

Innovative Acceleration:

Streamlining Medical Product Development with Renesas Synergy Software

Accelerated development process from prototype to certified product



For the development of a special medical product, the software developers of ICT Group have used the Renesas Synergy Software Package (SSP) development platform. With this, they have reduced the time-to-market by a factor of 5 and the safety of the product fully meets the extremely high standards of IEC 62304 and ISO 13485. In this white paper you can read about the importance of the Renesas SSP platform for software development and the opportunities it offers for healthcare product development in the future.

Universal basic product development

The start of the development process was an incomplete prototype that did not yet meet the standards of IEC 62304. ICT Group, in collaboration with a hardware supplier, has turned this into a working product that meets all the requirements of IEC 62304 for medical software development and ISO 13485 for Quality Management System. At the same time, ICT Group (itself ISO 13485 certified) has laid a solid foundation for the development of other medical products, because this innovation with Renesas SSP offers a 'proven' architecture for universal applications in the medical world and beyond.

Highest requirements 62304 and 13485

In the development of medical products, the safety requirements and the supporting test programs and documentation are exceptionally high, laid down in IEC 62304 and ISO 13485. When developing a completely new product, the development time can therefore quickly increase to 5 years. Especially in the case of the product that ICT Group has worked on in which software, electronics and mechanics (mechatronics) have not been combined in this way before. The Renesas SSP platform reduced development time, development costs and time-to-market. Moreover, Renesas uses an interesting cost model, which makes the development of lower numbers of products financially very attractive.

Pre-certified platform

The added value of Renesas lies in the fact that the platform is fully tested and documented and can therefore be used directly in the development process as pre-certified software. The SSP platform itself no longer requires testing, it has been shown to work and complete documentation is available. This is of great importance for medical devices and medical software. In the first place because the development process of embedded software and embedded components is much faster (up to a factor of 5). Secondly, because in the test phase many possible causes of disruptions can be ruled out.

Ultrasound product innovation

The medical device in question activates a specific contrast agent with microbubbles for ultrasound examination. It is possible to record a much sharper ultrasound image during an ultrasound examination in a hospital by releasing microbubbles into the organ to be examined, for example a kidney or a liver. With the device, a medically inert liquid with an inert gas is supplied with micro-bubbles in a cartridge. The doctor inserts this 'activated' fluid into the bloodstream to get the microbubbles into the organ in question. The bubbles ensure that the echo signal comes back amplified through resonance, so that you get much more contrast and therefore a much sharper image. In the future, this technique will also make it possible to introduce medicines into a body and activate them in exactly the right place with ultrasound.





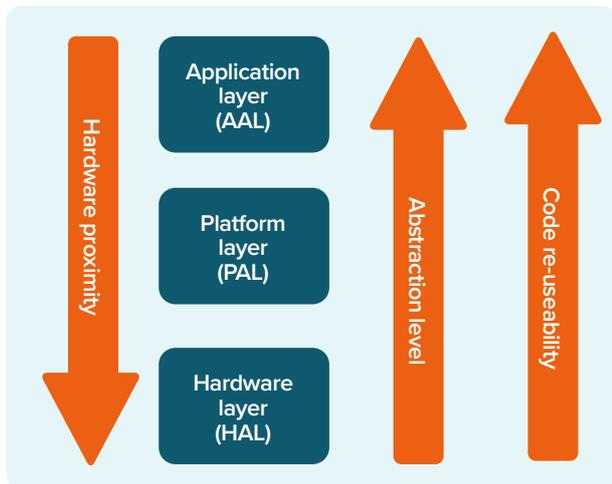
Development process

The development process for this product is not substantially different from other innovative (medical) products. The client provides the user requirements and relevant medical information. The hardware supplier translates these into the physical product characteristics and ICT Group into the software requirements for the application layer, whereby all parties involved work together in an integrated way and the number of hardware iterations is limited. A lean & mean solution that follows the usual process of design, implementation, unit testing, integration testing, system testing, documentation and delivery. Risk management plays an important role throughout the entire process. It is the client himself who applies to a certification body for a certificate as a legal manufacturer, whereby the suppliers provide all underlying documentation and test reports.

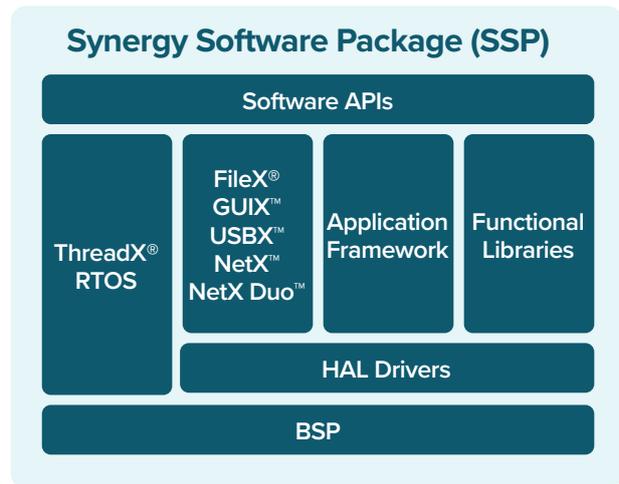
3-layer system

We use the 3-layer system in software development for a medical product that consists of mechanical parts, electronics and embedded software for the control of the process. This is a proven model to be able to develop a new product in a targeted and efficient manner.

