



OLYMPUS ACCELERATES TIME-TO-MARKET WITH WIND RIVER PLATFORM FOR MEDICAL DEVICES

High-Frequency Generator Hits Market Ahead of Schedule, on Budget

Company Profile Olympus

Industry

- Medical devices

Solutions

- Wind River Platform for Medical Devices
- Wind River Professional Services and Wind River Education Services

Results

- Launched FDA-approved product ahead of schedule
- Completed project on-budget
- Delivered a strong, differentiated product

OLYMPUS

Your Vision, Our Future

"Wind River helped us develop customized documentation in accordance to IEC 62304 and FDA guidance. We passed the software audit easily and in a timely manner—and launched the FDA-approved product to the market ahead of schedule."

— Lutz Kersten, Department Manager,
R&D Surgical Therapy Software,
Olympus

Olympus Surgical is the technology leader in the field of minimally invasive surgery. This subsidiary company of Olympus Europa Holding GmbH conducts research and develops medical instruments, partnering with leading doctors and scientists in various specialties.

THE CHALLENGE

When Olympus embarked upon developing the ESG-400, a high-frequency surgical generator, it faced several challenges. The company needed to be first to market while aggressively managing costs to stay on budget. The Olympus design team wanted to stay focused on core competencies, as opposed to spending time developing software that could be offered by a vendor. Finally, the team wanted to mitigate risk: In a highly competitive medical device landscape, IEC 62304 and U.S. Food and Drug Administration (FDA) documentation are required to demonstrate that products are completely safe. In a surgical environment where errors can be life threatening, there is no room for delays or mistakes.

To address these challenges, Olympus required a mature, proven, and comprehensive solution used in safety-critical systems. It also needed support for development in a regulated environment, education services and training, and competitive pricing.

THE SOLUTION

"Wind River® Platform for Medical Devices offered a combination of software components that fulfilled all of our requirements, including hardware support, board support package (BSP), operating system, middleware, and networking while ensuring robust real-time performance," says Lutz Kersten, department manager of R&D surgical therapy software at Olympus Surgical. "Wind River delivered a total solution that included not just software but also strong customer support, education, and professional services organizations to ensure the successful market launch of an FDA-approved product."

Olympus began working with Wind River on the project-planning phase in 2008. The ESG-400 is a more technically demanding device than its predecessor and requires the use of a large number of standard interfaces. Some of the interfaces included video to the display, video graphics array (VGA), graphic library, sound, MP3 files, Ethernet, and USB.

“If we had built our own OS, we would have had to develop all the standard interfaces in-house,” Kersten says. “We’re more successful when we focus our time developing strong, differentiated applications. With Wind River, we gained a partner who could provide a complete solution and services customized to best meet our needs—so we could stay focused on our core competencies.”

Wind River Professional Services developed full BSP support for Olympus’ target platform established on the PowerPC-based MPC5200 from Freescale. Wind River has a strong partnership with Freescale and experienced staff. Moreover, Wind River Professional Services provided Olympus with customized hardware support for VxWorks, including a touch-screen driver and USB host support.

“Wind River offers a mature and proven OS that’s highly customizable, scalable, reliable, and often specified in safety critical systems,” Kersten says. “Safety is a priority for our products, and Wind River has strong customer references in the aerospace and defense industry where safety is paramount. The company has a full understanding of how to successfully deliver products to safety critical environments.”

RESULTS

Wind River Professional Services helped Olympus achieve regulatory compliance by providing validation of the customized real-time operating system (RTOS).

“Wind River helped us develop customized documentation in accordance to IEC 62304 and FDA guidance,” Kersten says. “We passed the software audit easily and in a timely manner—and launched the FDA-approved product to the market ahead of schedule.”

Wind River education, support, and professional services contributed to the success of the project. Wind River Education Services offered on- and off-site classes tailored to the company’s needs. Fundamentals and basic-training classes helped Olympus developers get up to speed quickly.

“During our collaboration, Wind River always kept to the proposed schedule and budget,” Kersten says. “The Wind River team is well-trained, friendly, and highly motivated—with a focus on the right specialists getting things running for the customer. Customer support is always provided in a timely manner.”

SUMMARY AND FUTURE PLANS

Olympus used Wind River solutions to reduce development cycle time and costs while designing the ESG-400. The company continued its heritage of meeting first-to-market goals, minimizing risk, and delivering a high-quality, compliant product.

“Thanks to Wind River we can deliver a higher-quality product to the customer,” Kersten says. “The Wind River solution enables us to enhance product features and increase our productivity. We’ve been able to accomplish all this while staying on budget.” Olympus highly recommends Wind River as a strong partner and technology leader.

Moving forward, Olympus will continue working with Wind River to develop upgrades of existing software and new projects for different application uses. During these projects, the company will collaborate, plan, and align roadmaps with Wind River.

WIND RIVER