UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.
Petitioner,

v.

CLEVELAND MEDICAL DEVICES, INC.
Patent Owner.

Case IPR2025-00159
U.S. Patent No. 11,375,921

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 Plaintiff Cleveland Medical Devices Inc. ("Patent Owner" or "CleveMed") to submit this declaration in the matter referenced above. I have reviewed U.S. Patent No. 11,375,921 ("the '921 Patent"), its prosecution history, the *inter partes* review petition that Defendant ResMed Corp. ("Petitioner" or "ResMed") submitted regarding the '921 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 '921 Patent which is Nov 4, 2005.

II. MATERIALS CONSIDERED

2. In the above referenced IPR, I have reviewed both Petitioner's exhibits, including Kumar (Ex. 1008) and Toge (Ex. 1044), Patent Owner's exhibits, including Dr. Goodrich's declaration (Ex. 2015), and the PTAB papers.

III. EXPERIENCE AND QUALIFICATIONS

3. 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.

4. 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.

5. 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 and defined key elements of the curriculum. This program was announced in April of 2003 and launched in the fall of 2004, graduating the first students in the spring of 2008. The option provided a unique undergraduate curriculum teaching biomedical design that was usually offered only at the graduate level (see statement from Robert Bowman, department head for EE in https://www.rit.edu/news/rit-launches-biomedical-engineering-studies). 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.

6. 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.

7. 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.

8. 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).

9. 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).

10. 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.

11. 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.

12. 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.

13. 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.

14. 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.

15. 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.

16. 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.

IV. COMPENSATION

17. 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.

V. LEGAL STANDARDS

18. 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.

19. 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).

20. 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.

21. 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.

22. 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.

23. 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. Claim Construction

24. 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.

25. 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.

26. 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

27. 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.

28. 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.

29. 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.

30. 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.

31. 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.

32. 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.

33. 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

34. 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.

VI. PERSON OF ORDINARY SKILL IN THE ART

35. I understand that for purposes of this IPR, ResMed is asserting that the person of ordinary skill in the art ("POSITA") in 2005, as one having "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 12-13.

36. As detailed in my "Experience and Qualifications" section, I qualify as a POSITA. My opinion herein will be based on a medical device developer/network specialist who designs medical devices and their backend architecture. As described

above, I have worked in the development of numerous medical device systems and therefore have expertise in the overall design process.

VII. BIOMEDICAL DEVELOPMENT PROCESS INCORPORATING DISTRIBUTED ARCHITECTURE

37. In my opinion, a person of ordinary skill in the art in 2005, working in the field of medical devices, would not have independently combined the biomedical engineering aspects of a medical device with the network engineering aspects of wireless data transmission to a backend server. The two disciplines required distinct technical expertise that, at that time, did not typically reside in a single practitioner. This is one of the motivations for creating the biomedical option within electrical engineering at RIT I described in ¶ 4, to address this gap in education by creating understanding and capabilities in our graduates that is uncommon, even today.

38. In 2005, the development of medical devices that required wireless communication to a backend architecture would involve close collaboration between the medical device developer (such as a biomedical engineer) and network specialist (such as network engineer). In 2005, a medical device developer would have been primarily trained and experienced in areas such as human physiology, device design, bio-signal acquisition, sensor integration, and compliance with FDA and IEC safety standards. Their focus was on ensuring accurate and safe capture of patient data,

validating device performance through bench and clinical testing, and meeting stringent requirements for medical device approval.

39. The medical device developer's role is to design and validate the medical device itself, including the sensing components, embedded hardware, signal acquisition, signal conditioning, and device-level software necessary for capturing patient data in a reliable and clinically meaningful manner. Medical device developers ensure that the device adheres to regulatory standards for safety and efficacy, including considerations such as electrical isolation, biocompatibility, and compliance with standards relevant to medical electrical equipment.

40. Medical device developers worked with network specialists for their expertise in wireless protocols, packet routing, security protocols, and integration with backend IT infrastructure.

41. A network specialist would be responsible for designing and implementing the communication stack that enables secure and reliable transmission of patient data from the medical device to a backend infrastructure or server. This included selecting and configuring appropriate wireless protocols (such as Bluetooth, Wi-Fi, or proprietary RF protocols that were prevalent at the time), implementing error detection and correction mechanisms, addressing interference and signal strength limitations, and ensuring that data packets could be transmitted

consistently in real-world environments such as hospitals, clinics, or home care settings.

42. The integration process usually requires iterative collaboration. The medical device developer defines the data acquisition requirements (e.g., sample rates, data formats, latency tolerances), while the network specialist assesses how those requirements could be supported within the constraints of the available wireless technologies and backend infrastructure in 2005. For example, if continuous monitoring generated substantial amounts of data, the network specialist might recommend data compression or changes in the network's architecture.