In this approach, the team of software developers of the ICT Group developed the HAL using Renesas tooling. This has two advantages: a much shorter development time and the software part generated by Renesas is already pre-certified. In addition, the software team developed the PAL and AAL entirely in-house.



3-layer model for embedded software development.



The Renesas SSP Platform

Explanation of the 3-layer model

The bottom layer, the Hardware Abstraction Layer (HAL), provides the low-level communication abstraction between the parent software layer PAL and the hardware layer to connect the different systems, such as actuators, sensors, displays. By implementing user-friendly interfaces, the programmer can unlock the linked hardware more easily.

The middle layer, the Platform Abstraction Layer (PAL), realizes an interface for the AAL application layer so that it no longer needs specific hardware knowledge to use a device, such as a sensor.

The top layer, the Application Abstraction Layer (AAL), provides developers with an even higher level of abstraction. This provides more programming convenience and they can reuse code better, resulting in a shorter development time.

The frameworks developed by Renesas provide abstraction of different system level services and technology-specific services, enabling rich functionality with simple APIs. The various frameworks are integrated with ThreadX® RTOS features to manage resource conflicts and synchronization between multiple user threads.

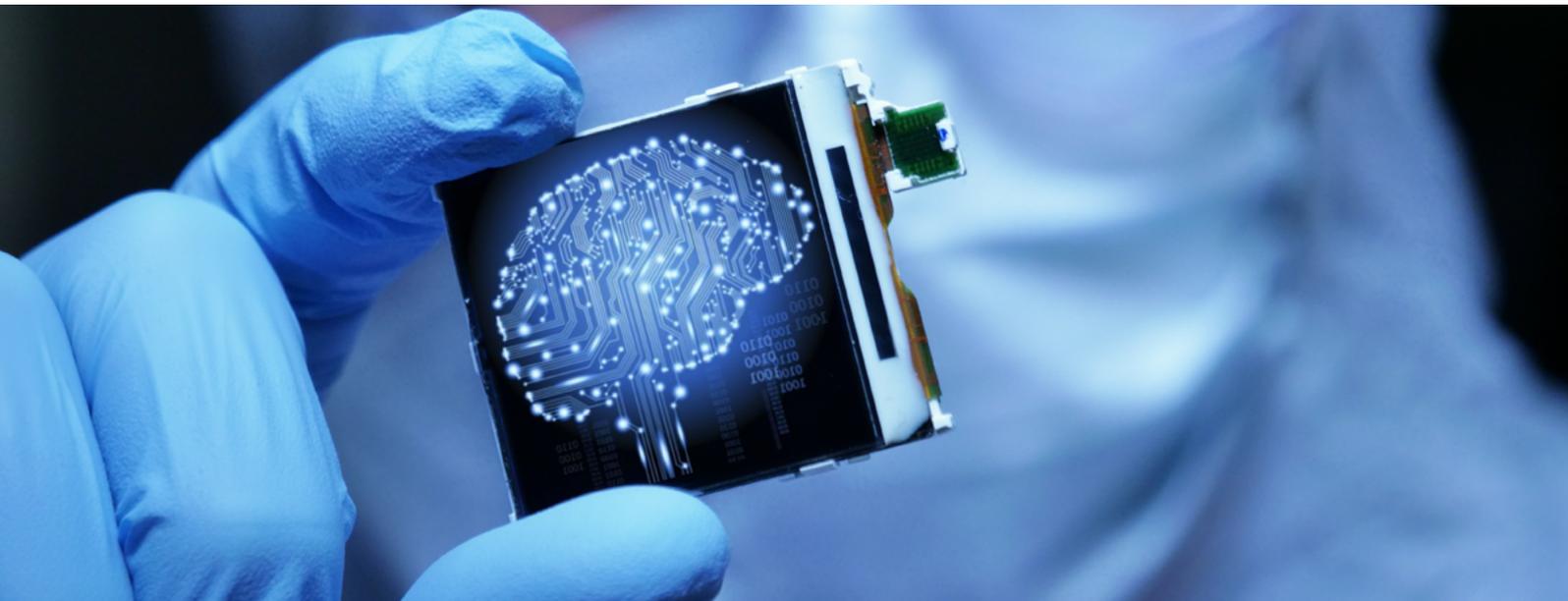
Extra feature Renesas

Messaging, a swift messaging system between parts of the software, delivers Renesas out of the box with the SSP platform. Normally, the implementation of this creates many pitfalls, but Messaging is reliable and works well right away, which also saves development time and costs.

Innovations with Renesas SSP

Not only in the medical world, but also in that of the automotive industry, high standards for product development apply and certification plays an essential role. The development process with Renesas SSP offers very interesting advantages for this, especially when mechanics,

electronics and software have to form an integrated unit. The basic template that ICT Group has developed makes it possible to develop innovative products for various industries with a short development time and clear costs. Based on the customer demand and the in-depth domain knowledge of ICT Group, it is possible to get an indication of the feasibility and preconditions at an early stage of product development. In a brainstorming session, our architects can outline the frameworks of a project, with Renesas SSP forming the basis and ICT Group being able to further specify the application and platform layer. This gives you a practical and experience-based product concept.



Learn More

If you would like to know more about (medical) device development and how, for example, the Renesas platform could be applied in the realization of your product, please contact ICT Group for more information.

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