WNDRVR

WIND RIVER LINUX
FOR MEDICAL DEVICES

Advanced Embedded Linux Development Platform with
Security, Compliance, and Support

LINUX AIDS AND CHALLENGES THE MEDICAL DEVICE INDUSTRY

Linux, as an open source operating system, brings both advantages and challenges to the development of medical devices. A significant pro is its cost-effectiveness: It eliminates licensing fees and allows resource allocation with greater efficiency. Linux also offers a high level of customization that enables developers to tailor the operating system to the specific requirements of diverse medical devices. This flexibility is crucial in the dynamic field of healthcare technology.

Safety and security are also important concerns for medical devices, however. They must be safe and secure to ensure patient health and life as well as to protect data privacy, and a cybersecurity breach could compromise all of these needs. With an active open source community addressing vulnerabilities and making timely updates, Linux provides strong security. However, new cybersecurity breaches and flaws are still being discovered in medical devices that are connected and communicate with other systems and the Internet.

This means cybersecurity is a challenge that must be actively worked. New U.S. Food and Drug Administration (FDA) and other regulatory guidelines further increase the need for medical device development to meet and maintain compliance, starting from first release and continuing throughout the lifecycle.

Software development challenges also arise in the adoption of Linux for medical device development. A detailed project plan must cover the full lifecycle, defining functional requirements and system architecture and identifying risks, to meet regulatory approval. The development and maintenance efforts associated with roll-your-own (RYO) or unsupported silicon vendor Linux can be significant. Proven artifacts are needed to support compliance for regulatory approvals. Keeping the code base up to date, tracking and fixing open source defects, applying security patches, avoiding technical debt, and customizing your purpose-built Linux to adhere to strict market specifications and certifications can be expensive and can consume valuable developer resources.

Addressing the Need

To help meet the challenges of using Linux to develop an innovative medical device or system, companies needs to utilize a leading Linux distribution, strong security resources, and an effective developer platform and tools. Wind River® offers Wind River Linux, the industry's most advanced embedded Linux development platform, with a comprehensive suite of products, tools, and services that support the creation of innovative medical devices to treat patients and save lives.

WIND RIVER LINUX: A ROBUST, RELIABLE, AND SECURE OPEN SOURCE OS

Wind River Linux enables medical device companies to develop, deploy, and operate robust, reliable, and secure embedded solutions running on a purpose-built Linux operating system. Developers can avoid the risk and effort associated with RYO or unsupported silicon vendor Linux.

WIND RIVER LINUX LTS: SUPPORT FOR THE RANGE OF DEVELOPMENT NEEDS

With Wind River Linux LTS with commercial long-term support, Wind River can keep the developer's code base up to date, track and fix defects, apply security patches, avoid technical debt, and customize the purpose-built Linux to adhere to strict medical market specifications and certifications. In addition, it provides support for Docker, OverC, and Kubernetes container technology on both x86 and Arm® devices and meets ISO 9001:2015 certification require-ments for quality. Wind River can also facilitate IP and export compliance and significantly reduce operational costs.

With Wind River Linux LTS, the medical device developer has the support of:

- Maintenance that includes CVE monitoring and fixes
- Daily testing and hardening to shrink the threat landscape
- Support for a minimum of 10+ years for every Long Term Support (LTS) release
- Board support packages (BSPs) for a wide range of x86 and Arm hardware
- Tracking of customizations to ensure transfer of knowledge even if teams change
- Compliance in the bill of materials (BOM) and in accordance with export regulations around the globe

Visit Wind River Linux for detailed information.

