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JUST WHAT THE DOCTOR ORDERED: A SOLUTION FOR SMARTER THERAPEUTIC DEVICES

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EXECUTIVE SUMMARY

There's little question that advances in therapeutic technologies have been responsible for saving or prolonging countless lives. Yet any time a patient's health or very life is at stake, there is no level of risk that can be considered acceptable. Many categories of therapeutic devices are prone to high rates of malfunction and recall. Between 2005 and 2010, a reported 4,343 medical devices were recalled in the United States by more than 800 companies across a wide range of therapy categories. Indeed, reports of injuries and deaths resulting from failures of infusion pumps prompted the Food and Drug Administration (FDA) to launch an "Infusion Pump Improvement Initiative" in 2010 to more tightly regulate manufacturers.

Intel and Wind River® have teamed up to explore a solution. The result is a concept reference design that combines Intel processing innovation with Wind River expertise in embedded technologies, tailored specifically to the needs of therapeutic device original equipment manufacturers (OEMs) and software developers. It will enable them to streamline the design and development process and accelerate time-to-market with more reliable and secure products. This paper outlines the challenges that developers and manufacturers face and how the Intel-Wind River therapeutic device concept helps address them.

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GETTING SMARTER

Recent years have seen a marked trend in the therapeutics industry toward "smart" devices. Advanced infusion pumps, for example, are expected to perform a myriad of tasks. Beyond administering medications, they are expected to accurately calculate dosages, maintain drug libraries, record dosing histories, feed data to central databases, display intelligible information, detect clinician programming errors, and sound alerts if medicine runs out. On top of that, they must be easy to learn and operate, with intuitive interfaces to reduce the risk of human error.

With increased intelligence, however, comes increased complexity, which in turn increases the risk of something going wrong. According to data from the Institute of Medicine, 35% of reported hospital errors involve medication administration, and half of those are pump related. Among the most common issues with pumps are software defects and inadequate, non-intuitive interfaces that confuse operators.

This has subjected device manufacturers to increased scrutiny from the FDA and other regulatory bodies. The FDA's Infusion Pump Improvement Initiative, launched in the wake of a reported 56,000 adverse events between 2005 and 2009, imposes strict guidelines on manufacturers for failure analysis, validation and verification testing, and design and engineering approval. Manufacturers must address these issues at the design stage.

TECHNICAL CHALLENGES

Meeting regulatory safety standards is just one of the issues facing manufacturers. The following are among the many challenges in designing reliable and effective devices:

- **Power consumption:** Manufacturers are looking for ways to build devices that use electrical energy efficiently and require less to run. This is especially critical for devices that need to run on battery power for extended periods of time.
- **Interoperability:** Increasingly, devices are required to integrate and exchange data with other devices or monitoring systems in centrally managed networks. Interoperability, not just basic connectivity, is necessary to ensure optimal outcomes. This means devices must be adaptable to the interoperable standards at play in the hospital or home to enable optimal workflows.
- **Security:** Once devices are networked wirelessly or hardwired, they are vulnerable to hacking and tampering, putting patients' lives at risk. Designers and developers need to figure out ways to prevent intrusions into a device's software, or at least mitigate the impact if an intrusion occurs.
- **Availability:** Importantly, devices must be designed so they can continue to perform their core mission—for example, administering prescribed medication doses—in the event of denial of service attacks or other network issues.
- **Manageability:** Devices must be able to be easily monitored for performance from remote locations, with the ability to diagnose issues without a physical inspection. Critical safety patches need to be installed with the least disruption in operations.
- **Ease of use:** The medical industry has recognized that ease of use is top of mind for customers. Clinicians are not programmers. End users expect and will ultimately require that device interfaces be as intuitive and easy to use as the smartphones or tablet computers they have become accustomed to using every day. Therapeutic devices are increasingly required to meet usability requirements that have typically been limited to non-medical devices.
- **Time-to-market:** Manufacturers need to streamline not only the development process but also the testing, certification, and approval process to accelerate time-to-market without compromising performance and reliability.

Clearly, there is room for improvement in the safety, security, manageability, and performance of therapeutic devices. And as devices become increasingly networked—communicating data wirelessly to each other and to central workstations—hacking and tampering become a greater concern. It's time to look at some new approaches and innovative technologies that can provide developers and manufacturers a safe and secure foundation on which to build the next generation of therapeutic devices.

