Job Description

Job title: Staff R&D Engineer (Medical Devices, On-Site Presence Required)

Department: Research & Development

Reports to: CTO

☒ **Full-time** ☐ **Part-time**	☒ **Exempt** ☐ **Nonexempt**

Essential Duties and Responsibilities:

Provide the technical expertise necessary to achieve fully functional and de-risked EVT and DVT prototypes ready for development testing, system integration, V&V testing, and commercialization of advanced wireless sensing systems for Urology. Technically lead and execute all system testing including integration activities from first EVT prototypes all the way to design transfer to manufacturing. Provide support to Project Management and Quality. Follow up on related deliverables.

- In-depth understanding of system test methods including integration for hardware (EE, ME) and/or software (FW, APP) including the programming, testing, and reporting of existing Urology medical devices to achieve product development goals
- Contribute to Engineering Verification Test (EVT) and Design Verification/Validation Test (DVT) prototype build, testing via verification protocols and/or external test agencies, bug creation, and documentation in bug database
- Experience leading design control activities including contributions to writing design inputs (e.g., requirements) and review of design outputs (e.g., product specifications, architecture documents, design descriptions, etc.)
- Support document control activities including review and release of medical device documentation in the company's electronic Quality Management System (eQMS)
- Experience with signal acquisition, circuit design, embedded systems, signal processing, and/or algorithm testing a plus
- Experience authoring and/or editing detailed medical device documentation under design control a must
- Experience with QMS per FDA Title 21 CFR Part 820 and ISO 13485:2016 a must
- Experience operating in an eQMS for all R&D phases (e.g., Greenlight Guru) a plus
- Experience scribing decisions, action items, and following up on them with related parties a plus
- Perform related duties as assigned by the CTO

Education and/or Work Experience Requirements:

- Chemical Engineering, Electrical Engineering, Mechanical Engineering, or Biomedical Engineering strongly preferred, graduate degree preferred but not required
- 7+ years of Research and Development (R&D) experience in a medical device product development and/or manufacturing company required
- Able to test the system behavior against its requirements and design specifications
- Excellent verbal and written communication skills, including ability to effectively communicate with internal and external R&D team members
- Excellent computer proficiency (MS Office – Outlook, Word, Excel, PowerPoint, and Project) a must
- Programming and/or scripting proficiency (Python) a plus
- Must be able to work under pressure and meet deadlines, while maintaining a positive attitude and providing exemplary customer service
- Ability to work independently and to carry out assignments to completion within parameters of instructions given, prescribed routines, and standard accepted practices

Physical Requirements:

- High level of personal/professional integrity and trustworthiness with strong work ethic and the ability to work independently
- Ability to develop and manage a high performance team focused on accountability and meeting and exceeding expectations
- Ability to technically lead, influence, create, and work within cross-functional team environments
- Ability to technically lead, influence, create, and work within cross-functional team environments while being detailed
- Proven technical leadership with a strong results orientation, positive "can do" attitude and a sense of urgency
- Attention to detail
- Strong self-organization and documentation skills

Print Employee Name:

Employee Signature/Date:

Manager Signature/Date: