



# 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

- **VxWorks:** With VxWorks hypervisor for virtual machine (VM) solutions, supports creation of medical device update functions
- **Wind River Linux:** Optimizing Kernel-based Virtualization Machine (KVM) technology, enables VMs to run update functions for devices and take advantage of optional Wind River Professional Services
- **Wind River Titanium Cloud:** Provides a virtualization platform that reliably runs applications and cost-effectively enables update capabilities for medical devices

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 announcement, the FDA released an article, "[Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health](#)," that outlines various 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

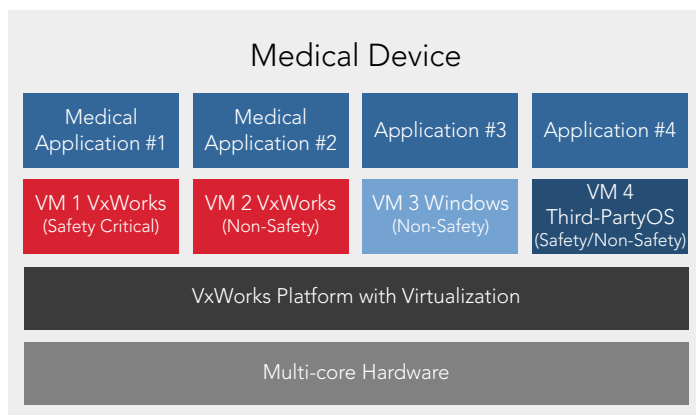
With every problem comes opportunity. More sophisticated device manufacturers can see the new guidelines as an opportunity to better understand their customers' needs and better enable interaction with their customers over the life of their product. As the use of medical

devices by hospitals and patients continues to grow, new safety concerns emerge that need to 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 VxWorks®, Wind River Linux, and Wind River Titanium Cloud™, that can help medical device companies create reliable software update capabilities in a cost-effective manner.

### VxWorks

VxWorks is found in more than 2 billion devices in medical, industrial, transportation, and defense solutions. 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®, x86, and PowerPC.

VxWorks can also be paired with a Type 1 hypervisor from Wind River that can operate unmodified guest operating systems, allowing greater flexibility, safety, and security as required for today's medical devices. This real-time embedded hypervisor has been used to manage safety and non-safety workloads in devices targeting a broad range of market segments, including medical, industrial, transportation, defense, and many more. Using market-leading virtualization technology, the VxWorks 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.



*Figure 1. Example of a VxWorks platform with virtualization running medical applications in virtual machine partitions*

Using the VxWorks hypervisor, medical device architects can use industry-leading virtualization technology to segregate different software applications into independent virtual machines (VMs) running VxWorks in separate partitioned processor cores as necessary, in order to more easily maintain, patch, or replace current software with new safety or security updates. Each VM can be securely partitioned and protected from any interference or conflicts from other partitions. Further, the system can be configured to enable or disable the ability to dynamically create new VMs as additional applications are required by the user. Updating and testing applications can occur without affecting other application workloads. Safety-critical applications can run in a single VxWorks VM that can be updated independently from other VMs, as well as run in multiple mirrored VMs. Using the VxWorks hypervisor to manage VMs in the secure partitions, safety and security applications and other functions can be more easily managed and updated.

### 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 security functions in a medical device, Wind River Linux, with its KVM hypervisor capability, can run non-safe applications in various VMs running Wind River Linux, VxWorks, or another guest OS. The 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 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.

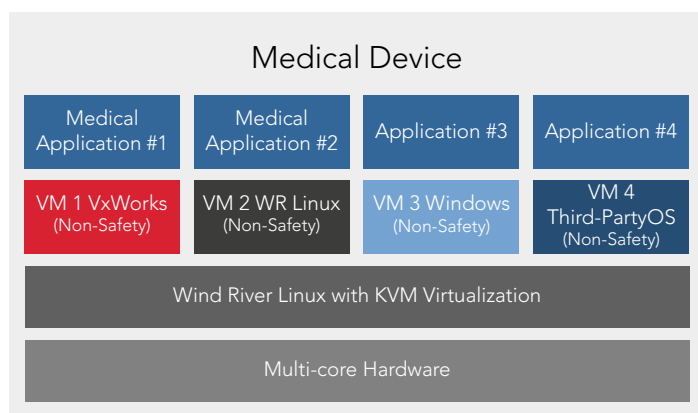


Figure 2. Example of a Linux platform with virtualization running medical applications in virtual machine partitions

## 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, the VxWorks hypervisor, Wind River Linux, or the Titanium Cloud product family, visit [www.windriver.com](http://www.windriver.com) or contact [salesinquiry@windriver.com](mailto:salesinquiry@windriver.com).

