Automation of Final Test Station in the Manufacturing Process of a Medical Device Facility

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Abstract *— The IS-4 Final Test Station will incorporate the entire test needed to assure that the leads that are manufactured in Boston Scientific are built with a high quality standard that will assure the safety of the patient. The leads are an important component of a final medical device which includes an active pharmaceutical ingredient. Currently, the tests performed by the IS-4 Final Test Stations are seal tests, leak test, resistance test and electrical tests. The electrical test will allow the operator acknowledge that electrical continuity is followed during the entire coil, in that way it can be assured that the coil is not internally broken. During the seal and leak tests an air pressure is introduced to the coil by an equipment component, and the equipment will measure the pressure at the other end of the coil to see if a leak is occurring in the coil.*

Key Terms *— Coil, Electrical Continuity, Lead, Patient.*

RESEARCH DESCRIPTION

Currently the seal, leak, resistance and electrical test are manually performed by the operators in the manufacturing room. There are different stations to perform the entire test, something that prove to be difficulty. Also the operators in the line have to perform the tests with a manual fixture that is residing in the manufacturing room. This makes the process slow and impacts the process yields. The cables used for the tests get deteriorated over time and get broken. Also, the process experience a problem with false negatives during the resistance test due to incorrect placement of the coil inside the fixture. This problem happened because the operator is not capable of seeing if the pins used for this operation are placed correctly in the metal part of the coil and instead the pins are placed in the plastic part of the coil thereof obtaining an incorrect electrical reading, sometimes indicating open circuit values that indicate a total absence of the coil.

The Reliance IS-4 Final Test Station integrates electrical testing (resistance and dielectric high voltage) and air leak rate testing (Seal and Leak) into a single system. The system PC equipped with a 24 Input/24 Output Channel to Channel Isolated Digital I/O card (National Instruments PCI 6527) with a custom program designed in Visual Basic 6.0 and running under a Windows 2000 operating system, provides the required controls and equipment communication functionality.

The custom fixture (E42286-200) provides the required interface between the tester equipment, instrument and lead to be tested. All leads manufactured in Reliance IS-4 at BSC Dorado are required to be tested in the Final Test Station.

There are two testers, the Air Leak and the High Voltage Dielectric testers. The third equipment is considered an instrument which is a multimeter for the resistance measurements. All three of them are controlled by the software. However, the equipment control is limited to start/stop the tests and receive the test results but no parameters are changed or modified. In the case of the Air Leak Tester the software also will change channels depending on the test, Seal or Leak, because the test parameters are different. Each equipment is configured individually by the technician following the corresponding Manufacturing Instructions.

The central piece of hardware in the system is the Relay Box which is a series of relays and

electronics designed to interface with the Air Leak and High Voltage Dielectric testers, the multimeter and the fixture test site. The PC connects to the Relay Box through its I/O card. The Air Leak tester sends the test results directly to the PC through the serial communications port, and the same is for the multimeter resistance measurements.

Contrary to the Air Leak and the High Voltage Dielectric testers which determine if the lead passed the test, or not, based on their configured parameters, the multimeter sends the measurement results and the software determines if the lead passed the resistance test or not. The computer will display the results for each of the tests performed and only if all tests passed (resistance, high voltage, seal and leak), the computer will indicate that the lead passed.

The operator is required to load the lead in the test site located in the fixture (E42286-200), scan the traveler, start the test and wait for the results. Once the results are displayed then the operator will enter the test results manually.

The Final Test Station (FTS) does not save any test results neither sends test results automatically to any other BSC system. The communication with other systems occurs at the beginning when the operator scans the traveler that the FTS contacts the Manufacturing database through our Production enviroment to check for the traveler and the corresponding part number. Once the part number is automatically populated, the part number is checked by the software against the FTSettings initialization file (which is part of the software) to verify that the part number is valid. If the part number is not found in the file, the test will not be performed and an error message will be displayed.

INTRODUCTION

The IS4 Final Test Station represent the final quality check of the lead before it get into the packaging area and reach its final destination. Due to the important check of all measures the project has to be really accurate in the measures it takes in the coil. The automated system incorporated in the manufacturing line not only got to have one of the higher quality standards but also need to provide the operator a very easy interface to work with.

