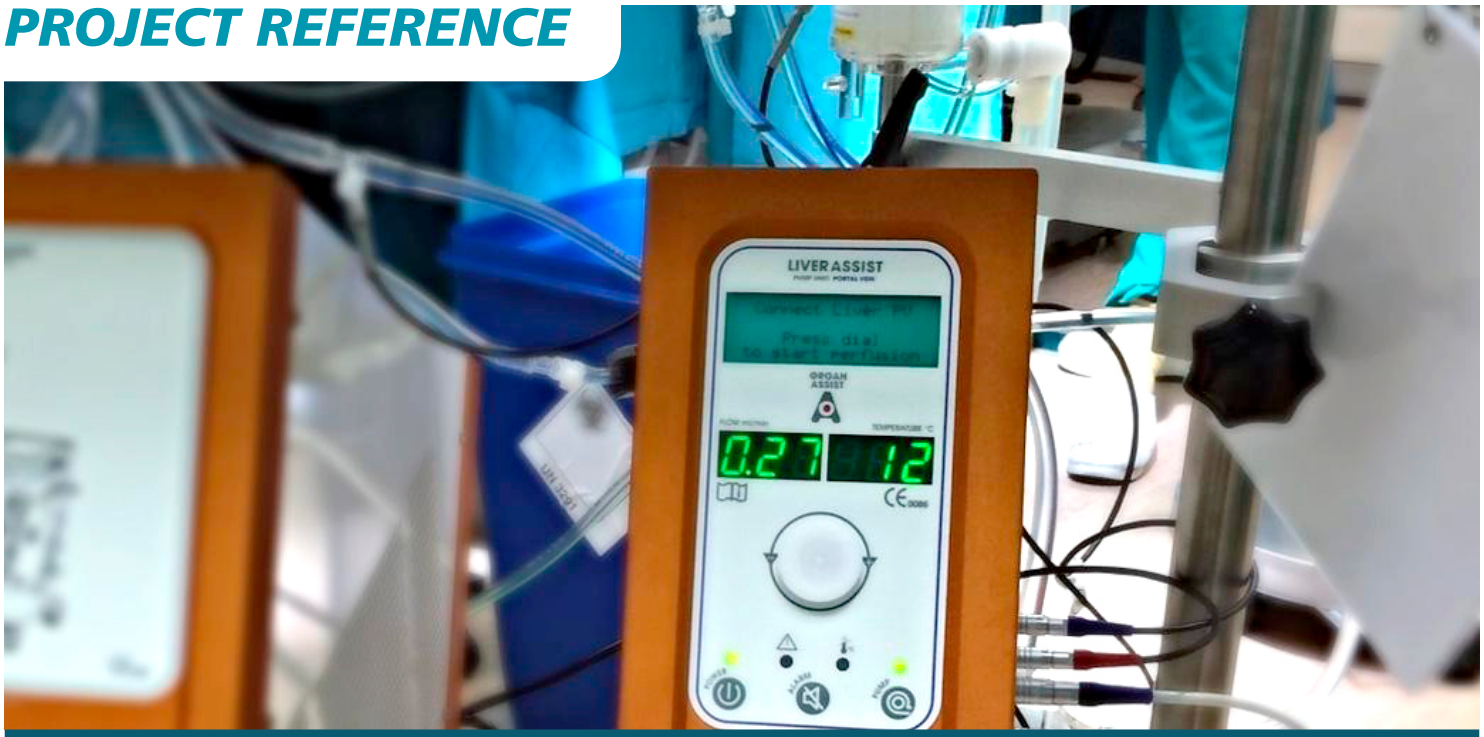
PROJECT REFERENCE



Liver Assist Organ Perfusion System

Second generation firmware

The Liver Assist is Organ Assists dedicated device for ex vivo perfusion of donor livers. Two different pump units provide a pulsatile perfusion of the hepatic artery and a continuous flow to the portal vein. The oxygenated perfusion is pressure controlled. Temperature can be set from hypothermic to normothermic conditions thanks to an integrated heater/cooler. The project focused on delivering ISO 13485/ IEC 62304 compliant embedded software including all deliverables required to be part of CE certification.

