
ALAN L. OSLAN

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MEDICAL DEVICE TECHNOLOGY LEADERSHIP*MBA / MS, Biomedical Engineering / BS, Electrical Engineering***SUMMARY OF CONSULTING CAPABILITIES**

- Manage complex technologies and designs for clinical applications such as minimally invasive surgery, cardiology, interventional radiology, capital equipment, disposables, and implants.
- Drive medical device development projects from concept through market launch in difficult environments.
- Assess new technologies for clinical requirements, market needs, regulatory paths, business risks, intellectual property protection, and funding.
- Provide oral and written expert witness testimony for patent litigation.
- Envision new technologies from concept through development to acceptance in today's healthcare environment.
- Support due diligence committees for medical device start-up funding decisions.

PROFESSIONAL EXPERIENCE**ELECTROSURGE, LLC**, Bedford, MA (www.electrosurgellc.com)**President & Founder**, (2010 to present)

Founded a technology and business consulting company to provide expertise for medical device technologies.

Clients include:

- **Knobbe Martens**: Expert witness for invalidity litigation (more details in **EXPERT WITNESS CASES** below).
- **Wilmer-Hale**: Expert witness for patent infringement and invalidity litigation (more details in **EXPERT WITNESS CASES** below).
- **[Confidential]**: Engineering assistance in NIH grant submission and developing start-up company infrastructure for a surgical navigation device.
- **Microline Surgical**: Support compliance testing and re-designs of energy generators and associated tools; enhance clinical understanding of tissue-modifying technologies.
- **[Confidential]**: Provide electrosurgery expertise and develop test methods.
- **[Confidential]**: Evaluated contract design and manufacturing companies for radiofrequency generator project for a surgical robot.
- **[Confidential]**: Developed and executed comparative study on electrosurgical forceps for neurosurgery.
- **[Confidential]**: Managed technical design of a trans-spinal stimulation system with external electrodes for neuromodulation in preparation for clinical studies.
- **Workman-Nydegger**: Successfully upheld the validity of a patent (PTAB and jury trial) as expert witness: Natus Medical Inc. et al. v. Nox Medical Ehf. (IPR2016-01822) and Nox Medical v. Natus Neurology (Civil Action No. 1:15-cv-00709-RGA).
- **Hologic**: Developed and executed an animal study and validation tests for a novel breast biopsy system; integrated biopsy system into image guidance system.
- **[Confidential]**: Assisted with design change on temperature-sensing spinal needle electrodes that create lesions using radiofrequency ablation to treat chronic pain.

- **Partners Innovation:** Managed patent portfolios, assisted with outside counsel on patent prosecutions, and negotiated licensing agreements for IP originating in research labs at Harvard-affiliated teaching hospitals such as Massachusetts General Hospital.

HEARTWARE, INC., Framingham, MA**Program Manager, Electronic Peripherals** (2011 to 2014)

Recruited into a company poised for growth in the left ventricular assist device (LVAD) market.

- Organized and led a complex hardware/software project for a Class III life-support medical device.
- Completed difficult contract negotiations with development/ manufacturing partners and implemented them.
- Managed critical supply-chain projects resulting in successful launch of key products into worldwide markets.
- Directed Program Investment team in resource forecasting for a successfully funded project.

DEPUY MITEK (A division of **Johnson & Johnson**), Raynham, MA**Principal Engineer** (2006 to 2011)

Hired into the sports and arthroscopic medicine division of this highly successful and well-known company.

- Led cross-functional development projects from concept to worldwide market releases, adding millions in revenue.
- Provided technical leadership to fluidic and radiofrequency systems used in minimally invasive surgery of knee and shoulder joints.
- Interacted with surgeons to understand user requirements.
- Performed freedom-to-operate analyses for patents.

BARD ELECTROPHYSIOLOGY (a division of **C.R. Bard, Inc.**), Lowell, MA**Technical Project Manager Consultant** (2006)

Led an international team at the electrophysiology headquarters of this mature medical device company in the development of new capital equipment for minimally invasive heart therapy procedures using radiofrequency ablation with temperature sensing.

- Created block and system diagrams for capital equipment.
- Mentored engineers in design control practices and safety standards (e.g., IEC 60601-1, IEC 60601-2-2).

BOSTON SCIENTIFIC CORP, Marlborough, MA**Program Manager/ Project Engineer** (2005 – 2006)

Coordinated a cross-functional team (engineering, pre-clinical, regulatory, marketing, and quality) at this large, well-respected medical device company in the development of a next-generation, single-use endoscope.

- Established a series of mechanical, electrical, and optical test methods that better-defined product specifications for a disposable colonoscope/ gastroscopes.
- Coordinated activity with a key vendor, accelerating manufacturing schedule of a critical sub-assembly.

