

# FIRMWARE TESTING FOR A CLASS-C MEDICAL DEVICE

using VectorCAST



**Services:** IoT Product Testing

## OVERVIEW

Europe based leading technology manufacturer operating in the optics and optoelectronics industries with presence in 50+ countries and 30k+ manpower. They offer innovative solutions for industrial metrology, medical technology solutions for diagnostics and treatment in microsurgery, and microscopy solutions for the life sciences.

## CHALLENGES



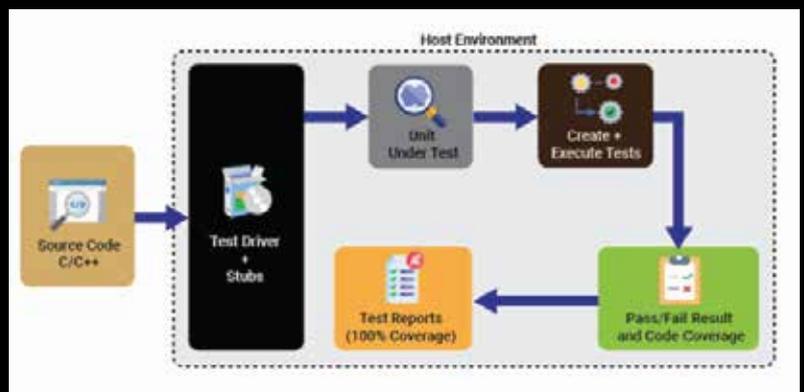
The client wanted to introduce FDA approved, class-C, microscopic medical device used for microsurgeries for healthcare domain. In order to get it approved from FDA and bring the medical device into the market, the client had to test the device using VectorCAST tool and submit the reports for the approval. For the same, the client was looking for a Quality Engineering partner with experience in the healthcare domain that would work as their extended team to test their healthcare device firmware and generate reports that shall help them achieve FDA approval.

## SOLUTION

VectorCAST test reports being a mandate for class-C medical device when submitted for FDA approval, we worked as the client's extended QE team to test their medical device firmware using VectorCAST and generated reports. We performed Whitebox testing and unit testing, involving device code coverage. The team achieved 90% plus code coverage ensuring quality and stability of the device firmware.

### 1 Quality Engineering

- › Developed unit test cases following the “correctness and completeness” approach, correctness referring to functional testing and verifying software design of the unit and completeness referring to code coverage goals of the program
- › Understand the C/C++ source code and perform White box testing
- › Environment set-up in vectorCAST using tool chain
- › Design verification for each function
  - Inputs
  - Expected outputs
  - Success and error paths
- › Detected logic errors and identified defects introduced by changes in code
- › Code coverage analysis/management/verification
- › Create compound test cases for control flow verification
- › Added user code to define custom function Input/Output
- › Created a regression script for repeatable use (three files format .bat, .env, .tst that will help to rebuild testing environment)
- › Executed following unit test type:
  - Parameter range check, includes global variable as inputs
  - Compound only
  - Expected return value
  - Coverage only
  - Combination tests
- › Performed unit testing with different code coverage type:
  - Statement
  - Branch
  - MC/DC
- › Test case generation
  - Manual
  - Automated (min/mid/max, basis path, mc/dc, partition)
- › Test case report generation (full report, matrix report, test case management report, aggregate coverage report)



## BENEFITS

- Reduced compliance failure risk by testing the Source Code (C/C++) via FDA approved tool – VectorCAST
- Improved code accuracy to 90% plus with efficient testing approach

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