


Brian D. Gross, BSEE, M.Sc., RRT, SMIEEE

<p>Summary</p> 	<p>With over 35 years of experience, Brian Gross is a leader with a proven record of bringing medical devices to market. As Founder and CEO of his LLC, he is focusing on SaaS/Subscription of licensed knowhow he originated while with Philips, services, and consulting. Domains include business and innovation leadership, strategy, intellectual property, standards, medical device regulatory pathways, and information systems. During his stint with Philips, he last served as the business leader for the <i>Genomics for Infectious Disease</i> Group and was responsible to scale the startup business. As a Fellow Scientist and Clinical Systems Architect, he was responsible to lead teams of multinational clinical, engineering and research resources on multiple organic and co-creation innovations. Many of these innovations have led to adjacent products, solutions, and new businesses for Philips.</p> <p>In his prior roles he was directed business funded research and advanced development focused on patient monitoring, AI based disease detection and prediction, time critical decision applications, advanced clinical decision support applications, and application interoperability. He was also responsible for clinical research and validation activities for the global Patient Monitoring businesses. Brian has extensive experience designing, developing, and conducting clinical research, and advanced product development, including large animal surgery and instrumentation.</p> <p>Brian is a senior member of AAMI Medical Alarm Standards Committee where he led the delivery of TIR documents and consensus-based alarm standards. He is a recognized technical and clinical expert on IEC/ISO TC62D committee. He served as an investigator on several very competitive publicly funded projects including the NIH-NIBIB funded Bioengineering Research Partnership with Massachusetts Institute of Technology and Beth Israel Hospital (MIMIC). More recently, he was an investigator responsible for the technical development and roll out of a Class 2 cloud based CDS medical device for ICU (Process AWARE) as part of the CMS Innovation Grant with Mayo Clinic and the NIH's US Critical Illness and Injury Trials Group.</p> <p>He was also a key contributor in several Department of Defense funded research projects focused at acquisition of clinical datasets to be used in AI/ML algorithm development (RATE) activities, as well as regulatory and commercialization activities needed to deliver the work products for DoD acquisition.</p> <p>Brian received his BSEE and MSc in Biomedical Engineering from Worcester Polytechnic Institute, in Worcester Massachusetts. He is a licensed Respiratory Care Practitioner in the Commonwealth of Massachusetts and was formally a Paramedic and Paramedic Skills Evaluator in New York. He is a senior member of the IEEE, a member of the American Association of Respiratory Care, and the Society of Critical Care Medicine.</p>
<p>Experience</p>	<p>2022 - pres. Founder and CEO– Genomics for Infectious Disease (G4ID), LLC, North Andover, MA</p> <ul style="list-style-type: none">• G4ID is focusing on SaaS/Subscription of licensed products from Philips, services, and consulting. Domains include business and innovation leadership, strategy, intellectual property, medical device standards, medical device regulatory pathways, and information systems.

