

SUSTAINING ENGINEERING breathes new life into IVD system

Since 1995, this leading provider of screening, diagnostic and monitoring systems has relied upon RTEmd as its software outsourcing partner to maintain and enhance the software in its installed base of patient fluid analyzers.

RTEmd's sustaining engineering team is responsible for a number of this customer's different chemistry systems, supporting more than 6,000 units installed in laboratories around the world. This includes embedded software for precision metering, sample distribution and incubation; software for data acquisition and results calculation; and interfaces including a touch screen user interface, lab automation interface, and LIS interface.

OBSOLESCENCE TO OPPORTUNITY

When the customer's standard chemistry system approached its end of life, the customer turned to RTEmd's sustaining engineering team for help.

"We wanted to not just eliminate the obsolescence issue, but turn it into an opportunity," said the manufacturer's Director of Product Support R&D. **"With RTEmd's experience in IVD technology, they understood immediately what we were trying to do.** They helped us identify changes, including speeding throughput and upgrading the user interface, that would enable us to launch a new product from the existing platform."

This new product would come at a much lower cost than a full-blown new product development effort.

Part of the challenge was to deliver best overall throughput for the most popular chemistry panels. The RTEmd team presented a number of potential solutions and the associated design trade-offs.

After getting the customer's agreement on the solution approach, RTEmd began developing the software requirements specification. This included modeling the solution: simulating the movement of the panels through the machine to estimate the throughput that could be achieved and to demonstrate basic feasibility of the project. The functional requirements specification was approved by a cross-functional customer team on the first pass.

"RTEmd is exceptional at defining the high level requirements—both manufacturing and marketing requirements—and then flowing those down to system-level and functional requirements," said the Director of Product Support R&D. "Getting the requirements right is key to a successful project."



QUICK READ

Customer

A leading provider of screening, diagnostic and monitoring systems.

Challenge

Increase throughput of its diagnostic chemistry system in response to user requests for faster time-to-first-result.

Solution

Engage RTEmd to explore and recommend solutions—and then to define, implement and test the new software to achieve them.

Results

- ▶ throughput boost of **10% to 25%**
- ▶ time-to-first-result improvement of **up to 12%**
- ▶ integration of a **new user interface** with flat panel display

These enhancements allowed the customer to launch the improved system as a newer, more advanced model.

Customer Benefits

- ▶ Enhanced customer loyalty through responsiveness to users' needs
- ▶ Generated new revenue from the installed base through sales of upgrade kits
- ▶ Enabled higher revenue from new system sales with the more advanced model
- ▶ Completed project on time and on budget by outsourcing sustaining engineering of the software to RTEmd

Next, RTEmd created a design detailing the software changes to be made. The design included updates to existing software as well as creation of new modules to support hardware changes: for example, the addition of a flat panel touch screen. The team also drafted a unit test procedure that would be used to verify the changes.

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RTEmd developed the software based on the design and executed the unit test procedure to verify that the software functioned according to the requirements. The results were documented for the design history file, and the project was then turned over to a combined RTEmd and customer team for verification and validation. RTEmd provided technical support during the V&V testing.

FDA-COMPLIANT LIFE CYCLE

RTEmd completed the entire project, from feasibility through validation support, in 12 months. Development and verification conformed to an FDA-compliant life cycle, drawing from RTEmd's extensive experience with medical device software development and testing.

RTEmd demonstrated its hallmark flexibility by working within the customer's established quality system and other processes.

"Many software outsourcing partners use their own software development process, which means their work would have to be translated to fit our product delivery system," said the Director of Product Support R&D. "RTEmd eliminates this redundancy by working within our processes; for example they can write a report and it goes right into our system. **Their flexibility really speeds the process.**"

RESULTS: NEW REVENUE, LOW DEVELOPMENT COST

The software enhancements and new flat panel display allowed the customer to release the improved system as a new, more advanced model. Their studies indicate that the new system has 10% to 25% higher throughput and up to 12% faster time-to-first-result than the original system.

The manufacturer has generated new revenue from its installed base through sales of upgrade kits with flat panel displays, and realized higher revenue from new system sales with the more advanced model. The company also demonstrated responsiveness to its customers and sustained customer loyalty.

"FLAWLESS EXECUTION"

"RTEmd understood our end game and our goals, and executed flawlessly—from requirements definition through system verification and validation," said the Director of Product Support R&D. "A successful product launch like this takes a whole company, and we couldn't have done it without RTEmd as a key part of the team."

Throughout the process, RTEmd emphasized its core values: excellent project management, constant communication and dedication to meeting commitments.

"You can count on RTEmd to do what they say they are going to do," said the Director of Product Support R&D. "When there are issues, as there will be with any project, they bring them up and solve them. This honesty, together with the fact that they understand our goals and our technology, makes for **a very successful software outsourcing relationship—one that has truly become a long-term partnership.**"

How can RTEmd sustaining engineering help you?

You can generate more revenue from existing products, at a fraction of the cost of full-scale new product development. The possibilities include adding remote diagnostics, updating a user interface, supporting updated peripherals, increasing throughput or performance, and much more. With our knowledge of medical devices and the software that drives them, RTEmd's sustaining engineering team can help you evaluate your current products and identify system modifications to generate new revenue, fast—while at the same time strengthening customer satisfaction and loyalty.

Contact us today to explore the possibilities:
email solutions@RTEmd.com
or call 585.383.1290 x130.

ABOUT RTEmd

RTEmd provides outsourced software development and testing for complex medical equipment. We develop and maintain software in IVD, therapeutics, microbiology, nephrology and diagnostic imaging. We offer **New Product Development** delivering high-quality, FDA-compliant software for your new medical devices; **Sustaining Engineering** to maintain and enhance your existing software and extend the value of your installed products; and **Verification and Validation** to speed FDA approvals, leveraging our expertise in FDA compliance and testing. Our 27 years of experience with major device manufacturers, ISO9001:2000 certified quality system, commitment to disciplined project management and client-focused flexibility power our promise: we will never compromise your time-to-market.

RTEmd
160 Office Park Way
Pittsford, NY 14534
phone 585.383.1290

solutions@RTEmd.com
www.RTEmd.com

RTEmd
medical device software services