

SECTOR Medical Device
STANDARD IEC 62304

Case Study

FastFocus

FastFocus



Wireless Patient Monitoring System

ABOUT THE COMPANY

FastFocus began as an internal research team of Agis Automatisering. The company has been developing high-tech sensor technology for various markets since 1984 and has been an independent company since 2013, developing innovative e-health solutions for the healthcare market.

FastFocus strives to develop practical monitoring solutions for healthcare that work more efficiently, sustainably and successfully.

The company is headquartered in Harmelen in the Netherlands.

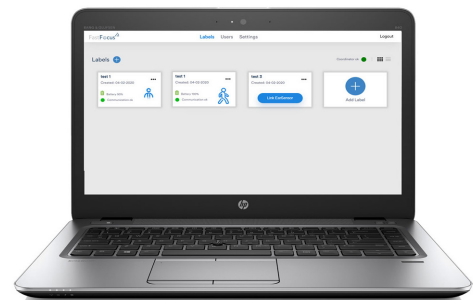
www.fastfocus.nl

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Background

FastFocus is a medical device manufacturer who are part of a group that has previously developed sensors for dairy milk production. Their most recent product is the FastFocus Wireless Patient Monitoring System. Their EarSensor™ medical device allows patients to be monitored in hospitals and home care settings remotely with a device worn on the patient's ear. This was classified under the international medical device software standard IEC 62304 as a Class 2 device.

The EarSensor™ software was implemented in C11, compiled with MinGW GCC under the IAR Embedded Workbench 8.0 IDE to run on the MKW24D512 NXP ARM Cortex M4 processor.



EarSensor™ (left) and example of the Patient Monitoring System (right)

Tool Selection

To comply with the requirements of the IEC 62304 standard for an embedded software unit test framework, FastFocus created a stringent set of tool requirements. They wanted a trustworthy vendor who could provide active technical support, and a tool with an established medical device pedigree. The tool had to provide advanced technical capabilities for: automatic test case generation, control of function calls (e.g. mocking/stubbing), intuitive code coverage and certification evidence ready results reporting. A more process-oriented objective was to 'shift-left' their software verification activities.

After some initial market research, FastFocus evaluated Cantata against CppUTest (an open-source tool) and another commercial framework (C/C++ Test from Parasoft). Less than two months later Cantata was selected and purchased. In summarising the reasons for choosing Cantata, Leon Solinger, lead developer for the EarSensor project said, **“Cantata was easier to setup than the other tools and was more feature complete.”** Intercepting function calls was a crucial feature for FastFocus, as Leon added **“no other tool seemed to have the wrapping feature.”**

IEC 62304:2006 Certified

Getting Started

After the initial setup and thanks to built-in tutorials, Leon was fully productive with Cantata within only 2 weeks.

The software was originally written for cross-compilation and one of the first challenges was to replicate the compiler defines from IAR Embedded Workbench to the Eclipse Cantata test projects. This was overcome quickly with the help of QA System's technical support team, enabling Fast Focus to simulate their code running on their target hardware. Leon commented **"QA Systems were friendly, and we appreciated their approach and commitment. The support we received was timely and they helped us a great deal."**

Working with Cantata

FastFocus adopted a risk-based waterfall approach to software verification, but with an emphasis on shift-left testing. All components connected to risks were unit tested with Cantata. Much of the EarSensor™ application was SOUP microcontroller libraries, so only the application code function call interfaces needed verification - hence the requirement for mocking provided by Cantata wrapping.

To ensure tests were created to the required standard, the team followed the tool Safety Manual guidance for tests including using the in-built Cantata code coverage ruleset for IEC 62304 Class 2 to ensure 100% decision coverage was achieved. Leon was impressed by the coverage diagnostics in Cantata, commenting **"I liked that I could see how much code was covered using the coverage viewer and also how it was visually represented."**

Data at global, file static and local function static scopes were verified using Cantata white-box testability instrumentation to check both correct changes (positive testing) and the absence of unintended changes (negative testing). Static functions within source files were verified using the same white-box approach directly called from test scripts. Leon summarised the teams' experience with test creation in Cantata as **"I found the GUI, the tree view and the table view very helpful for assessing test case values. Editing test cases in the UI saves on a lot of typing."**

Conclusions

With the testing completed and the results submitted to the IEC 62304 safety body, the EarSensor™ product is being brought to market. Unit testing with Cantata and ongoing test maintenance are now firmly embedded in the development process and FastFocus plan to use it on other projects in future. Operations Manager Ron van Oudenallen recognised a positive return on investment and summed up reporting **"we had a very positive experience using Cantata."**

CERTIFICATION

Cantata has been certified as usable in development of safety related software up to SW safety Class C, as defined by the **IEC 62304** standard.



For information on tool certification, please visit:
www.qa-systems.com/tools/cantata

MORE ON MEDICAL DEVICE SECTOR:

Our Sector Briefs provide more information on how Cantata was successfully used by relevant customers in various medical projects worldwide.

All Sector Briefs can be found on the QA Systems website.

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All case study text has been approved by the relevant customer.