Medical Stent Production Test

by
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Category:
Biomedical

Products Used:
LabVIEW™
NI-DAQ™
SCXI™-1100 analog input module
PXI™-1010 PXI chassis integrated with SCXI
PXI-6025E multifunction I/O board

The Challenge:
Automating a high volume production test for a medical device manufacturer that analyzes properties of a medical stent (a device that is placed in an artery to support the arterial walls) and increases existing test throughput by a factor of ten.

The Solution: Building an automated test system that tests 30 stents simultaneously by simulating the action of the medical device as it is inserted into the body and measuring its expansion properties.

Abstract
A stent is a temperature-sensitive spring-like device. Compressed and supercooled, the stent is inserted into an artery, routed through the body and deployed at the point of an aneurysm, at which time the stent expands to its desired diameter and supports the walls of the artery. During production, stent manufacturers must ensure that the stents expand at the proper rate and to the proper size within extremely rigid specifications. Using LabVIEW, PXI, and SCXI, Cal-Bay Systems designed, developed, and implemented a fully automated, FDA-approved test system for measuring and comparing the rate of expansion and the maximum expanded diameter of medical stents.
**Introduction**

The world of medical treatment is improving every day. Medical research and development is expanding rapidly. Devices that get inserted into the body to assist or sustain are becoming more widely used. In the case of an aneurysm, the walls of an artery become weakened and are susceptible to breakage. A device that supports the walls of the artery in the area of the aneurysm could prove to be invaluable. But how would one get such a device into an artery (some arteries are the diameter of a silver dollar) without disturbing the sensitive area and possibly causing a premature rupture?

A device called a stent props open and supports an artery that is weakened by an aneurysm. A stent is a spring that starts out very small, compressed and supercooled, and is inserted into an artery at a convenient location (usually the inner thigh). The stent is then routed through the artery and deployed at the point of the aneurysm at which time it expands to its desired diameter and supports the walls of the artery. The stents must expand at the proper rate and to the proper size within extremely rigid specifications. A mistake could be life threatening.

Cal-Bay Systems designed, developed, and implemented a fully automated test system, based on National Instruments PXI and SCXI hardware, for measuring and comparing the rate of expansion and the maximum expanded diameter of medical stents through a range of temperatures. This system replaced an older test system and provided a 10x increase in number of stents that are tested at one time.

**The System**

Using National Instruments LabVIEW and PXI and SCXI data acquisition hardware, Cal-Bay designed a state of the art production test system. The system tests the expansion of 30 stents at one time, using linear variable displacement transducers (LVDTs) to determine the diameter of the stents as they are heated from a supercooled state to normal body temperature.

A PC running a LabVIEW application collects the data and graphs expansion versus temperature in real time for each stent under test. The user can select up to three stents to view at one time. At the end of the test when the test bath reaches body temperature, analysis is performed on the displacement curve to determine if the stents meet the desired specification. A report is generated for each test.
The software also controls the temperature of the test bath and a pneumatic valve that controls lowering the LVDT sensors onto the stents under test.

With the new test system 30 stents can be tested at one time, where only three stents were being tested simultaneously with the old system.

**FDA Validation**
The software for this test fixture required FDA validation and using LabVIEW we wrote an application to test every input and every output of the system. We provided complete documentation of calculations, expected results, and actual results to the FDA.

**Conclusion**
Because of the success and popularity of medical stents in aiding aneurysm patients, and recent FDA approval, production of stents has skyrocketed. With the automated test system that Cal-Bay Systems developed, 30 stents can be tested at one time – an increase of 10x. Currently five production test systems are in use.