JASON MESSNER

Irvine, CA (Looking to Relocate to New York) • 805-585-8396 • jasonmessner1019@gmail.com • U.S. Citizen

PROFESSIONAL SUMMARY

Mechanical & Sensor R&D Engineer with 3+ years at Vena Vitals taking a Class II wearable medical device from early-stage prototyping through FDA 510(k) submission and preparation for commercial launch. Experienced across the full R&D cycle: prototype design, sensor fabrication, data acquisition and analysis, and rapid iteration, with additional contributions to FDA 510(k) regulatory documentation and submission, quality management, and manufacturing setup. B.S. in Mechanical Engineering from UC Irvine (2023).

PROFESSIONAL EXPERIENCE

Vena Vitals (Y Combinator-backed) - **Sensor R&D Engineer** | Oct 2025 - Present

- Improved sensor fabrication yield from 14% to 25% within four months through targeted process improvements, including revised work instructions to reduce sample damage risk and updated in-process QC acceptance criteria based on downstream risk assessment, directly increasing manufacturing throughput and reducing material waste.
- Built ISO 13485-compliant QMS for in-house sensor manufacturing from the ground up, covering process control, manufacturing traceability, inspection and testing protocols, equipment calibration, and device master records.
- Led risk management workstreams within the QMS including PFMEA, risk control implementation and verification, process validation (IQ/OQ/PQ), and test method validation across all sensor manufacturing and QC process steps, directly enabling commercial manufacturing readiness.
- Conducted holistic statistical risk analysis of final sensor performance QC acceptance criteria, incorporating use application and patient harm risk, resulting in revised acceptance criteria that increased fabrication yield from 25% to 30%.
- Manage a team of four interns across sensor fabrication, process R&D, root cause analysis, and QMS documentation, sustaining ~30 sensors/week in manufacturing output and driving 2 full-time conversions through performance evaluation and advocacy.

Vena Vitals (Y Combinator-backed) - **Mechanical R&D Engineer** | May 2023 – Oct 2025

- Collaborated in a team of 3 to develop Vena Vitals' primary wearable biosensor device across 4 iterative versions from early concept to market-viable product in support of FDA 510(k) submission, balancing reliable signal acquisition, usability, and patient safety and comfort through rapid prototyping and functional testing.
- Managed verification and validation of 226 product, technical, and hazard requirements for FDA 510(k) submission, translating requirements into a structured V&V program, coordinating weekly standups, and driving action items to completion across the team.
- Authored and revised ~25% of the 510(k) IFU, fully owned and produced the IFU instructional video through multiple revision cycles, and developed device labels and packaging requirements for all system components in accordance with 21 CFR Part 801.
- Managed device deployment and data acquisition for a clinical study across 66 unique patients at a single site, training and evaluating clinical staff on device setup, coordinating daily patient consents and data collections/transfers, and implementing iterative improvements to staff training, collection protocols, and device form factor that increased average signal quality from 51% to 72% over 66 collections.
- Extended core wearable platform into 2 additional functional device prototypes with distinct form factors, developed for investor presentations and industry conferences, demonstrating platform versatility through rapid prototyping and functional testing for data-validated demo devices.
- Designed and managed a custom device tracking and quality control system for all clinical and internal use devices, overseeing a fleet of ~150 devices across 10 clinical sites, supporting ~350 dataset acquisitions, and maintaining assembly, inventory, refurbishment, and QC records throughout each device's lifecycle.

TECHNICAL SKILLS

Prototyping & Fabrication: FDM & SLA 3D printing, laser cutting/engraving, PCB design, soldering & electrical assembly, industrial sewing, CNC machining, Keyence digital microscopy

Regulatory & Quality: ISO 13485, risk management (PFMEA, risk controls & verification), verification & validation (IQ/OQ/PQ, test method validation), QMS development, 21 CFR Part 801, device labeling, IFU development

CAD & Software: SolidWorks (CSWA Certified), AutoCAD, MATLAB, Microsoft Office (Excel, Word, PowerPoint)

Clinical Operations: Device deployment & management, clinical data acquisition, clinical staff training & evaluation, data quality assessment

EDUCATION

University of California, Irvine | B.S. Mechanical Engineering, 2023 | GPA: 3.325

Division I Student Athlete - Cross Country & Track and Field (2019–2023)