# Jay T. Eisch

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## SUMMARY

A proven leader specializing in medical design, program management, and test with extensive experience in program and people leadership bringing medical products from concept to market. Six Sigma certified with expert knowledge in foreign and domestic medical standards, regulations, and requirements.

## PROFESSIONAL EXPERIENCE

***EISCH ENGINEERING LLC***, Wyoming, MN 05/23 – Present
**Consulting Engineering Services**

***MEDTRONIC, INC.***, Minneapolis, MN 04/04 – 05/23
**Program Director / Core Team Leader** 12/22 – 05/23
Cardiac Rhythm and Heart Failure
Program Development Director for Next Generation Cardiac Defibrillation Lead

- Responsible for development through market release of a multiyear, $80M effort with over 50 planned resources
- Program management responsibilities including resource planning, cost estimation, schedule creation, and objective tracking
- Responsible for phase reviews and regular updates with Senior Management

Core Team Leader for Next Generation Holter Monitor 04/20 – 05/23

- 3 year, $10M program to design and produce a novel Holter system used to collect patient ECG and device EGM data for data analysis vital to the development of new Medtronic therapies
- Multi-function leadership including Development, Systems, Software, Mechanical, Firmware, Quality, and Regulatory

Primary Program Management Office Liaison for the Transvenous Cardiac Pacing Operating Unit 04/20 – 05/23

- Worked with General Manager and staff on Scope, Cost, Schedule estimations
- Closely partnered with Senior Leadership to assist in solidifying the Operating Units Strategic Plan

**Senior Product Development Program Manager** 12/18 – 12/22
Cardiac Rhythm and Heart Failure
Program Development Lead for CRHF Operations group 01/20 – 02/21

- Leadership of a 50-person high-profile, high-impact effort to replace last time buy epoxy used in the manufacture of 95% of CRHF and RTG AIMD's and Lead's
- Leadership of a 20-person effort to replace obsolete and environmentally hazardous cleaning solution used in the manufacture of all CRHF and RTG AIMD's and Lead's

Program and Core Team Development Lead for CRM portfolio market release in China 04/20 – 9/20

- Program management of multi resource international team to achieve Chinese regulatory approval and market release for legacy CRM products including all Heart Failure and Brady Pacing leads and devices

Program and Core Team Development Lead for next generation CRHF Brady Pacemaker 12/18 – 04/20

- Responsibility for ideation through market release of a multiyear, $30M effort with over 50 planned resources
- Program management responsibilities including resource planning, cost estimation, schedule creation, and objective tracking
- Strategic involvement in project planning, estimation, and down select of device features based on voice of customer needs
- Accountable for all aspects of design including Systems, Software, Firmware, Hardware, Integrated Circuit, and Mechanical
- Responsible for multiple Program Management Office (PMO) phase reviews and regular updates with Senior Management

**Senior Engineering Manager** 08/14 – 12/18
Cardiac Rhythm and Heart Failure
Responsible for hardware verification test for Medtronic's Cardiac Rhythm and Heart Failure division

- Sr. Management of organization consisting of 31 employees and 15 electrical design, test, and development labs
- Management of 5M annual budget with 6,000 pieces of test equipment
- Incorporated state of the art RFID tracking system to maintain test equipment management and calibration
- Leadership of annual strategic planning effort of >12 projects guaranteeing appropriate lab space, equipment, and staffing
- Incorporated DRM Six Sigma and system techniques to enable clear decision making and increase efficiency including: Five Whys, Conjoint Analysis, Pick Charts, Weighted Analysis, Kanban Charts, Scrums, Risk Burndown and Burnup Charts
- Innovation lead for the design of a custom 6 axis robotic test system used in leadless pacemaker development and test
- Program lead of multiyear project to automate data collection across 200 test stations resulting annual savings of $365K
- 29% improvement in group engagement scores through focused and strategic effort

