SOLUTIONS FOR THE MEDICAL SECTOR

Driving Digital Transformation in Healthcare

MEDICAL SECTOR CHALLENGES

- Accelerate device time-to-market
- Reduce development, deployment, and ongoing maintenance
- Meet stringent regulatory compliance requirements
- Update or replace legacy, standalone devices and systems
- Improve flexibility and agility to deploy new technologies
- Connect and manage medical devices and healthcare facility systems
- Ensure system security from outside intrusion

WIND RIVER SOLUTIONS

- **Wind River® Helix™ Device Cloud:** Remotely monitor, manage, secure, and update hundreds to thousands of networked devices and equipment remotely in the Internet of Things
- **Wind River® Titanium Cloud™:** Enable digital transformation from legacy hardware to a virtualized computing environment, reducing IT infrastructure and increasing agility
- **VxWorks® and Wind River Linux:** Employ the industry-leading real-time operating system and open source operating system that help meet rigorous certification standards for safety, security, and performance in connected medical devices

THE CHALLENGE

As medical device developers and manufacturers strive to deliver high-quality products at a profit, a number of interrelated challenges exist. Manufacturers are under pressure to accelerate time to market—a particular challenge when introducing new medical functions that require lengthy clinical trials and certification processes. At the same time, they are trying to hold down the costs of development, deployment, and ongoing system maintenance. But quality cannot be compromised for cost savings or faster cycle times. Products must meet stringent compliance requirements for safety, security, and industry standards across projects. And ultimately, patients' health and lives are at stake.

The concept of the "connected hospital" and greater connectivity among healthcare providers holds the promise of further advancements, such as centralized patient monitoring and data-enabled predictive medicine. Though today's devices can be designed for connectivity from the ground up, many facilities will be facing extensive efforts to replace legacy, standalone, manually monitored devices. And with increased connectivity comes the increased risk of malicious hacking, with potentially threatening consequences for privacy and life. The FDA has issued strict guidance on cybersecurity for medical devices. Security at both the network and device levels needs to be addressed early in the design phase in order to meet compliance requirements and to guarantee the privacy and safety of patients. Moreover, operators need assurance that devices will be secure throughout their lifecycle despite frequent updates and patches.

THE SOLUTION

A combination of Internet of Things (IoT) technologies and software-defined architecture (SDA) from Wind River® is enabling medical technology developers to accelerate the digital transformation of healthcare, ushering in a new era of innovation, operating efficiency, and improved patient care. Through virtualization, healthcare facilities can move beyond the constraints of legacy equipment to the cloud and realize the vision of centralized device monitoring and data aggregation. With centralized device management, updates can take place instantly and remotely, via software that also allows for seamless device failover. By enriching data with analytics and machine learning, today's technologies can help providers make more informed decisions for their patients.

Wind River delivers a comprehensive set of solutions that enable medical technology providers and their customers to start reaping the benefits of digital transformation. Wind River also provides information and services to assist medical device manufacturers in doing the following:

- Fully evaluate Wind River products' suitability for use and establish that requirements, including quality requirements, are met.
- Design their medical devices using Wind River products in a safe and effective manner.
- Satisfy FDA requirements for information in premarket submissions for off-the-shelf software components from Wind River.

Wind River Titanium Control

Part of our Wind River Titanium Cloud™ virtualization platform, Wind River Titanium Control is an ultra-reliable, on-premise cloud infrastructure platform that delivers the uptime and performance needed for controlling and communicating with networked devices at any scale. Its open architecture gives operators the flexibility to:

- Accelerate device deployment by eliminating the need to integrate, test, and document multiple technology components from different vendors.
- Incorporate equipment and software components from multiple sources and avoid vendor lock-in.
- Replace components quickly without affecting other areas of operation.
- Take advantage of technological innovations as they become available.

