumar combination allows for the recording of background experiences such as whether a patient has been drinking all day or feeling ill. *See e.g.*, Ex. 1029 at 5 (showing use of a "simple mail-in [SD] card" for storing compliance and quality-of-life data). Thus, a POSITA would not be motivated to make the Truitt-Kumar combination to "obtain more representative data."

67. *Second*, a POSITA would not seek to implement Kumar's "real-time monitoring" in at-home CPAP systems taught by Truitt, for physician convenience because at-home CPAP therapy is prescribed in situations where the patient does not require live monitoring. Pet., 8-9; Kumar at Title. Indeed, neither Petitioner nor its experts identify any issue with the monitoring methods known at the time. If anything, Kumar identifies an issue with the "standard in-laboratory" sleep apnea diagnostic testing methods which required real-time monitoring by a medical professional, a standard not applicable to at-home CPAP therapy use.

'029 Patent at 1:63-66 (“The second [sleep apnea diagnosis method] is via physiological based evaluations such as all-night polysomnography to evaluate the patients sleep architecture (e.g., obtaining respiratory disturbance index to diagnose sleep apnea)”).

68. While Kumar is directed to telemedicine applications, its application regarding sleep apnea is focused upon replacing the in-lab monitoring of sleep apnea diagnostic tests, not sleep apnea therapies. Kumar seeks to replace sleep apnea tests that were “collected in the lab by attended monitoring” with “on-line live monitoring” of “polysomnography and oximetry with newer portable and/or disposable devices.” Kumar, [0240-241]. As Petitioner’s expert has written, the “standard polysomnographic recording techniques” include capturing signals such as “electroencephalograms (C3-A2, A2-O1), left and right electrooculograms, submental electromyogram, tibial electromyogram, electrocardiogram, oxyhemoglobin saturation, body position via infrared video camera, nasal cannula for measuring airflow (Nights 2 and 3), and thoracic and abdominal belts for measuring respiratory effort.” Ex. 2021 (McGinley et al., “A Nasal Cannula Can Be Used to Treat Obstructive Sleep Apnea,” Am. J. of Respiratory and Critical Care Med., 176:194-200 (2007)) at 195. At-home CPAP would not be used in situations where a patient needs “live monitoring” by a medical practitioner on a nightly basis.

69. The Petition does not argue that the inclusion of polysomnography and oximetry is necessary to complete their combination because inclusion of such capabilities in CPAPs requires the integration of sleep diagnosis and treatment functionalities as first taught in the '029 Patent. See '029 Patent at 2:66-3:1 (“The present invention relates to an *integrated sleep diagnosis and treatment device*, and more particularly to an *integrated apnea diagnosis and treatment device*.”) (emphasis added). Indeed, additional data calculations of symptom severity required by polysomnography utilize sensors not taught in Truitt’s CPAPs and the real-time monitoring of Kumar requires wireless data communication techniques between CPAPs and a distributed computing system not disclosed in Truitt or Kumar.

70. *Third*, configuring a CPAP to operate on a network has no effect on increasing the “health access to more people” to CPAP therapy because the only way to increase the access to CPAP therapy is by making home sleep testing more available and getting more patients diagnosed with sleep apnea and prescribed a CPAP. Pet., 62-63. While the PAP devices of the '029 Patent are capable of providing diagnostic metrics, a CPAP would not be used in the diagnosis of patents for sleep apnea.

71. Even today, the only way to increase access to CPAP therapy is by way of a home sleep test, which is why ResMed recently acquired VirtuOx, an

independent diagnostic facility, to “accelerate the time between evaluation and treatment, reduce drop-off, and help more people access the life-changing benefits of therapy for sleep apnea.” Ex. 2022 at 1. In 2005, there was no motivation for a POSITA to implement a system with home sleep test diagnostics, as CMS would not yet reimburse for those tests. “The evidence is not adequate to conclude that the use of unattended portable multi-channel sleep testing . . . is reasonable and necessary in the diagnosis of OSA and these tests will remain noncovered for this purpose.” Ex. 2023 (NCA - Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (CAG-00093R) - Decision Memo) at 1 (decision summary).

72. As Kumar shows, the traditional sleep test was done using overnight polysomnography and oximetry analysis in a lab setting. Kumar, [0239-241]. Therefore, it is my opinion that a POSITA is unable to increase the accessibility of CPAP treatment by placing it within a network, without first having a diagnostic test made more readily available. Furthermore, there is no reason a physician required networking a CPAP to have a telemedicine conference. In fact, medical teleconsultations were quite common, with over 85,000 sessions performed in 2002 in the US. Ex. 2024 (Craig 2005) at 6.

73. *Lastly*, neither “advances in mobile computing and wireless communications” or the “general [IoT] market trend” show that a POSITA would

be motivated to combine Truitt with Kumar. Pet., 9-10. The Petition contends that Truitt's pressure and flow sensors would be "ideal to improve" with the "advantages of [] wireless, as opposed to wired, sensors." Pet., 9. But that is not motivation to arrive at the claimed invention of the '029 Patent which requires an "airflow sensor. . .internal to the enclosure of the PAP device," i.e. wired sensors. '029 Patent at Claim 1.

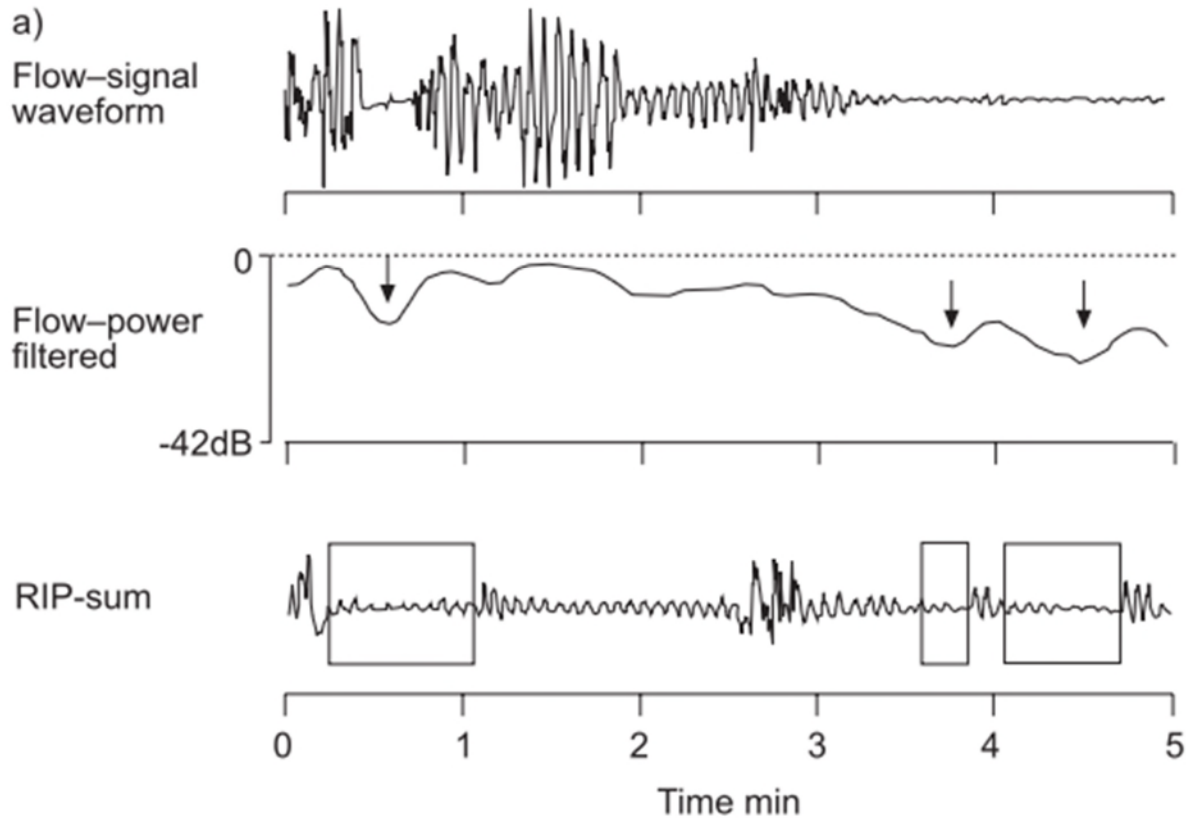
74. A POSITA would not draw a general motivation from the general market trend of connecting consumer devices to the internet. Pet., 10. Sending restricted health information over the internet is not the same as sending refrigerator data. *Id.* Further, the Petition holds Kumar out as a simple "plug-and-play" solution for Truitt, but that is not the case. *Id.* As discussed above, Kumar is directed to replacing in-lab polysomnography and oximetry, not CPAP therapy. Further, Truitt does not disclose calculation of sleep apnea diagnostic metrics and requires wireless data communication functionalities not disclosed, before it could be considered for a networked system.

