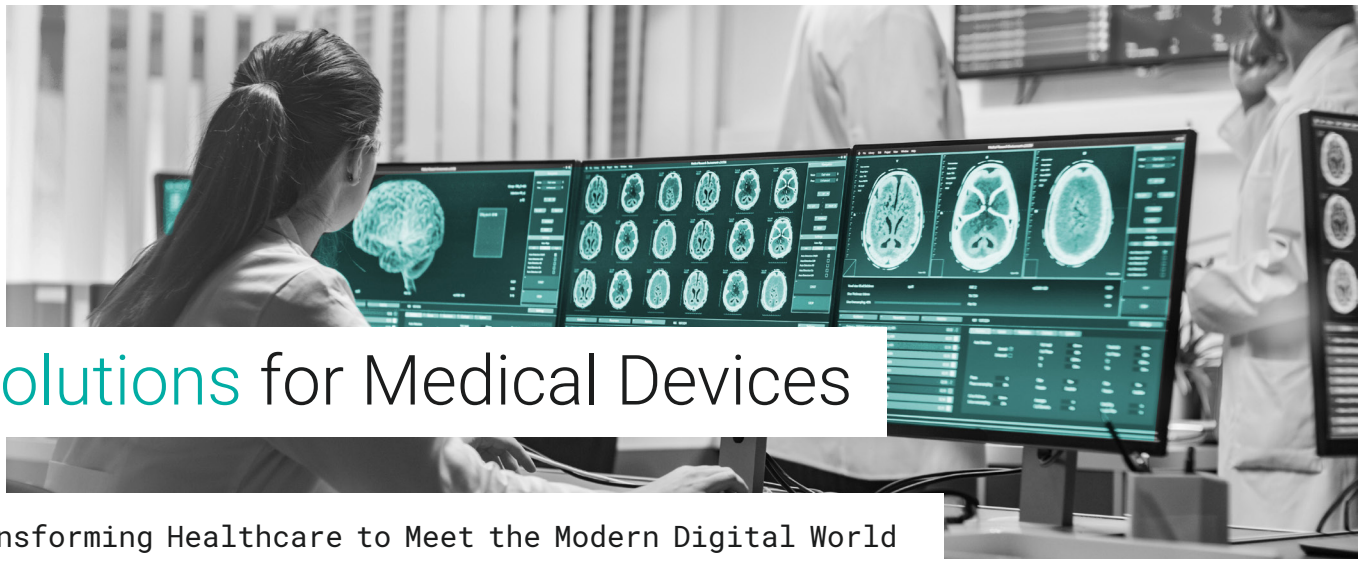

Solutions for Medical Devices

Transforming Healthcare to Meet the Modern Digital World

THE CHALLENGE

As medical device manufacturers and developers deliver high-quality products at a profit, they must overcome difficult and interrelated challenges. The pressure to accelerate time-to-market is a particular challenge to introducing new medical functions that require lengthy clinical trials and FDA certification processes that are crucial for quality and compliance requirements — ultimately, patients' health and lives are at stake. These processes drive up costs of development, deployment, and ongoing system maintenance, but quality cannot be compromised for cost savings or faster development cycle times.

Replacing legacy, stand-alone, manually monitored medical devices in hospitals is another challenge. The "connected hospital" and "connected healthcare" concepts have become more prevalent and hold promise for global healthcare. Increased connectivity among healthcare providers and between doctors and patients enables medical advancements, from remote-enabled robotic surgery to data-enabled predictive medicine to at-home care supported by data transmission via 5G wireless communication from medical devices and health sensors at patients' residences directly to the doctor. But such connectivity also increases the risk of malicious hacking and potentially threatening consequences for privacy and patient lives. FDA oversight and guidance on cybersecurity for medical devices means that medical equipment operators and IT need to address compliance early in the design phase to provide assurance of security throughout the device lifecycle, despite frequent updates and patches.

MEDICAL TECHNOLOGY CHALLENGES

- Accelerate device time-to-market
- Reduce development, deployment, and ongoing maintenance
- Meet stringent regulatory compliance requirements
- Update or replace legacy, stand-alone devices and systems
- Utilize safe and secure over-the-air wireless communications to update systems or transmit medical data
- Improve flexibility and agility to deploy new technologies
- Connect and manage medical devices and healthcare facility systems
- Ensure system security from outside intrusion

THE APPROACH

Wind River® delivers a comprehensive set of solutions that enable medical technology providers and their customers to take advantage of the benefits of digital transformation. Offering intelligent edge technologies, software-defined architecture, virtualization, modern DevOps technology, and cloud-native tools, Wind River is enabling medical technology developers to accelerate the digital transformation of healthcare, ushering in a new period of innovation, operating efficiency, connectivity, data transmission, security, and improved patient care.

Wind River also provides information, development tools, and services to assist medical device manufacturers in:

- Fully evaluating Wind River products' suitability for use and establishing that all requirements are met
- Designing their devices using Wind River products in a safe, secure, and effective manner
- Delivering strong, secure device and system connectivity capabilities for data transmission and updates
- Satisfying FDA requirements for information in premarket submissions for off-the-shelf software components from Wind River

WIND RIVER STUDIO

Wind River Studio is the first cloud-native platform for the development, deployment, operations, and servicing of mission-critical intelligent edge systems, such as medical and healthcare devices.

- Develop in the cloud using secure public, private, and hybrid clouds. Leverage the scalability, collaboration, and almost unlimited resources of cloud computing through our own distributed edge cloud (powered by Studio Cloud Platform), Microsoft Azure, or AWS.
- Utilize CI/CD to connect all workflows through Studio Pipelines, a single pane of glass for agile, secure, and cyber-protected development and deployment of mission-critical applications and devices on the edge.
- Automate processes with AI and machine learning, workflow automation, and digital feedback loop capabilities.

