

ROBERT T. STONE, Ph.D.

SUMMARY

Dr. Stone has over thirty years of academic and industry experience in the field of medical electronics systems and instrumentation. As Chief Executive Officer and founder of Medical Design Solutions, Inc, Dr. Stone is responsible for all phases of product development including concept definition, prototyping, design, evaluation, patenting and technology licensing. He is an experienced expert witness both as a background consultant and testimonial expert.

Expertise

Carbon Monoxide Monitoring	FDA Product Certification
Doppler Ultrasound	Ultrasonic Imaging
Analog Electronics	Telemetry (remote monitoring)
Medical Electronics	Newborn Hearing Screening Devices
Portable Vascular Analysis Systems	Pulse Oximetry
Pulse Oximetry Signal Processing	Technology Licensing
Invasive and non-invasive thermometry	

PROFESSIONAL EXPERIENCE

2011 to Present Medical Design Solutions, Inc
Founder and CEO

Responsible for virtually all phases of product development including concept definition, prototyping, design, evaluation, patenting, technology licensing, for various products directed at various markets.

2008 to 2011 Tronics MedTech, Inc
CTO

Responsible for virtually all phases of product development including concept definition, prototyping, design, evaluation, patenting, technology licensing, for various products directed at various markets.

2004 to 2008 MedTech Development, LLC
Founder, CTO

Responsible for virtually all phases of product development including concept definition, prototyping, design, evaluation, patenting, technology licensing, for various products directed at various markets.

1997 to 2004 Pacific Consultants, LLC
Director of Medical Electronics

Responsible for virtually all phases of product development including concept definition, prototyping, design, evaluation, patenting, technology licensing, for various products directed at various markets.

1991 to 1996 Natus Medical, Inc.
Vice President Research & Development, Chief Technical Officer

Responsible for all phases of new product development including concept definition, prototyping, design, clinical trials, FDA clearance, regulatory compliance including UL, CSA, CE listings, patenting and technology licensing for products directed at the pediatric hospital market. Responsibilities included contract negotiation, international distributor technical support, distributor evaluation and contract negotiations, Federal Research Grant proposal and management. Developed and patented broad patents for a new concept in breath analysis, covering design, embodiment, and a disposable element. Other achievements included:

- Conceived and guided the development of, and maintained the second generation of newborn hearing screening devices, a product that was the current backbone of the Natus product line. Worked extensively with researchers in refining and defining product specifications and performance parameters. Wrote and managed the FDA 510(k) clearance process during the peak of the FDA logjam in 1993-1994. The introduction of this product caused growth in sales to virtually double in the marketplace, and was a major factor in the company's pending profitability.
- Conceived the re-design of the company's first generation product to incorporate some of the major benefits of the second-generation product in a package, which allowed major expansion of the product market, both domestically and internationally.

- Invented a device, which can be used to diagnose the most significant contributing factor of the most common disorder present in newborns. Developed and obtained three patents covering the devices design plus a valuable disposable. Managed early clinical validation trials, expanded the concept to other applications, and executed a Federal Grant which demonstrated successfully the application of the patent to forensic breath alcohol analysis. Current plans to market this device are based upon pressing marketplace needs and the potential application in virtually every birthing center, pediatric clinic, and emergency in the developed countries.
- Obtained a license from the Medical Research Council of the UK to a new generation of auditory screening devices, and developed the technology into a device that is generating pressing demands upon the company for launch and distribution.

1989 to 1991 **MedaSonics, Inc.**
Vice President Engineering

Managed a group of 15 engineers, technicians, designers in the design and development of portable vascular analysis equipment designed for clinics, hospitals, and physicians offices. Coordinated the development of specifications, project planning, cost analysis and resource allocation for multiple simultaneous projects, evaluated new technological

opportunities, negotiated technology licensing and consulting agreements, participated in company directors strategic planning. Wrote several patent disclosures. Took over an engineering department that was in great disarray, faced with an urgent need for products late for a closing market window, and key engineers were leaving in frustration. Completed the urgent projects in a timely fashion, helped develop a new direction for the corporation, and defined the product lines which could provide the needed growth and stability.

