CHRISTOPHER J. POLETTO, PH.D.

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Summary

Innovative biomedical engineer, scientist, thought leader, and teacher who is passionate about creating novel therapies to meet challenging unmet medical needs. Effective at identifying connections between seemingly disparate data sets and synthesizing them into usable knowledge. Accomplished inventor and intellectual property strategest. Well-rounded with a wide range of experience spanning the central and peripheral nervous system, clinical and non-clinical research, computational modeling, and experimental technologies, including hardware and software design. Significant contributions in academia and industry, from start-ups to Fortune 200 companies. Excellent communicator, creative problem solver, critical thinker, and rapid learner. Skilled at facilitating communication between engineers, scientists, executives, and physicians.

Professional Experience

Neurovation, LLC, North Oaks, MN **2011 - Present**

Founder and President

Consultant for medical device industry, academic researchers, and intellectual property concerns. Provides guidance on researching and developing therapies utilizing neural stimulation, with emphasis on intellectual property creation and strategy, experimental design for mechanism of action and electrical safety studies, regulatory interaction, cross-functional team formation, formulating research strategy, data analysis, and publication preparation.

- Provides expertise in science, engineering, and medicine to bridge gaps in client expertise.
- Provides program management with a focus on intellectual property strategy and execution, scientific research strategy and execution, and cross functional integration.
- Aids communication with top medical and scientific experts and key opinion leaders in the fields of neuroscience, neurosurgery, neurophysiology, neurology, anesthesiology, psychophysiology, and pain specialists.
- Provides independent scientific reviews to assure legal and ethical compliance, scientific merit, and feasibility of proposed research.
- Provides scientific content for communicating with regulatory agencies to obtain approval for clinical research or therapy commercialization.
- Provides specialized custom hardware and software design for simulation, data acquisition, and data analysis.
- Provides technical writing assistance.

Medtronic Neuromodulation, Fridley, MN **2007 – 2011**

Prinicpal Research Scientist 2007 - 2011

Key neural stimulation and headache global expert for cross-functional team charged with bringing a novel headache therapy to market. Obtained FDA IDE approval for major clinical trial. Managed the headache research portfolio, setting global headache research strategy for internal projects and review criteria for external projects and served as primary stimulation safety expert.

- Served on multiple boards for intellectual property and innovation strategy, therapy development, pre-clinical research oversight, quality systems planning, commercialization planning, and regulatory interaction.

- Wrote protocols for internal and contract research to improve responder rate, improve patient selection, and explore mechanism of action for a novel headache therapy.
- Proposed and experimentally verified hypothesized mechanism of action for novel headache therapy (occipital nerve stimulation, ONS)
- Cultivated and managed relationships with top experts and key opinion leaders in multiple countries across multiple disciplines.
- Conducted scientific reviews and managed projects to assure legal and ethical compliance, scientific merit, and timely completion.
- Served on multiple cross functional teams for technology and product development, risk analysis, reimbursement strategy, clinical research, innovation management, and marketing.
- Negotiated solutions to product safety concerns with regulatory agencies and obtaining product marketing approvals for diverse therapies in multiple countries.
- Served as thought leader for device and therapy innovation, creating an extensive intellectual property portfolio.

Principal Research Scientist **2007**

Designed and performed computational and animal model research aimed at improving an obesity therapy that had not performed well in clinical trials.

- Identified potential scientific explanations for unexpected clinical trial data
- Designed a technical solution using computational modeling
- Verified improvement experimentally *in vivo*

National Institutes of Health (NIH), Bethesda, MD **2000 – 2007**

Staff Research Biomedical Engineer, Laryngeal and Speech Section, Medical Neurology Branch, National Institute for Neurological Disorders and Stroke (NINDS)

Sole engineer for large, interdisciplinary team investigating normal and abnormal neural control of the larynx. Responsible for innovative technical development of research designs, analytical methods, instrumentation, including custom hardware and software, and staff training.