OPERATING SYSTEMS

Wind River is the market leader in real-time operating systems (RTOSes) for embedded and networked devices. We offer a choice of solutions for medical systems and devices:

WIND RIVER SOLUTIONS

- **Wind River Studio:** A cloud-native toolset for developing, deploying, operating, and servicing mission-critical intelligent systems across the edge
- **VxWorks®:** The first and only RTOS in the world to support application deployment through containers, helping to meet rigorous certification standards for safety, security, and performance in connected medical devices
- **Wind River Linux:** The industry-leading open source operating system with a comprehensive suite of products, tools, and lifecycle services to build and support intelligent edge solutions
- **Wind River Helix™ Virtualization Platform:** A real-time, embedded, Type 1 hypervisor that consolidates multi-OS and mixed-criticality applications onto a single edge compute software platform, simplifying, securing, and future-proofing critical infrastructure solutions such as medical equipment

VxWorks

VxWorks is the world's most widely deployed real-time operating system, powering some two billion devices. It delivers unrivaled deterministic performance and sets the standard for a scalable, future-proof, safe, and secure operating environment for connected devices for digital transformation. Independent researcher VDC has named VxWorks the #1 RTOS for the edge. Key features are:

- **A proven real-time operating system:** VxWorks is proven in mission-critical medical applications, where security is paramount.
- **Compliance documentation:** VxWorks provides documentation for medical device manufacturers for inclusion in compliance-related vendor qualification and for use in premarket submission to the FDA according to the recommendations of "Off-the-Shelf Software Used in Medical Devices" and the SOUP requirements of IEC 62304. It also addresses FDA guidance in "Cybersecurity of Networked Medical Devices Containing Off-the-Shelf (OTS) Software."
- **Artificial intelligence/machine learning:** Technologies such as pandas, TensorFlow lite, and others are integrated to easily add AI/ML applications into the device.
- **Security:** The VxWorks product line provides best-in-class, pre-integrated security functionality including foundational capabilities for bringing enhanced device, communication, and management security and privacy.
- **Safety-critical certification support:** Wind River VxWorks 653 Platform provides a commercial off-the-shelf solution for functional safety applications that must be certified to IEC 61508, as when medical devices require full IEC 62304 device certification.
- **Multi-core capabilities:** With virtual machines, you can consolidate your core safety-certified and non-safe code on a single VxWorks real-time hosting safety platform. VxWorks on Intel® architecture supports such a virtualized safety environment.
- **Integrated virtualization:** Helix Platform, working with VxWorks, integrates a real-time embedded, Type 1 hypervisor with support for virtual machines into the VxWorks core for consolidation of multiple stand-alone hardware platforms onto a single multi-core platform.
- **OCI container support:** The latest releases of VxWorks includes support for OCI containers. Now you can use traditional IT-like technologies to develop and deploy intelligent edge software better and faster, without compromising determinism and performance.

Wind River Linux

For over 15 years, Wind River Linux has been providing the most advanced embedded Linux platform to the global industry, with a comprehensive suite of products, tools, and lifecycle services to build and support intelligent edge solutions. It has been the embedded operating system of choice for device software developers who want a combination of open source flexibility and commercial-grade reliability. It provides an optimized cross-architecture runtime and more agility, so you can focus scarce resources on creating differentiated features. Wind River Linux also includes security and privacy capabilities that build on our robust development and commercialization processes.

- **Yocto Project:** Wind River Linux is a Yocto Project–compatible open source baseline, and Wind River is one of the project's largest contributors of technology. Developers can take advantage of the flexibility of an optimized open source platform without compromising security.

- **Wind River Studio Linux Services:** Security and compliance scanning services target vulnerabilities and license compliance ahead of 510(k) applications.
- **Long-term commercial support:** Commercial support lasts 10+ years and includes CVE monitoring and fixes, board support packages (BSPs) for x86 and Arm® hardware, and more.
- **ISO 9001 certification:** Wind River Linux development and maintenance processes have been certified to the ISO 9001:2015 quality management system standard. This certification provides developers support for inclusion in compliance-related vendor qualification and for use in premarket submission to the FDA.
- **Security support services:** Ongoing threat mitigation in deployed systems protects against common vulnerabilities and exposures (CVEs).
- **Lifecycle performance assurance:** Monitoring, analysis, mitigation, remediation, and support help manage BSP CVEs and defects.

The Wind River suite of products provides medical device developers and system operators with a complete solution for transforming healthcare both in the hospital and in patient homes: an industry-leading operating system connecting to an ultra-reliable, on-premises network virtualization platform, working in tandem with a secure, centralized device management platform.

THE RESULT

With 40+ years of experience building safe and secure intelligent systems, Wind River provides the products, tools, and services for modern software and device development to drive the digital transformation of healthcare and to enable medical technology developers to spearhead a new period of innovation, operating efficiency, security, and improved patient care.

Through intelligent edge technologies, virtualization technology, and wireless technology, healthcare facilities and at-home patient care can move beyond the constraints of legacy equipment to the cloud, realizing the vision of centralized device monitoring, data aggregation, faster health assessments, and more immediate patient treatment. With centralized device management, updates can take place instantly and remotely via software that allows seamless device failover. By enriching data with artificial intelligence and machine learning as well as analytics, today's technologies help doctors, healthcare providers, and patients make more informed decisions.

WNDRVR

Wind River is a global leader of software for mission-critical intelligent systems. For 40 years, the company has been an innovator and pioneer, powering billions of devices and systems that require the highest levels of security, safety, and reliability. Wind River offers a comprehensive portfolio of software and expertise that are accelerating digital transformation across industries.