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Infra-Red Thermometer Testing - case study

Lasertec provide complete backend test equipment for mass production of a Class 2 medical device

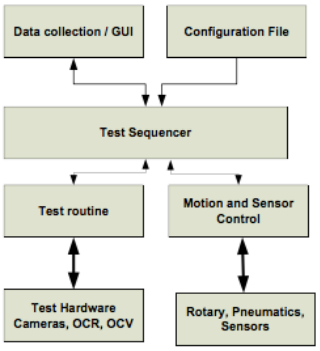
Summary

Lasertec was engaged by a leading medical device component manufacturer to design and build semi automatic test stations for inline sub assembly, final assembly and battery test. The lasertec engineering team engaged with the customer,design and build shops to develop the user requirement specification (URS) the functional design specification (FDS) as well as 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. Lasertec also provided input to the enclosure design of the final product which allows for easy access to vital test points that can provide power and connectivity to enable functional tests to be performed while the internal battery is removed.

Background

An International Medical Device company put out the 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. By implementing the life cycle approach to software and hardware validation regulations and guidance 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 and LabVIEW, Lasertec found themselves in a position to generate optimised sequencing of functional test code very quickly.



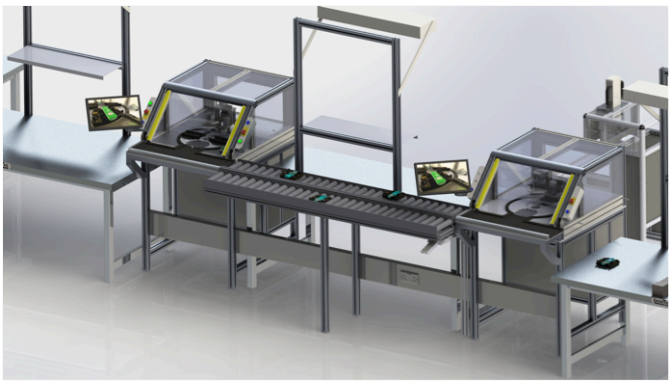
Overview of Test System

Approach

The Sub-assembly and the Final Assembly Functional Testers along with the AAAA Battery Test system (all with CE Marking) are integrated system-Workstations linked by conveyor into the production line as a validated test system.

Both Sub-assembly and Final Assembly Testers consists of a pedestal style test platform incorporating a rotary Indexing table with a Z-Axis probe plate assembly. When the DUT is in the test position. The Z-axis is lowered and probes engaged to apply power and initiate the test sequences. High resolution cameras utilising OCR technology are employed to carry certain optical inspections and a scanner utilised to read the DUT serial number.

Located at the rear of the Final Assembly Tester is the AAAA Battery Test system, which allows one battery to be tested and presented to the operator every two seconds. This consists of a Pedestal style test platform incorporating a battery load hopper, rotary indexing unit with an output conveyor for “good batteries “ and “fails bin" for all failed batteries.



Results for Total Test Cycle Time of DUT

Sub assembly - no greater than 12 seconds
Final assembly - no greater than 14 seconds
A batch of 240 batteries - no greater than 12 minutes