RESEARCH OBJECTIVES

One of the objectives of the project is to perform the seal, leak, resistance and electrical test in the same station. The project requirements considered avoiding using the manual fixture for the electrical tests and avoiding manually data collection. The intention of the visual aid is the avoidance of false negatives during the test by allowing the operator monitor the actual positions of the pins in the electrical test. Other project's aims include the elimination of the problem of manual data collecting and centralization of all the pass/fail decisions in the same computer screen. Also the actual values of all the measures will be displayed to the operator. The speed of the operation will be significantly enhanced by the automatic procedure allowing more speed in the lot generation and helping with the unit production target of the plant.

RESEARCH CONTRIBUTIONS

One of the key contributions of this automated process is the time consumed operating the station. By avoiding the manual fixture more units can be produced by all the shifts. Also the quality of the process will be tightly observed in the station and the station will provide visual aids to the operator of the station indicating the failing units and the parameter of the failure. The cost of the replacing cables for the manual fixture that is currently implemented will be eliminated. This will result in a yield increase without affecting the product quality.

RESEARCH BACKGROUND

Currently the IS4 Final Test Station is running in manual mode. The manual mode is described as follows:

- A separate manual test fixture is used for the resistance and hipot tests.
  - The fixture is placed on the open clean area in front of the IS-4 Final Test Station. (See Figure 1)

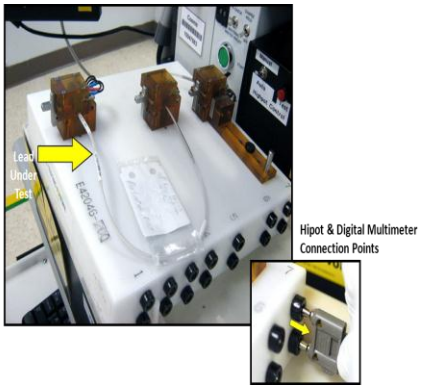

Figure 1
Manual Fixture in Front of IS-4 Final Test Station

- The Hipot Tester and the Digital Multimeter[1] used in the station are connected manually to a fixture using their front connections and, cables 905021-400 and 905020-100, respectively.
- The Operator changes manually the cable connections in the fixture to make the hipot and resistance measurements.
- The Seal and Leak tests are executed using the same Air Leak Tester (COSMO LS-1842) installed in the IS-4 Final Test Station using the same collets for the lead terminal and tip sides but using the manual controls provided in the station for the Air Leak Tester. (See Figure 2)

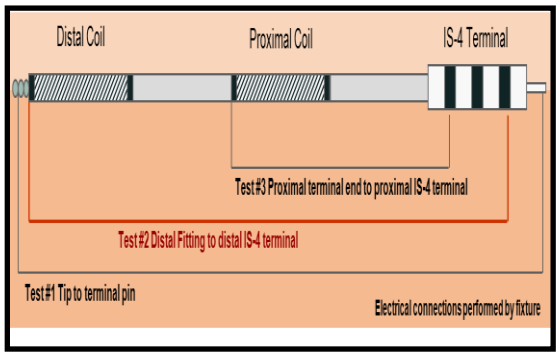

Figure 2
Resistance Test Performed at the IS-4 Final Test Station for a Reliance IS-4 Dual Coil Lead

The FTS in Automatic mode performs four different tests; The Figure 3 shows the station and its main components.

The four tests are:

- Resistance [1]
  - Tip to Terminal pin (measures the sensing coil resistance which is connected on one end to the helix and on the other to the terminal pin)
  - Distal Fitting to Distal Ring on the IS-4 Terminal (measures the distal shocking coil resistance connected to the cable)
  - Proximal shocking coil end to the Proximal Ring on the IS-4 Terminal (measures the proximal shocking coil resistance connected to the DBS cable when it is a dual coil lead)
- Dielectric or Hipot Test
  - Sensing to Distal coil
  - Sensing to Proximal coil (in dual coil leads only)
  - Distal to Proximal coil (in dual coil leads only)
- Leak Test
  - Nitrogen at 14 psi is injected into the lead body to detect if there is leakage
- Seal Test
  - Nitrogen at 2 psi is injected through the lead tip only (helix side) to detect if there is any leakage into the lead