**Senior Principal Systems Engineer** 08/12 – 08/14
**Principal Systems Engineer** 02/10 – 08/12
Corporate Ventures and New Technologies
Technical lead of a system for the treatment of Obesity consisting of an implantable device and external instruments

- **FY2013 Medtronic Technical Contributor of the Year Award Winner** - Exilis Gastric Stimulation Therapy for Obesity
- Collected customer needs from researchers, physicians, and industry experts in obesity
- Created design specifications including design inputs document, system specification, and system requirements
- Led design engineering group and performed systems validation testing to guarantee device design met customer needs
- Provided clinical field support for all implants and explants
- Risk Assessment owner and lead of post clinical risk assessment effort
- Corrective and Preventative Action (CAPA) lead including authorship, management of redesign, and field follow up activity

**Senior Principal Electrical Engineer** 04/04 – 02/10
Neuromodulation Instruments – Electrical Instruments Lead 12/06 – 02/10

- Created the Neuromodulation electrical instruments design group
  - Hired and managed 5 employees including mentoring, merit increases, and performance reviews
  - Responsible for electrical instruments budgeting and capital expenditures for annual operating plan
  - Created innovative design lab space including installation of all lab fixtures and purchase of >$500K of test equipment
- Primary electrical technical lead of next generation Neuromodulation instrument projects including:
  - Patient Therapy Manager – Handheld touch screen device enabling a patient to interact with the implant using RF telemetry
  - Clinician Telemetry Module – Allowing clinician the ability to program the implant during surgery and follow-up visits using distance RF and low frequency telemetry
  - Recharge Therapy Module – Magnetic coil and control circuit giving the patient the ability to recharge their implant
  - Screener - Allows for clinical test screening to verify the efficacy of therapy before implant of a neurostimulator

Neuromodulation Research - Brain Sensing 05/06 – 12/06

- Developed human brain simulator and test system including fluid selection and Labview program to evaluate multiple lead concepts for the detection of EEG and ECG

Neuromodulation Product Development - Epilepsy 04/04 – 05/06

- Architecture and electrical design of a prototype to detect epilepsy seizures using a proprietary detection algorithm
- Telemetry Integration Lead for companywide distance telemetry approach using MICS transmission frequencies
- Design and specification of hardware, software and user interface for the next generation physician's programmer

***TRANSOMA MEDICAL*** (Data Sciences International, Inc.), St. Paul, Minnesota 09/01 – 04/04
**Principal Electrical Engineer**
Design of a microprocessor controlled medical implant to measure and wirelessly transmit left ventricular heart pressure

- Designed compact implantable device with very low current draw resulting in implant life of >7 years
- Designed embedded microcontroller subsystem and extensive safety circuits to guarantee patient safety
- Performed Risk Assessment and design FMEA
- Wrote numerous specifications as well as verification and validation test reports
- Managed firmware design and verification, validation and test efforts

***EISCH ENGINEERING***, Wyoming, MN 01/01 – 02/10
**Consulting Engineering Services, Sole Proprietor**
Banner Engineering Corporation

- Wrote test plans and report and provided regulatory and design guidance on safety light curtain project

Possis Medical, Inc. (MEDRAD / BAYER AG / BOSTIN SCIENTIFIC)

- Design, verification, and regulatory guidance on development project for next gen electro-mechanical drive unit
- Designed solution and developed test systems using FPGA that automatically selects drive unit modes

Stereotaxis, Inc.

- Electrical design and regulatory approach for heart ablation device that uses magnetic fields for catheter steering

Biotherapeutics, Inc.

