

Heart Valve Durability Testing at Dynatek's Contract Testing Lab

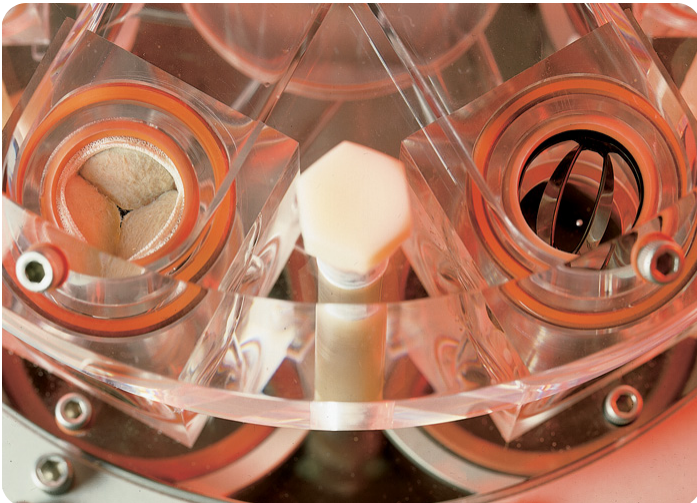


Fig 1: Tissue valve and mechanical valve mounted on M6 Heart Valve Tester.

With 31 years of experience in heart valve testing, Dynatek Labs leads the world in heart valve testing that meets ISO 5840 requirements. In addition to this decades-long experience in heart valve prosthesis testing, Dynatek Labs and our customers benefit tremendously by Dr. Jim Conti's participation in ISO/AAMI/ASTM standards committees. Dr. Conti's participation in the activities of the standards committees gives Dynatek Labs significant insight and understanding of the regulatory framework as it impacts heart valve prosthesis testing. Customers who have their heart valve devices tested in Dynatek's contract testing lab benefit from understanding exactly what tests are required by regulatory bodies, and how to accomplish the test objectives in the most cost-effective manner.

The contract testing lab at Dynatek can test all heart valve designs including percutaneously-delivered valves. We can also test septal defect closure devices, artificial heart bladders, membranes/sheets, sutures/clips and intra-aortic balloons on the M6 Heart Valve Tester.

The M6 has been the gold standard in heart valve durability testing for nearly 30 years and can test from two to six heart valves or cardiac prostheses at a time. All four cardiac valves, the tricuspid, pulmonary, mitral and aortic valve can be tested on the M6 Heart Valve Tester. Dynatek Labs can test valves made of virtually any material on the M6 Heart Valve Tester.

The following tests conforming to ISO 5840 series- Cardiovascular Implants –Cardiac Valve Prostheses, and FDA Draft Guidance

for Industry and FDA Staff: Heart Valves – Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications 2010 are performed at Dynatek's contract testing lab:

Accelerated Wear Testing (AWT) or Valve Durability Testing:

AWT or valve durability testing is also referred to as valve fatigue testing and is performed on Dynatek's M6 Heart Valve Tester. The M6 can test from two to six valve prostheses at a time. Our contract testing lab is equipped with M6 Heart Valve Testers, stroboscopes, high-performance pressure transducers, still and video cameras, and high speed cameras to carry out heart valve substitute testing under all conditions described in the standards.

For rigid or mechanical valves, valve prostheses are tested on the M6 for 400-600 million cycles, and flexible leaflet prostheses are tested for 200 million cycles with closing pressures between 125 and 150 mm Hg, according to FDA recommendations. Dynatek can work with your protocol or assist you in developing a test protocol for accelerated wear testing of your heart valve substitute.

Testing Unstented Valves in Compliant Chambers

Dynatek's contract testing lab has the expertise to design and fabricate compliant chambers or vessels in which you can test unstented valves. Based on your valve or valve construct, we can design a compliant vessel or chamber that can be mounted in the M6 Heart Valve Tester to test an unstented valve. Dynatek is the only contract testing lab that has the in-house capability to fabricate our own precision mock silicone vessels, used in both heart valve prosthesis and vascular device testing.

Dynamic Failure Mode Testing

FDA recommends that heart valve substitute manufacturers subject valves that have survived the durability testing or accelerated wear testing described above to further testing called dynamic failure mode testing, to evaluate the conditions under which the valve prosthesis will fail. By testing your heart valve substitutes on the M6 Heart Valve Tester, Dynatek can assist you in performing both quantitative and qualitative analyses of the conditions under which your valve will fail. Dynamic failure mode testing data can be used to support computational analysis of stresses on valve components. Other draft regulations that are close to being published as standards also require dynamic failure mode testing to be performed on heart valve prostheses.