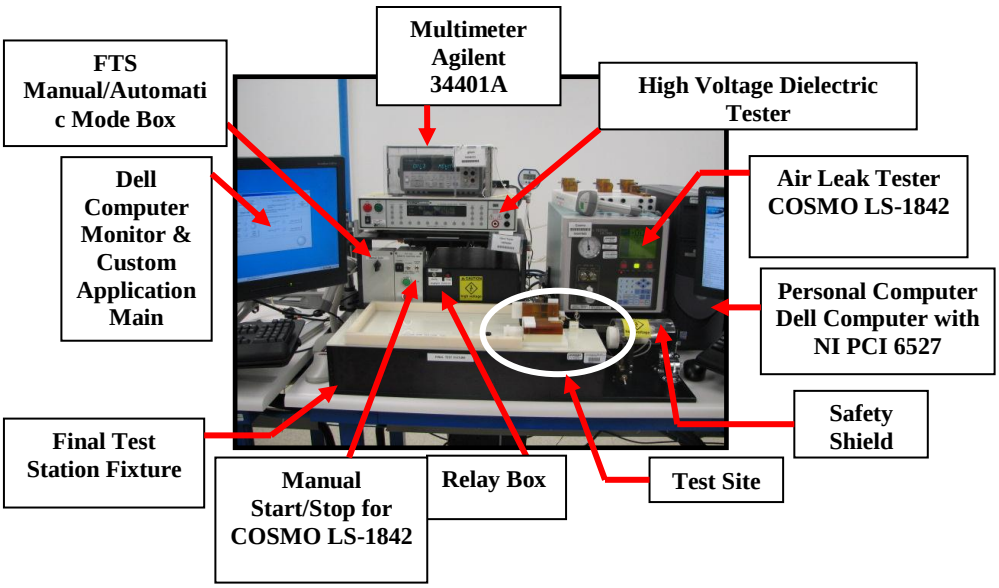

Figure 3
IS-4 Final Test Station

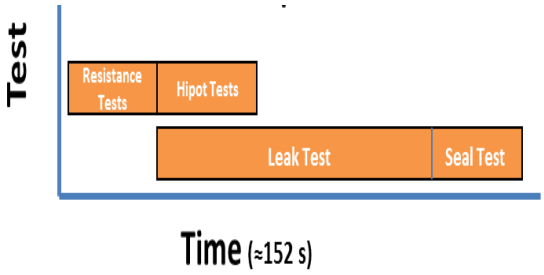

Figure 4
Tests Sequence

Test Sequence

The test sequence (see Figure 4) will be performed in a way that the electrical tests will run in parallel with the pneumatic tests to perform the resistance tests first (no other test started) and when finished then proceed with the remaining tests in parallel. This will not only reduce the time of the test but it will also reduce the possible electrical noise interference while executing the resistance measurements.

In addition, this implementation also is a throughput time improvement because the operator will load the lead once and will not have to disconnect the terminal side and reconnect it before the Seal Test.

Vision Enhancement

The collets allow the use of a camera by means of a fiber optic, because it is the only side where the operator does not have a reference to know how far the lead has to go into the collet. (See Figure 5) Additionally, with the camera, the Operator can position the lead and guarantee that none of the electrical contacts will be on the sight hole covered with Manufacturing Adhesive. The camera implementation is only a visual aid to help the Operator to place the lead correctly and it is not used to measure nor does make Pass/Fail decision. (See Figure 6)

