

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.
Petitioner,

v.

CLEVELAND MEDICAL DEVICES, INC.
Patent Owner.

Case IPR2025-00246
U.S. Patent No. 11,857,333

**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. 11,857,333 (“the ’333 Patent”), its prosecution history, the *inter partes* review petition that Petitioner ResMed Corp. (“Petitioner” or “ResMed”) submitted regarding the ’333 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 ’333 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

A. Claim Construction

17. I have been informed through counsel that during this inter partes review proceeding (because this petition for inter partes review was filed after November 13, 2018), claims terms should be given their “ordinary and customary meaning as would be understood by a person of ordinary skill in the art in question at the time of the invention.” I have further been informed that for determining the meaning of a disputed claim term, it is appropriate to “look principally to the intrinsic evidence of the record, examining the claim language itself, the written description, and the prosecution history.” I understand that a term is introduced with an indefinite “an” article and subsequently referred to with the definite “the” article. I further understand that extrinsic evidence can be helpful in demonstrating how a term is

used in the art, and how the plain meaning is applied in the context of the intrinsic record.

18. I understand that the Patent Office will look to the specification and prosecution history in construing a given claim term. I understand the Patent Office will also sometimes look to other evidence, which I am informed is called “extrinsic” evidence, including dictionary definitions, for how a person of ordinary skill in the art would have understood a claim term.

19. I understand that a patent’s “specification” includes all of the figures, discussion, and claims within the patent, including those that are incorporated by reference. I understand that the “prosecution history” includes the statements made to and dialogue with the patent office in the course of obtaining the patent, and that the prosecution history of any parent application can contain relevant information.

B. Obviousness

20. 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 is 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.

21. 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.

22. 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.

23. 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.

24. 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.

25. 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.

26. 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

27. 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

28. 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. Additional experience could substitute for less education, and additional education could likewise substitute for less experience.” Pet. at 3-4. Based on my training and experience (*see* CV), I meet this definition and use this POSITA for my opinions.

VI. THE RELEVANT ASSERTED ART

A. Toge (Ex. 1044)

29. Toge’s system enables a physician to remotely monitor a patient who is being treated with a PAP device. Toge at Abstract. The physician can set one or more threshold values that, when met, trigger the relay device to push alerts to the physician’s computer or mobile device. *See Id.* at ¶¶ [0050]-[0058], [0061]. For example, if a patient’s oxygen saturation falls below 90%, the relay device pushes this “crucial data” to the physician’s devices. *Id.* at ¶¶ [0054], [0057]. In response

to these alerts, the physician can, for example, increase the prescribed pressure that the PAP machine provides to the patient. *See Id.* at ¶ [0047].

B. Kumar (Ex. 1008)

30. Kumar operates a web-based central server that hosts patient data and sends data to physicians upon request. In Kumar’s system, patient data is sent from **patient-side device 102** to **web-based central server 106** where it is stored for later retrieval. When physicians wish to view a particular patient’s data, they use physician’s devices 104 to request and view data using a webpage interface:

