

# New Scalable Software Platform for High-Performance Medical Infusion Pumps

Enea Global Services completes a system-wide software redesign and a comprehensive test and validation framework to deliver faster and smarter pain management devices.

## Enea Software Expertise for the Healthcare Industry

Our team of experts excels at understanding technical challenges and solving complex problems.

We help our customers accelerate their R&D cycles and bring innovative products to the market.

### Linux & RTOS Development and Porting

- ▶ Drivers & BSP
- ▶ Kernel
- ▶ Applications
- ▶ GUI / UI / UX

### Bare Metal Development

- ▶ Applications

### Testing and Validation

- ▶ Automated Testing Framework Development
- ▶ Test Script Development
- ▶ Functional, Performance, Unit and System Testing & Validation

### Medical Certification and Standards

- ▶ FDA 510(k), IEC 62304

## The Customer

A global pharmaceutical and medical device company based in the USA, this customer specializes in injectable pharmaceuticals, infusion therapy and medication management solutions. There is a strong focus on the integration of technologies at the point of care to improve patient's safety, clinical outcomes, cost management, as well as caregiver efficiency and effectiveness management.

## The Challenge

Constant focus on product innovation and ongoing efforts to meet high clinical safety standards are critical for the customer to stay at the edge of the highly competitive pain management devices market.

To increase the performance of its medical infusion pumps, the customer needed a new scalable hardware and software infrastructure capable of managing and monitoring the pumps in a faster and easier way. The new infrastructure would enable the pumps to deliver more and richer features, thus reducing medication errors, improving quality of care and streamlining clinical workflows.

At the central management system level, the challenge was to improve the management and automation of processes that were previously performed manually. At the level of the pumps, the challenge was to completely redesign and implement a new firmware platform based on a real-time operating system (RTOS), thus enabling the pumps to offer a new range of complex features: syringe pre-filling with medication centrally identified using the patient's barcode, medication administration and management, auto-programming and auto-documentation to help improve safety and clinical workflow efficiency.



## The Solution

Enea completed a system-wide software redesign, going from a bare-metal to an RTOS solution, both in the infusion pumps and in the hospital servers that managed and controlled the connected pumps. This was accompanied by a comprehensive automated test and validation framework to ensure the correct functioning of the pumps at all times.

Powered by a global team of 100+ software engineers, this large-scale project successfully met both the customer's internal technical requirements and the medical industry's safety standards. It consisted of the following:

- **New software architecture design and development**  
to enable a complete new set of pump features and to comply to stringent healthcare standards:
  - Automated second-line delivery improving ease-of-use and efficiency
  - Single channel (2 concurrent medications)
  - Hard and soft dosing limits
  - Ability to enhance medication management practices and drive patient safety through advancement of Continuous Quality Improvement (CQI)
- **Built-in scalability**
  - Connects hospital information systems for optimal medication management
  - Integrates hospital-defined customized drug library (20,000+ drug entries)
- **Comprehensive testing and validation process**  
This included the design and development of:
  - A flexible automated test framework for further customization and 3rd party system integration
  - Software and hardware test harness
  - Language-agnostic testing scripts
  - A fully functional emulated hardware environment
  - Use case testing: Visual scenarios (UML diagrams) and testing engine for use case validation
  - FDA tests and validation

## The Benefits

Throughout the project, the customer benefited from Enea's in-depth expertise in embedded software development and real-time operating systems (RTOS), and proven experience in managing complex projects with multiple technical requirements and large international engineering teams.

Enea demonstrated a great understanding of the healthcare sector, provided valuable new insights on complex technical issues inherent to highly regulated fields, and successfully achieved all necessary regulatory requirements: FDA 510(k) for the USA and IEC 62304 for the USA and the EU.

In addition, the comprehensive and customizable testing framework delivered by Enea's testing experts added great value to the project: they developed use case testing procedures that were further incorporated into the customer's standard practice and implemented into several other projects. The customer also appreciated the technical skills of Enea's specialists, as well as their ability to facilitate knowledge transfer through the training of all the teams involved in the project.

Thanks to the new scalable software platform developed by Enea Global Services, the customer was able to double the performance of its pumps, add new features and make them three times faster to operate, significantly strengthening its infusion system business.



## Enea Global Services

Enea's professional service offering is based on flexible engagement and delivery models for all phases of a software life cycle, from feasibility and specification, to development, testing, integration, deployment, maintenance, support and training. Services range from on-site experts, to complete outsourcing of R&D activities.

Find out more on the  
Enea website!



Enea develops the software foundation for the connected society with a special emphasis on reducing cost and complexity at the network edge. We supply open-source based NFVI software platforms, embedded DPI software, Linux and Real-Time Operating Systems, video traffic management, cloud data management and professional services. Solution vendors, Systems Integrators, and Service Providers use Enea to create new networking products and services faster, better and at a lower cost. More than 3 billion people around the globe already rely on Enea technologies in their daily lives. For more information: [www.enea.com](http://www.enea.com)