- Research interests included basic research of normal laryngeal control, spasmodic dysphonia and stuttering, as well as neuroprosthesis development for dysphagia.
- Developed two systems for treating dysphagia, one implanted, one external
- Proved that an FDA-approved system for treating dysphagia . had different physiological effects than commonly believed.
- Technologies utilized include: functional and anatomical MRI, magnetoencephalography (MEG), electroencelphalography (EEG), functional electrical stimulation (FES), electrictromyography (EMG), neural stimulation, video motion analysis, 3-D articulography, and videoradiography.
- Served as lab Safety officer, member of NINDS Safety Committee, and Controlled Substance Custodian.

LoomShuttle, Inc., Denver, CO **1998 – 2001**

President and Chief Executive Officer

Chief executive for international consulting services corporation with 25 employees producing digital signal processor firmware and software. Primary client was Texas Instruments, Inc.

Case Western Reserve University, Cleveland, OH **1993 – 2000**

Research Assistant, Functional Electronic Stimulation Institute & Department of Biomedical Engineering, Conducted research as graduate student in functional electrical stimulation,

psychophysics and electrotactile stimulation. Extensive computational modeling, hardware and software design. Cumulative GPA: 4.0
PhD Dissertation: *Fingertip Electrocutaneous Stimulation through Small Electrodes*
MS Thesis: *Perceptual Interactions between Electrocutaneous Loudness and Pitch*

Schlumberger Evaluation Services, Africa, Italy **1990 – 1993**
Senior Field Engineer,
Managed independent team of people and equipment to provide high-stakes oilfield logging services in high-risk countries with limited or no support. Team generated some of the highest revenues (~$14 million/annum) with the best safety record in West Africa. I achieved expert status in all technologies offered including cased and open hole logging, and seismic and explosives services. Success required leadership, rapid troubleshooting/problem solving, diplomacy, and cultural sensitivity. Served as radiation and explosive safety officer in multiple postings.

Baylor College of Medicine, Houston, TX **1989 – 1990**
Design Engineer, Division of Restorative Neurology, Design engineer for functional electrical stimulation projects to develop solutions for stroke, spinal cord injury, and demylination disease patients. Designed eight-channel TENS stimulator, gait path analysis hardware, EMG recording hardware, and audiovisual control and integration systems.

Baylor College of Medicine, Houston, TX **1988**
Robotic Design Engineer, Human Tissues Division,
Principal researcher for robotics applications in human tissues. Developed a commercially marketable automated system for cell preparation prior to staining in amniocentesis.

Rice University and **Texas Institute for Rehabilitation and Research**, Houston, TX **1988**
Research Assistant, Department of Mechanical Engineering, Researched and designed robotic applications for the handicapped. Designed sensors and sensory integration hardware and firmware. Managed project that resulted in two semi-autonomous personal robots that were successfully used in patients homes and could be controlled by voice, hand, or mouth.

Rice University, Houston, TX **1987**
Research Assistant, Department of Electrical and Computer Engineering, Investigated parameter optimized computational models of heart cells. Helped develop model for human Purkinje fiber. Implemented numerical methods library.

Academic Degrees

PhD	Case Western Reserve University	2000	Biomedical Engineering
	Dean's list for 4.0 GPA, Case Western Reserve University, every semester, 1993-2000.		
MS	Case Western Reserve University	1995	Biomedical Engineering
BSE	Rice University	1990	Robotic (EE & ME) Engineering

Professional Leadership Roles:
Pain Patent Board, Medtronic: Set intellectual property (IP) strategy and priorities
ONS Patent Board, Medtronic: Set IP strategy and priorities
PNS strategy Board, Medtronic: Suggest and prioritize potential therapies
Non-Clinical Research Board, Medtronic: Oversight of all neuromodulation animal studies
ONS Core team, Medtronic: everything related to bringing a novel headache therapy to market
ONS Product Development Team, Medtronic: product development, validation, labeling, etc.

