



Defibrillator Testing - case study

Lasertec provide complete backend test equipment for production of a class 3 medical device

Summary

Lasertec was engaged by a leading Medical device Component Manufacturer to design and build semi automatic test stations for inline sub assembly and final assembly. The lasertec engineering team engaged with the Customer, external Designer and Build Shop to develop the user requirement specification (URS), the functional design specification (FDS) and the trace analysis that integrated with the shop floor data collection system (SFDC). Lasertec also provided guidance on the initial PCB panel design layout with design for manufacture (DFM) in mind to optimise the test capability for a real world sub assembly production test environment.

Background

An International Medical Device company put out to tender the functional testing of a new product. Lasertec was selected to develop the entire backend test suite of test equipment to be installed.



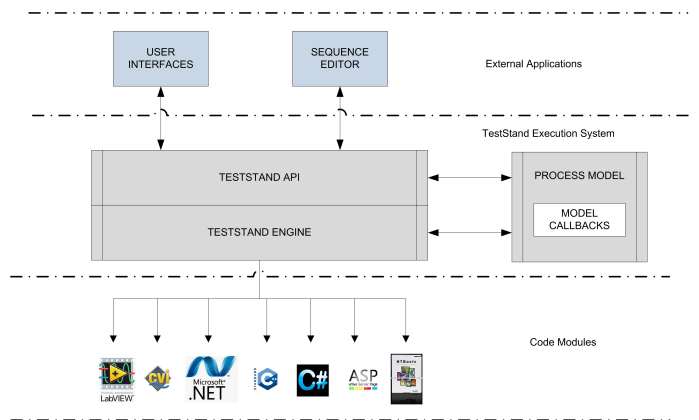
The project was completed within the agreed timeframe of three months. Lasertec used GAMP® 5 to manage the in-house electromechanical design, software development, the manufacture and validation of the test equipment. Implementing the lifecycle approach to software and hardware validation regulations and guidance ensured Lasertec were quickly able to determine the applicable regulations, define requirements including intended use, manage risk, develop a validation plan and execute to the customers satisfaction. By utilising National Instruments TestStand API as the communication interface and TestStand Engine to control the software and test sequencer, this allowed lasertec to generate a process model to define the flow of execution of the TestStand system which gave the ability to generate optimised sequencing of functional test code very quickly. Various code modules were used for writing each of the test scripts (Labview, .Net, C/C+, LabWindows, CVI).

Approach

The system design was based on a pedestal test based platform incorporating a dual bed of nails fixture, integrated test and control hardware and software designed for operation as a standalone or integrated tester within the manufacturing production process. This

system design allows the test operator to load one UUT whilst the second UUT is undergoing test, thereby increasing the overall productivity and efficiency of the test process.

The test system was designed for accurate, repeatable and safe testing of each UUT utilising the best in class hardware and software design principles. The test controller managed all aspects of the system i.e. test sequencing, monitoring, safety controls, interactive GUI and reporting. A scanner was utilised to read the UUT serial number to track each UUT to integrate with the SFDC system and reporting purposes. HVI (Intelligent High Voltage) design was also implemented to ensure the safe discharge of high voltage stored in capacitors if the sequence of tests need to be aborted for any reason. Solenoid interlocks were also implemented to prevent the operator from accessing or removing the UUT from the fixture when the test was in progress. All test devices built were CE compliant.



Results for Total Test Cycle Time of UUT

- no greater than 3.5 minutes