1983 to 1989 **Nellcor, Inc.**
Manager, Electronic Research

Performed general research and development of new products in the area of blood gas monitoring, oxygen saturation, carbon dioxide gas analysis, and cardiac output. Early prototype development, clinical validation, and presentation of results to corporate officers for development selection. Wrote several patent disclosures, some of which were filed and granted, and some of which were maintained as trade secrets. Contributed to several marked advances in pulse Oximetry signal processing (two US patents issued), and developed an Oximetry telemetry system. Two of the patents were vital to market growth of Pulse Oximetry. One of the patents allowed the positioning of the second-generation product in awake, agitated, or ambulatory patients. The second patent significantly improved the product performance during physiologic transients, and is currently in use in as many as 50% of the pulse Oximeters in the world. The Oximetry marketplace expanded from critical care facilities to step down wards and general wards

with the introduction of the OXINET telemetry system that was a sole contributor definition, design, and development

1981 to 1983 **Virginia Polytechnic Institute and State University**
Assistant Professor, Engineering

Taught classes in system analysis, instrumentation, thermodynamics, and signal analysis. Developed and taught classes in microprocessor applications in instrumentation and control. Obtained research funding in analysis of control systems for nuclear reactors.

1979 to 1980

On sabbatical from Virginia Polytechnic Institute as a NSF Fellow at Stanford University to earn Ph.D.

1971 to 1979 **Virginia Polytechnic Institute and State University**
Nuclear Reactor Supervisor

Managed and maintained a research and teaching reactor which routinely performed neutron activation analysis as a research service to university, state, and industry laboratories. Scheduled, supervised, and assisted in performing all laboratory functions, participated in University Safety Committee and Reactor Safety Committee, directly interfaced with the Nuclear Regulatory Commission, assuring compliance with all nuclear device regulations, upgraded all reactor controls, shielding, and instrumentation to allow five-fold power increase for increased laboratory sensitivity. Performed these duties while studying continually for BSEE and MSEE degrees.

1965 to 1971 **United States Navy**
Nuclear Reactor Operator, Electronics Technician & Engineering
Watch Supervisor

Highest rank achieved, Electronics Technician (Nuclear) First Class (E-6) Qualified in Officer position as Engineering watch supervisor/Engineering watch officer on the USS Bainbridge, DLG-N25. Spent two years as an instructor in nuclear theory and instrumentation at Schenectady New York Nuclear Power Prototype facility

Ph.D., Electrical Engineering, Stanford University, 1981
MSEE, with distinction, Virginia Polytechnic Institute and State University, 1979
BSEE, Virginia Polytechnic Institute and State University, 1977

LITIGATION RELATED EXPERIENCE

Type of Matter: Patent Infringement
Law Firm: Mayer Brown LLP
Brian K. Andrea
Direct: 202 263 3487
Case Name: Masimo v. Philips
Services Provided: Patent Infringement matter involving frequency domain signal processing of biological signals and Oximetry electronics on behalf of defendant. Advised attorneys, interpreted technology, wrote expert reports, will likely testify at jury trial.
Status: Ongoing

Type of Matter: Patent Infringement
Law Firm: Merchant and Gould, PC
Peter Gergely
Telephone (303) 357-1646
Mobile (303) 358-8716

Case Name: Bosch vs Cardiocom
Services Provided: Patent Infringement matter involving remote health monitoring systems. Prepared declarations for re-examination of patents..
Status: Ongoing

Type of Matter: Product Liability/Malpractice
Law Firm: MacDonald-Devin PC
David M. Macdonald
Direct: 214-651-3300
Case Name: Guinn Vs Nonin
Services Provided: Opined on performance, design and operation of Pulse Oximeter, wrote expert report
Status: Ongoing

Type of Matter: Product Liability
Law Firm: Lewis Brisbois Bisgaard Smith LLP
Case Name: Individual v Pomona County Hospital
Services Provided: Patient controlled analgesia. On behalf of defendant, wrote expert report, was deposed on financial damages.
Status: Settled 2007

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