- Electrical design, firmware, and regulatory of a pneumatic device used to clear the lungs of Cystic Fibrosis patients

***POSSIS MEDICAL, INC.*** (MEDRAD / BAYER AG / BOSTON SCIENTIFIC), Coon Rapids, MN 06/99 – 01/01
**Principal Electrical Design Engineer**

- Technical Lead of a multi-million-dollar project that involved 3 Consultants, 4 Engineers, and 2 Technicians
- Managed the Electrical Design group consisting of 2 Engineers, and 1 Technician
- Established electrical development capability by hiring personnel, configuring lab space, and acquiring equipment
- Designed electrical hardware for device to remove blood clots utilizing a real time operating system with LCD touch-screen
- Design of multiple circuits including dual path safety circuit, 600W power supply, analog signal conditioning circuit, digital interface circuit, and digital multiplexer circuit
- Performed SPICE simulation and schematic capture using ORCAD

***NELLCOR PURITAN BENNETT*** (MALLINCKRODT), INC., Plymouth, MN 11/97 – 06/99
**Senior Electrical Design Engineer**

- Technical Lead for Diagnostics and Monitors group facilitating the design and fabrication of six unique electrical devices
- Performed ESD, EMI, Safety, and validation tests on two products as defined by EN60601-1 requirements
- Design of multiple circuits including a self-powered fiber-optic serial link, a robust battery charging, and capacity circuit, a low power passive 50/60 Hz notch filter, and an automatic emergency power disconnect circuit

***AVECOR CARDIOVASCULAR, INC*** (MEDTRONIC CARDIOVASCULAR), Brooklyn Park, MN 04/95 - 11/97
**Senior Electrical Design Engineer** 04/97 - 11/97
**R&D Engineer II** 04/95 - 4/97

- Coordinated the development efforts for domestic and international cardiovascular electrical projects
- Established electrical design capabilities including the setup and management of an electrical design lab
- Budgeted multimillion dollar project while managing 3 Consultants, 1 Engineer, and 1 Technician
- Wrote the company Standard Operating Procedure (SOP) on Software Development
- Designed an innovative arterial pump used to sustain life during cardiopulmonary bypass surgery
- Designed the digital, embedded, and analog circuitry for the company's electrical designs
- Helped obtain FDA 510k, TUV, UL, and CSA approvals on the arterial pump system
- Designed instrument that used optics to analyze blood properties during surgery
- Automated numerous test lab processes using Labview and a National Instruments data acquisition system

***MEDICAL DEVICES, INC.*** (REHABILICARE, INC.), New Brighton, MN 11/92 - 04/95
**Engineering Manager** 02/94 - 04/95
**Development Engineer** 11/92 - 02/94

- Managed Development and Documentation Engineering of external neuromuscular stimulators and diagnostic devices
- Performed budgeting and expenses for department while managing 5 direct report employees
- Managed projects including EMG diagnostic devices, neuromuscular and Carpal Tunnel Syndrome stimulators
- Coordinated effort and attained FDA 510(k) and TUV approval on five company products
- Member of the steering committee for a successful companywide ISO9000 effort and two cGMP quality audits
- Extensive experience in microcontroller programming, analog, digital, and amplifier design

***KEBCO, INC.***, Eden Prairie, MN 10/91 - 11/92
**Product Manager** (1/92 - 11/92)
**Applications Engineer** (10/91 - 1/92)

- Managed sales, marketing, and application assistance of AC motor drive product line

## EDUCATION

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|---|---|---|
| MSEE | University of Minnesota, Minneapolis, MN | Ongoing |
| BSEE (6/1991) | University of Minnesota, Minneapolis, MN | 10/86 - 06/91 |

- Degree emphasis in Biomedical Engineering and Integrated Circuit Design

## CERTIFICATIONS, ASSOCIATIONS, PUBLICATIONS, PATENTS

- Member of IEEE 10/87 - Present
- Member International Council on Systems Engineering 05/11 - Present
- US Patent 9623257 – Recharge Tuning Techniques for an Implantable Device 04/17
- US Patent 9216297 - Flexible Recharge Coil Techniques 12/15
- Patent Application 20130110008 Communication Between External Devices & Implantable Medical Devices 10/11
- DRM / DFSS Green Belt Certified through Medtronic DRM initiative 03/13
- NSC5540: Advanced Survey of Biomedical Neuroscience – University of Minnesota 09/05