

Dynatek delta

Leading the world in medical device testing

heart valve testing

FAQS

1. What are the FDA durability guidelines for biological and mechanical heart valves?

The FDA requires that valves be tested for 600 million cycles with examination every 40 million cycles for mechanical valves, and 200 million cycles with examination every 20 million cycles for biological valves.

2. How many valves should be tested?

The population size is determined by the safety rating of the product and the number of sizes of your product to be marketed. At a minimum, "worst case" sizes should be used for testing proposed (i.e., the largest and smallest). Ideally, a sample of each size or material should be tested.

3. What should be used as a control?

Depending upon whether or not there is a similar product on the market, the control would be an already approved valve. If not, the population size might need to be increased for further comparative studies.

4. What are the durability AAMI/ISO requirements for biological and mechanical heart valves?

According to the ANSI/AAMI/ISO 5840-1996, mechanical heart valve substitutes should be tested to at least 380 million cycles or to failure and biological heart valve substitutes should be tested to at least 200 million cycles or to failure. In general, the CE board tends to follow ISO standards.

5. At what frequency can valves be tested? (i.e. How long does the testing take?)

The frequency that valves can be tested is determined by the frequency at which the target closing pressure is obtained in 95% of the cycles, and full opening and closing of the valve is obtained.

6. What information is generated by Dynatek's testing?

The typical data recorded during durability testing are temperature, cycle count, pressures, and speed. Other statistical information can be derived upon request. A final report of testing is presented at the end of every project. This report includes, but is not limited to, full description of the test, including the fluid, test parameters and protocol, tester, and visible changes in the device that occurred during testing. These reports are directly submissible to all regulatory agencies.

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heart valve testing cont.

FAQS

7. When testing is started on a new heart valve product, what are the most important tests for prototypes to undergo?

Hydrodynamic performance and durability.