Building a Test System for Medical Stents

by Dave Weisberg, Principal,
Cal-Bay Systems, Inc.

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.**

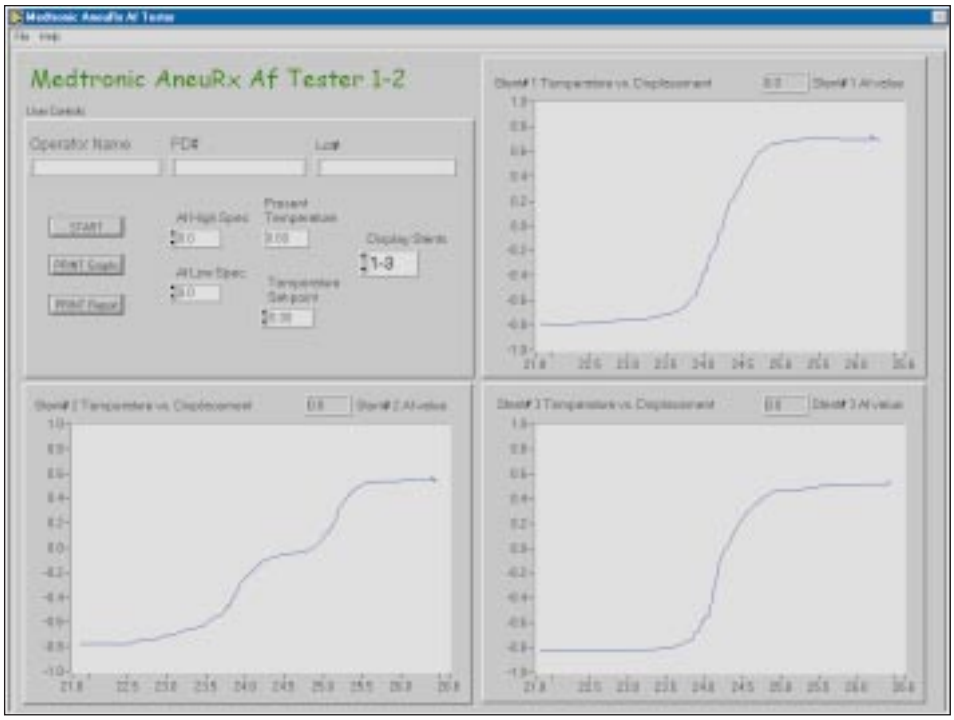
The Solution: **Building an automated test system that tests 30 stents simultaneously by simulating the action of the medical device as it is inserted into the body, and measuring its expansion properties.**

Introduction

Medical research and development is expanding rapidly and devices 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 is used to prop open and support an artery that is weakened by an aneurysm. A stent is a spring that starts out very small, compressed and super-cooled, 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. It is necessary to ensure that the stents expand at the proper rate and to the proper size within extremely rigid specifications. A mistake could be life threatening.

A device called a stent is used to prop open and support an artery that is weakened by an aneurysm.



National Instruments LabVIEW Main Screen for Test System

The System

Cal-Bay Systems designed, developed, and implemented a fully automated test system, based on National Instruments PXI/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.

Using National Instruments LabVIEW and PXI/SCXI data acquisition hardware, Cal-Bay designed a state of the art production test system. We designed the system to test 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. You can select up to three stents to view at one time. At the end of the test (when the test bath reaches body temperature), we performed analysis 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 lowers the LVDT sensors onto the stents under test.

With the new test system, we can now test 30 stents at once, 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. The automated test system developed by Cal-Bay Systems allows 30 stents to be tested at one time (an increase of 10x), and there are currently five production test systems in use.■

For more information, contact Dave Weisberg, Cal-Bay Systems, Inc., tel (415) 258-9400 ext. 15, e-mail dweisberg@CalBay.com.

We provided complete documentation of calculations, expected results and actual results to the FDA.

Visit ni.com/zone *for information on LVDT measurements.*