Verification & Validation for Neonatal Ventilator Software

01 THE CHALLENGE

In the world of medical devices, ensuring equipment works as it should is vital.

A well-known manufacturer of neonatal ventilators was developing new equipment which meant complex software had to be developed that also required certification as a class C device according to IEC 62304, an EU standard defining the lifecycle requirements for medical device software.

As usual in certification processes, the manufacturer needed an independent assessment of the software to ensure its security and suitability for use with newborns.

02 THE SOLUTION

Critical Software provided a detailed and complete analysis of all the V&V processes in order to support the complex software certification activity required for the ventilator.

This process and all the necessary evidences were developed in compliance with IEC 62304 governing software lifecycle requirements in the EU. The set of activities described in this standard established a common framework for the medical device software lifecycle processes used in this project.

The team of engineers assigned to the project created a test environment which ensured compliance with the standards for the defined software class (in this case, class C). This test environment was key to enabling test automation and automatic regression testing.

Development of all test specifications and procedures, including the execution of test cases along with a critical analysis of the test results, were key to ensuring the manufacturer's requirements were achieved.

03 THE RESULTS

With a dynamic team, we were able to offer complete V&V support capable of accommodating late requirements and error corrections.

The team provided an independent assessment of all control functions of the critical system alongside generating all the evidences required for risk mitigation.

Our efforts meant the relevant software used by the neonatal ventilator was fully certified and is now used in several hospitals and clinics worldwide.

04 THE ACTIVITIES

- Verification & validation
- Documentation for IEC 62304 standard compliance
- Automated test environment
- Risk mitigation



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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.