75. Therefore, a POSITA would not be motivated to combine Truitt with Kumar as argued in the Petition.

4. Truitt and Kumar Do Not Disclose “wherein the airflow sensor data is processed by the second processor, at least in part using one or more of the signal processing techniques from the group. . .” (Claims 8 and 11)

76. Challenged Claims 8 and 11 further limit the how the signal processing techniques used upon the airflow sensor signal data of Claim 1, that are necessary for measuring or deriving the respiratory airflow of the subject such that data indicative of the severity of the subject’s symptoms can be calculated. The claimed signal processing techniques would be used on the airflow sensor data to determine the severity of each sleep apnea symptom experienced by the subject. For example, as demonstrated shortly after the ’029 Patent time and frequency analysis of physiological waveforms, including respiration airflow, could dynamically detect symptoms and quantify the severity of that symptom. In 2007, Nakano et. al, explored variations in respiratory airflow using “a fast Fourier transformation (FFT) of the airflow signal... to obtain the short-time power spectrum within the bandwidth of respiratory frequency. This power spectrum was designated as ‘flow-power,’ [and was] performed every 2 s (overlapped windows).” Ex. 2025 (Nakano 2007) at 729. Automatically detected dips in this flow-power were highly correlated with apnea/hypopnea events as shown below (*id.* at Figure 3), where the RIP-sum is the respiratory inductive plethysmography

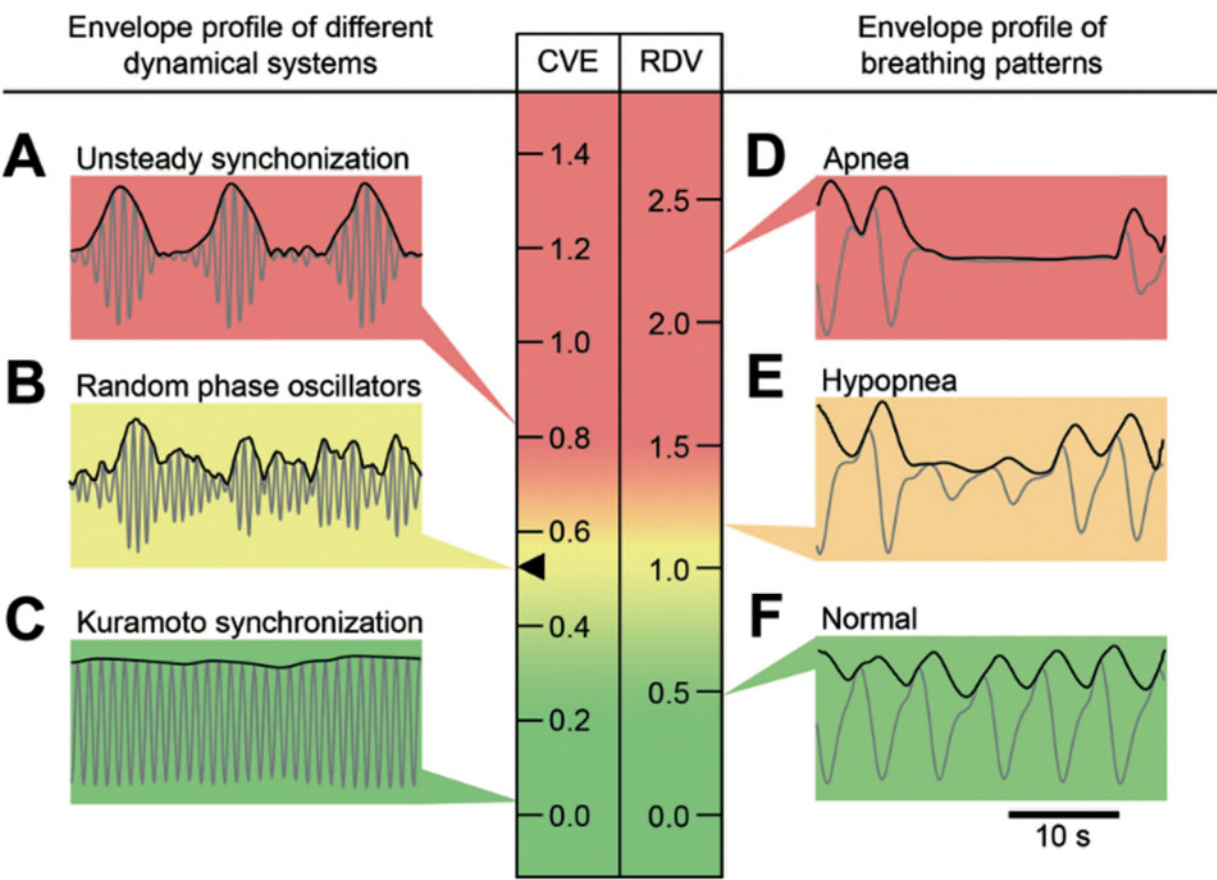
of chest and abdominal signals used for visual identification of apnea/hypopnea events.



Ex. 2025 (Nakano et. al.) at 730, Figure 1.

77. Another example is of a standard deviation technique that was also shown by Diaz to “assess sleep breathing disturbances as a **gradual phenomenon**” with a respiratory disturbance variable (RDV). Ex. 2026 (Diaz 2014) at Abstract (emphasis added). This study analyzed the envelope of respiratory waveform signals, calculating a filtered signal envelope (fse) and the coefficient of variation of that envelope “ $CVE = sd/\mu$ ” where sd is the standard deviation and μ is the

mean of the *fse*. *Id.* at 200. This CVE was then normalized to the RDV. As shown below, the RDV provided a gradual quantification of sleep disorder severity for 30-second segments of the respiratory airflow and its envelopes.



Id., Figure 1.

