beacon EmbeddedWorks

CASE STUDY

Helping to bring lifesaving technology to market faster.

Summary

A defibrillator saves lives when seconds count. Because of this, the demand is on the rise for portable defibrillators in schools and businesses. In response, healthcare companies continue to research and develop (R&D) defibrillators that are easier-to-use, lighter weight for ease of transport, provide faster battery recharge time, and can be used on adults, children, or infants. This customer came to Beacon EmbeddedWorks to create a next generation defibrillator while accelerating time to market.

Challenge

A major global healthcare company sought to designing a new defibrillator that is faster, lighter, and more intuitive than previous models. The device was to be used by both basic life support (BLS) and advanced life support (ALS) personnel.

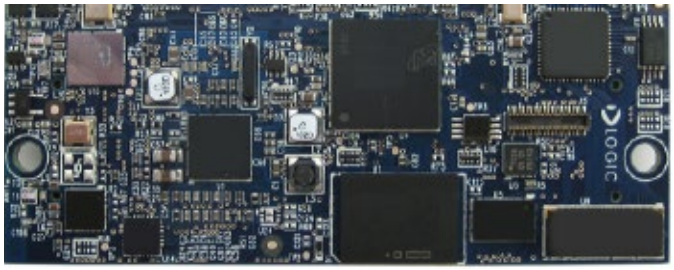
As a Class III medical device used in life-critical applications, this new system would be subject to the most stringent design methodology. Every step of the development process would be carefully controlled, reviewed, and documented. Even with a team of 100+ employees and ideal circumstances, this new system would require up to four years to complete. Additional unanticipated problems could add additional months or years to that timeframe. This healthcare company wanted to accelerate the development process to deliver its new system to market in less than four years.

Solution

To meet this aggressive timeframe, the company needed more expertise in the areas of electrical and software engineering. The development team had already selected one of Beacon EmbeddedWorks' System on Modules (SOM) to speed up the development process so the customer decided to also employ our product lifecycle management services to solve resource and technical expertise constraints.

The Beacon EmbeddedWorks OMAP3530 SOM-LV was chosen because a medical device like this one can have a 10- to 15-year lifespan, unlike many other SOM driven devices. Our SOM used in the device was engineered with customer-selected options that included:

- ARM reduced instruction set architecture
- Ethernet
- USB power management
- I2C bus for connection of the audio codec, analog digital converter, realtime clock and secure ID chip
- Controllers for the LCD display and touchscreen



The OMAP3530 SOM provided additional benefits during the FDA approval process. Our client found peace of mind because we could be trusted to manage continuation-engineering throughout the product lifecycle using ISO 13485-compliant processes. If a component on the SOM becomes obsolete, our team identifies, designs-in, and tests a replacement component.

Another advantage of selecting our SOM was the head start it enabled with software testing. Developing software can be the most time-consuming part of development and debugging requires that the software be run on the same hardware that will be used in the finished product. If that hardware is developed from scratch, software developers often have to wait until the hardware is completed before they can begin testing the software. Using the Beacon EmbeddedWorks SOM, however, the company was able to gain access to SOMs early in the development process. With early access to SOMs they could be quickly inserted onto evaluation boards to start testing the software, even while the hardware was still in the development process.

Our software engineering team was trusted to get the SOM up and running on a medicalspecific operating system from Green Hills Software. Based on successful completion of that work, the healthcare company asked our team to assist in additional work on the application software.

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Solution Continued

Over the lifecycle of the product, our engineers played several critical roles, including:

- Designing and helping to build the baseboards for the SOM.
- Designing verification for both hardware and software components.
- Developing a Field Programmable Gate Array (FPGA) chip that directs internal data flow to a variety of software components, including drivers and enhancements for the Green Hills Integrity RTOS (Real Time Operating System), a custom bootloader, the printer subsystem controller and driver software, and the system software upgrade manager for tracking system software revisions and coordinating software upgrades.
- Participating in Failure Mode and Effects Analysis (FMEA) and risk mitigation efforts.
- Helping to implement Agile software development methodologies to accelerate the project timeline.
- Participating in development of the system's therapy software, and in development and test of the system's incident recorder.
- Providing ongoing software engineering services as needed, including optimization and performance tuning of the system software, ongoing support of system enhancements and quality assurance testing.

Testimonial

"Across high tech industries, a lot of development efforts—maybe even the majority—seem to go over budget and past deadline. We had challenges along the way, but we made our goals, on time and within budget. Getting a whole team working together the way we did is a huge accomplishment.

There were some pretty aggressive milestones along the way, and when it took extra effort to achieve them, our people and Beacon EmbeddedWorks' stepped right up. What differentiates an effective partner isn't whether you have problems; it's how they deal with them, and the people we dealt with at Beacon EmbeddedWorks were always open, always had solutions, and were never adversarial. We would certainly consider Beacon EmbeddedWorks again for work on other products we have in the pipeline."

- Head System Architect,
Customer Development Team

Results

With our team's assistance the system was delivered to market months ahead of the original timeframe.

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