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	<p>2019–2022 (Retired) Business Leader – Genomics for Infectious Disease, Philips, Cambridge MA</p> <ul style="list-style-type: none"> Created and advanced new business through Bell-Masson Alpha phase. Focused on de-risking new-to-world minimally viable proposition (MVP) involving next generation sequencing, bioinformatics and clinical informatics, creation of new SaaS/Subscription business models in traditionally capital Order-to-Cash business system, manage evidence / proof creation, launch vitality, and delivering committed EBIT. <p>2014 – 2022 (Retired) Fellow Scientist / Clinical Systems Architect- Patient Care and Monitoring Solutions, Clinical Science, and Innovation. Philips, Andover / Cambridge MA</p> <ul style="list-style-type: none"> Drove innovation across the cluster including creating internal and external funding and clinical partner opportunities. Created and drove integrated global teams, target landing business's QMS, and SAFE-agile methodologies to ensure rapid co-creation of MVP, design / execute meaningful outcome studies through clinical partners. Expanded clinical KOL, and key customer relationships. <p>2006 - 2014 Principal Scientist / Clinical Systems Architect- Patient Care and Monitoring Solutions, CTO- Research and Advanced Development. Philips, Andover MA</p> <ul style="list-style-type: none"> Synthesized and drove strategy through system specification including risk management, usability strategy and design goals. Managed innovation funnel through internal external clinical research assets to support long range business goals. Evaluated M&A opportunities for clinical, technical and business fit. Drove consistency, simplicity and value to the Philips businesses and solutions while demonstrating progress toward Clinical Decision Support innovation funnel and prioritization. Lead external standards activities, clinical KOL, and key customer relationships. <p>2001 – 2006 Senior Manager of Clinical Research. Ultrasound and Monitoring, Research and Development, Philips, Andover MA</p> <ul style="list-style-type: none"> Reorganized validation efforts from a product / box perspective, to a system and solution approach. Originated and owned execution of new process to drive down effort, cost and complexity of prerelease testing. Enhances services to include creation of regulatory and basic science clinical data. <p>1993 – 2001 Field Trial/Clinical Validation Manager, Patient Monitoring Division, Research and Development. Agilent Technologies - Hewlett Packard Medical Systems, Andover MA</p> <ul style="list-style-type: none"> Developed ISO 9001 / globally complaint process for conducting prerelease testing of regulated medical devices. Service multiple businesses and product teams through planning and execution of the process. Demonstrated reduction in post release defect density and increase NPS while ensuring global regulatory compliance. <p>1991– 1993 Scientist, Product Development Engineering: VivaScan Corporation, Southboro, MA</p> <ul style="list-style-type: none"> Start-up contract research company, prototyping Near Infrared Acousto-Optic Tunable Filter (solid state optical filter) system for non-invasive
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	<p>medical applications. Designed and build discrete instrumentation and delivered animal and human testing results.</p> <p>1989– 1991 Research Fellow, Sponsored Research, Worcester Polytechnic Institute, Worcester, MA</p> <ul style="list-style-type: none"> • Small medical device manufacturer funded treatment modality for splanchnic ischemia. Developed novel artificial lung, instrumentation system and optimized system though POC animal testing. <p>1985– pres. Respiratory Care Practitioner, University of Mass. Medical Center, Worcester, MA, St. Joseph’s Hospital and Health Center, Syracuse, NY</p> <ul style="list-style-type: none"> • Devised treatment plan based on diagnostic evaluation and monitoring of critical care neonatal, pediatric, and adult patients. Initiate life sustaining modalities and care for chronic home care patients. <p>1983– 1988 Paramedic/Skills Evaluator, Syracuse University Ambulance, Carrier Dome Medical, Baldwinsville Ambulance, WAVES Ambulance, Syracuse, New York</p> <ul style="list-style-type: none"> • Coordinated, scheduled, and supervise deployment of other paramedics while providing emergency medical care and team coverage for 50,000 spectators. Delivered emergency care in the streets to sick and injured
<p>Awards</p>	<p>2019 Visionary Award, Cambridge Chamber of Commerce- Philips for their development of the Precision Infection Prevention software: IntelliSpace Epidemiology Information System.</p> <p>2016 Outstanding Innovation Award, Philips (global companywide award) - Genomics for Infectious Disease</p> <p>2016 Third Prize Poster Presentation, “Information Reign From The Cloud- A Time Critical Cloud-Based Decision Support System Operating On De-Identified Data” IEEE/EMBS-BHI and HIMSS Conference, Las Vegas</p> <p>2015 Outstanding Innovation Award, Philips (global, companywide award) - Monitoring as a Service- A Rapid Co-creation</p> <p>2014 Outstanding Innovation Award, Philips (global, companywide award) - Project AWARE with Mayo Clinic</p> <p>2011 Best Research Paper of 2011 Awarded by Biomedical Instrumentation & Technology Editorial Board for Physiologic Monitoring Alarm Load on Medical/Surgical Floors of a Community Hospital</p> <p>2002 Employee of the Month (October) Philips Medical Products Group</p> <p>1990 First Prize Biomedical Research Competition - Worcester Polytechnic Institute, “Design and Evaluation of a Fiber Optic Fluorescent Sensor System”</p>