ONS Reimbursement Team, Medtronic: set strategies for obtaining third party payment
Microstimulator Technology Team, Medtronic: product design specification and validation
ONS Clinical Evidence Team, Medtronic: Set publication strategy and reviewed literature

Honors and awards

- 'Top Abstract' at North American Neuromodulation Society meeting, 2010
- Multiple awards for exceptional performance at Medtronic
- National Institutes of Health Quality Step Increase based on high quality performance, 2001 and 2004.
- National Institutes of Health Staff Recognition Award for high quality performance, 2001, 2002, 2003, 2005.
- National Institutes of Health training fellowship, 1995-1996, 1999-2000.
- Winner, Student Poster Competition, Case Western Reserve University Biomedical Research Day, 1999.
- Outstanding College Students of America, Rice University, 1985-1990.
- Two-Ten National Scholarship, Rice University, 1985-1990.
- National Merit Scholarship, Rice University, 1985-1990.

Specific Skills

- Project management
- Strategic planning
- Scientific review
- Experimental design
- Technical writing
- Intellectual property
- Product development
- Clinical and non-clinical research
- Functional electrical stimulation (FES)
- Deep brain stimulation (DBS)
- Peripheral nerve stimulation (PNS)
- Electrotactile stimulation
- Neuroprosthetic design
- Medical imaging
- Anatomy and physiology
- Computational modeling and simulation
- Algorithm development
- Analog and digital circuit design
- Statistical analysis and design
- Programming (C, C++, Matlab, Labview)
- Technical Presentation
- Sensory psychophysics
- Graphical display of data
- Laboratory design

Peer reviewed Publications

- **Poletto CJ** and Van Doren CL. Perceptual interactions between electrocutaneous loudness and pitch, IEEE Rehab. Eng., vol. 3, pp. 334-342, 1995
- **Poletto CJ** and Van Doren CL. A high voltage, constant current stimulator for electrocutaneous stimulation through small electrodes. *IEEE Trans Biomed Eng* 46: 929-936, 1999.
- Trautmann S, Cheung N, **Poletto C**. Applications of the Processor Enhanced Memory Module for Music Signal Processing. *Proceedings of the International Computer Music Conference* 1999, Beijing, China p. 92-93
- **Poletto CJ** and Van Doren CL. Elevating pain thresholds in humans using depolarizing prepulses. *IEEE Trans Biomed Eng* 49: 1221-1224, 2002.
- Andreatta RD, Mann EA, **Poletto CJ**, and Ludlow CL. Mucosal afferents mediate laryngeal adductor responses in the cat. *J Appl Physiol* 93: 1622-1629, 2002.
- Bhabu P, **Poletto CJ**, Mann E, Bielamowicz S, and Ludlow CL. Thyroarytenoid muscle responses to air pressure stimulation of the laryngeal mucosa in humans. *Ann Otol Rhinol Laryngol* 112: 834-840, 2003.
- **Poletto CJ,** Verdun LP, Strominger R, Ludlow CL. Correspondence between laryngeal vocal fold movement and muscle activity during speech and nonspeech gestures. *J Appl Physiol*. 97(3): 858-66, 2004 .
- Kearney PR, **Poletto CJ**, Mann E, and Ludlow CL: Suppression of Thyroarytenoid Muscle Responses During Repeated Air Pressure Stimulation of the Laryngeal Mucosa in Awake Humans: Annals *of Otology Rhinology and Laryngology*. 114(4): 264-270, 2005
- Loucks TMJ, **Poletto CJ,** Saxon KG, Ludlow CL. Laryngeal Muscle Responses to Mechanical Displacement of the Thyroid Cartilage in Humans. *J Appl Physiol*. 2005 Sep; 99(3): 922-30.
- Ludlow CL, Humbert IJ, **Poletto CJ**, Saxon KG, Kearney PR, Crujido L, Sonies B. The Use of Coordination Training for the Onset of Intramuscular Stimulation in Dysphagia. *Proc. Of the 10th Annual Conference of the International FES Society July 2005 – Montreal, Canada*
- **Poletto CJ**. "Tactile Stimulation" in *Encyclopedia of Medical Devices and Instrumentation, 2nd Edition*, JG Webster ed. 6: 291-302, March 2006
- Ludlow CL, Humbert I, Saxon K, **Poletto C**, Sonies B, Crujido L. Effects of Surface Electrical Stimulation Both at Rest and During Swallowing in Chronic Pharyngeal Dysphagia. *Dysphagia*. 2007 Jan;22(1):1-10
- Humbert IA, **Poletto CJ**, Saxon KG, Kearney PR, Crujido L,Wright-Harp W, Payne J, Jeffries N, Sonies BC, and Ludlow CL. The Effect of Surface Electrical Stimulation on Hyo-Laryngeal Movement in Normal Individuals at Rest and During Swallowing. *J Appl Physiol* (July 27, 2006).
- Loucks TM, **Poletto CJ**, Simonyan K, Reynolds CL, Ludlow CL. Human brain activation during phonation and exhalation: common volitional control for two upper airway functions. Neuroimage. 2007 May 15;36(1):131-43.
- Simonyan K, Saad ZS, Loucks TM, **Poletto CJ**, Ludlow CL. Functional neuroanatomy of human voluntary cough and sniff production. Neuroimage. 2007 Aug 15;37(2):401-9.