By virtually any measure, Titanium Control delivers the results healthcare operators demand:

- **Uncompromising reliability:** Titanium Control meets and often outperforms legacy system standards for reliability, uptime, and low latency. When devices must not fail, Titanium Control ensures that your services run when, where, and how they need to, always.
- **Security:** An extensive, built-in, fully integrated, and multilayered security framework protects your systems against network-borne threats.
- **Reduced costs:** Titanium Control lowers the cost of deployment, maintenance, and replacement compared to legacy systems and equipment and further reduces costs by allowing the use of standard, off-the-shelf servers.
- **Significantly lower TCO, higher ROI:** Wind River has developed a comprehensive modeling tool to compare total cost of ownership and return on investment with Titanium Control against existing hardware infrastructure. Taking into account a number of factors, including reliability; scalability; costs of support, software, servers, and more; and actual customer data, we can model TCO across installations over a multiyear horizon. Given this analysis, customers can anticipate enormous potential savings by replacing hardware-based infrastructure with Titanium Control.

Wind River Helix Device Cloud

Wind River Helix™ Device Cloud is the IoT device management platform that enables correctly functioning medical equipment, both inside and outside of clinical environments. Medical professionals are usually not skilled in diagnosing a device's operational issues. Remote connectivity is therefore integral for medical device manufacturers to provide the additional support required without hiring additional technician staff.

From a centralized web-based management console, operators can remotely and securely monitor, manage, service, and update a wide range of devices, from vital sign monitors to infusion systems to imaging and diagnostic equipment. The system also collects and integrates data from any number of devices, machines, and systems, enabling medical IT teams to track device status and content, diagnose problems remotely, and proactively determine when updates are needed.

- **Avoid costly downtime:** Device Cloud helps keep operations humming smoothly by immediately alerting operators to any issues. Avoiding medical device downtime positively impacts patient treatment and care.
- **Support predictive maintenance:** Sensors on equipment tell operators when a medical device is behaving abnormally, eliminating the need for routine preventive maintenance and downtime.
- **Leverage device data:** Device Cloud can collect and aggregate real-time operational data about medical devices to give healthcare administrators insights for better informed and tailored healthcare.
- **Enhance security:** Device Cloud enables system operators to monitor devices and their communications for vulnerabilities and securely deliver software patches and upgrades at scale to mitigate threats.

Operating Systems

Wind River was a pioneer and is still the market leader in real-time operating systems for embedded and networked devices. Today, we offer a choice of solutions for medical systems and devices:

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 in IIoT, including medical devices. 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. This follows the FDA guidance in *Off-the-Shelf Software Used in Medical Devices* and the SOUP requirements of IEC 62304. It also addresses the FDA guidance given in *Cybersecurity of Networked Medical Devices Containing Off-the-Shelf (OTS) Software*.
- **Security:** Best-in-class, pre-integrated security functionality throughout the VxWorks product line includes foundational security capabilities for devices, while Security Profile for VxWorks brings enhanced device, communication, and management security and privacy.
- **Safety-critical certification support:** Wind River VxWorks Cert Platform provides a commercial off-the-shelf solution for functional safety applications that must be certified to IEC 61508, such 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:** Virtualization Profile for VxWorks integrates a real-time embedded, Type 1 hypervisor with support for virtual machines into the VxWorks core for consolidation of multiple standalone hardware platforms onto a single multi-core platform.

Wind River Linux is the embedded operating system of choice for device software developers who want a combination of open source flexibility and commercial-grade reliability. It provides improved out-of-box experience with optimized cross-architecture runtime. Wind River Linux also includes security and privacy capabilities that build on our robust development and commercialization processes, making Wind River the world's leading embedded Linux OS.

- **Yocto Project:** Wind River Linux is a Yocto Project Compatible open source baseline and one of the project's largest contributors of technology. Developers can leverage the flexibility of an optimized open source platform without compromising security.
- **ISO 9001 certification:** Wind River Linux development and maintenance processes have been certified to the ISO 9001:2015 quality management system standard, providing support for inclusion in compliance-related vendor qualification and for use in premarket submission to the FDA.
- **Security support services:** Wind River Linux provides ongoing threat mitigation in deployed systems against common vulnerabilities and exposures (CVEs).

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

With more than 30 years of experience building safe and secure intelligent systems, Wind River is enabling the next generation of IoT and virtualization technologies to drive the digital transformation of healthcare.

WIND™

Wind River is a global leader in delivering software for the Internet of Things. The company's technology is found in more than 2 billion devices, backed by world-class professional services and customer support. Wind River delivers the software and expertise that enable the innovation and deployment of safe, secure, and reliable intelligent systems.