78. The '029 Patent discloses various techniques for calculating symptom data from respiratory airflow data. *See, e.g.*, '029 Patent at 19:61-64 (“The quantitative method for estimating or determining the severity of the subject's sleeping disorder or symptoms is preferably accomplished by using signals or data from the one or more sensors described herein.”). Indeed, a POSITA would

recognize from the '029 Patent that different “sleeping disorders have symptoms that can be predicted based on various combinations of physiological signals or data” and algorithms are used to “quantify the level of severity of the subject's sleeping disorder or symptoms.” *Id.* at 20:16-55.

79. The '029 Patent further teaches that the present invention identifies the sleep disorder symptoms at their “onset by identifying various characteristic shifts in the power spectrum of the sensors” used to monitor the subject’s physiological condition. *Id.* at 20:26-30. To accomplish this method of monitoring, the '029 Patent discloses specific algorithms used to identify the symptoms severity through the use of signal processing techniques upon the airflow sensor signal. *Id.* at 20:33-46; *see also id.* at 20:47-22:13 (describing the application of the signal processing techniques).

80. While Truitt is devoid of any teachings for the algorithms used to process the airflow sensor data to measure or derive a subject’s respiratory airflow such that the severity of their symptoms can be derived, the '029 Patent discloses and claims the use of specific signal processing techniques, such as, “a standard deviation technique, a recursively fit ARMAX system identification model, a short-time Fourier transform technique, a discrete Fourier transform technique, a fast Fourier transform technique, a time-frequency signal analysis with a variety of different kernels, [or] a wavelet analysis.” *See* '029 Patent at Claims 8 and 11; *id.*

at 20:24-22:13 (disclosing signal processing methods to quantitatively determine the severity of the subject's symptoms).

81. Through use of these signal processing techniques, a POSITA can utilize the airflow sensor data to derive the quantitative severity of each individual symptom. *See, e.g.*, '029 Patent at 19:61-64 (“The quantitative method for estimating or determining the severity of the subject's sleeping disorder or symptoms is preferably accomplished by using signals or data from the one or more sensors described herein.”). Thus, a POSITA would understand that determining the “data of a severity” for the subject's symptoms indicates “the degree of deviation from the baseline characteristics of a patient without sleep disorder symptoms.” Ex. 2020 (Jafari Decl.) at ¶¶ 41-42, 46.

82. Further, Truitt's measurement of airflow to the patient is not a measurement of the patient's respiratory airflow, and Truitt does not teach or suggest deriving the patient's respiratory airflow for calculating symptom severity from this data. Under Petitioner's theory of how treatment is adjusted, a change in pressure or flow is based upon the frequency of events regardless of whether the severity of the current symptom is greater or less than those before it. Pet. at 19 (asserting that the changes in therapy are determined by AHI). Truitt's feedback loop is used to adjust the blower pressure and is based upon its airflow system readings of the system without any consideration of the patient's present

respiratory airflow or the severity of the symptom. *See* Truitt at 5:35-6:10 (describing pressure and motor control), 6:38-53 (describing the controller for calculating the flow and/or volume of gas passing through the conduit for control of the motor), 6:60-62 (describing that “other sensors” are needed “to provide additional information to the controller”). This is because Truitt does not teach or suggest using the patient’s respiratory airflow for calculating symptom severity.

83. Under Petitioner’s view of Truitt’s auto-titration, there can be no “precisely controlled treatment” because just relying upon the presence of a respiratory event does not provide the necessary information to “enable adaptive model selection for the subject’s physiological condition” that alters the pressure and flow of the patient’s treatment. Indeed, the claimed signal processing techniques provide the system with the ability to identify the severity of each symptom, allowing for a precise pressure change in response to the severity of each symptom.

84. Because Truitt does not disclose how its airflow sensor data relates to the patient’s respiratory airflow and fails to disclose calculation of a level of severity for the subject’s symptoms, it is my opinion that Challenged Claims 8 and 11 are patentable.

5. Truitt in View of Kumar Does Not Disclose the system wherein the remote internet site is adapted to retransmit to the first radio frequency wireless transceiver on the cell phone . . .” (Claims 9 and 13)

85. It is my opinion that Challenged Claims 9 and 13 are patentable because Kumar does not disclose transmitting data from the PAP device to a remote internet site which is then retransmitted to the patient’s cell phone, as claimed. Petitioner does not rely on Truitt for these limitations. Pet. at 50-51.

86. There is no disclosure in Kumar of separately sending the data of severity of the subject’s symptoms and/or an index based in whole or in part on the subject’s symptom severity data generated and transmitted by the PAP device to a remote internet site and then to a cell phone, as claimed. See ’029 Patent at Claims 9 and 13. Petitioner’s allegation that the remote internet site is hosted at Kumar’s central server 106, and is accessible to patient-side device 102 (Pet. at 34-40), means that the data pathway from the patient side device 102 always traverses computing device 110 (which is alleged to be the claimed “cell phone”) (*id.* at 41):

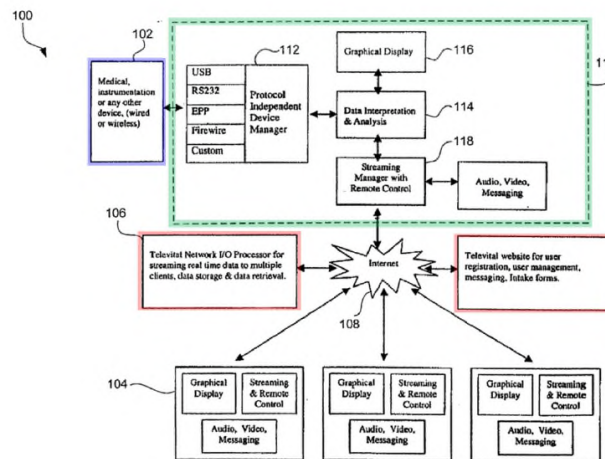


Fig. 1A

EX1008, FIG. 1A

Pet. at 35 (Kumar, Fig. 1A annotated by Petitioner).

87. Accordingly, Petitioner does not identify where Kumar teaches “the remote internet site is adapted to retransmit to the first radio frequency wireless transceiver on the cell phone the data, in whole or in part, the data of i) and ii), or i), ii), and iii) or a second index related to the data of the subject's treatment and the treatment's efficacy calculated and transmitted by the PAP device.” ’029 Patent at Claim 9, 13. A POSITA would not design a system to send redundant data back to the device in which originally received and transmitted the data in the first instance, and Petitioner does not attempt to explain why a POSITA would design the remote internet site to retransmit information back to its original source. A medical device designer would not send redundant medical information back to the device responsible for transmitting the data to the server for several reasons. First,

every transmission of data uses bandwidth, and the medical device designer would be motivated to streamline these transmissions to use as little bandwidth as possible. Second, every data transmission comes with cybersecurity and data integrity risks. The medical device designer would not add an unnecessary transmission of data that exposes that data to interception or malicious alteration. In fact, this would likely emerge as a risk in a software hazard analysis were a designer to propose implementing this transmit, transmit-back architecture into a medical device. Finally, every step in data transmission needs to be documented with requirements, and then the system is fully tested against those requirements. Sending redundant data back to the device that originally sent that data would create additional, unnecessary regulatory burden on the medical device designer that a POSITA would be motivated to avoid.

