

Dynatek delta

Leading the world in medical device testing

testing

Overview

Dynatek has conducted testing of cardiac and vascular devices for more than twenty years. While we have tested a variety of device types, including ultrasounds and ventricular assist devices, we specialize in the testing of heart valves, vascular stents and stent-grafts.

Contract testing through Dynatek offers several advantages. First, Dynatek's staff specializes in performing this type of testing, reducing the time for test completion, eliminating the need for specialized training at the client facility, and freeing up staff for other tasks. Second, having testing performed by an independent laboratory eliminates any appearance of bias that can come from testing ones own device. Finally, testing at Dynatek is a more cost-effective way to test, often allowing for multiple rounds of testing to be run for the cost of one testing unit.

Services

Dynatek provides the highest degree of service available in accelerated durability testing. Our standard testing includes the following services:

- Daily visual inspection of devices
- Weekly measurement of pressure amplitudes/differentials (pressure-regulated testing)
- Weekly measurement of device deflection (deflection-regulated testing)
- High-speed video of device motion in silicone mock vessels
- Monthly progress reports
- Comprehensive final report in a format to be submitted directly with other submission documents.

Stents and stent-grafts:

Radial fatigue testing of vascular stents and stent-grafts is conducted in a Dynatek Large Vascular Prosthesis Tester (LVP) or Small Vascular Prosthesis Tester (SVP), depending on the design of the device. These testers are designed to test at frequencies as low as 1Hz, and as high as 50Hz. The acceptable frequency of testing is determined by the size and design of device, the testing protocol, and the type of testing being performed. Two acceptable types of testing include pressure-regulated testing and deflection-regulated testing, both of which can be accomplished through Dynatek's testing services.

Heart Valves:

Accelerated durability testing of heart valves is performed in a Dynatek M6 heart valve tester. ISO Standard 5840 provides guidance for testing heart valves, and Dynatek's testing services conform to this standard by providing documentation of consistent pressure differentials with each cycle, as well as data demonstrating full closure of the valve in greater than 95% of the cycles.

Your Tester or Ours:

We offer the option of conducting tests on client-owned testers, even if not a Dynatek-manufactured tester. If the client has performed tests at their facility, or has contracted another laboratory to conduct tests on client-owned testers, we would like the opportunity to demonstrate how we can provide cost-effective alternatives with a higher level service.

Custom tests:

Custom testing services, such as rotational and bend tests, are also available through Dynatek's testing services. We will work with the client to custom-design a test that meets their needs.

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