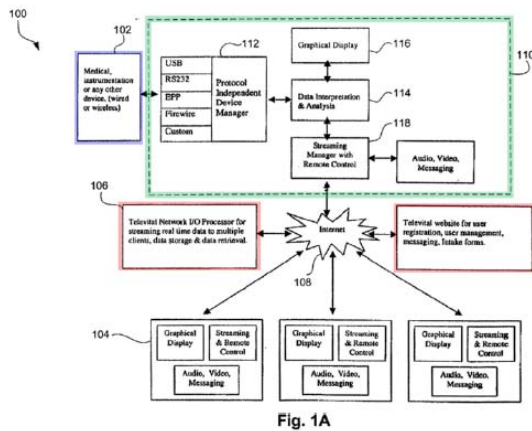


Fig. 1A

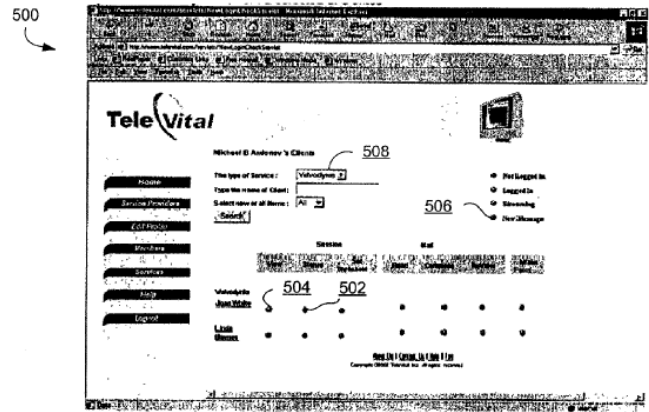


Fig. 5

Pet. at 24 (citing Ex. 1008, FIG. 1A (annotated)); Kumar at FIG. 5 (showing the webpage interface to central server 106); *see also id.* 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.”), ¶¶ [0078]-[0083], [0091]-[0092].

C. Norman (Ex. 1059)

31. Norman describes a method and system for the automated titration of the CPAP with a processing arrangement that is one of many distinct components in providing CPAP therapy. Norman at Abstract. Norman's system 1 reproduced below includes a mask 20, tube 21, flow generator 22/flow control device 25 (*i.e.* the PAP/CPAP device),¹ a processing arrangement 24, and a titration device 26. Norman at FIG. 6; *see also Id.* at ¶¶ [0019]-[0020], [0023]. Unlike the invention disclosed and claimed in the '333 Patent, Norman discloses determining counts/indexes based on collected data with a processing arrangement of 24/titration device 26 that is separate from the PAP/CPAP device:

¹ The components of a PAP/CPAP machine are the "Flow Generator, Air Pressure Hose, and [mask] interface." Ex. 2023 at 2-3.

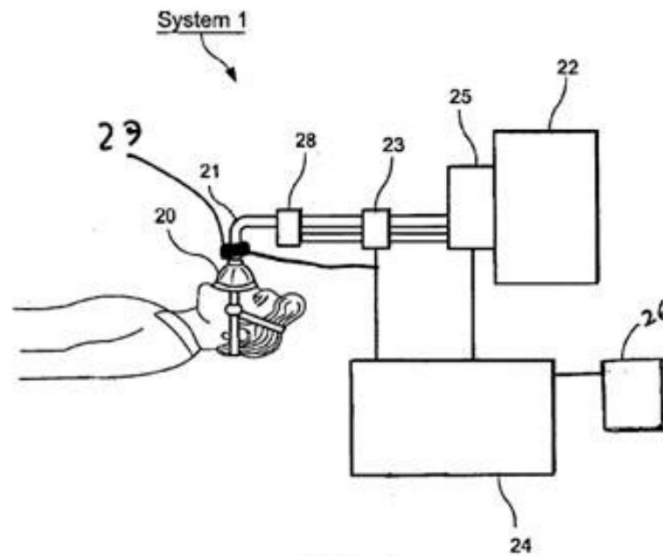


FIG. 6

Norman, Fig. 6; *id.*, Claim 28 (reciting the “coupling to a positive airway pressure supply system a removable diagnostics unit . . . including a processor”). Titration device 26, which receives the calculated data and adjusts the PAP pressure, may be part of, or separate from and communicatively connected to, processing arrangement 24. *See id.* at ¶¶ [0024]-[0033], FIG. 7.

VII. GROUND 1: TOGE IN VIEW OF KUMAR DOES NOT DISCLOSE A PAP DEVICE THAT CALCULATES “QUANTIFIED LEVEL OF SEVERITY DATA”

A. Claim Construction: “Quantified Level of Severity Data”

32. In my opinion, a POSITA would understand that the claimed “quantified level of severity data” is a value that indicates how dire a patient’s symptoms are. This is consistent with the plain language of the term and with the

interpretation taken by D'Ambrosio during claim construction briefing in the parallel litigation between the parties:

Since the time of the invention, a commonly used term within the clinical sleep setting has been “*level of severity*” which clinicians understand to represent the *how dire a patient’s calculated symptom data may be*. For example, a clinician would recognize a patient’s symptom’s as severe if their data shows a *respiratory disturbance index (RDI) or apnea-hypopnea index (AHI)* of greater than or equal to 30 events per hour of sleep. The RDI is the sum of all the apneas, hypopneas, and Respiratory Effort Related Arousals (RERAs) divided by total sleep time. The AHI is the sum of all the apneas and hypopneas divided by the total sleep time.

