

## **Principal Systems Engineer**

### **Job Summary:**

We're looking for a talented Systems Engineer who has the experience, dedication, and technical leadership skills necessary to help define, create, and implement the architecture of our innovative system. We're a growing company with a team of highly dedicated professionals who are focused on creating a meaningful solution for patients with Acute Decompensated Heart Failure (ADHF).

### **Job Responsibilities and Duties:**

Lead the translation of stakeholder needs into architectural design, including requirements definition and risk management. Work collaboratively with all stakeholders and players to successfully realize the system. Lead complex problem-solving activities, ultimately coming up with solutions to complex problems. Act as the first line of defense as systems-level issues are identified. As issues are uncovered, drive the issue resolution process through a combination of hands-on or group problem-solving activities. Effectively serve as a member of the product development team by collaborating on all aspects of product development including Concept, Design, Verification/Validation, Clinical, Regulatory, and Commercial release. This position also has primary responsibility for the external stimulation system, overseeing the creation and verification of our stimulator electronics per specifications with an OEM.

### **Qualifications and Skills:**

- BS or MS in Electrical Engineering with 15+ years of experience
- Electrical and Systems Engineering experience in development of acute use electrical catheter devices and/or chronic implantable devices, covering all phases of development
- Knowledge of heart failure, cardiac anatomy and physiology required
- Demonstrated ability to serve as technical leader of a complex electromechanical medical device system (working under FDA design control processes)
- Demonstrated ability to work effectively with physicians, clinical consultants and scientific advisors.
- Strong communication skills, including the ability to present results and train as needed
- Strong analytical and problem-solving skills with a demonstrated ability to analyze and solve complex problems across electrical, mechanical, and software elements. Ability to lead technical and management team members through rigorous analyses, conclusions, and recommendations in order to gain alignment on approach to solutions.
- Ability to manage, organize, and oversee OEM development activities of stimulator electronics
- Experience with overseeing and managing contract engineering and technician resources
- Ability to work independently as needed
- Exercises substantial independent technical judgement in assigned tasks, work methods and goal interpretation
- Capable of working in a fast paced, small company atmosphere. Able to identify and evaluate inside and outside resources to accomplish tasks.
- Experience and comfort with pre-clinical and clinical activities, including procedure observation and concept evaluation
- Able to travel periodically, including some international travel. Required travel time will vary with project phase (less in development phases, a little more in clinical phase).
- Experience with and understanding of analog and digital electronics. Can troubleshoot to component level of printed circuit board assemblies.

- Working knowledge of microprocessor/microcontroller firmware, PC/Tablet hardware software and OS. Working knowledge of C programming language.
- Working knowledge of applicable medical electrical equipment, EMC, usability, and risk management standards
  - ANSI/AAMI ES60601-1:2005/(R)2012
  - IEC 60601-1 3.1 Ed 2012-08
  - IEC 60601-1-2 4th Ed 2014-02
  - IEC 62366-1:1.0 Ed 2015
  - ISO 14971:2012
- Experience with electronic device usability evaluations
- Experience with Hazard Analysis and other risk management techniques
- Experience with reviewing engineering quality systems documents and Standard Operating Procedures
- Familiar with imaging technologies including CT, Fluoroscopy/angiography, Ultrasound
- Familiar with neurostimulation and/or electrophysiology techniques
- Skilled with physiological sensors (especially pressure and impedance) and associated signal processing techniques
- Strongly prefer working knowledge of MatLab
- Familiar with schematic capture (OrCAD), and other engineering design tools
- Familiar with AD Instrument's PowerLab and Chart physiologic data acquisition system
- Familiar with Low power battery operated systems
- Prefer experience with test fixture design and fabrication