

SECTOR Medical Device
STANDARD IEC 62304

Case Study



GE Healthcare
(Formerly Datex-Ohmeda)



Patient Monitoring and Anaesthesia

ABOUT THE COMPANY

GE Healthcare provides transformational medical technologies and services that are shaping a new age of patient care.

Our broad expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, drug discovery, biopharmaceutical manufacturing technologies, performance improvement and performance solutions services help our customers to deliver better care to more people around the world at a lower cost.

Headquartered in the United Kingdom, GE Healthcare is a unit of General Electric Company.

www.gehealthcare.com

Requirements: Safety Critical & Flexible

Most of GE's products are classified at the highest level defined by the FDA for software in medical devices. For good reason – in patient monitors, a failure to raise an alarm can harm a patient. For GE, full white-box unit testing was required for about 10% of the software platform, in addition to functional black-box testing of all of the code at sub-system level.

The software was developed in C++ on a Windows NT host, using the Microsoft Visual C++ compiler, and cross-compiled using the Diab Data and CAD-UL C++ compilers. The target system is a Mpc823e PowerPC target running the Nucleus Plus RTOS. Risto Repo, the Software Process Improvement and Verification Officer, said, *"We needed a C++ testing tool that was flexible enough for testing both object-oriented C++ components and whole sub-systems in both host and target environments, and also across different sites."*



Critical Care Monitor in Use

Selection

Repo requested a competitive evaluation of Cantata against another tool on two sites: Helsinki, FI and Louisville, KY. The evaluation resulted in the selection of Cantata. *"Put simply,"* Repo explained, *"Cantata did what it promised for C++."*

Testing was conducted with Microsoft Visual C++ and the Diab Data cross-compilers, despite the latter compiler's limited support for templates (at that time). They purchased Cantata for use in Helsinki, as well as for USA locations Madison, WI and Louisville, KY.

IEC 62304:2006 Certified

Cantata in Action

Cantata was put to use in white-box component testing of the safety-critical code in both host and target environments. These components were first unit-tested on the host (Windows NT), and then the same tests were re-run on the PowerPC target. All tests required 100% coverage of entry-points, statements, and decisions. The non-safety-critical code was subjected to black-box functional tests at sub-systems level, using Cantata coverage analysis. Sub-systems typically contained between 10 and 80 classes.

Engineers at the three sites were soon up and running. ***“Cantata was very easy to get to know,”*** Jutta Luosta, a leading test developer in Helsinki, explained. ***“Development testing of sub-systems was really quite fast with Cantata.”*** The C++ code became more object-oriented with the growth of source code generated by the project’s UML modeling tool. ***Cantata was shown to work well with both manually and automatically generated source code.***

“Cantata did what it promised for C++”

Easy, Flexible, and Well-Supported

Cantata was accepted by developers with ease. ***“For testing with Cantata, it is nice that I can stay in the same environment (Microsoft Visual C++) that we use for programming,”*** explained Erno Muuranto, an engineer. ***“Cantata has a lot of powerful features, but the tester can use as much or as little as you need to get the job done.”***

For many of the developers, the introduction of Cantata has proved to be beneficial in unexpected ways. For example, Cantata testing has had a positive impact on the way code is written, reducing coupling between objects and making isolation testing with stubs easier. Such a full-featured testing tool also needed good support for developers to trust it, and ***Cantata’s fast-responding technical support has proved invaluable.***

Conclusions

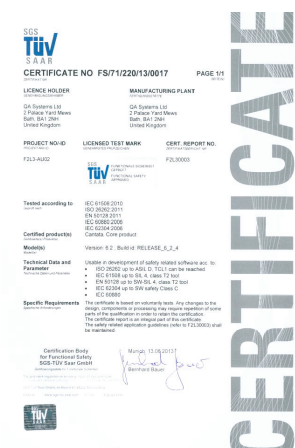
Since the initial phases of the project, Cantata has been successfully extended to further phases such as New Patient Monitor targeting Renesas H8S, and other projects such as the safety-critical Non-Invasive Blood Pressure measurement unit. ***“I expect that use of Cantata will continue to grow at GE Healthcare,”*** Repo concluded. ***“I hope that all new projects will consider using Cantata.”***

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

QA Systems acquired the Cantata business taking over all development, support and sales from IPL in March 2012. Cantata is the extension of the Cantata++ tool.

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/cantata

MORE ON MEDICAL DEVICE SECTOR:

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

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

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