Testing, Testing, 1, 2, 3...

Verifying Safety-Critical Medical Equipment

01 THE CHALLENGE

Verification and validation are universal challenges for medical device manufacturers. Yet some are unable to carry out these activities to the extent needed to ensure product certification, especially when these include software.

A global leader in medical technology was developing a product supporting surgical staples, incorporating features such as real-time control over the stapling of different types of human tissue. The software element required specialist and independent certification which couldn't be addressed by internal V&V competencies. As a result, the company approached Critical Software to fill in the gap.

02 THE SOLUTION

In preparation for testing, Critical defined a verification strategy in compliance with EU and FDA regulations, which governs software safety classification in medical devices.

An automated testing environment was created for the code, ensuring the surgical stapler could operate in all circumstances. Using VectorCast, a user-friendly software testing tool which was specified for use by the client, we were able to ensure maximum traceability and coverage when implementing the software validation test procedures (SVTP).

Following this, the procedures were delivered to the client. These not only described the test procedures developed but also outlined how each procedure contributed to the traceability of requirements.

Lastly, test reports were produced as further evidence towards certification.

03 THE RESULTS

The test specification and procedures established by Critical meant a number of defects in the software coding for the surgical stapling product could be identified early in the process, reducing the total cost of product development. This involved introducing new algorithms and updating existing ones within the manufacturer's code, and ultimately producing code documentation to prove certification in line with EU and FDA standards.

Coupled with highly flexible and rapid testing procedures, Critical's support enabled full certification of the product within a short timeframe, opening up the possibility of a quicker time-to-market for the manufacturer.

04 THE TECHNOLOGY

- VectorCast
- Test automation
- Test specifications and reports
- Certification based on compliance with EU and FDA regulations

Critical software



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ABOUT CRITICAL SOFTWARE

Critical Software provides systems and software services for safety, mission and business-critical applications. We work closely with our clients, helping them to meet the most demanding standards for performance and reliability.

We were founded in 1998, with NASA our very first client. Today, we work across many international industries and have offices across the globe.

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We are CMMI Maturity Level 5 rated.
For a list of our certifications & standards visit our website.