harborlabs
CYBER . SCIENCE

Medical Device Cybersecurity:
Expert Cyberscience for Secure Clinical Systems and Devices

Harbor Labs engineers are recognized in the healthcare industry as experts in medical device security and standards compliance, and have provided the cyberscience underlying many of the medical industry's leading clinical products. With extensive experience in a broad array of therapeutic, diagnostic and clinical systems, Harbor Labs staff are often integrated as the cyber component of client OEM development teams and provide independent cybersecurity quality assurance as part of client release cycles.

By combining expert cyberscience with extensive experience in the clinical functions and common therapies of medical devices, Harbor Labs staff have proven to be the ideal go-to-market partner for medical device OEMs.

Harbor Labs is a leading provider of cyber science consulting services, specializing in cryptography, network security audits, software vulnerability assessments, and secure programming. Our elite staff of cyberscientists comprises many of the industry's foremost experts in their respective cyber disciplines and are among the first to be contacted when a high-profile, national-level cyber event occurs.

Regulatory and Certification Support

Harbor Labs is an ideal partner for regulatory and certification submissions, including FDA, FIPS and UL CAP applications. Our staff conducts testing and analyses to identify and remediate disqualifications prior to submission, and provides accredited report documentation to support and expedite the application process.

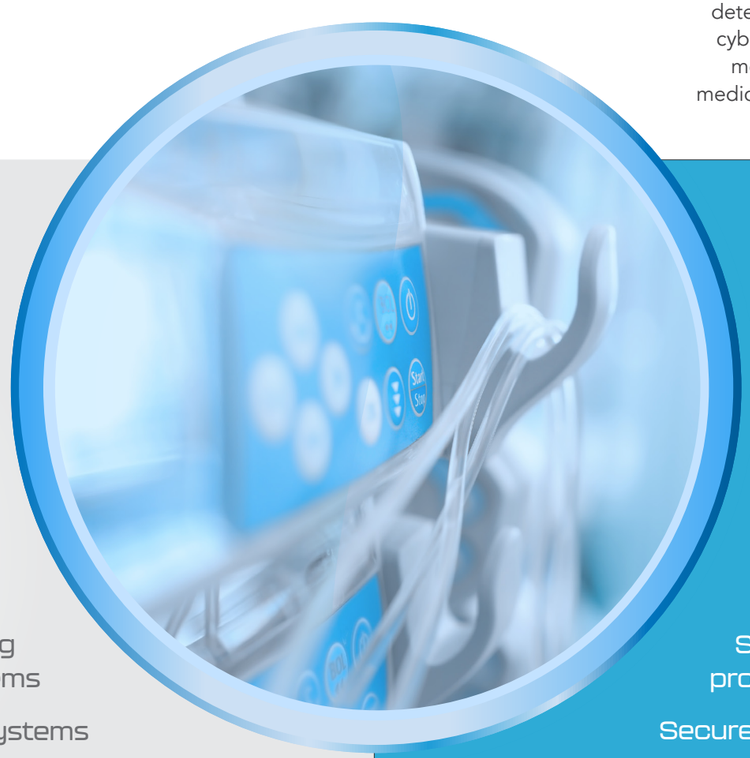
Cybervigilance Services

The threat landscape for medical devices is constantly evolving, and tracking new exploits and determining their impact on a medical product line can be challenging. Harbor Labs provides cyberviligance services that are tailored to our clients' product lines. By providing continuous monitoring and mapping of new CVEs to the software components of our clients' products, medical device OEMs can be alerted to new vulnerabilities before their users can be impacted.

Harbor Labs staff understands the common firmware architectures found in medical devices, as well as medical networking topologies and their clinical operation. This allows our staff to go beyond basic cybersecurity solutions, and provide a comprehensive set of defenses that protect against common medical device exploit methods.

Our staff has worked directly with leading industry medical device manufacturers to harden and secure a diverse set of clinical devices and their associated networks and peripherals.

- Cardiac Monitors and Pacemakers
- Radiometers
- Drug Infusion Systems
- Hemodialysis and Renal Devices
- Automated Compounding Systems
- Insulin Delivery Systems
- Clinical Patient Monitoring Systems
- Imaging Systems
- Home Healthcare Systems
- Electronic Healthcare Records (EHR) Systems



areas of expertise

- Premarket Approval (PMA) and 510(k) Support
- UL-2900-2-1 CAP Standards Compliance
- Secure Programming
- FIPS Support and Compliance
- Common Medical Device Exploit Methods
- Cryptographic Design
- Secure Remote Access and Clinician Monitoring
- Access Controls
- Secure Wireless Protocols (802.11, BLE, ad-hoc/ proprietary protocols)
- Secure Cloud Integration
- Secure Hardware Components and Interfaces Device Security Technical Training
- Device Security Technical Training

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