



# VXWORKS FOR MEDICAL DEVICES

Rely on a Proven, Secure, Safe, Reliable, and Certifiable RTOS

## MEDICAL SECTOR CHALLENGES

- Accelerate next-generation device time-to-market
- Meet stringent regulation compliance requirements
- Attract talented software developers
- Satisfy real-time medical application requirements
- Simplify and speed up software updates
- Implement robust cybersecurity

## WHY VXWORKS

- Mature, proven, and comprehensive RTOS solution
- IEC 62304 medical certification
- Modern tools and support for emerging languages
- Guaranteed latency and determinism
- Medical device update support
- Best-in-class, pre-integrated security capabilities

## MEDICAL INDUSTRY SNAPSHOT

Medical device manufacturers are under pressure to accelerate time-to-market for their next-generation devices as they pursue global outreach efforts, particularly in China, Japan, and Europe. This challenge includes finding ways to minimize the time and cost to certify systems and satisfy regulatory safety and security requirements. Regulatory agencies are requiring higher levels of security and faster update processes to quickly resolve safety and security issues to ensure continuing patient safety.

On the application side, emerging medical devices require real-time and deterministic performance—for example, a surgical robot must restrict where cuts are made based on pre-operation programming by the surgeon. The trend for such medical applications is for next-generation device designs to be more software focused than hardware focused, which requires providing software developers with modern software programming methods and tools. There is also fierce competition for talented software developers who want to apply the latest techniques they learned in school and not be forced to use outdated software environments.

To help device manufacturers address these challenges, Wind River® invests heavily in its VxWorks® real-time operating system (RTOS), adding new features and maintaining its very high level of security, safety, and reliability. VxWorks delivers hard real-time performance, determinism, and low latency, along with the scalability required for medical applications. It is the world's most widely used commercial RTOS, with more than 30 years in the field and billions of deployments.



Figure 1. Robotic surgery requires hard real-time performance

## VXWORKS: PIVOTAL TO SUCCESS

### Get to Market Faster with a Modern RTOS Platform

It takes an average of three to seven years to bring a new medical device to market, a lengthy amount of time that device manufacturers are eager to reduce. VxWorks Cert Edition helps shorten two of the longer phases, software development and device certification, by providing modern languages and tools and pre-certification of safety standards. For example, VxWorks Cert Edition is pre-certified for medical applications (e.g., IEC 62304) as well as for safety-critical applications in other industries: IEC 61508 SIL 3, DO-178C DAL A, and ISO 26262 ASIL-D.

### Deliver Real-Time Performance

The reaction time for many medical devices, such as surgical robots, MRI/CAT scanners, and blood filters, is critical to ensure patient safety. To help device manufacturers

meet stringent performance requirements, the VxWorks enhanced scheduler can guarantee that safety-critical applications get sufficient CPU cycles and memory for latency and determinism. This capability also helps prevent a faulty application from adversely impacting the rest of the platform.

### Give Software Developers the Tools They Want

The value proposition of next-generation medical devices is tied closely to software, requiring modern software programming methods and tools in order to gain a competitive advantage. With all the powerful programming languages and tools available today, many device manufacturers feel it's a big disadvantage to develop with their vendor's old or proprietary software environment. This is why VxWorks leverages low-level virtual machine (LLVM) as a tools foundation to support current popular languages and libraries such as C++17, Rust, Boost libraries, and Python. Newly recruited developers are happy to use what they learned in school instead of having to train on one-off software environments.

### Simplify the Delivery of Software Updates

As more devices are connected to networks, regulatory agencies such as the FDA are mandating quick software updates to address software holes and bugs that impact safety and security. VxWorks and Wind River Helix™ Virtualization Platform enable manufacturers and their customers to safely and promptly update firmware and software through the simple and cost-effective creation of update functions. Updating and testing functions can be loaded into virtual machines that isolate them so they cannot negatively impact other application workloads, thus helping to improve the safety and reliability of the system.

### Reduce Device Certification Cost and Risk

Medical device certification is a complex process, especially for device manufacturers introducing new medical functions with real-time requirements. Safety and security must be built in to safeguard patients and their health. To help streamline the certification process, VxWorks Cert Edition provides documentation (e.g., binaries and artifacts) for inclusion in IEC 62304 compliance-related vendor qualification and for use in premarket submission to the FDA and other international regulatory offices. This follows the FDA guidance in “Off-the-Shelf Software Use in Medical Devices” and “Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software,” as well as IEC 62304 software of unknown provenance (SOUP) requirements.

### Implement Persistent Data and Device Protection

The FDA has issued strict guidance on cybersecurity for medical devices, concerned that the increase in device connectivity will elevate the risk of malicious hacking, with potentially threatening consequences for privacy and life. To help device manufacturers address growing security threats, VxWorks integrates an extensive and continuously evolving set of security capabilities that safeguard device and data during boot-up, app execution, data transmission, idle, and power off. Capabilities such as secure boot, Trusted Platform Module (TPM), data encryption, and kernel hardening allow developers to implement protection at every stage of operation.

## TRUSTED SOFTWARE SOLUTIONS

VxWorks and its tools suite provide medical device developers with a complete solution for developing advanced and innovative solutions. With more than 30 years of experience building safe and secure embedded systems, Wind River is well versed in satisfying the real-time requirements of the medical industry and enabling the next generation of highly competitive medical devices.