	1987	Student Scholarship Award, New York Society of Respiratory Care , Syracuse NY
	1986	Honorary Life Membership, Syracuse University Ambulance , Syracuse NY
Education	1991	M.Sc. Biomedical Engineering , Worcester Polytechnic Institute, Worcester, MA. Master's Thesis: <i>The Design and In-vivo Evaluation of an Intestinal Intraluminal Membrane Oxygenation system (Artificial Lung)</i> .
	1990	BSEE Electrical Engineering and Biomedical Engineering (With Distinction), Worcester Polytechnic Institute, Worcester, MA. Senior Thesis: <i>A non-invasive Fluorescent Fiber Optic PCO₂ Sensor for pH Monitoring</i> .
	1986	AAS Respiratory Care (With Honors), State University of New York, Syracuse, NY, NBRC registered, and Mass Licensed Respiratory Care Practitioner (RT-1918).
	1985	Certified Paramedic Upstate Medical Center, Syracuse, NY, (EMT-P 63993)
	1982-1986	Industrial Design and Engineering (attended) Syracuse University, Syracuse, NY
Professional Interests and Appointments	2014 – pres.	Appointed by ISO to IEC - TC 62/SC 62D/JWG 22, Medical Devices and Alarm Systems - Technical and Clinical Expert
	2012	Affiliate Researcher, Massachusetts Institute of Technology, Cambridge, MA.– Informatics CSAIL
	2011– pres.	Society of Critical Care Medicine – General Member
	2011	AMA/IEEE Conference Session Chair- Clinical Decision Support and Individualized Medicine- Boston.
	2009 - 2013	IEEE EMBS Industry Relations - Committee Member
	2008 - 2022	AAMI/HE Human Factors Engineering Committee - Member Liaison
	2007 - 2022	AAMI/AL Medical Device Alarms Committee- Member
	1989	Advisor and founding member of Worcester Polytechnic Institute Emergency Medical Service, Worcester, MA
	1988 – pres.	Institute of Electrical and Electronics Engineers - Senior Member
	1986 – pres.	National Board Respiratory Care - Registered member

	<p>1985 – pres. American Association of Respiratory Care - Active Member</p> <p>1999 – 2001 American Heart Association, Merrimack Valley MA Chapter - Board of Directors</p>
Community Service	<p>2011 – 2017 Elected Official - School Committee- North Andover, MA</p> <p>2004 – 2012 Board of Directors – North Andover Music Association - North Andover, MA</p> <p>2004 – 2016 Instructor – Kenpo Karate (second degree Black Belt) - North Andover, MA</p> <p>1988 – 1990 Paramedic (Worcester Polytechnic Institute EMS– Worcester, MA</p> <p>1983 – 1988 CPR/ First Aid Instructor – Syracuse, NY</p> <p>1983 – 1988 Paramedic (Greater Baldwinsville Ambulance Corps, West Area Volunteer Ambulance, Syracuse University Ambulance) – Syracuse, NY</p>
Publications (selected)	<p>Genomics for Infectious Disease</p> <p>KR Hansen, RT. Ellison, DV. Ward, DJ. Holler, JL. Ashworth, MM. Fortunato-Habib, JJ. Carmona, BD. Gross. “Accuracy of Infection Control Surveillance in Identifying Genomically Confirmed Cross-transmission Clusters”. <i>The 6th Decennial International Conference on Healthcare Associated Infections</i>, Decennial 2020, co-sponsored by the Infectious Diseases Society of America (IDSA) and Centers for Disease Control and Prevention (CDC), Washington, DC; 26 – 30 March 2020; Abstract 563, Poster No. 930 Accepted Dec 2019</p> <p>DS. Chen, M Quinn, RM. Sussner, T Rowland, G Rinck, S Labrecque, L Mack, B Clones , G Wang, M Chanza, W Huang, C Scurlock, CD. Becker, AJ. Doty, JL. Ashworth, MM. Fortunato-Habib, B E. Wong, KR. Hansen, A Abdolahi, JJ. Carmona, BD. Gross. “Precision Infection Prevention (PIP) as a New Standard of Practice Within Longitudinal Infection Prevention and Surveillance”. <i>The 6th Decennial International Conference on Healthcare Associated Infections</i>, Decennial 2020, co-sponsored by the Infectious Diseases Society of America (IDSA) and Centers for Disease Control and Prevention (CDC), Washington, DC; 26 – 30 March 2020; Abstract 556, Poster No. 929 Accepted Dec 2019</p> <p>DS. Chen, RM. Sussner, M Quinn, G Wang, M Chanza, W Huang, C Scurlock, CD. Becker, JT. Fallon, KR. Hansen, JL. Ashworth, MM. Fortunato-Habib, JJ. Carmona, BD. Gross. “Minimizing pseudo-cluster suggestions in infection control surveillance using pathogen DNA sequencing and artificial intelligence”. European Society of Clinical Microbiology and Infectious Diseases, ECCMID 2020, Paris, FR, Apr. 18-21, 2020—Abstract Accepted January 2020</p> <p>Chen, D., Xu, L., Fortunato-Habib, M., Hoss, A., Chanza, M., Yin, C., Kolde, R., Dhand, A., Sussner, R., Carmona, J.J., Wang, G., Huang, W., Gross, B.D., Fallon, J. (2018). Genomic sequencing and clinical data integration for next-generation Infection Prevention. <i>Infectious Disease (ID) Week 2018</i>, Abstract #72682 (Accepted); 3-7 October 2018; San Francisco, CA</p>

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