Ex. 1058 at ¶ 32 (emphasis added). I understand that this is also consistent with Petitioner’s expert’s, Dr. Schwartz’s understanding in a related PGR proceeding. Ex. 2026 at ¶ 46 (asserting that sleep apnea indices represent the level of severity of sleep disordered breathing with sleep apnea indices).

33. A POSITA would understand that an index such as AHI or RDI is calculated based on breathing events that are collected over time and calculated to assess the severity of symptoms. *See* Ex. 2027 at 175. For instance, the patient’s respiratory airflow data may be analyzed to identify sleep disordered breathing events, including apneas and hypopneas (symptoms). With a further analysis

counting the number of the events that occur over a period of time to get the index to quantify the level of severity of the sleep disorder symptoms. Ex. 2016 at 516.

34. In view of the above, it is my opinion that a POSITA would recognize “quantified level of severity” as a calculated value that represents how dire a patient’s symptoms are, not a simple breathing metric or symptom.

B. Toge’s Tidal Volume Data is Not a “Quantified Level of Severity Data”

35. Toge’s tidal volume data is not a “quantified level of severity data,” as properly construed. Tidal volume data is not a calculated AHI, RDI, or other “quantified level of severity data,” it is a breathing metric that may be used to identify obstructive breathing events, such as apneas and hypopneas.

36. To the extent that tidal volume is relevant to the claims, it refers to the “data” collected “with the PAP or CPAP device from the flow or pressure sensor,” not “the subject’s sleep apnea symptoms” or “a quantified level of severity” of those symptoms. Tidal volume refers “the volume of air that is inspired or expired during a respiratory cycle.” Ex. 2028 at 13-14. Toge discloses measuring this value directly with a flow meter located in the patient’s mask or, if a dedicated flow meter is not provided, with several different flow meters and pressure gauges located throughout the system. Toge at ¶¶ [0033] (“Among the transmission data, if a flow meter (not illustrated) is provided near the patient’s nose within the nasal

mask 21, the measured value from this flow meter is used for the patient's tidal volume V_T . *see also id.* at ¶¶ [0034]-[0038] (measuring the patient's tidal volume with internal flow sensors and mask-based pressure gauges).

37. Consistent with the record evidence, tidal volume does not represent the subject's symptoms or their severity, although it can be analyzed to identify individual apnea and hypopnea events. Ex. 2028 at 13-14 (“[H]ypopnea events are defined as a reduction of $\geq 50\%$ or 74% in tidal volume from baseline and apnea events as absence of tidal volume for at least 10s.”); *see also* Ex. 2029 at 1 (“Sleep apnea can be characterized by reductions in the respiratory tidal volume This study investigates the feasibility of estimating the severity of sleep apnea, as quantified by the apnea/hypopnea index (AHI) using the estimated tidal volume. . . . The reductions in tidal volume were detected as potential respiratory events [apneas or hypopneas]”).

38. Accordingly, while tidal volume may be analyzed to identify “the subject's sleep apnea symptoms,” it is an indirect measure that does not directly represent those symptoms, let alone “a quantified level of severity data based on the subject's sleep apnea symptoms during the therapy,” absent further analysis. *See* Ex. 1058, ¶ 32. In this regard, Petitioner's reference to tidal volume amounting to “zero milliliters per breath” represents the breathing metric data used to determine the apnea event, not the calculated “quantified level of severity data,”

which indicates how dire a patient's calculated symptoms are. Pet. at 16-17; *supra* § VII.A.

39. Considering the foregoing reasons, it is my opinion that Toge's tidal volume data is not "quantified level of severity data," as claimed.