SD 531
050620



DYNATEK LABS
Leading the world in medical device testing

Cavitation

Rigid or mechanical valves are known to be prone to cavitation under some conditions. The occurrence of bubble formation with a rigid valve is defined as cavitation and the USFDA recommends testing rigid valves for cavitation. The M6 Heart Valve Tester can be set up to induce cavitation in vitro and is therefore an excellent test platform for rigid heart valves. An accelerated wear test or long-term durability test of a rigid valve on the M6 Heart Valve Tester can also be designed to evaluate the occurrence of cavitation damage, thus saving time and expense in testing your rigid heart valve. The M6 can also be adjusted to eliminate or reduce all cavitation during accelerated testing.



Fig 2: Test sections for a variety of tissue and mechanical heart valves.

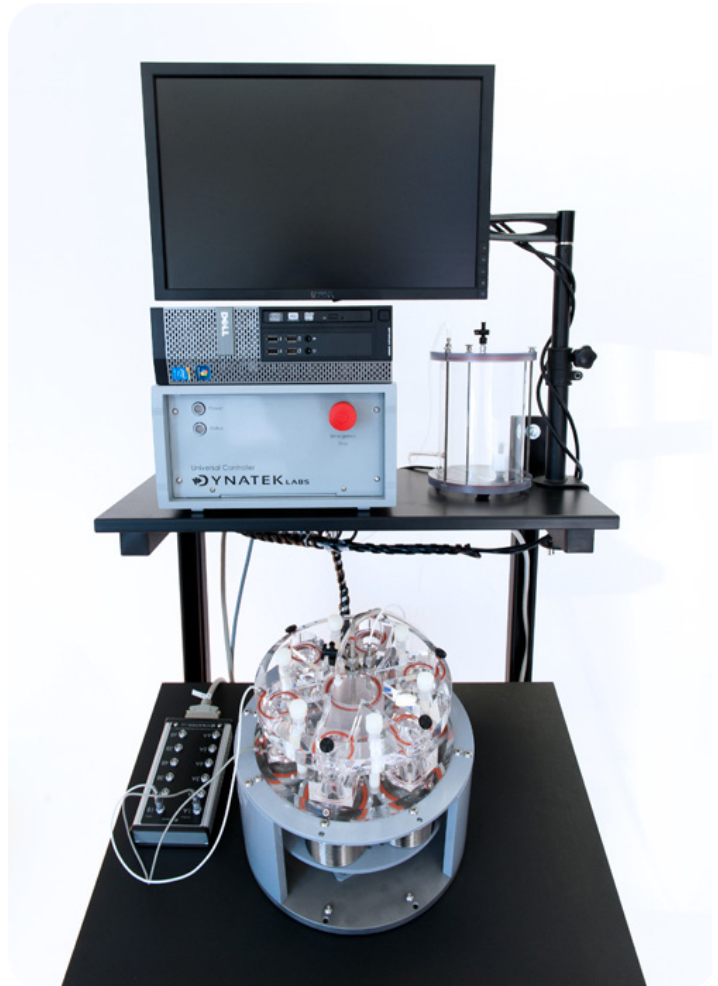


Fig 4: M6 Heart Valve Tester

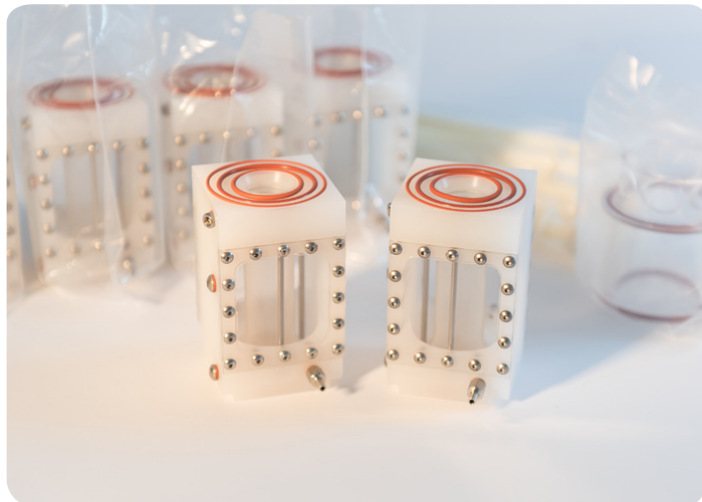


Fig 3: Test sections for stentless heart valves.



Fig 5: MP3 Pulse Duplicator

To receive a customized proposal, contact us today at:



Dynatek Labs, Inc.

105 East 4th Street

Galena, MO 65656

800.325.8252

1.417.357.6155

www.dynateklabs.com

salesdd@dynateklabs.com