- Humbert IA, **Poletto CJ**, Saxon KG, Kearney PR, Ludlow CL. The effect of surface electrical stimulation on vocal fold position. Laryngoscope. 2008 Jan;118(1):14-9.
- Lowell SY, **Poletto CJ**, Knorr-Chung BR, Reynolds RC, Simonyan K, Ludlow CL. Sensory stimulation activates both motor and sensory components of the swallowing system. Neuroimage. 2008 Aug 1;42(1):285-95.
- Chang SE, Kenney MK, Loucks TM, **Poletto CJ**, Ludlow CL. Common neural substrates support speech and non-speech vocal tract gestures. Neuroimage. 2009 Aug 1;47(1):314-25. Epub 2009 Mar 25.
- Loucks TM, Shosted RK, De Nil LF, **Poletto CJ**, King A. Coordinating voicing onset with articulation: a potential role for sensory cues in shaping phonological distinctions. Phonetica. 2010;67(1-2):47-62.

Professional Societies

- IEEE Engineering in Medicine and Biology Society
- Society for Neuroscience
- American Academy of Neurology
- American Headache Society
- International Headache Society
- North American Neuromodulation Society
- International Neuromodulation Society
- Functional Electrical Stimulation Society

Patents

- **Poletto CJ**, JE Heape, and S Trautmann, "Automatic detection and correction of relatively rearranged and/or inverted data and address signals to shared memory", U.S. Patent #*6,701,418*, 2004, EP Patent #1,215,579, 2002
- Ludlow CL, **CJ Poletto**, I Humbert, "Recovery of motor control via vibro-tactile stimulation to an affected area", Patent pending
- Ludlow CL, N Morgan, **CJ Poletto**, "Vibro-tactile stimulation to the neck to enhance volitional control of swallowing, speech or voice in patients with motor control disorders", Patent pending
- Pilarski, CS, TI Miller, **CJ Poletto**, "System and method for implanting a paddle lead", Patent pending
- Pilarski, CS, TI Miller, **CJ Poletto**, "Tool for retracting a tine element of a medical lead", Patent pending
- **Poletto, CJ**, "Steering stimulation current by employing steering current", Patent Pending
- Ludlow CL, **CJ Poletto**, I Humbert, "Systems and methods of recovery from motor control via stimulation to a substituted site to an affected area", Patent pending
- 20+ unpublished patent applications.