Improve software quality

The first generation software, developed by a self-employed software engineer, was created on product bases. Due to the growth in product lines and continuous tightening of regulations, the support on these products could not be guaranteed and behavior became inconsistent. That is why the project involved a redesign of the existing Liver Assist solution focused on improving quality, including a future prove architectural concept for all perfusion products and complying to the applicable standards.

Customer

Organ Assist is a knowledge-based company. It has its origins in the University Medical Centre Groningen (UMCG) in the Netherlands. The company was founded in 2005 by two medical scientists (Prof.dr. G. Rakhorst and dr.ir. A. van der Plaats) who, after six years of dedicated academic research, had developed and refined a liver perfusion pump. Organ Assist combines preservation research with the actual development and optimisation of best-in-class life-saving devices in this specialized discipline. The company has grown to around 15 employees and extended its product lines to: Liver Assist, Lung Assist, Kidney Assist Transport (cold perfusion), Kidney Assist (warm perfusion), Donor Assist. For more information, visit their website: www.organ-assist.nl

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Role ICT Healthcare within the project

ICT Healthcare was responsible for making the second generation embedded software that would meet all the software deliverables required to comply to the applicable CE certification. This implies the full scope of redefining, redesigning, testing and releasing the software as well as delivering the required supporting documentation according to the ISO 13485/IEC 62304 standard. Working with this standard implies (additional) focus on product risk management and the relation between requirements and documented verification of the product (test management and review of the deliverables). With respect to product risk management, ICT Healthcare performed periodic FMEA sessions focused on the software delivery and transformed the findings into a supplement for the overall product Hazardous Analysis Report.

In the Liver Assist project, the first steps to consistency for all perfusion systems had to be taken into account. For that reason, a senior architect analysed and prepared an architecture that applies to current and future products. During the Liver Assist project, the software was divided into logical layers. This is the baseline for a modular approach for all future perfusion products.

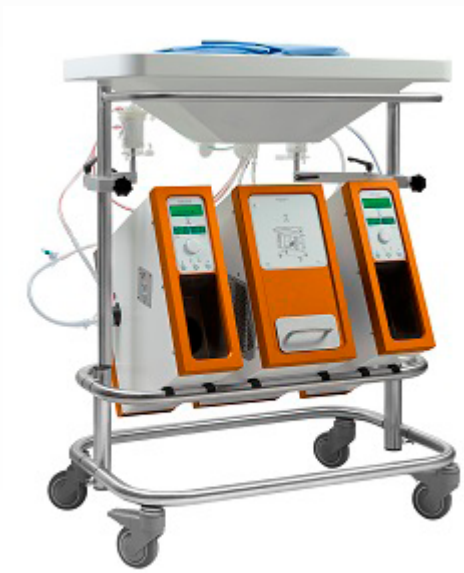
The Liver Assist project was a strategic project intended to get familiarized, align processes and start the cooperation between both parties. After a positive evaluation, ICT Healthcare took over the support and maintenance, including QA/RA activities for the existing and future products.

Keywords
ATMEL ATmega 128, ISO 13485:2003/2016, IEC 62304:2015, Kanban, JIRA, SVN (with external access by customer), FMEA (on software deliverable), DHF (software focus), Requirements, Verification, Traceability Matrix, Product Risk Management, Medical Software, Embedded Software.

PROJECT RESULT

The Liver Assist project is delivered according specifications, on time and within budget. The first clinical trials performed with the second generation software and the Liver Assist product behaved as expected.

Internal audits performed by an certified external auditor at ICT, proved that the Liver Assist project complies to ISO 13485/IEC 62304 standard. By that means, it fulfils the software needs for applicable CE certification. According to the customer, the delivered quality meets their expectations and needs. Due to this positive project result of Liver Assist, ICT Healthcare was granted the overall upgrade to second generation software and maintenance of all perfusion systems from Organ Assist, including QA/RA activities to comply to the requested standards.



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