88. According to the combination proposed in the Petition, the subject would already have the data from the PAP device to review so retransmission back to the subject's device is unnecessary and nonsensical. Furthermore, the Petition does not argue that a "second index" would be sent back to the patient's cell phone indicating that there are no new calculations performed by the remote internet site nor retransmission of the data back to the cell phone. Pet. at 50-51.

89. For at least the foregoing reasons, it is my opinion that Challenged Claims 9 and 13 are patentable.

B. Grounds 4-6: The Challenged Claims are Patentable Over Truitt in View of Kumar and in Further View of Mumford

90. Petitioner recognizes Truitt’s inability to calculate the claimed symptom severity data and seeks to fill the gap using the sleep efficacy algorithm of Mumford. Pet. at 64-71. However, Mumford’s sleep efficacy algorithm relies upon sensor inputs not present in Truitt, and Mumford’s algorithm detection of apneas provides the same functionality already present in Kumar’s external computing device. *Id.* at 64-66. Thus, it is my opinion that a POSITA would not be motivated to modify Truitt’s PAP device with Mumford’s sleep efficacy algorithm absent of hindsight.

1. Petitioner And Its Experts Fail To Show A POSITA Would Find Motivation Or Success In Combining Mumford And Truitt

91. Petitioner presents only generic reasons for combining Mumford with Truitt. Pet. at 64-66 (citing Ex. 1003 at ¶¶311-312). In the two paragraphs devoted to this issue, Petitioner discusses some interrelated teachings of each reference without explaining why or how a POSITA would have combined Mumford’s sleep efficacy algorithm (which is reliant upon multiple sensor inputs) with Truitt’s device (which is only equipped with an internal airflow sensor). *Id.*; *see also* Pet. at 70-71 (citing Ex. 1003 at ¶¶328-331).

92. Implementing Mumford’s sleep efficacy algorithm on Truitt’s device requires sensor inputs that are outside the scope of the claims. At institution, the

Board interpreted the Petition as accounting for data produced from Truitt’s “other sensors, such as a microphone” as rationale for utilizing Mumford’s electrodes and sleep efficacy algorithm. Paper 12 at 35. This is incorrect, as neither the Petition nor the Challenged Claims utilize any other sensor data to perform its calculations of severity data or an index, other than the internal airflow sensor. *See* ’029 Patent at Claim 1; Pet. at 64-71 (alleging that only Mumford’s sleep efficacy algorithm would be incorporated into Truitt, not the entire mask assembly with its integrated sensors and its algorithm). While the ’029 Patent discloses several different embodiments of its integrated diagnostic and treatment PAP device, the claims are limited to determining its diagnostic level of severity based only on the internal airflow sensor. ’029 Patent at Claim 1. And while a POSITA would recognize that additional sensors could be added to Truitt’s system, those sensors would be external to the PAP device and go beyond the scope of the Challenged Claims.

93. It is my opinion that a POSITA would not have had a reasonable expectation of success combining Mumford’s sleep efficacy algorithm with a PAP device like Truitt’s, where its only input to the algorithm would be from its flow sensing assembly. Petitioner and its expert’s assertion that an expectation of success exists because “Truitt and Mumford are analogous art” and the “proposed modification involves a simple change” is inaccurate. Pet. at 66.

94. The Petition only points to Truitt's CPAP with an internal flow sensing assembly that sends signals to its controller used in determining the flow or volume of gas in the system, not external sensors. See Pet. at 17 ("The output of the flow sensor is provided to controller 38 "for calculating the flow and/or volume of gas passing through conduit 56."). There is no embodiment taught or suggested in Mumford, where the pressure transducer of an internal or external airflow assembly is the sole provider of information for its sleep efficacy algorithm. Mumford at 4:24-35 (pressure transducer in combination with a pulse oximeter or position sensor), 12:62-13:22 (pressure transducer is optionally used in combination with the electrodes and other sensors), Claims 10, 13 (pressure transducer used in combination with electrodes and other sensors). Moreover, Mumford's pressure transducer is found integrated within the mask worn by the patient, not within the CPAP device like Truitt. *Id.* at 11:66-12:17.

95. Thus, Mumford suggests to a POSITA that its sleep efficacy algorithm is not compatible with data from only one sensor. Mumford at 10:66-11:16 (discussing why it is "preferable, and more robust, although not necessary, to use a subset of electrodes that contains ***at least three electrodes***. However, in some cases ***it may be possible to use only two electrodes.***") (emphasis added). It is my opinion that POSITA would not look to use Mumford's algorithm with Truitt's

device where only a flow/pressure sensor within the device and not the mask is utilized.

2. Mumford's Sleep Efficacy Algorithm Relies On Electrodes Not Present in Truitt

96. Petitioner's argument that Mumford furthers the objective and purpose of Truitt, ignores that Mumford defeats Truitt's purpose of providing an "accurate flow or volume measurement of the gas passing therethrough, without the need for a dedicated flow element." Truitt at 3:42-46.

97. The entire premise of Truitt's invention is to eliminate the extra sensors and achieve the same functionality as standard CPAP machines with only an internal airflow sensor. Truitt, 3:42-46 ("In particular, it is an object of the present invention to provide a pressure support system that allows for a relatively accurate flow or volume measurement of the gas passing therethrough, without the need for a dedicated flow element."); *id.* at 3:66-4:7 (describing the object of the invention to "be used in the same manner as the signal from a conventional flow sensor.") It is my opinion that the idea of adding only mask-based sensors back into Truitt's device is antithetical to Truitt's purpose.

98. To implement Mumford's sleep efficacy algorithm, one of ordinary skill would have to include a combination of electrodes and pressure transducers integrated into the mask. Pet. at 64-66; Mumford at 12:14-16 ("The *pressure*

transducer 316 is disposed within the nasal mask 20 preferably in close proximity to the gas inlet 28.”); *id.* at 12:42-44 (“The pressure transducer 316 is used to ***detect the pressure within the cavity of the nasal mask 20 . . .***”) (emphases added). It is my opinion that a POSITA would not look to Mumford’s algorithm when attempting to interpret Truitt’s internal flow or volume reading sent from its flow-sensing assembly found within the PAP device to determine “data of severity of sleep disorder symptoms” or an “index [] based in whole or in part on a data of severity of sleep disorder symptoms of the subject and/or a data of usage of the PAP device by the subject.” Pet. at 68-70.

99. I understand that Petitioner’s obviousness case must provide a reasoned analysis explaining how the references are combined and how the proposed combination works to meet the claim limitation. *Pers. Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 993-94 (Fed. Cir. 2017). Here, neither Petitioner nor their experts demonstrate how Mumford’s algorithms would need to be modified to be successfully operational with Truitt’s PAP device and the data it measures. Pet. at 66-71

100. The integration of Mumford’s sleep efficacy algorithm requires “at least the electrode signals” received from the sensors and electrodes integrated into its mask assembly and not alleged as part of the Mumford combinations. Pet. at 64 (“A POSITA would have been motivated to modify the Truitt PAP device to

incorporate the sleep efficacy algorithm of Mumford.”). Mumford’s sleep efficacy algorithm determines two things: (1) the present sleep stage of the wearer and (2) how many arousals they experienced. Mumford at 7:34-42. Mumford teaches that determination of these data points each require multiple streams of data as inputs because the “information is weak” and the “signals are more difficult to detect because they do not originate in the frontal lobes of the brain.” *Id.* at 10:66-11:16. Thus, a POSITA considering Mumford’s sleep efficacy algorithm understands that it must be used in conjunction with the electrodes integrated into Mumford’s mask assembly, contrary to the configuration of Truitt and the Challenged Claims.

