UPDATE CAPABILITIES FOR MEDICAL DEVICES BUILDING IN SAFETY AND SECURITY TO MEET REGULATORY REQUIREMENTS

MEDICAL DEVICE CHALLENGE

- Build in the ability to update safety and security functions in medical device products to meet FDA and other regulatory requirements for medical devices

WIND RIVER SOLUTIONS

- **Wind River Helix Virtualization Platform:** An OS-agnostic edge compute platform with a real-time, embedded, Type 1 hypervisor that can manage unmodified guest operating systems running in VMs, consolidating workloads for medical devices.
- **VxWorks:** The world's leading RTOS, enabling deterministic applications scaling from very small compute packages
- **Wind River Linux:** Optimizing Kernel-based Virtualization Machine (KVM) technology, enabling VMs to run update functions for devices and take advantage of optional Wind River Professional Servicess
- **Wind River Titanium Cloud:** Virtualization platform that reliably runs applications and cost-effectively enables update capabilities for medical devices

With the objective to achieve better results in patient healthcare and lifesaving techniques, regulatory agencies such as the U.S. Food and Drug Administration continue to announce rules and regulations to make medical devices safer and more secure for patients. In a recent 2018 announcement, the FDA released an article, "Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health," that outlines various new FDA actions to improve medical device safety. One of the components of this plan is the call for mandatory built-in capabilities providing safety and security updates to medical devices.

THE CHALLENGE

The challenge for medical device manufacturers is to securely, reliably, and cost-effectively build in these safety and security update capabilities. Device manufacturers can no longer consider the development phase the only or even the most significant cost driver in the product lifecycle. The ability to update is necessary to meet new and evolving FDA and other regulatory requirements for medical devices. This use case outlines solutions for designing such update capabilities into a medical device.

THE SOLUTION

With every problem comes opportunity. More sophisticated medical device manufacturers can see the new guidelines as an opportunity to better understand their customers' needs and better enable interaction with their customers over the life of their product. As the use of medical devices by hospitals and patients continues to grow, new safety concerns emerge that must be dealt with to maintain patient health. Additionally, as new cybersecurity vulnerabilities are discovered, they need to be mitigated to ensure continuing patient safety. Wind River® offers a portfolio of products, including the use of virtualization technology available with Wind River Helix™ Virtualization Platform, the VxWorks® real-time operating system, Wind River Linux, and the edge cloud solution Wind River Titanium Cloud™, that can help medical device companies create reliable software update capabilities in a cost-effective manner.

Wind River Helix Virtualization Platform

Helix Platform provides a safe, secure, and reliable software development environment with a Type 1 hypervisor solution. This virtualization platform manages and allows the creation of virtual machines (VMs) on a single compute platform with a mix of operating systems and mixed-criticality workloads to allow greater flexibility, safety, and security, as required for today's medical devices.

Helix Platform's hypervisor can manage multiple VMs running VxWorks, Wind River Linux, and other guest operating systems such as Windows® and Android. It supports multiple software applications, including those for safety-critical or security systems, running together or segregated. Thus, safety-critical applications on a medical device can be reliably run and updated via the network. Medical device architects can use our industry-leading virtualization technology to segregate different software applications into independent VMs in separate partitioned processor cores as necessary, in order to more easily maintain, patch, or replace current software with new safety or security updates.

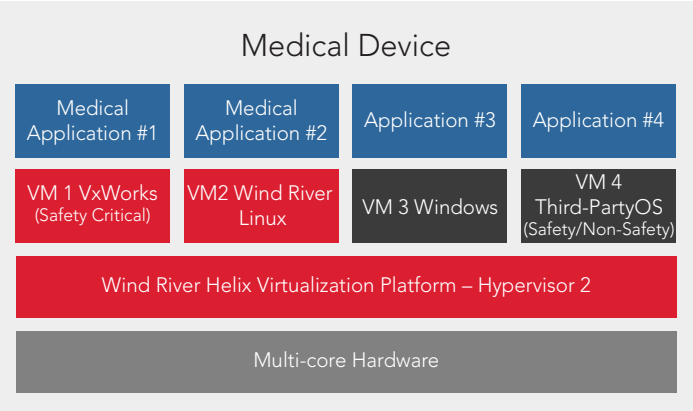

Figure 1. Example of a Helix Virtualization Platform with virtualization running medical applications in virtual machine partitions

VxWorks

VxWorks is a real-time operating system found in more than 2 billion devices in medical, industrial, transportation, and defense solutions. VxWorks is proven in mission-critical medical applications, where security is paramount. Its small footprint enables devices to meet hard real-time operating requirements in scaling from small to large medical devices. It works on all major processor architectures, Arm® and x86.

Best-in-class, pre-integrated security functionality in VxWorks includes foundational security capabilities for devices, communication, and management for security and privacy.

VxWorks provides documentation for medical device manufacturers for inclusion in compliance-related vendor qualification, and for use in premarket submission to the FDA.

Wind River Linux

Wind River Linux is the Linux distribution of choice for IIoT software developers who want a combination of open source flexibility, commercial grade reliability, and support to help achieve low total cost of ownership. Wind River Linux delivers vital components for the productization and commercialization of any medical device or Internet of Things (IoT) device. The KVM hypervisor is a component of Wind River Linux.

A Linux solution can be utilized with a Wind River Linux platform for the medical device system. To provide the capability to easily update FDA-approved and security functions in a medical device, Wind River Linux, with its KVM hypervisor capability, can run applications in various VMs running Wind River Linux, VxWorks, or another guest OS. An FDA-approved or security application or functions would each be running in their own separated VM, so they are safe from interference or conflicts from applications in other VMs. Each medical application and security VM can be easily updated via the network, or a mirrored VM can quickly be updated and then swapped with the updated functions.

Wind River Professional Services can support a medical device company in developing a Wind River Linux solution that can easily update VMs and be secure, protecting the operations and data on the medical device.

Wind River Titanium Cloud Product Family

The Titanium Cloud product portfolio provides an application-ready software platform that runs virtual functions with high reliability and is built to support the intensive performance, reliability, and security requirements of the world's most demanding computing and communications networks. If you are looking to consolidate control systems in a cloud environment (on premise or centralized), Titanium Cloud provides the low latency and reliability needed. Titanium Cloud is built from the ground up to be secure and flexible and is capable of in-service upgrades and hitless patching so you can keep your systems up to date without having to take them down.

Wind River Development Tools

To create a workload consolidation solution for your specific manufacturing components and needs, Wind River provides powerful and time-saving development tools:

- Wind River Simics®: This simulation platform can simulate anything, chip to system. It provides the access, automation, and collaboration tools required for agile development practices.
- Wind River Workbench: The Workbench suite of tools allows the developer to configure the operating system, analyze and tune the software, and debug the entire system.
- Wind River Diab Compiler: Diab Compiler helps boost application performance, reduce memory footprint, and produce high-quality, standards-compliant object code for embedded systems.

More Information

To learn more about VxWorks, Helix Platform, Wind River Linux, or Titanium Cloud, visit www.windriver.com, or contact salesinquiry@windriver.com.

WIND™

Wind River is a global leader in delivering software for IoT. Its technology is found in more than 2 billion devices and is backed by world-class professional services and customer support. Wind River is accelerating digital transformation of critical infrastructure systems that demand the highest levels of safety, security, performance, and reliability.