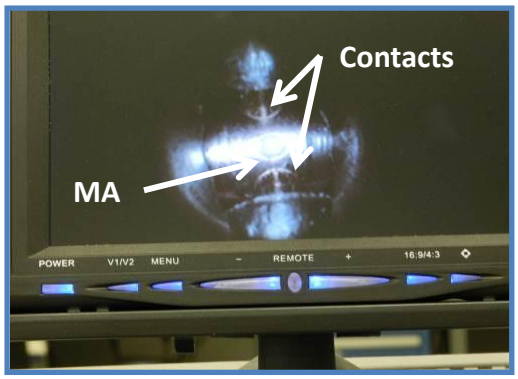

Figure 5

Lead inside Distal Collet as seen by the Operator

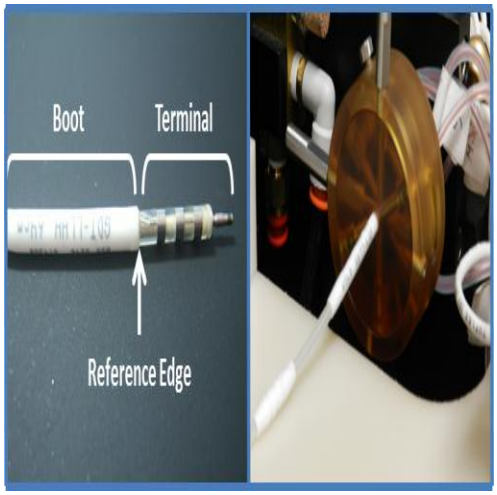

Figure 6

Lead Terminal Side - Lead Inside Proximal Collet

RESEARCH METHODOLOGY

The methodology that will be utilized to develop the research and accomplish the objectives established in the problem statement will consist of the following steps:

- New 3 Port Valve Installation & Verification
- Leakage Standards
- Station Hardware & Documentation
- Visual Aid & Documentation
- Software Final Test & Verification
- Validation Requirements

This methodology steps will be explained in detail below:

New 3 Port Valve Installation & Verification

A replacement valve & its associated hardware will be ordered and the new valve will be installed also the pneumatic circuit verification will be executed.

Leakage Standards

A quote for COSMO solutions for Leak Master quote will be obtained and after that I will place the order. The Leakage Standards will be verified & the documentation will be submitted.

Station Hardware & Documentation

Verify calibration dates for hipot, COSMO LS-1842 & New Agilent, send out for calibration DMM 34420A (25025103), verify station electrical wiring & pneumatic circuits (including regulators), verify test station is working properly, prepare I/O signals table for manual. Update station manual, station drawings & approve also a station Evaluation Form Approval will be needed.

Visual Aid & Documentation

Place and Fix fiber optic & associated equipment in fixture, document visual aid in station manual.

Software Final Test & Verification

Need to enter PC to BSC domain, Verify P/N retrieval from MATT using traveler number, verify time & correct resistance range during test, verify resistance value readings are close to manual measured values, verify integrated & individual tests, verify all displays & functionality and update FTS configuration file to include all new part numbers.

After all this automation and changes in the manufacturing process, the cost of all this

equipment and assemble cost the organization around $45,000.

Validation Requirements

The following items need to be completed for the equipment to be considered validated:

- caf phase 1 Prep & Approval
- SWO builds
- COSMO LS-1842 10054419 Cal & PM
- TMV Samples Preparation
- IQ/SQ Protocol & Approval
- IQ/SQ Protocol Execution
- IQ/SQ Report & Approval
- TMV Protocol & Approval
- TMV Protocol Execution
- TMV Report & Approval

CONCLUSIONS

The benefits of automation results in great savings for companies. In our case automating the Final Test Stations results in a significant time reduction per production unit.

Previously submitted time study was 5.71 min/unit. For the new Production Test the new time study shows that the cycle time for the station is 3.92 min. This reduction represents 1.79 min/unit less per unit. This is a huge reduction that implies producing 80 more units per day and implies in a yearly savings of $102,779.44. It will also gain ergonomics benefits and savings in cost avoidance of broken resistant tester cables. The project payback is expected to be obtained after the first year. After executing all the steps described in this article objective evidence was provided that guarantee that all key aspects of the Final Test Station adhere to Boston Scientific CRM approved specifications and recommendations; operates properly, has been properly documented, and that the software installed operates as intended.

FUTURE PROJECTS

The next steps of this project will consist in the creation of backup stations for the production environment. Also a new station will be developed for another of our production lines. The project leader will leverage the knowledge acquired by creating this project to reduce the development time of the construction of new stations to greater improve the benefits.

REFERENCES

[1] Creek, Stevens, “Agilent Technologies user manual”, *Agilent 34401A Multimeter Manual, Volume Number 1* Fifth Edition, March 2000, US.