

SECTOR Medical Device
STANDARD IEC 62304

Case Study



Hamilton Medical



Hamilton Intelligent Ventilation

ABOUT THE COMPANY

Hamilton Medical specializes in the design and development of ventilation equipment for patients ranging from neonates to adults.

Innovative Intelligent Ventilation Solutions such as Adaptive Support Ventilation (ASV®), invented by Hamilton Medical, are part of our mission to deliver a unique combination of: Ease of use, Improved patient outcome and Efficiency through innovation.

www.hamilton-medical.com

Background

Hamilton Medical’s latest state-of-the-art ventilator product, Galileo, has proved highly effective with hard-to-ventilate patients. Adaptive Support Ventilation (ASV), invented by Hamilton Medical, guarantees that patients receive set-minute ventilation, by automatically fine-tuning settings to the patient’s needs. Central to Galileo’s success is the integrated software used to control its systems.

The software used to run Galileo needed to be tested to the highest standards. Research and Development Director, Urs Reidt, was assigned the task of identifying suitable tools and, as expected, Cantata was the front runner. He noted, *“We were highly impressed with Cantata’s track record in testing high integrity software in avionics, military applications and, of course, in medicine. It was the natural choice for us.”*

Adaptability

At the start of the project, issues arose that needed to be considered. Hamilton Medical used their own proprietary system that had been specifically built for their applications. *“We were unsure as to whether we could get tool support for this platform as it is a unique environment,”* stated Christian Frehner, the Lead Software Developer of the project. *“An out-of-the-box solution would not be possible. We were therefore very impressed when we were informed that a custom part of Cantata could be provided, specifically for this environment. There existed a very professional approach to meeting our particular needs.”*

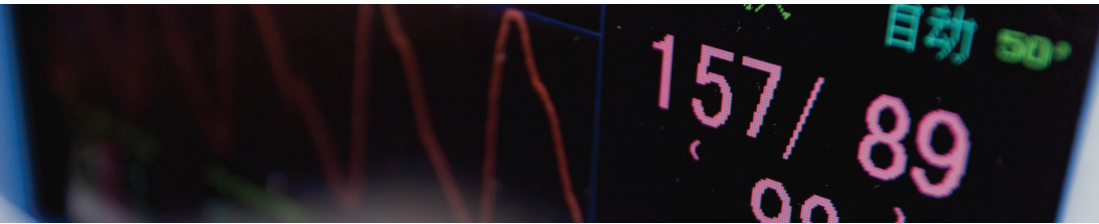
Embedded Unit and Integration Testing

Hamilton Medical’s development on this platform was implemented in the C language, using functional decomposition techniques. Initially, Cantata was used to test the system calls at unit and integration levels. The tool’s **batch-mode facility** was very useful, helping to automate the Galileo tests by using command files.

“Once the first tests had been run, we developed a framework based around Cantata that allowed developers to use templates. Soon, all developers were testing to exactly the same standard. Maintaining each other’s test scripts became much easier as a result of this standardization,” said Rolf Keller, software engineer on Galileo.

Technical support and training were crucial in the early days to help establish this framework effectively. Frehner noted, *“The technical support capability that was provided was fast and efficient. Responses to difficult problems were often received within 1 hour. The fact that support and training was available in German too, was an added bonus for us.”*





**IEC 62304:2006
Certified**

Process Integration

For the new generation of ventilators, Hamilton Medical upgraded their proprietary solution to Wind River’s Tornado/VxWorks environment. *“Again, Cantata’s flexibility and extensive platform support really helped us,”* asserted Gion Durisch, the project leader for the introduction of VxWorks. *“We ported our existing tests, and used Cantata to verify that our software still behaved as expected. In doing so, we found several bugs in third party libraries.”* Hamilton Medical used fault injection methods to deliberately stress-test their functions, and used Risk Analysis techniques to determine which operating system functions should be avoided.

“The technical support capability that was provided was fast and efficient”

Coverage and FDA Guidelines

Hamilton Medical also used Cantata’s coverage analysis facilities. Encouraged by both the FDA Guidelines on Software Development, and their own rigorous internal standards, Hamilton Medical elected to check for 100% decision coverage on all code, using Cantata’s **stubs and wrappers**, to increase coverage and simulate difficult-to-test conditions. *“Using coverage helped us to really think about whether certain functions and blocks were needed,”* stated Keller. *“We optimized our code, eliminated unnecessary code, and re-factored parts of the application to make them more efficient. We confirmed great confidence in our software as everything had been tested to 100% decision coverage.”*

“There existed a very professional approach to meeting our particular needs”

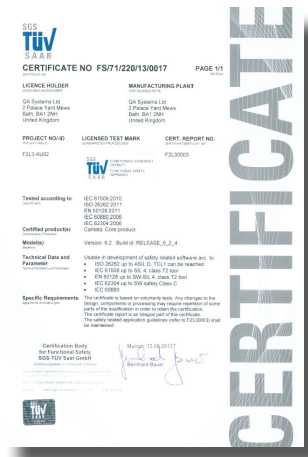
Conclusion

Hamilton Medical is currently using the UML tool, Rhapsody, from I-Logix, into which Cantata has a powerful integration. Rolf Keller concluded, *“We have standardized now on Cantata - it will be used for all new C or C++ developments.”*

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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