101. Neither Petitioner nor its expert show how Mumford’s “frontal staging algorithm, based on at least the electrode signals,” would operate within Truitt’s device without Mumford’s “electrodes.” Mumford at 15:39-16:3. Indeed, the primary inputs used in Mumford’s algorithm come from multiple electrode signals such that it would not be a “simple change in a programming algorithm” because the very inputs upon which Mumford’s algorithm is built must change significantly to operate with Truitt’s lone flow sensor. Pet. at 66; Mumford at 15:42-45 (“[t]he information provided by the electrodes is important since it is well known that some sleep apnea events occur more frequently in some of the sleep stages rather than others.”). Neither the Petitioner nor their experts propose any methodology whereby airflow information within a CPAP can be used to

determine the present sleep stage of the wearer, a key objective of the Mumford system.

102. For at least the foregoing reasons, it is my opinion that the Challenged Claims are patentable over the Mumford combinations.

IX. CONCLUSION

In view of the foregoing, it is my opinion that the Board should hold patentable the Challenged Claims.

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

Executed on October 22, 2025, in Canandaigua, NY.



David Borkholder, Ph.D.

APPENDIX A

David A. Borkholder, PhD

PROFESSOR EMERITUS, COLLEGE OF ENGINEERING, ROCHESTER INSTITUTE OF TECHNOLOGY

PROFILE

Dr. Borkholder is an engineer and entrepreneur who has been PI on over \$21MM in research funding from the National Institutes of Health, National Science Foundation, Department of Defense, and industry. He has served as an executive in four startup companies, two of which were spin-outs from his laboratory at RIT. The most recent was Casana, a healthcare technology firm he co-founded focused on in-home cardiovascular monitoring. Dr. Borkholder previously founded BlackBox Biometrics (B3) providing wearable sensor capabilities for the warfighter to help combat traumatic brain injury. B3 was successfully acquired in 2021. In Silicon Valley, he led electronics and ASIC development at ZONARE Medical Systems and developed advanced DNA diagnostic systems for the military and healthcare sector at Cepheid, leading to a successful IPO in 2000. Dr. Borkholder was a member of the DARPA Defense Sciences Research Council (DSRC) and former Chair of the NIH Bioengineering of Neuroscience, Vision, and Low Vision Technologies (BNVT) study section. He currently serves on the Rochester Board for the American Heart Association and as a member on two NATO Science and Technology panels focused on repetitive low-level blast exposure and brain injury. Dr. Borkholder is a Fellow of the American Institute for Medical and Biological Engineering.

EDUCATION AND TRAINING

- Stanford University; Stanford, CA – MS / PhD Electrical Engineering, 1994 / 1999
- Rochester Institute of Technology; Rochester, NY – BS Microelectronic Engineering, 1992
- Marine Biological Laboratory, Woods Hole, MA - Short Course: Biology of the Inner Ear: Experimental & Analytical Approaches, 2007

AREAS OF EXPERTISE

- Drug delivery
- Cochlear pharmacokinetics
- Auditory dysfunction and pharmacologic therapies
- Microelectromechanical systems (MEMS)
- Implantable micropumps
- Cardiovascular modeling and monitoring
- Sensors and biosensors
- Medical device development and FDA clearance
- Wearable technologies
- Measurement of explosive blast overpressure
- Mild traumatic brain injury (mTBI) from repetitive overpressure exposure
- Sample processing and DNA diagnostics
- Ultrasound
- Analog electronics and signal conditioning
- Product development and compliance testing

EXPERIENCE

ROCHESTER INSTITUTE OF TECHNOLOGY (RIT); ROCHESTER, NY – 2004-PRESENT

PROFESSOR EMERITUS – 2024-PRESENT

BAUSCH + LOMB PROFESSOR, MICROSYSTEMS ENGINEERING – 2012-2024

PROFESSOR, MICROSYSTEMS ENGINEERING AND ELECTRICAL ENGINEERING – 2004-2012

Assistant professor from 2004 - 2007, associate professor from 2007 - 2015, and full professor from 2015 until retirement in 2024 with undergraduate and graduate education and research in the areas of electronics, sensors, MEMs, and biomedical engineering. During this period Dr. Borkholder also held adjunct appointments at the University of Rochester in Otolaryngology (2006-2020) and Biomedical Engineering (2007-2020). Courses taught include Electronics I and II, Fundamental Electrophysiology, Biomedical Sensors and Transducers, Biomedical Instrumentation, Introduction to Nanotechnology and Microsystems, Introduction to Product Development, Reverse Engineering, and The Design Process. Primary research areas included microsystems for inner ear drug delivery / cochlear pharmacokinetics; non-invasive in-home cardiovascular monitoring / modeling of cardiovascular function; and personnel borne sensors for blast dosimetry and traumatic brain injury.

FOUNDING DIRECTOR, PERSONALIZED HEALTHCARE TECHNOLOGY (PHT180) – 2016-2020

Established an institute-wide initiative (<https://www.rit.edu/pht180/>) focused on applied healthcare research aiming to transform the landscape of healthcare access, efficacy, and cost. At the end of Dr. Borkholder's term as Director, there were over 83 affiliated faculty members representing 9 colleges at RIT. This diverse network with research collaborations across disciplines tackled healthcare challenges in unconventional ways. The initiative engaged student talent in the College of Art and Design to create artwork and visualizations for affiliated faculty that were used in proposals, conference presentations, journal publications and websites. The initiative also established resources for faculty including grant development and review, grant management, and website development and management to increase success rates, especially for young faculty or those transitioning to a new research domain.

CASANA; ROCHESTER, NY – 2018-2024

CHIEF RESEARCH OFFICER – 2020-2024

CO-FOUNDER, CHAIRMAN OF THE BOARD – 2018-2020

Technology spin-out company based on an in-home cardiovascular monitoring system developed in the Borkholder laboratory at RIT and exclusively licensed to Casana (casanacare.com). The company closed seed financing in September 2019, Series A financing in August 2020, and Series B financing in January 2022, for a total investment of \$46MM. Dr. Borkholder led organization elements including research, electrical and mechanical hardware engineering, clinical affairs, and supply chain / manufacturing, contributing to successful FDA clearance for the system.

BLACKBOX BIOMETRICS (B3); ROCHESTER, NY – 2011-2021

FOUNDER, EXECUTIVE CHAIRMAN, CHIEF TECHNOLOGY OFFICER

Technology spin-out company based on the Blast Gauge Technology (blastgauge.com) developed in the Borkholder laboratory at RIT and licensed exclusively to B3. Developed leadership team, engineering, manufacturing, and customer service capabilities for commercialization of the Blast Gauge system. Championed efforts to treat blast overpressure exposure as an occupational hazard influencing congressional legislation in the FY18 and FY19 National Defense Authorization Acts, and specific brain health policies for the Department of Defense and Special Operations Command. The company was acquired by Airboss Defense Group in 2021. The Blast Gauge has become the *de facto* standard for quantifying individual blast exposure and has been used for this purpose in over 31 journal publications exploring the relationship between blast

exposure and acute neurocognitive deficits. Use of the technology has also shown it is possible to mitigate blast overpressure exposure during training by adjustment of body position, thereby reducing risk of injury. Dr. Borkholder is routinely interviewed and quoted for news stories relating to blast overpressure exposure from weapon systems and the associated brain injury risk.