BARD ELECTROPHYSIOLOGY (a division of **C.R. Bard, Inc.**), Lowell, MA**Technical Project Manager Consultant** (2004 to 2005)

Led an international team at the electrophysiology headquarters of this mature medical device company in the development of new capital equipment for minimally invasive heart therapy procedures.

- Re-vitalized and accelerated an early-stage development effort in cardiac radiofrequency ablation, resulting in design documentation package, operator's guide, and units ready for pre-clinical studies.
- Authored user requirements, technical specifications, and graphical user interface documents.

AURORA IMAGING TECHNOLOGY, INC. (formerly CAPRIUS), North Andover, MA**Program Manager** (2000-2003)

Re-hired (after financial reorganization) into this breast MRI start-up company to manage a cross-functional project team (clinical, engineering, manufacturing, quality, supply chain, and external vendors) in the development of an MRI navigation system for breast biopsy procedures.

- Developed and released first-of-its-kind integrated image-guided breast biopsy system to the marketplace.

- Interacted with physicians and technologists in development and training phases, resulting in a system well accepted by physicians.
- Marketed system to potential customers.

SMITH + NEPHEW ENDOSCOPY, Andover, MA**Project Manager** (1998-2000)

Appointed cross-functional project team leader (engineering, licensor, manufacturing, marketing, quality, and regulatory) at this recognized endoscopy product leader to develop a major, new licensed technology platform for electrosurgery systems comprising hand-held powered disposables and capital equipment consoles.

- Determined appropriate vendor for rapid development & manufacture of radiofrequency generator.
- Monitored vendor progress.
- Developed system architect and requirements for new generator.
- Evaluated and utilized licensed technology from a research entity.

CAPRIUS, Wilmington, MA**Program Manager** (2000-2003, 1997-1998)

Recruited into this breast MRI start-up company to manage a cross-functional project team (clinical, engineering, manufacturing, quality, supply chain, and external vendors) in the development of an MRI navigation system for breast biopsy procedures.

- Designed first prototype of an MRI guided breast biopsy system.

MICROWAVE MEDICAL SYSTEMS, INC., Acton, MA**Project Manager** (1996-1997)

Rehired at this early start-up company to design and manage engineering development of microwave technology into unique medical devices.

- Guided a microwave-based dialysis disinfecting system, the company's first key product, from proof-of-concept to production release, resulting in OEM contractual payments from an established company.
- Led animal study to evaluate microwave catheter and generator system for cardiac ablation.

BOSTON SCIENTIFIC CORP, Natick, MA**Project Engineer** (1992-1996)

- Released first temperature-sensing, radiofrequency ablation catheter for BSC with millions in annual revenue.
- Developed, performed, and analyzed an animal study to investigate pulse amplitude vs. pulse width for cardiac pacing using electrophysiology catheters.

MICROWAVE MEDICAL SYSTEMS, INC., Littleton, MA**Senior Project Engineer** (1988-1992)

Brought on board at this early start-up company to design and manage engineering development of microwave technology into unique medical devices.

- Developed microcontroller hardware and software for real-time control of and interface to microwave electronics, with design used as basis for two other products.

ZOLL MEDICAL INSTRUMENT CORP., Cambridge, MA**Design Engineer** (1987)

- Transferred CRT controller with 25 integrated circuit packages into a small, single package application-specific integrated circuit (ASIC) for a portable ECG/ external pacemaker instrument. ASIC responsibilities included circuit design, schematic capture, test vector generation, simulation runs, interfacing with fabrication vendor, and successful testing of hardware.
- Designed analog drive circuitry for magnetic deflection of CRT display.

CONSULTING ENGINEER IN MEDICAL INSTRUMENTATION, (1987-1988), Somerville, MA

- Analyzed low-noise, lock-in amplifier design for low-level signal measurements of magnetic field currents.

- Wrote technical portions of grant proposal for heart-assist device driver, resulting in funding award.

THERMEDICS, INC., Woburn, MA

Project Engineer (1983 to 1987)

- Characterized, tested and analyzed a implantable left ventricular assist device (LVAD) involving pressure, flow, force, and displacement transducers.
- Supported instrumentation for animal surgical procedures.
- Designed and tested a signal analysis module for monitoring the implanted LVAD using signals from its external power source, a patient-worn TETS (transcutaneous energy transmission system).

CORNING MEDICAL & SCIENTIFIC, Medfield, MA

Electrical Engineer (1981-1983)

- Designed ultrasonic driver for a spectrophotometric-based blood hemoglobin analyzer.
- Designed power supply for worldwide voltages and frequencies.

CHILDREN'S HOSPITAL MEDICAL CENTER, Boston, MA

Research Engineer (1978-1981)

- Designed a battery-powered device to measure frequency parameters of neuromuscular signals (was also part of Master's thesis at Boston University).