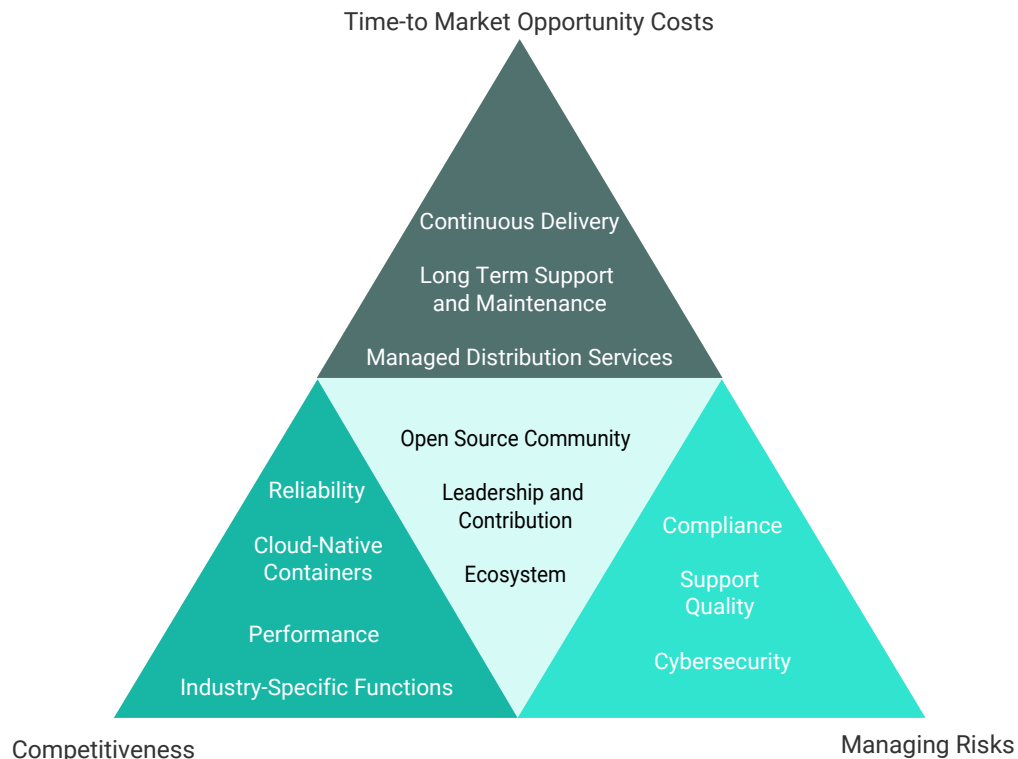Time-to Market Opportunity Costs

Continuous Delivery

Long Term Support and Maintenance

Managed Distribution Services

Open Source Community

Reliability

Leadership and Contribution

Cloud-Native Containers

Compliance

Ecosystem

Support Quality

Performance

Cybersecurity

Industry-Specific Functions

Competitiveness

Managing Risks

Figure 1. Benefits of using Wind River as your Linux partner

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WIND RIVER STUDIO LINUX SERVICES: DESIGN, IMPLEMENTATION, SECURITY, AND LIFECYCLE MANAGEMENT

Wind River Studio Linux Services delivers embedded Linux platform solution design, implementation, security, and lifecycle management capabilities that help reduce open source project risk while accelerating time-to-deployment, so medical device developers can lower their total cost of ownership and focus valuable resources on innovation for better care. Services include:

- **Architecture and Implementation:** Wind River offers comprehensive solution services from an experienced team of industry experts who can interpret system requirements, architect platform options, and provide recommendations for meeting business, technical, and program goals. Their engineering expertise will help you accelerate time-to-deployment, increase quality, lower risk, and ensure greater long-term project success. Learn More >

- **Security Scanning:** Our security scanning service uses your SBOM or manifest to identify critical Common Vulnerabilities and Exposures (CVEs). The results allow us to provide a deeper analysis to determine the impact and the effort required to mitigate. Get Details >

- **Security and Compliance Analysis and Remediation:** Security and compliance scanning with analysis and remediation services help you build higher-quality code and accelerate your time-to-deployment. Explore >

- **Lifecycle Performance Assurance:** Lifecycle management services for Linux platforms and board support packages bolster your embedded systems project. View Details >

- **Lifecycle Security:** Receive ongoing CVE monitoring, mitigation, and management of your Linux platform throughout the software development and deployment lifecycle. Visit Page >

WIND RIVER LINUX DISTRO

Based on more than 15 years of experience with embedded Linux, Wind River Linux Distro is the first Yocto Project–compatible binary distribution, built specifically for embedded solutions such as medical devices. This binary is optimized for popular reference hardware and leverages Fedora CoreOS components for streamlined updates and maintenance. Benefits include access to:

- **Yocto Project:** Overarching open source project consisting of a suite of tools and processes enabling developers of all levels to build an embedded Linux distribution on a wide set of hardware architectures

- **Core OS:** Group of developer tools to assemble packages into images, install images to targets, customize installed software on targets, and keep targets current

- **Open Embedded:** A build framework of recipes, packages, and related metadata compatible with the Yocto Project build engine

Visit Wind River Linux Distro to learn more.

Using open source Linux to build and develop innovative medical devices and systems makes improving patient health care and saving human lives easier, less expensive, and more secure. Wind River and Wind River Linux products, tools, and services can bring success to medical device companies and the healthcare community. Contact Wind River to learn more.

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