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Manufacturer of Endoscopes Increases Overall Throughput And Reduces Test Time By 67%

Customer
Manufacturer of Endoscopes

Industry
Medical

Location
USA

Application
**IEC 60601-1 Electrical Safety Testing,
Functional Testing**

Product Used
**Guardian 6100 Medical Safety Analyzer &
CaptivATE Automation Software**

The Challenge:

This medical device manufacturer employed five manually operated test instruments to perform six IEC 60601-1 electrical safety tests, resulting in seven process steps and a total test time of 15 minutes per device under test (DUT). Test results were a handwritten check in a pass/fail box.

The Solution:

The customer chose the Guardian 6100 Medical Safety Analyzer and CaptivATE Automation Software allowing him to increase the number of compliance tests, decrease test time, and decrease the number of instruments to maintain. He also achieved fully automated data acquisition and gained the capability needed to be in compliance with 21 CFR Part 11, Electronic Records; Electronic Signatures.

Summary & Metrics:

- Increased overall throughput
- Reduced electrical safety & functional test time by 67%
- Lowered program costs by 60%
- Decreased test time from 15 minutes to 5 minutes for each device
- Decreased the number of test process steps from 4 to 1
- Decreased the number of test procedures from 6 to 2
- Decreased the number of test instruments from 5 manual to 2 automated
- Searchable, collaborative database

Benefits:

This medical device manufacturer realized a 60% savings in labor cost in the first year and achieved his ROI for the test solution in 14 weeks.