ZONARE MEDICAL SYSTEMS; MOUNTAIN VIEW, CA – 2001-2004

DIRECTOR, HARDWARE ENGINEERING

Directed the Hardware Engineering group in the development of a portable ultrasound system utilizing non-traditional imaging techniques. Team responsibilities included analog, digital and power board design, FPGA programming, ASIC development, thermal management, integration, design verification and environmental testing. Resources, budgets, schedules, equipment, laboratory space, and all related projects for these disciplines were managed. Dr. Borkholder's team successfully developed three ASICs (analog, mixed signal and high voltage) from concept, to design, packaging, and qualification. Successfully engineered a full featured medical diagnostic imaging system following ISO / FDA requirements.

CEPHEID; SUNNYVALE, CA – 1998-2001

DIRECTOR, ELECTRONIC SYSTEMS

Started as a Sr. Scientist with rapid promotion to Director where Dr. Borkholder led electrical and test Engineering groups in development of advanced DNA analysis systems. Responsible for development of all electronic systems and components, design verification and environmental testing of subsystems and instruments, and development of electronic, mechanical and optical test systems for both engineering and manufacturing. All work was performed according to ISO / FDA requirements. Managed resources, budgets, equipment, laboratory space, and projects for these disciplines. Dr. Borkholder also served as Technical Lead for development and commercialization of the GeneXpert, a fully automated sample processing system capable of extracting DNA from raw samples and performing quantitative DNA analysis. Responsibilities included understanding marketing constraints, driving critical path, managing system integration and interdisciplinary conflicts, and management of personnel in electrical, mechanical, and software engineering, molecular biology, precision injection molded disposables, and lyophilized PCR reagents. This GeneXpert platform was chosen by the United States Postal Service for screening the mail for the bioterrorism agent *Bacillus Anthracis* (Anthrax). CPHD was publicly traded (NASDAQ) from 2000 to 2016, achieving a peak market cap in excess of \$4.5B. In 2016, Cepheid was acquired off the public market by Danaher Corp for \$4B.

EXPERT WITNESS ENGAGEMENTS

Engaging party is in bold with the date of initial engagement provided.

- Resmed Corp v **Cleveland Medical Devices, Inc** (IPR2023-00565); patent trial and appeal board – 2024
- **Cleveland Medical Devices Inc.** v. ResMed Inc (1:22-cv-00794-GBW); patent infringement case – 2023

GOVERNMENT SERVICE

- Member, NATO HMF-338 Human Factors and Medicine Panel on “Guidelines to mitigate military occupational brain health risks from repetitive blast exposure.” 2021-Present
- Member, NATO HFM-371 RSM Human Factors and Medicine Research Specialists Meeting on “Blast Exposure Monitoring in Military Training and Operations.” – 2023-Present
- DARPA Defense Sciences Research Council (DSRC) – 2009-2015
Chaired year long neuroscience studies including: “What is Information in the Brain”, “New Tools for Neuroscience”, and “Towards non-invasive measurement of neural activity in humans.”

GRANT REVIEW

- NIH, CSR: small business grant applications in Hearing Science Special Emphasis Panel (SEP) – 2025
- MRMC Extramural Medical Research on the Medical Simulation and Information Sciences (MSIS) panel – 2019
- NIH, CSR: Bioengineering of Neuroscience, Vision, and Low Vision Technologies (BNVT) study section (Ad Hoc) – 2018-2019
- Army Rapid Innovation Fund - Traumatic Brain Injury Assessment and Treatment – 2014
- NIH, CSR: Bioengineering of Neuroscience, Vision, and Low Vision Technologies (BNVT) study section chartered member – 2012-2016; **Study Section Chair** – 2014-2016
- Defense Threat Reduction Agency – 2010-2011
- Swiss National Science Foundation – 2010
- NSF: Research to Aid People with Disabilities – 2009
- Office of Naval Research (ONR) Force Health Protection Initiative – 2008
- NIH, CSR: Neurotechnology (NT) study section (Ad Hoc) – 2007-2011
- NIH, CSR ZRG1 IFCN-G 10 B, Small Business: Ear (Ad Hoc) – 2007
- NIH, CSR: Neurotech/Engineering Special Emphasis Study Section Panel – 2002-2007

PROFESSIONAL SERVICE

- Board of Directors, American Heart Association, Rochester, NY – 2023-Present
- Editorial Section Board member, Micromachines – 2020-Present
- Associate Editor, IEEE Journal of Translational Engineering in Health and Medicine (JTEHM) – 2019-Present
- Board of Directors, RedSky (Biomedical Institute of the Americas) – 2014-2020
- Transducers 2013 Technical Program Committee – 2013
- UNYBECC 2010 Conference organizer, Translational Research Session moderator. Upstate New York Biomedical Engineering Career Conference – 2010
- Journal reviewer for numerous engineering and medical journals – 2006-2020

PROFESSIONAL AFFILIATIONS AND DATES OF ADMITTANCE

- American Institute for Medical and Biological Engineering – 2020
- American Heart Association – 2018
- Biomedical Engineering Society – 2007
- Association for Research in Otolaryngology – 2006
- IEEE Engineering in Medicine and Biology Society – 2005
- Institute of Electrical and Electronics Engineers (IEEE) – 1991

SELECTED HONORS

- Fellow of the American Institute for Medical and Biological Engineering – 2020
- Distinguished Inventor of the Year - Rochester Intellectual Property Law Association – 2016
- Rochester Business Journal Health Care Achievement Award: Innovation for research leading to the successful commercialization and fielding of the Blast Gauge System – 2014

RESEARCH FUNDING

Dr. Borkholder has been the PI on over \$21MM in research funding from federal and industrial sponsors, and contributed to an additional \$5.4MM as Co-I. His research spans drug delivery and pharmacokinetics; cardiac physiology, modeling and monitoring; and sensors and devices. A subset of representative research grants where Dr. Borkholder served as PI are provided below.

NIH / NIDCD (1R01DC014568) *Enabling Microsystem Technologies for Advanced Drug Delivery* – 2015-2020

This research resulted in novel implantable micropumps for inner ear drug delivery in the mouse cochlea and established a new approach to quantify cochlear pharmacokinetics using micro-computed tomography and a learning-prediction model for transport parameter determination. (\$2.7MM)

Google *Inconspicuous Daily Medical Analyses* – 2014-2016

This research resulted in a toilet-seat-based cardiovascular monitor that measured a single lead electrocardiogram, a thigh photoplethysmogram, and the ballistocardiogram. The technology formed the basis of the startup company Casana who licensed the associated patents from RIT. (\$1.5MM)

DARPA MTO (HR0011-11-9-0006) *Blast Gauge Field Research Studies* – 2011-2013

This research supported pilot deployment of the Blast Gauge overpressure sensor on US and allied troops in Afghanistan to validate device performance, refine distribution and recovery logistics, and evaluate wearability of the device. The sensors were deployed on over 10,000 troops and recorded thousands of blast events. While the device was intended to capture exposure to improvised explosive devices and incoming munitions, the data revealed that over 75% of all exposures were from troops firing their own weapons. This data revealed, for the first time, that there were significant overpressure exposures occurring with heavy weapons use in training. (\$9.9MM)

