VxWorks for Medical Devices

Proven, Secure, Safe, Reliable, and Certifiable RTOS

INDUSTRY SNAPSHOT

The medical technology (medtech) industry, which includes devices for diagnosis of health conditions, patient care, medical treatment, and health improvement, went through 10 years of major innovation and growth prior to 2019, according to McKinsey's report "Medtech Pulse: Thriving in the Next Decade" (2023). Medtech is working to bring further innovation and value to hospitals, healthcare, patient care, and the home to result in a new period of medical and healthcare advancements across the world.

Medical device manufacturers and the medtech industry are changing from "doing digital" to "being digital." Rather than trying to update medical technology and devices to digital, Deloitte notes, now new medical technology must be digital from the original design, tying together hardware, software, and the healthcare ecosystem ("Navigating the Future of the Medtech Industry"). Software is the major growth factor in medical innovation, with data analytics, artificial intelligence, machine learning, and the adoption of modern software development processes and tools. This is driving medical advancements such as the growth of digital robotic surgery, diagnostic imaging, radiotherapy devices, remote patient monitoring, and more for patients in medical facilities and at home.

The ongoing challenges continue to be decreasing time- and cost-to-market; certification of systems to meet safety and security mandates; and systems update processes to meet regulatory requirements and to keep patients alive, safe, and secure. On the software side, many of the needs for new innovative medical technology, such as digital robotic surgery and automated treatment responses, require real-time and deterministic performance. For example, a surgical robot must be able to reactively restrict where scalpel cuts are made based on preoperative programming by the surgeon. Next-generation device designs are driven more by a software than a hardware focus, so that new capabilities and improved treatment

MEDICAL SECTOR CHALLENGES

- Accelerate next-generation device time-to-market
- Meet stringent regulation compliance requirements
- Drive modern software development capabilities and tools
- 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 device software certification
- Modern tools and support for modern development languages
- OCI container support for ease in deployment of software
- Guaranteed latency and determinism
- Medical device update support
- Best-in-class, pre-integrated security capabilities

methods can be quickly implemented. To accomplish this, software developers need modern software programming methods and tools. In addition to real-time and deterministic performance, they need the flexibility and the power of technologies such as containerization, AI, machine learning, and new programming languages.

VXWORKS: PIVOTAL TO SUCCESS

To equip medical technology and device manufacturers to resolve these challenges, Wind River® invests heavily in its VxWorks® real-time operating system (RTOS), adding new features and maintaining its 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 first RTOS to utilize OCI containers, and it supports the widest range of modern programming languages. It is the world's most widely used commercial RTOS, with 40+ years in the field and billions of deployments.

FASTER TIME-TO-MARKET WITH A MODERN RTOS PLATFORM

Shortening time-to-market and lowering costs is one key to success for medtech and medical device manufacturers. On average, it takes three to seven years to bring a new medical device to market, a period that device manufacturers are striving 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, such as IEC 61508 SIL 3, DO-178C DAL A, and ISO 26262 ASIL-D.

REAL-TIME PERFORMANCE

For medical devices, reliable response time is key to providing effective procedures and treatment for patients. Reaction time for many medical devices, such as surgical robots, MRI/CAT scanners, and blood filters, is critical to ensure patient health and safety. The VxWorks enhanced scheduler can guarantee that safety-critical applications have sufficient CPU cycles and memory for latency and determinism. This capability helps prevent a faulty application from adversely impacting the rest of the platform.

MODERN SOFTWARE DEVELOPMENT TOOLS

With more focus on software to design next-generation medical devices, modern software programming methods and tools are required to gain a competitive advantage. To enable leading-edge software development, 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 for more efficiency. VxWorks is also the only RTOS supporting application deployment with OCI container support. Developers benefit from the continuous feature and performance optimizations made in VxWorks to support the most advanced processors and SoCs.

APPLICATIONS DEPLOYED AT THE SPEED OF IT

As the only RTOS supporting OCI container support, VxWorks can package and deploy all applications using IT-like tools and methods. This easily allows the management and deployment of software on VxWorks, leveraging existing cloud infrastructure. Medtech and medical device manufacturers can push their applications to standard container registries (such as Docker Hub, Amazon ECR, or Harbor) and pull them from deployed VxWorks-based devices. Native support for kubelets enables VxWorks-based devices to be seen as nodes in a Kubernetes cluster so that the containers in deployed pods are running and healthy, vastly improving device management in the near and far edge.

SIMPLIFIED DELIVERY OF SOFTWARE UPDATES

With the introduction of 5G wireless technology and more devices being connected to networks, the FDA and other regulatory agencies are mandating quick and timely software updates to address software issues and bugs that impact medical device safety and security. VxWorks, Wind River Helix™ Virtualization Platform and the VxWorks OCI container capability, and Wind River Studio Over-the-Air (OTA) Updates enable manufacturers and their medical and healthcare customers to update firmware and software safely and promptly 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, helping to improve the safety and reliability of the system. Update deployments can be automated and timed to occur during device downtime, with rollbacks possible when updates do not complete correctly.

DECREASED DEVICE CERTIFICATION COST AND RISK

Medical device certification helps provide required assurance that safety and security are built into a device to safeguard patients and their health. Certification is a complex process, especially for device manufacturers introducing new medical functions with real-time requirements. To help streamline certification processes, 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.

PERSISTENT DATA AND DEVICE PROTECTION

The increase in device connectivity risks elevating the risk of malicious hacking, with potentially threatening consequences for privacy and life. With deep concern for patient safety and security, the FDA has issued strict guidance on cybersecurity for medical devices. To assist device manufacturers and address growing security threats, VxWorks integrates an extensive and continuously evolving set of security capabilities that safeguard device and data during powerup, app execution, data transmission, idle, and power down. 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 40 years of experience building safe and secure embedded systems, Wind River is well versed in satisfying the real-time requirements of the medical technology industry and enabling the next generation of highly competitive medical devices.

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.