



T&VS provides Medical Device Software Testing Services for Cardiopulmonary Rehabilitation Market

About the Client

T&VS's client is a leader in the cardiopulmonary rehabilitation market in North America. The client provides a range of solutions for the cardiac rehab and diagnosis. Test and Verification Solutions LLC was selected to provide comprehensive software testing of the client's next generation product.

Background

The client's next generation product is capable of simultaneously monitoring, recording and storing cardiopulmonary data of multiple patients undergoing a rehabilitation program. The product has been established as a safety class B software and is currently in an advanced stage of development. The client has set a goal of completing the product V&V within a timeframe of four to five months. The successful and timely release of this product would mark an important milestone in this client's future roadmap. The software has multiple modules interacting under complex rules, receiving live patient health data from sensing hardware, making the scope of testing both complex and extensive.

The T&VS Technical Solution

During the test planning stage, T&VS engineers consulted with a cross-functional team consisting of product development engineers, clinical specialists, marketing and services personnel of the client. T&VS engineers performed an initial assessment of the software architecture and design, followed by an in-depth analysis of the design and functional requirement specifications. With an overall understanding, T&VS engineers created the test strategy document that defined the test environment, phases of testing, specified criteria for 'entrance into' and 'exit from' the different phases of testing, and the effort required to implement the test plan. It was identified that the testing effort must progress in parallel with the system development, to meet the business goals of the client.

Following the creation of test strategy, T&VS engineers performed exploratory testing, extensive dry runs, mapped the system functionalities with existing requirements, and analysed the shortfalls in the existing requirements based on features and functionalities. The thorough approach helped the client in improving the overall system requirements specification. By performing several iterations of the above approach along with corner case testing, T&VS engineers discovered a significant number of bugs, unmapped features and system instability issues that are currently being fixed by the product development team.

With the product still under development, feature change requests from Clinical, Services & Marketing teams has led to code changes, impacting the existing system functionalities and resulting in deviations from the test plan. To mitigate this, T&VS engineers have adopted the method of continuous test development and perform periodic iterations in the test designs.

At the start of each test case development, T&VS engineers created detailed test outlines and scenarios based on the initial top-level test plan. This led to a much shorter test design time. Due to the high number of manual tests, T&VS engineers and the developers created a reliable test data set and test environment which optimized the testing effort.

Additional deliverables from T&VS include a traceability matrix that maps test cases to requirements and creating Risk Management Files. T&VS is directly contributing to product development by engaging with diverse technical teams and creating documentation that will become part of the product design history file (DHF).

The Result

In conclusion, the comprehensive reviews at the initial phase and continuous test development strategy, helped the customer identify unmapped features and explore corner case scenarios. As a result, T&VS engineers enabled the creation of a robust requirement specification, efficiently managed the change requests, and identified bugs at the early stages of system development. Also, the test case development was meticulously planned and documented, which helped in significant reduction of test design time.

Additional Information

For additional information please visit: www.testandverification.com