NSF Research to Aid People with Disabilities (CBET-0967732) *Adaptive User-Guided Assistive Listening System* – 2010-2014

This research resulted in an assistive listening system with dynamic, user-controlled directional characteristics to enable future research on improvements in communication for the hearing impaired relative to traditional fixed-directional systems. (\$300K)

DARPA MTO (HR0011-10-C-0095) *Soldier Wearable Blast Dosimeter* – 2010-2011

This research resulted in the Blast Gauge System, a wearable sensor that constantly monitors the environment and automatically detects and records blast overpressure waveforms. The technology provided a unique capability to measure, for the first time, what warfighters were exposed to in the combat environment. (\$1.2MM)

NIH / NIDCD (5K25-DC008291-02) *Improved Micro-Technologies for Inner Ear Drug Delivery* – 2006-2011

This Mentored Career Development Award resulted in surgical techniques and cochlear infusion approaches to optimize intra-cochlear dosing profiles for future gene therapy studies in the mouse while preserving cochlear function. An implantable micropump was developed enabling nanoliter per minute flow rates which expanded drug delivery capabilities and allowing repetitive cochlear infusions of multiple agents over extended periods for more complex deafness therapies. This work was in collaboration with Dr. Robert D. Frisina at the University of Rochester. (\$922K)

TRAINEES MENTORED

POST-DOCTORAL

- Nicholas Conn – 2016-2019
- Farzad Forouzandeh – 2019-2020
- Armando Arpys Arevalo Carreno – 2018-2019
- Ahmed Alfadhel – 2016-2018
- Masoumeh Haghpahani – 2012-2015

DOCTOR OF PHILOSOPHY (PHD)

- Meng-Chun Hsu, Microsystems Engineering (Advisor until 2020) – 2024
Design and Implementation of a Modular, Standalone Microfluidic Flow Control Platform for Cell Culture Applications
- Krittika Goyal, Microsystems Engineering (Advisor until 2020) – 2023
Large Dry Metal Electrodes for Physiological Monitoring
- Sanketh Moudgalya, Imaging Science (Co-Advisor) – 2022
Cochlear Compartments Segmentation and Pharmacokinetics using Micro Computed Tomography Images
- Farzad Forouzandeh, Microsystems Engineering (Advisor) – 2019
Implantable Microsystem Technologies For Nanoliter- Resolution Inner Ear Drug Delivery
- Jing Ouyang, Microsystems Engineering (Advisor) – 2018
Enhanced Piezoelectric Performance of Printed PZT Films on Low Temperature Substrates
- Jeff Lillie, Microsystems Engineering (Advisor) – 2017
Non-invasive Continuous Blood Pressure Monitor
- Nicholas Conn, Microsystems Engineering (Advisor) – 2016
Robust Algorithms for Unattended Monitoring of Cardiovascular Health
- Jirachai Getpreecharsawas, Microsystems Engineering (Advisor) – 2015
Low-Power, Low-Voltage Electroosmotic Actuator for an Implantable Micropumping System Intended for Drug Delivery Applications
- Dean Johnson, Microsystems Engineering (Advisor) – 2013
Integration Technologies for Implantable Microsystems
- Miriam Gladstone, Biomedical Engineering - University of Rochester (Co-Advisor) – 2011
Gene Therapy in the Inner Ear via Intracochlear Infusion into the Mouse Cochlea

MASTER OF SCIENCE (MS)

- Kevin Wilson, Electrical Engineering (Advisor) – 2018
Modeling and Extraction of Transport Parameters to Simulate Drug Delivery in the Murine Cochlea
- Joseph Kubek, Electrical Engineering (Advisor) – 2017
Inconspicuous Daily Weight Tracking Using an Artificial Neural Network
- Danielle Walters, Electrical Engineering (Advisor) – 2016
RF Energy Harvesting
- Terence Binotto, Electrical Engineering (Advisor) – 2016
Direct write integration of commercial off the shelf electronics on non-traditional substrates
- Matthew Kelly, Electrical Engineering (Advisor) – 2014
The Focal Index as a Singular Metric for Beamforming Effectiveness

- Cody Czesler, Computer Engineering (Advisor) – 2014
Using Least Variance for Robust Extraction of Systolic Time Intervals
- Nicholas Conn, Electrical Engineering (Advisor) – 2012
Compressed Sensing for Power Efficient Physiological Monitoring
- Matt Kenyon, Electrical Engineering (Advisor) – 2011
Photonic Neural Stimulator
- Mathew Waldren, Electrical Engineering (Advisor) – 2009
Low Power Flow Rate Sensors for Biomedical Applications
- Sean O'Brien, Microelectronic Engineering (Advisor) – 2009
Low Voltage Actuation Mechanism for Micropump Applications
- Jesse Steiner, Electrical Engineering (Advisor) – 2009
A Self-Contained Bicycle Power Center
- Murtuza Quaizar, Electrical Engineering (Advisor) – 2008
Simulation of a User Guided Acoustic Beamforming Assistive Listening System
- Avery Sonnenberg, Electrical Engineering (Advisor) – 2007
Single-Actuator Peristaltic Micropump

PUBLICATIONS AND PATENTS

Dr. Borkholder is an inventor on a total of 25 US patents and 4 international patents on physiological and cardiovascular monitoring, inner ear drug delivery, measurement of blast overpressure for correlation to traumatic brain injury, DNA diagnostics, and cell-based biosensors. He has authored 48 journal papers, 35 referred conference manuscripts, 29 conference abstracts, and has delivered 5 invited talks. He has an H-index of 30, an i-10 index of 60, and has been cited over 3800 times. His doctoral thesis on cell-based biosensors has been cited over 260 times. His full bibliography can be found on his google scholar profile (<https://scholar.google.com/citations?user=5ZbxhwUAAAAJ&hl=en>). Selected patents and journal papers focused on his core contributions in inner ear drug delivery, blast exposure monitoring, and cardiovascular modeling and monitoring are provide below.

INNER EAR DRUG DELIVERY JOURNAL

1. Borkholder, David A. "State-of-the-art mechanisms of intracochlear drug delivery." *Current opinion in otolaryngology & head and neck surgery* 16, no. 5 (2008): 472-477.
<https://doi.org/10.1097/MOO.0b013e32830e20db>
2. Borkholder, David A., Xiaoxia Zhu, Brad T. Hyatt, Alfredo S. Archilla, William J. Livingston III, and Robert D. Frisina. "Murine intracochlear drug delivery: reducing concentration gradients within the cochlea." *Hearing research* 268, no. 1-2 (2010): 2-11. <https://doi.org/10.1016/j.heares.2010.04.014>
3. Johnson, Dean G., Robert D. Frisina, and David A. Borkholder. "In-plane biocompatible microfluidic interconnects for implantable microsystems." *IEEE Transactions on Biomedical Engineering* 58, no. 4 (2010): 943-948. <https://doi.org/10.1109/TBME.2010.2098031>
4. Pararas, Erin E. Leary, David A. Borkholder, and Jeffrey T. Borenstein. "Microsystems technologies for drug delivery to the inner ear." *Advanced drug delivery reviews* 64, no. 14 (2012): 1650-1660.
<https://doi.org/10.1016/j.addr.2012.02.004>