43. Finally, both engineers would coordinate to ensure compatibility with backend systems. The medical device developer would be concerned with the clinical integrity of the data, while the network specialist ensures that the communication infrastructure could authenticate devices, protect patient privacy, and deliver the data into server-side applications for storage, analysis, and/or retransmission.

VIII. A MEDICAL DEVICE DEVELOPER/NETWORK SPECIALIST WOULD NOT HAVE MODIFIED TOGE'S PHYSICIAN-SIDE COMPUTER INTO A WEB SERVER

44. I understand that Petitioner and its experts, Dr. Kirkness and Dr. Chatterjee, allege that a POSITA would have found it obvious to implement Toge's physician-side computer as a web server, as Dr. Chatterjee states:

> A person of ordinary skill in the art would have understood that if data can be transmitted through the Internet to and from the physician-side computer, ***the physician-side computer could be implemented as a web server***.

Ex. 1005 ("Chatterjee") at ¶ 146 (emphasis added); *see also id*. at ¶ 147 ("Alternative, a person of ordinary skill in the art would have been motivated and found it obvious to implementing [sic] the physician-side computer of Toge [as a web server] using the implementation detail taught by Kumar."); *see also* Pet. at 15.[1]

45. I disagree. Whether Toge is taken alone or with Kumar, neither reference would have prompted a medical device developer/network specialist to change Toge's principle design by modifying its physician-side computer into a web server.

[1] I understand that Petitioner and its experts consistently identify "a browser-based engine" on a server that is accessible through a web page as the "remote internet site." *See* Pet. at 50, 52, 54, 56, 60, 65; Chatterjee at ¶ 66; Ex. 2018 ("Chatterjee Tr.") at 22:20-23:1 (identifying "Apache web server" as web server software that is run on a server). For brevity, Petitioner's identification of a "remote internet site" is referenced herein as a "web server."

46. Toge's system includes a PAP device, a relay device (incorporated in the PAP device or at a nurse station), a physician-side computer, and a mobile device. *See* Toge at Fig. 1. In Toge's system infrastructure, the PAP device pushes treatment data to physician-side computer and mobile device without any request. *id*. at ¶¶ [0039], [0047], [0054].

47. With Toge's system, the PAP device selectively pushes crucial data to the physician's personal devices when a threshold is met, and emergency action is needed:

> By setting thresholds in this manner, it becomes possible to selectively ***transmit only the necessary or crucial data to the physician-side computer 4 or portable device 5***.

Toge at ¶ [0054] (emphasis added). For instance, Toge explains that by setting a threshold (for example, 90% oxygen saturation), the physician's personal devices are pushed "crucial data" when the threshold is met such that physicians "can take emergency measures" (adjusting the pressure of the PAP device, for example). *Id*. at ¶ [0047]; *see also id.* at ¶ [0039]. In this way, physicians actively monitor and manage their patients' PAP devices without having to login to a web page and make any request for the data.

48. A medical device developer would understand that Toge's sender-push model ensures that crucial treatment data is received by a physician. The developer

would appreciate the time challenges faced by physicians and as such kept with a system design that provides only the required information in a way that limits the time required by the physician for such monitoring. Indeed, part of an effective medical device monitoring system is minimizing physician burden.

49. A developer/network specialist therefore would not have moved to a web-based application, as Petitioner and its experts propose, that requires proactive monitoring by physicians. Particularly, Petitioner's proposed modification presents a client-server architecture where a client presents the treatment data and the web server stores the data and transfers it upon a client accessing a web page and making an HTTP request. Pet. at 16 (In the proposed modification, "the physician or provider can access the data" through web pages "as opposed to downloading specialized software"); Chatterjee at ¶ 87; Chatterjee Tr. at 26:11-27:5; Ex. 1003 ("Kirkness") at ¶136; Ex. 2019 ("Kirkness Tr.") at 98:19-99:4. Such an application would have interfered with Toge's sender-push model and made the system more difficult for the physician to use as they are extremely limited in their time.

50. For at least the foregoing reasons, a POSITA would not have found it obvious to change Toge's physician side computer into a web server.

IX. CONCLUSION

51. In view of the foregoing, it is my opinion that a medical device developer/network specialist would not have made the modification proposed by Petitioner and its experts.

52. 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 September 16, 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

4752 WEST LAKE ROAD, CANANDAIGUA, NY 14424 585.402.2806 DBORKHOLDER@GMAIL.COM

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 neurcognitive 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."

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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)

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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

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- Cody Cziesler, 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

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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

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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

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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.