VIII. GROUND 2: THE CHALLENGED CLAIMS ARE PATENTABLE OVER TOGE IN VIEW OF KUMAR AND NORMAN

40. It is my opinion that Norman does not cure Toge's deficiencies with respect to claim limitation [15.c] because Norman does not determine "a quantified level of severity data" (identified as counts/indexes) using a processor "integrated" into the PAP device, and a POSITA would not have been motivated to determine such calculations at Toge's control unit 250, which Petitioner maps to the claimed "processor . . . integrated into the PAP or CPAP device." Toge, Kumar, and Norman all disclose analyzing data collected from a PAP machine at a dedicated external processor.

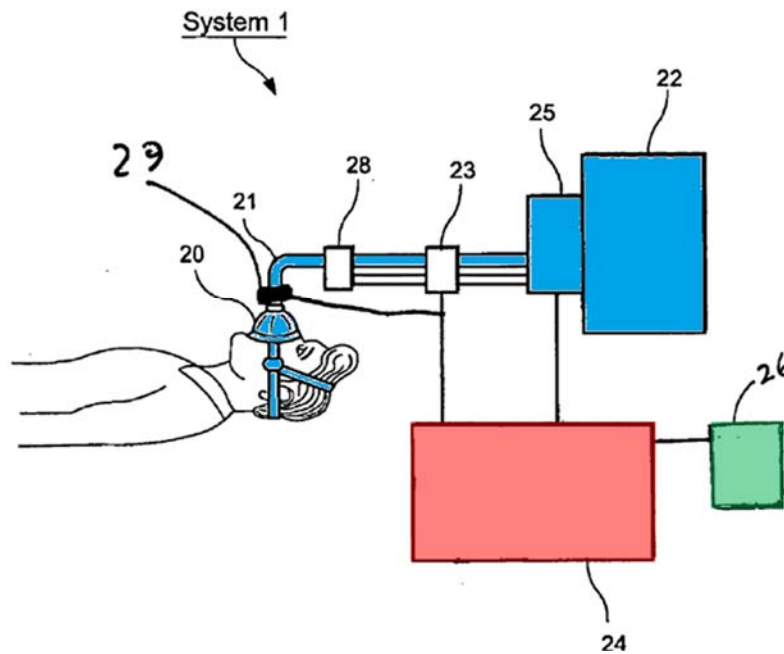
A. Neither Toge nor Norman Discloses a PAP Device that Quantifies the Level of Severity of the Patient's Symptoms

41. Neither Toge nor Norman discloses the claimed "processor . . . integrated into the PAP or CPAP device" that "analyz[es] the collected data to determine a quantified level of severity data based on the subject's sleep apnea symptoms during the therapy." '333 Patent at Claim 15. In the context of the claim, a POSITA would read "integrated into" to mean that the processor is inside

the PAP/CPAP device because “into” indicates inside. *See* Ex. 2030 at 1 (defining “into” as “the inside . . . of a place”); Ex. 2031 at 1 (defining “into” as “insertion”).

42. As I discussed above, Toge discloses collecting sensor data, including the patient’s tidal volume, and analyzing that data on an external device, like the physician’s computer. *See* § VII.B, *supra*. Norman does not cure Toge’s deficiency because it also discloses analyzing sensor data at an external processing arrangement rather than with a processor inside the PAP/CPAP device.

43. Norman’s system does not include a processor that is inside a PAP device to determine counts/indexes. Instead, Norman’s **processing arrangement 24** and **titration device 26** (identified as the claimed “processor”) are external to the **PAP/CPAP device**, as the Figure 6 annotation below illustrates. *See* Ex. 2023 at 1.



Norman at FIG. 6 (annotated); *see also id.* at ¶¶ [0019]-[0020], [0023], Claim 28 (“coupling to a positive airway pressure supply system a removeable diagnostics unit . . . including a processor”), Claim 33. In fact, the titration device is a portable stand-alone unit that may be easily attached to conventional therapy systems. *Id.* at ¶ [0032].