5. Haghpanahi, Masoumeh, Miriam B. Gladstone, Xiaoxia Zhu, Robert D. Frisina, and David A. Borkholder. "Noninvasive technique for monitoring drug transport through the murine cochlea using micro-computed tomography." *Annals of biomedical engineering* 41 (2013): 2130-2142. <https://doi.org/10.1007/s10439-013-0816-4>
6. Snyder, Jessica L., Jirachai Getpreecharsawas, David Z. Fang, Thomas R. Gaborski, Christopher C. Striemer, Philippe M. Fauchet, David A. Borkholder, and James L. McGrath. "High-performance, low-voltage electroosmotic pumps with molecularly thin silicon nanomembranes." *Proceedings of the National Academy of Sciences* 110, no. 46 (2013): 18425-18430. <https://doi.org/10.1073/pnas.1308109110>
7. Borkholder, David A., Xiaoxia Zhu, and Robert D. Frisina. "Round window membrane intracochlear drug delivery enhanced by induced advection." *Journal of controlled release* 174 (2014): 171-176. <https://doi.org/10.1016/j.jconrel.2013.11.021>
8. Johnson, Dean G., and David A. Borkholder. "Towards an implantable, low flow micropump that uses no power in the blocked-flow state." *Micromachines* 7, no. 6 (2016): 99. <https://doi.org/10.3390/mi7060099>
9. Hsu, Meng-Chun, Ahmed Alfadhel, Farzad Forouzandeh, and David A. Borkholder. "Biocompatible magnetic nanocomposite microcapsules as microfluidic one-way diffusion blocking valves with ultra-low opening pressure." *Materials & design* 150 (2018): 86-93. <https://doi.org/10.1016/j.matdes.2018.04.024>
10. Frisina, R. D., M. Budzevich, X. Zhu, G. V. Martinez, J. P. Walton, and D. A. Borkholder. "Animal model studies yield translational solutions for cochlear drug delivery." *Hearing research* 368 (2018): 67-74. <https://doi.org/10.1016/j.heares.2018.05.002>
11. Antoine, Michelle W., Xiaoxia Zhu, Marianne Dieterich, Thomas Brandt, Sarath Vijayakumar, Nicholas McKeenan, Joseph C. Arezzo et al. "Early uneven ear input induces long-lasting differences in left-right motor function." *PLoS biology* 16, no. 3 (2018): e2002988. <https://doi.org/10.1371/journal.pbio.2002988>
12. Moudgalya, Sanketh S., Kevin Wilson, Xiaoxia Zhu, Mikalai M. Budzevich, Joseph P. Walton, Nathan D. Cahill, Robert D. Frisina, and David A. Borkholder. "Cochlear pharmacokinetics-micro-computed tomography and learning-prediction modeling for transport parameter determination." *Hearing research* 380 (2019): 46-59. <https://doi.org/10.1016/j.heares.2019.05.009> **Cover Article**
13. Forouzandeh, Farzad, Xiaoxia Zhu, Ahmed Alfadhel, Bo Ding, Joseph P. Walton, Denis Cormier, Robert D. Frisina, and David A. Borkholder. "A nanoliter resolution implantable micropump for murine inner ear drug delivery." *Journal of controlled release* 298 (2019): 27-37. <https://doi.org/10.1016/j.jconrel.2019.01.032>
14. Forouzandeh, Farzad, and David A. Borkholder. "Microtechnologies for inner ear drug delivery." *Current opinion in otolaryngology & head and neck surgery* 28, no. 5 (2020): 323-328. <https://doi.org/10.1097/MOO.0000000000000648>
15. Forouzandeh, Farzad, Nuzhet N. Ahamed, Meng-Chun Hsu, Joseph P. Walton, Robert D. Frisina, and David A. Borkholder. "A 3D-printed modular microreservoir for drug delivery." *Micromachines* 11, no. 7 (2020): 648. <https://doi.org/10.3390/mi11070648> **Cover Article**
16. Forouzandeh, Farzad, Arpys Arevalo, Ahmed Alfadhel, and David A. Borkholder. "A review of peristaltic micropumps." *Sensors and Actuators A: Physical* 326 (2021): 112602. <https://doi.org/10.1016/j.sna.2021.112602>

ISSUED PATENTS

1. Forouzandeh, Farzad, David Borkholder, Robert Frisina, Joseph Walton, and Xiaoxia Zhu. "Miniature pressure-driven pumps." U.S. Patent 11,603,254, issued March 14, 2023.

2. Forouzandeh, Farzad, David Borkholder, Robert Frisina, Joseph Walton, and Xiaoxia Zhu. "Implantable drug storage devices for drug delivery." U.S. Patent 11,583,627, issued February 21, 2023
3. Ahmed Alfadhel, Meng-Chun Hsu, David A Borkholder. "Capsule, in-line magnetic valve system and method." U.S. Patent 11,035,498, Issued June 15, 2021.
4. David A Borkholder, Farzad Forouzandeh, Robert Nash Carter, Denis Roger Cormier, Joseph P Walton, Robert Dana Frisina. "Peristaltic micropumps and fluid delivery devices that incorporate them." U.S. Patent 11,020,524, Issued June 1, 2021.
5. Getpreecharsawas, Jirachai, and David A. Borkholder. "Ultra-thin nanometer scale polymeric membranes." U.S. Patent 10,086,336, issued October 2, 2018.

BLAST OVERPRESSURE EXPOSURE MONITORING

ISSUED PATENTS

1. Borkholder DA, DeBusschere D, "Methods for Monitoring Exposure to an Event and Devices Thereof," CA 2824597, issued May 21, 2019.
2. Borkholder, David A., Werner Fassler, Andrew Blair, Kim Sherman, and Derek Debusschere. "Event monitoring dosimetry apparatuses and methods thereof." U.S. Patent No 10,292,445, issued May 21, 2019.
3. Borkholder, David A., Gregory TA Kovacs, and Jeffrey Rogers. "Event Dosimeter Device and Methods Thereof." U.S. Patent No 9,668,689 B2, issued 6 June 2017.
4. Borkholder, David A., Gregory TA Kovacs, and Jeffrey Rogers. "Event dosimeter devices and methods thereof." U.S. Patent No. 9,339,224. issued 17 May 2016.
5. Borkholder DA, DeBusschere D, "Methods for Monitoring Exposure to an Event and Devices Thereof," AU 2012222109, issued April 21, 2016.
6. Borkholder DA, DeBusschere BD, "Method for Monitoring Exposure to an Event and Device Thereof." US 9,138,172, issued September 22, 2015.
7. Borkholder DA, Kovacs GTA, Rogers J, "Event Dosimeter Device and Methods Thereof," AU 2012222110, Issued August 6, 2015.
8. Borkholder, David A., Matthew Kenyon, Ryan Ramplin, Michael H. Ostertag, Kim Sherman, Matthew Wellman, and Micah Harrison. "Devices, systems and methods for detecting and evaluating impact events." U.S. Patent 9,380,961, issued July 5, 2016.
9. Borkholder DA, Fassler W, Blair A, Sherman K, DeBusschere D, "Event Monitoring Dosimetry Apparatuses and Methods Thereof," AU 2012222107, Issued June 11, 2015.

CARDIOVASCULAR MODELING AND MONITORING

JOURNAL

1. Goyal, Krittika, David A. Borkholder, and Steven W. Day. "Dependence of skin-electrode contact impedance on material and skin hydration." Sensors 22, no. 21 (2022): 8510. <https://doi.org/10.3390/s22218510>
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