A NEW APPROACH

Given the advances in technology that have made multi-core architectures prevalent at all levels of the computing and pricing continuum, there is an opportunity to rethink the way hardware and software are deployed within any device. Today's therapeutic devices must perform multiple tasks with multiple applications. To enhance the security of the device and assure continuous availability, it is essential to separate safety-critical applications, such as dosage calculations or flow control, from non-safety-critical applications. Historically, designers have had to compromise and draw a line during the design cycle between what was in the separate motor control mandated by the FDA for safety and what would be on the main computer user-interface engine. Multi-core technology now allows many more options for the designer to develop levels of safety within the design.

Because of limited device performance in past years, manufacturers have often had to build their own proprietary device drivers to accommodate limited performance and address security and safety concerns. This, too, prolongs development and adds to the cost, particularly if support must last 10 to 15 years. Today, however, standard off-the-shelf software is available that can not only streamline the process but actually improve the performance of the end product.

To help developers and manufacturers overcome the limitations of prevailing practices, Wind River and Intel have developed a concept reference design to illustrate what is possible with today's more advanced technologies. The concept combines Intel's high-performance multi-core processing technology with Wind River virtualization software, enabling multiple operating systems and applications to run on a single, scalable hardware device. Virtualization allows critical and non-critical applications to run independently in separate hardware partitions, controlled by an embedded hypervisor. Further, the design leverages the COM Express™ form factor to allow scalability across different types of devices, and from Intel® Atom™ to Intel® Core™ processors. This type of scalability is important to device manufacturers that want options to scale the platform across different devices that they develop in a cost-effective manner. Utilizing COM Express allows the computing complex to be changed easily to accommodate different market segments and performance needs, while the hardware specific to the application can be designed to accommodate different strategies in the marketplace.

The multi-core, hypervisor approach yields enormous potential benefits for developers and manufacturers. It allows developers to create systems with small footprints, eliminating a large measure of complexity while improving both operating and energy efficiency. It also enables components to be added or removed as needed, affording the flexibility to modify devices without the need for a total redesign and rebuild. The design is effectively "future-proof," mitigating against obsolescence with the ability to continually add functionality and upgrade existing designs as new processors are introduced. Developers can also test and develop software on new-generation processors without investing in a whole new board design, further accelerating time-to-market.

Secure partitioning also makes the device less vulnerable to external threats and tampering. Each application could be designed to run on a different operating system protected by its own partition, rather than relying on a single operating system for all the applications. If a malware breach occurs in any part of the system, its effect on other parts of the system can be limited. This essentially provides performance security for the modality.

INTEL AND WIND RIVER

The therapeutic device solution leverages the combined expertise of two companies with long-standing track records of innovation: Intel, providing industry-leading semiconductor technology, and Wind River, the standard-setter in embedded software technology. Wind River applies expertise developed through a proven track record of success in industries in which security and safety are paramount—aerospace, automotive, mass transportation, and critical infrastructure, to name a few.

The total solution, moreover, is more than an elegant integration of hardware and software. The Intel-Wind River team is actively working with therapeutic device manufacturers to optimize their designs. Wind River has been designing software used in safety-critical and secure applications in a variety of industries for many years. Wind River also provides a wealth of support services, ranging from board design to validation and verification testing to complete device design.

CONCLUSION

There is no magic bullet to ensure complete security and safety in every therapeutic device implementation. Many decisions the manufacturer makes will affect overall device performance. And end-user training and judgment, combined with clinical policies and practices, are still major factors in patient security and safety.

What manufacturers can do is deliver smarter, more efficient, higher-performance devices with more intuitive interfaces that enable users to take full advantage of their advanced functionality. The Intel-Wind River reference design for embedded systems in therapeutic devices is intended to make it easier for manufacturers to achieve these goals and bring more effective products to market more quickly. That is where the industry is headed, and manufacturers who embrace new underlying technologies and new thinking will lead the way.

WIND RIVER

Wind River is a world leader in embedded and mobile software. Wind River has been pioneering computing inside embedded devices since 1981, and its technology is found in more than 1 billion products. Wind River is headquartered in Alameda, California, with offices in more than 20 countries. To learn more, visit Wind River at www.windriver.com.