44. Based on this configuration, the identified processor’s determination of “counts/indexes” (Pet. at 57) is not taught as being “integrated into the PAP or CPAP device.” *See id.* at ¶ [0028]. Therefore, it is my opinion that Norman does not disclose this limitation, or cure Toge’s deficiencies, at least because the identified processor is not inside the PAP/CPAP device. Pet. at 56-57, 61. And for

the reasons discussed below, it is my opinion that a POSITA would not have been motivated to determine Norman's counts/indexes teachings at Toge's PAP device.

B. It is my Opinion that a POSITA Would Not Have Modified Toge Based on Norman and Arrived at the Claimed Invention

45. I disagree with Petitioner's argument that a POSITA would have implemented Norman's calculations at Toge's PAP processor. Neither reference suggests analyzing sensor data at the PAP machine.

46. Petitioner's argument that a POSITA would have performed Norman's data analysis at Toge's PAP processor relies on the untenable premise that "Toge already discloses a PAP device that collects sensor data and analyzes the sensor data using a processor." Pet. at 60-61. As I have detailed above, Toge's control unit 250 does not *analyze* collected sensor data, it collects that sensor data and sends it to the physician's computer for analysis. *See supra*, VII.B. Thus, the patient's tidal volume is measured directly or indirectly from sensor data and sent to the physician's device at regular intervals so that the physician can remotely evaluate the trend in the patient's condition over time. Toge at ¶ [0039] (describing a physician evaluating "decreasing trends in the tidal volume" that could require "adjusting the prescription pressure to a higher level."); *see also id.* at ¶ [0051] (sending tidal volume data to the physician-side device).

47. Accordingly, to the extent symptom identification and severity analysis occurs in Toge's system, a POSITA would understand that such activity is performed at the physician's device, not the PAP machine's processor. Because determinations of whether to make adjustments are, at best, performed at physician-side devices, a POSITA would not have been motivated to implement Norman's count/indexes determinations at the PAP processor, absent using the '333 Patent as a guide.

48. A POSITA would also consider the purpose of the Toge system when considering potential changes. As described above, all changes to the PAP system are made by the physician at a remote site with the physician-side devices. "The present invention pertains to a **remote monitoring method** for monitoring the condition of a patient using a positive pressure artificial respiration assisting device remotely." Toge at ¶ [0001] (emphasis added). Implementing the architecture of Norman into the Toge system would be a fundamental architecture change. The Toge system leaves changes in prescription pressure in the hands of the physician. "[M]easures, such as adjusting the prescription pressure to a higher level, can be taken remotely from the physician-side computer 4 or mobile terminal 5." Toge at ¶ [0039]. From a regulatory perspective, there is a dramatically elevated burden to shift from a physician-decision system to an automated-decision system, especially when those changes are directly impacting therapy. A POSITA would recognize

this burden and would not be motivated to modify the fundamental architecture of Toge absent hindsight bias.

IX. GROUNDS 3 AND 4: DEPENDENT CLAIM 19 IS PATENTABLE OVER TOGE IN VIEW OF KUMAR AND BURTON AND/OR KUMAR, NORMAN AND BURTON

49. Because Petitioner fails to demonstrate that Toge in view of Kumar or additionally in view of Norman renders obvious Independent Claim 15, Petitioner also fails to establish that Dependent Claim 19 is unpatentable.

X. CONCLUSION

In view of the foregoing, it is my opinion that the Challenged Claims are patentable over the asserted references.

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 28, 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 Haghpanahi – 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 McKeehan, 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 11020524, 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>
2. Goyal, Krittika, David A. Borkholder, and Steven W. Day. "A biomimetic skin phantom for characterizing wearable electrodes in the low-frequency regime." Sensors and Actuators A: Physical 340 (2022): 113513. <https://doi.org/10.1016/j.sna.2022.113513>
3. Conn, Nicholas J., Karl Q. Schwarz, and David A. Borkholder. "In-home cardiovascular monitoring system for heart failure: comparative study." JMIR mHealth and uHealth 7, no. 1 (2019): e12419. <https://doi.org/10.2196/12419>

