

SECTOR Medical Device
STANDARD IEC 62304

Case Study



CROMA Generator

ABOUT THE COMPANY

Creo Medical is a medical device company focused on the development and commercialisation of minimally invasive surgical devices, by bringing advanced energy to endoscopy. The company’s mission is to improve patient outcomes by applying microwave and RF energy to surgical endoscopy. Creo Medical has developed the CROMA Advanced Energy Platform powered by Kamaptive™ full-spectrum adaptive technology to optimise surgical capability and patient outcomes.

Kamaptive™ is a seamless, intuitive integration of multi-modal energy sources, optimised to dynamically adapt to patient tissue during procedures such as resection, dissection, coagulation and ablation of tissue. Kamaptive Technology™ provides clinicians with increased flexibility, precision and controlled surgical solutions.

www.creomedical.com

“Overall the experience has been a positive one”

Project Background

The CROMA Advanced Energy Platform was brought to market for use in the emerging field of gastrointestinal therapeutic endoscopy and enables surgeons to perform less invasive, cost-effective surgery. The device generates microwave and RF waves to the tip of a surgical instrument that cuts tissue and cauterizes wounds during lower intestine surgery. CROMA has been in development since 2013 and was certified for human use in 2019 with FDA and CE approval as a Class IIb device. CROMA is already in use worldwide, with over 100 surgeons in the USA, Italy, UK and South Africa having already completed training on the device. The product is planned to be enhanced to cover bronchoscopy and laparoscopy procedures in the future. The CROMA Generator software was written in C using the Softune Workbench IDE and compiler for running on the MB91F465 Fujitsu microcontroller. The software is classed as IEC 62304 Class C, the highest class of integrity, as it controls energy delivery within the human body.



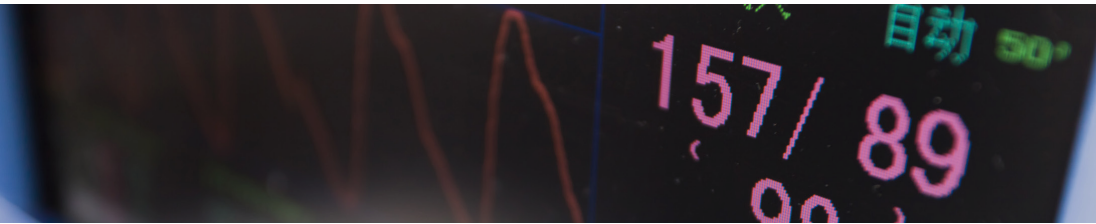
Surgical Instruments

Tool Selection

Creo Medical have been using Cantata successfully since the inception of the CROMA Generator product in 2013. At the time of tool selection, they required an independently certified automated unit testing tool to verify their software under IEC 62304. Tool selection was finalized after an independent tech consultant recommended Cantata over other commercial tools and was successfully deployed for running on their target environment. According to Jim Thomas, Software Development Director at Creo Medical **“certification for use under IEC 62304 was a key factor in the selection of Cantata and we have invested a lot of time building up a unit test suite in the tool”**.

Working with Cantata

Initial unit testing was undertaken by TVS (an offshore testing consultancy) and then handed over to Creo Medical. Recalling the handover, Jim said, **“our engineer took to Cantata really quickly, and acceptance was not an issue”**. He continued by praising the ease of use in the tool **“since then it’s been straightforward to maintain the unit tests and create new ones. We can unit test the CROMA Generator software automatically, and the tool is now an integral part of our development process”**. TVS originally had some queries regarding test target environment configuration, but these were quickly resolved by QA Systems support. Jim commented **“QA Systems support was helpful, and it was provided on time. We couldn’t have asked for more.”**



**IEC 62304:2006
Certified**

Test Maintenance

Due to Creo Medical’s agile software development processes, frequent regression testing and automated execution upon Subversion branch check-in, together with refactoring of tests was important. Jim summarized the process **“test scripts are easy to understand and change, which the team does using the text editor”**. Cantata test scripts can be edited either in the GUI or in the command line allowing for total flexibility and ease of use.

Key Benefits

The accessing of hardware registers throughout the CROMA software presented a challenge for testing software units on host native PCs. This was overcome by memory mapping the registers in Cantata tests to control the unit testing. This allowed unit tests to be developed and run on host machines, and then re-executed on the target.

Code coverage was required to achieve compliance with IEC 62304. It is recommended that for Class C devices, 100% Modified Condition / Decision Coverage (MC/DC) is achieved. Jim explained that as they wanted to achieve the highest level of code coverage, **“being able to check for 100% MC/DC integrated with tests was important for us.”** They also wanted to test the software units in isolation adding **“being able to easily simulate and control calls to external functions using the Cantata stub feature for that was also important”**. A final key benefit for them was **“for every software release Cantata provides evidence of unit testing which can be easily reviewed by regulators at any time.”**

Conclusion and Future Plans

Reflecting back on the experience with Cantata, Jim said, **“overall the experience has been a positive one, and we are now looking forward to using the latest Cantata features when we redevelop the next generation of the CROMA Generator.”** When asked which new features of Cantata they were most looking forward to, Jim replied, **“Custom Code Insertion, so we can modify loop variables to reduce test output and speed up testing.”** Another anticipated new capability is **“function scope static variable access which looks interesting, so we can write testable code correctly rather than with file scope static data.”** Finally, they expect to use the new **“certified HTML test report as a record of testing”**. In future, Creo Medical plan to use the latest version of Cantata to produce two new devices, one a major improvement on the existing hardware and the second an entirely new device that will be more flexible and modular.

Jim summarised their overall experience with Cantata as **“the ability to easily test software units in isolation, measure code coverage, maintain and extend our unit tests as our software has developed was important. Even though these were standard features of Cantata, they were impressive.”**

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 Medical Device Sector Brief provides more information on how Cantata was successfully used by relevant customers in various 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.