

MEDICAL DEVICE TEST SOFTWARE

TESTING MEDICAL DEVICES WHILE MEETING FDA REQUIREMENTS

Client

Curbell Inc., Orchard Park, New York

Problem Scope

The customer required a modular test system to test many varieties of room communication pendants and record results to a central database, while meeting FDA compliancy. The communication pendants are the bedside remote controls used by patients in hospitals. If you've been in a hospital, chances are you've used a Curbell communication pendant. In general, the test system needed to communicate with an external ERP system and make available test results in real time. For this particular instance, it was necessary to use a generic test software framework with a set of predefined test steps because of the many different product variations. The customer ultimately wanted the ability to test their entire product line, which includes well over 2000 variations. All test stations are required to post test results to a central database and obtain product information from their existing ERP system.

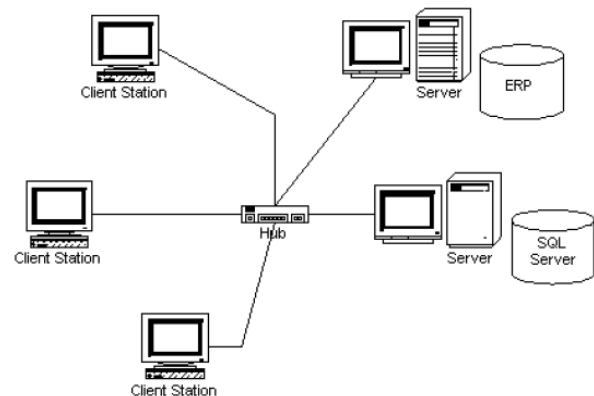
Viewpoint's Solution

With the appropriate National Instruments hardware (see below for more details) and a combination of TestStand and LabVIEW software, a unique test system was created for Curbell, Inc. Tests on the pendants range from basic continuity measurements to performing timing analysis on the various TV functions. The system allows a manufacturing engineer to create many different types of test sequences by selecting from a predefined test step list. Each test step could be uniquely configured to eventually describe a particular pendant test sequence. This sequence can be executed in potentially three different test modes, such as engineering, service, and production, where each mode has been specifically designed for various departments throughout the manufacturing floor. Typically, the manufacturing engineer would verify the sequence by executing it in engineering mode.

Once the test sequence parameters pass, it was then approved for production testing. All of this occurs with a few button clicks and within a matter of minutes.

During actual product testing, an approved and digitally signed test sequence is loaded and executed via a user-friendly test sequencer, designed with production automation in mind. Upon execution, test results are displayed to the operator and pushed to a database. Each pendant has a record of what was tested and how it performed. All result data is digitally signed and protected from tampering.

The architecture of the test system follows a typical client – server model as demonstrated below.



All client stations communicate with a central ERP and SQL server and each computer is secured by applying operating system security. The SQL server contains all of the test definitions, device history records and results. Information from it can be queried at anytime by quality engineers throughout the organization, assuming they have proper login access. This provides real time status about products going out the door. Also, other than the software running on the client stations, no other user has permission to write or modify any information in this database. Curbell Inc., is able to keep the server in a protected area separating it from the manufacturing environment while the

client test stations are placed throughout the manufacturing area.

Surprisingly, there are only twelve test steps needed to uniquely configure and be combined to create sequences to test well over 2000 unique products. Test steps are capable of measuring basic resistance, current, and voltage parameters as well as perform sound quality measurements and high speed digital waveform analysis. Several tests were designed to be subjective while others are fully automated and test to a specified acceptable tolerance. During configuration, each test step requires the manufacturing engineer to enter expected values and tolerance limits to define pass-fail status. Upon testing, the pendants are attached to a generic interface connection box and the test system makes the appropriate connections and measurements.

The System

As a high level overview, the system was created using the following components:

- National Instruments LabVIEW 7.1 and TestStand 3.0.
- Latest Dell mini-tower Windows-based PC for the client test stations with touch screen monitor.
- Dell PowerEdge server, running Windows 2000 OS and SQL Server 2000.
- Various other hardware from NI.
- Texas Instruments audio amplifier.

Upon test execution, the software connects to Curbell's main ERP system to obtain client information, and then connects to SQL Server to obtain additional testing parameters. After completion of a test, results are then pushed into SQL Server. Validated builds of the core software and validated test sequences are protected and managed adhering to Good Manufacturing Practices (GMP) and FDA guidelines (CFR Part 11, Software Validation Guidelines). The test system is designed not to allow any product testing if it finds that the software signature has been altered by any form of tampering or file corruption.

Conclusion

In using this automated software, Curbell Inc., can rest assured that all aspects of the pendant are being fully tested and all results are recorded while following FDA guidelines. Having the ability to create custom test sequences makes this system versatile in testing the entire product line and adding new features or additional test steps will require minimal effort. Also, adding testing modules in the future to the core framework is easily accommodated, thereby making the overall validation effort a little less painful!