4. Conn, Nicholas J., Karl Q. Schwarz, and David A. Borkholder. "Nontraditional electrocardiogram and algorithms for inconspicuous in-home monitoring: comparative study." *JMIR mHealth and uHealth* 6, no. 5 (2018): e9604. <https://doi.org/10.2196/mhealth.9604>
5. Liberson, Alexander S., Yashar Seyed Vahedein, and David A. Borkholder. "Application of Variational Principle to Form Reduced Fluid-Structure Interaction Models in Bifurcated Networks." *Journal of Fluid Flow, Heat and Mass Transfer* 4 (2017). <https://doi.org/10.11159/jffhmt.2017.001>
6. Lillie, Jeffrey S., Alexander S. Liberson, and David A. Borkholder. "Quantification of hemodynamic pulse wave velocity based on a thick wall multi-layer model for blood vessels." *Journal of Fluid Flow, Heat and Mass Transfer* 3 (2016). <https://doi.org/10.11159/jffhmt.2016.007>
7. Lillie, Jeffrey S., Alexander S. Liberson, and David A. Borkholder. "Improved blood pressure prediction using systolic flow correction of pulse wave velocity." *Cardiovascular engineering and technology* 7 (2016): 439-447. <https://doi.org/10.1007/s13239-016-0281-y>
8. Liberson, Alexander S., Jeffrey S. Lillie, Steven W. Day, and David A. Borkholder. "A physics based approach to the pulse wave velocity prediction in compliant arterial segments." *Journal of biomechanics* 49, no. 14 (2016): 3460-3466. <https://doi.org/10.1016/j.jbiomech.2016.09.013>
9. Lillie, Jeffrey S., Alexander S. Liberson, and David A. Borkholder. "Quantification of hemodynamic pulse wave velocity based on a thick wall multi-layer model for blood vessels." *Journal of Fluid Flow, Heat and Mass Transfer* 3 (2016). <https://doi.org/10.11159/jffhmt.2016.007>
10. Lillie, Jeffrey S., Alexander S. Liberson, Doran Mix, Karl Q. Schwarz, Ankur Chandra, Daniel B. Phillips, Steven W. Day, and David A. Borkholder. "Pulse wave velocity prediction and compliance assessment in elastic arterial segments." *Cardiovascular engineering and technology* 6 (2015): 49-58. <https://doi.org/10.1007/s13239-014-0202-x>
11. Liberson, Alexander S., Jeffrey S. Lillie, and David A. Borkholder. "Numerical solution for the boussinesq type models with application to arterial flow." *Journal of Fluid Flow, Heat and Mass Transfer (JFFHMT)* 1 (2014): 9-15. <https://doi.org/10.11159/jffhmt.2014.002>

ISSUED PATENTS

1. Borkholder, David A., Nicholas J. Conn, and Masoumeh Haghpanahi. "Apparatus, system and method for medical analyses of seated individual." U.S. Patent 12,036,044, issued July 16, 2024.
2. Borkholder, David A., and Hamed Shamkhalichenar. "Systems, devices, and methods for measuring body temperature of a subject using characterization of feces and/or urine." U.S. Patent 11,969,229, issued April 30, 2024.
3. Borkholder, David A., Austin McChord, Nicholas Joseph Conn, and Steve Petrucelli. "Systems, devices, and methods for measuring loads and forces of a seated subject using scale devices." U.S. Patent 11,650,094, issued May 16, 2023.
4. Borkholder, David A., Alexander S. Liberson, Jeffrey S. Lillie, and Steven W. Day. "Pulse wave velocity, arterial compliance, and blood pressure." U.S. Patent 11,622,730, issued April 11, 2023.
5. Borkholder, David A., Nicholas J. Conn, and Masoumeh Haghpanahi. "Apparatus, system and method for medical analyses of seated individual." U.S. Patent 11,234,651, issued February 1, 2022.
6. Borkholder, David A., Nicholas J. Conn, and Masoumeh Haghpanahi. "Apparatus, system and method for medical analyses of seated individual." U.S. Patent 10,292,658, issued May 21, 2019.