VECTOR

Medical Device Testing

Whitepaper | Vx.x 2018-04

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1 Introduction

This case study provides details about a recently completed services engagement for a global manufacturer of medical devices and supplies. Our customer engaged Vector Services (VS) to perform the Software Unit Testing for one of its devices. The device contains software that monitors human actions such as button pushes and dial rotations, and controls the operation of the motors that control rotation and articulation.

2 Customer Challenge

This case study provides details about a recently completed services engagement for a global manufacturer of medical devices and supplies. Our customer engaged VS to perform the Software Unit Testing for one of its devices. The device contains software that monitors human actions such as button pushes and dial rotations, and controls the operation of the motors that control rotation and articulation.

The FDA requires formal software testing to ensure that medical device operation conforms to its requirements – this includes unit, integration, and system testing that is traceable to established requirements, as well as code coverage analysis to prove testing completeness.

The customer did not have the sufficient internal resources to perform the required testing within schedule. To help the customer meet its schedule, VS provided a turnkey test solution that met the FDA test requirements and customer schedule.

2.1 Application Metrics and Test Environment

The application is comprised of 26,000 lines of “C” code that runs on an ARM processor. The software was tested using VectorCAST in two configurations. Initial test development used the IAR ARM-Cortex Simulator. Once testing was completed, all tests were then run on a development board with download provided by an IAR J-Link PLUS JTAG debug probe.

The table below captures the environment details:

Item	Detail
Files	73
SLOC	26,000
VCAST Test Env 1 Simulator	VectorCAST 6.3b [IAR ARM - Cortex Sim (c)] IAR ARM Compiler 6.7 available with IAR Workbench 6.5
VCAST HW Test Env 2	VectorCAST 6.3b - Target HW
Target Hardware Power Pack Electronics	Custom ARM-Cortex M4 board / HW Prototype Board

3 Project Details

3.1 Software Testing Goals

- Prove application correctness at the unit level
- Achieve 100% Statement and Branch Coverage on all files
- Achieve 100% MC/DC Coverage on a subset of 36 files
- Provide completely automated regression testing on hardware

3.2 Project Overview

Based on the fact that the software was still in development, the project was split into three phases, with each phase mapping to a software release.

- Phase I initial test development, software release 1, test execution using the IAR Simulator
- Phase II, new test development for software release 2, test execution on prototype hardware
- Phase III, new test development for software release 3, test execution on prototype hardware

3.3 Defect Identification and Tracking

Vector Services submitted 124 defects, using Jira to capture, track and report defects/issues. As the customer fixed the issues, updates were rolled into the next phase for re-test.

3.4 Weekly Status Reports

Vector Services provided weekly status reports to the customer every Monday morning. On Tuesday mornings VS and the customer would have a call to cover the status report that was submitted and discuss any other topics, issue/concerns and activities to be performed for the current week.

3.5 Deliverables

Final deliverables consisted of the VectorCAST unit test scripts to allow for automated regression testing at the customer's facility, along with test reports, Jira bug reports, and code coverage metrics.

3.6 Mentoring and Training

One of the goals of each VS engagement is to mentor our customers to self-sufficiency. In this case VS not only delivered a complete set of tests, but also provided on-site VectorCAST training for the customer's engineers to ensure that they are able to easily maintain the tests as the application code continues to evolve.

4 Project Results

Phase I was completed in five weeks – one week ahead of schedule. Phases II and III were completed in a highly compressed schedule of two weeks each.

End result: 26,000 lines of code completely tested on target hardware in nine weeks.

This level of productivity far surpassed what the customer could have accomplished with internal resources. VS was able to meet this aggressive schedule because the VectorCAST tools provide high levels of automation, and our staff is well experienced with working under demanding deadlines.

The use of VS resources allowed the customer's developers to focus on building the application code, which provides a competitive advantage for the customer.

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