TUFTS-NEW ENGLAND MEDICAL CENTER, Boston, MA

Biomedical Electronics Technician (1976 - 1978)

- Repaired and calibrated medical equipment (such as ECG, pressure, impedance respiration monitors) at a teaching hospital.
- Solved equipment problems in active patient environments such as ICUs and ORs.
- Observed and corrected misuse and misunderstanding of medical equipment by end users.

EDUCATION

Master of Business Administration (2013), Babson College, Wellesley, MA. Intensity track in Managing Technology-Intensive Enterprises, life sciences innovation leadership:

- Independent Study: "How Medical Device Startups Get Funded" (included venture capital field experience and participation on due diligence committees of a medical angel investment group).
- Patents and Licensing in the Life Sciences.

Advanced graduate studies in electrical engineering, University of Connecticut at Storrs. 1980 to 1981. Course work in estimation theory, Kalman filtering, pattern recognition, and image processing. Teaching of Bachelor's level course in signal and systems analysis.

Master of Science in Biomedical Engineering (1980), Boston University, Boston, MA. Concentration in areas of signal analysis, human anatomy, and biomaterials. Thesis topic: Measurement of frequency parameters of neuromuscular signals.

Bachelor of Science in Engineering (1975), University of Connecticut at Storrs. Electrical engineering with concentration in biomedical engineering principles.

PROFESSIONAL ACTIVITIES

Mentor (volunteer): Advise medical device start-up companies in Massachusetts Medical Device Development (M2D2) center accelerator programs. (2022 – present)

Certified Project Management Professional (PMP): member Project Management Institute (PMI) (2004-2020).

Member: Eta Kappa Nu (HKN) Electrical Engineering honor society (1973 – present).

Member: Institute of Electrical and Electronic Engineers (IEEE) and subgroup in Biomedical Engineering (1973 – present).

Member: Medical Development Group; Forum Moderator and presenter for forum on "Advances in Energy Devices" (2021); Co-Champion for forum on "Advances in Brain Stimulation" (2019).

Invited presenter: American Society of Breast Surgeons (Boston 2002) on MR-Image guided breast biopsy.

Invited panel member: “Biopsy and Intervention Working Group of the International Working Group for Breast MRI,” sponsored by the US Department of Health and Human Services (DHHS).

FDA 510(k) Market Clearance: No. K023686, “MR-Guided lesion localization system.”

PUBLICATIONS

Publications: Klimberg, V.S., R. Henry-Tillman, T. B. Julian, D. Robinson, D. M. Smith, J. Mark, T. Schubert, A. Oslan, R. M. Gibson, and S. E. Harms, “Report of the Working Groups on Breast MRI: Report of the Biopsy and Intervention Working Group,” *The Breast Journal*, Vol. 10(s2), pgs. S13-S16, September 2004.

Oslan, A.L., Sherman, C.S., Clay, W.C., “Non-Percutaneous Monitoring of a Permanently Implanted Ventricular Assist System,” IEEE Proc. 7th Ann. Conf of IEEE/Engr. Med. & Biol. Soc., pgs. 819-823, Sep. 1985.

PATENTS

USPTO Patent No. 7,171,256: “Breast Magnetic Imaging System with Curved Breast Paddles”

USPTO Patent No. 5,833,688: “Sensing temperature with plurality of catheter sensors”

USPTO Patent Application No. 20040030330: “Electrosurgery Systems”

WIPO Patent Application No. WO2002085230A2: “Electrosurgery systems”

Australian Patent Application No. AU2002254642A1: “Electrosurgery Systems”

EXPERT WITNESS CASES

Sotera Wireless, Inc. v. Masimo Corporation (Knobbe Martens)

Represented Masimo (patent owner) on wearable monitoring device for the following cases: IPR2020-00912, IPR2020-00954, IPR2020-01015, and IPR2020-01054. PTAB decided all patents were unpatentable.

Avanos Medical Sales, LLC v. Medtronic Sofamor Danek USA, Inc (Wilmer-Hale)

Represented Medtronic (defendant) on cooled radiofrequency ablation patents for the following case: Civil Action No. 2:19-cv-02754. Authored expert reports and was deposed. Case settled out of court.

Nox Medical v. Natus Neurology (Workman Nydegger)

Represented Nox Medical on sleep monitoring patent; was deposed and testified in court before a jury. Nox Medical prevailed. Civil Action No. 1:15-cv-00709-RGA.

Natus Medical Inc. et al. v. Nox Medical Ehf (Workman Nydegger)

Represented Nox Medical on sleep monitoring patent; was deposed. Nox Medical prevailed. IPR2016-01822.