JOB DESCRIPTION
SENIOR EMBEDDED SYSTEMS ENGINEER

Company Overview

At Prytime Medical Devices, we have a bold vision: No one should bleed to death, and the sooner you stop bleeding, the better. We are working to revolutionize the care of severely injured patients by enabling trauma teams to gain control of life-threating bleeding as a bridge to definitive repair. We partner with leading trauma centers to enable endovascular bleeding control through innovative devices and fanatical customer support. In support of our vision, we design, develop, and commercialize minimally invasive solutions for hemorrhage control. Our flagship product is the ER-REBOA-PLUS™ Catheter, the market leader for endovascular aortic occlusion in trauma. In addition to our national roll out of the ER-REBOA-PLUS™ catheter, Prytime was recently granted FDA clearance on a next generation partial REBOA catheter designed specifically to reduce ischemic insult and reperfusion injury called pREBOA-PRO™. We are following a very selective, data intensive approach to releasing this product. In doing so, Prytime is poised to create additional strategic opportunities and to lead the introduction of these devices in trauma and adjacent specialties. Concurrently, we are expanding our product line to include internet enabled embedded systems to provide advanced physiological monitoring and decision support. We look forward to continuing to improve patient outcomes and improving the physician experience as we build and launch of these new devices into the trauma and critical care market.

Position Overview

Reporting directly to the Senior Vice President, Research and Product Development.

Working within a team to develop real-time embedded software systems for new products, from early concept and feasibility work through complete development, testing, release and sustaining of systems and final product.

The individual who will thrive in this position is a self-motivated professional who is a good communicator, technically proficient, detail oriented, and not afraid to learn new skills. This individual enjoys the fast pace and accountability of a small company and wants to make a contribution as we deliver critical medical devices to the market.

Job Responsibilities

- Work well in a team and demonstrate strong communication and collaborative skills
- Participate in Cross-Functional Teams developing real-time embedded software systems, to include system requirements definition, system functional decomposition and requirements allocation, system architecture definition, system modeling, and requirements traceability and compliance including verification plans and reports
- Create and maintain engineering requirements and develop products to meet those specifications
- Design, document, test, iterate, commercialize and support single/multi-use embedded electronic and electro-mechanical medical devices
- Develop open loop, semi-closed loop, and closed loop decision support
- Demonstrate knowledge of microcontroller-based systems: architecture, software development, synthesis, analysis, problem solving, troubleshooting and testing of embedded software and hardware

- Create, modify and maintain software, firmware, and hardware and integrate such systems into an electro-mechanical device
- Assemble prototypes and iterate design including troubleshooting, bug tracking and resolution
- Create, execute, document risk management processes, including FTA and/or FMEA activities on electrical and embedded software systems
- Create, execute and document validated test methods for functional testing of electronics and software
- Establish compliance with electronic medical device safety standards
- Provide engineering support for the manufacturing of products, including creation of drawings, work instructions and in-process quality testing
- Create, maintain and execute to a project schedule and budget
- Write and review technical reports, compile technical data for Design History Files and regulatory submissions per FDA and MDR requirements
- Embrace, codify, and implement applicable cyber security standards

Qualifications

Primary - Required

- BS in software engineering, electrical engineering, computer electrical engineering or computer science
- Minimum 10 years hands-on design and development experience with medical related software-electronic devices
- Experience creating, developing and maintaining system architecture design for complex electro-mechanical medical devices
- Experience designing electrical schematics including fabricating, and testing PCBAs
- Testing and validation of software and electronic systems
- Strong experience with Design of Experiments and statistical techniques
- Experience taking at least one medical device from concept to commercialization
- Competent working under Quality Systems, FDA, Cybersecurity, and ISO regulations (ISO 13485 and ISO 14971)
- Excellent ability to multi-task between projects
- Experience with creating, documenting and supporting intellectual property (IP)
- Excellent interpersonal/communication skills
- Confident taking initiative
- Ability to share knowledge in a team setting

Secondary - Desired

- MS in software engineering, electrical engineering, computer electrical engineering or computer science
- Project lead and/or management experience
- Understanding of clinical and regulatory pathways, IP and internal processes
- Knowledge of basic human anatomy
- Knowledge and experience in trauma
- Knowledge of clinical settings such as in vivo labs and hospital operating rooms

Skills and Abilities

Software Engineering skills:

- Communication Protocol Stacks: Bluetooth, BTLE, 3G, Wi-Fi, Mesh Networks, ANT, Gazelle, LTEM, Proprietary protocols
- Embedded microprocessor and microcontroller software development
- Operating Systems: iOS, Android, Windows CE, Windows XP embedded, Windows, Embedded Linux, RTOS, BSP, etc.
- TCP/IP wireless and Ethernet networking
- I2C, UART Serial and SPI Driver and implementations for device-to-device communications

- Embedded graphical user interfaces and drivers
- Software development for VHDL FPGA
- Digital Signal Processor algorithm and software development
- Simulations utilizing Matlab, Labview, MathCAD
- Architecture design, algorithm identification and integration
- Embedded Systems User Interface Design and Devopment
- Software Sustainment and Maintenance

Electrical Engineering skills:

- Safety critical systems engineering, redundancy, FMEA, etc.
- Digital signal processing
- PCB design / Functional prototype / rapid PCB
- EMC mitigation design
- Application specific integrated circuits
- Analog and digital design / simulation
- Spice modeling and simulation
- Broad array of microprocessor experience: CISC, RISC, DSP, PIC, PSoC, TI MSP430, Atmel AVR, Motorola HC05/12/16, 56000DSP, ARM Family single and multi-core, Thunderbolt, Freescale IMX etc.
- High-end Field Programmable Gate Array (FPGA) experience: Xilinx Spartan, Virtex, Artix families; Altera/Intel Cyclone, Stratix families

Regulatory and agency testing and support

- Testing through Nationally Recognized Test Labs to standards such as IEC 60601 Series, including general safety, EMC and EMI compliance
- IEC 62304 (Medical Device Software)
- *FDA Guidance for Software Contained in Medical Devices*

Travel

- Yes, 15% to other R&D sites and to manufacturing partners