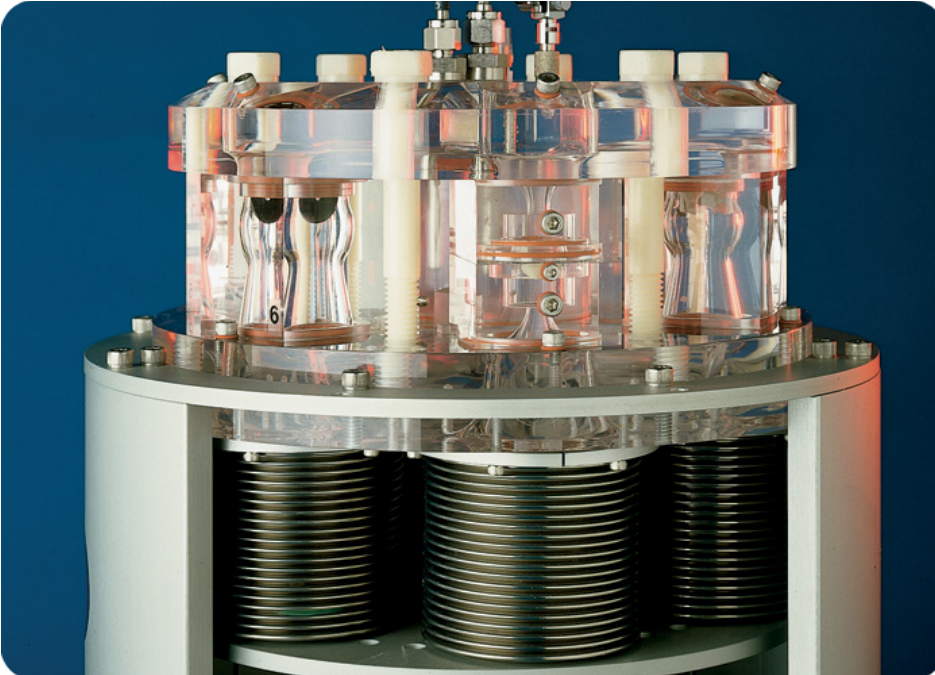


M6 Heart Valve Durability Tester



Exceptionally Capable Heart Valve Tester from the Market Leader

Dynatek Labs is proud to offer the M6™ Heart Valve Durability Tester, the industry benchmark for over 30 years. The benchtop M6™ is a powerful platform for replacement heart valve durability protocols that form a critical component of heart valve feasibility testing, design verification and validation.

Powerful Versatility in a Compact Unit

The M6™ can evaluate the widest range of heart valve-related devices for durability and failure mode analysis or testing to failure:

- Heart Valves
- Septal Defect Closures
- Artificial Heart Bladders
- Membranes/Sheets
- Sutures/Clips
- Intra-aortic Balloons
- Transcatheter Valves

Intuitive Design replicates *In Vivo* Cardiac Hemodynamic Conditions

The M6™ features a clear acrylic flow chamber with six custom-designed valve test chambers that host the valve test samples. The valve test chambers are radially arranged beneath the upper flow reservoir and each is served by a single channel that directs the test fluid to the valve. The upper and lower heads, the test valve chambers and the fluid supply channels are CNC-machined from a substantial block of clear cast acrylic offering complete visibility of fluid flow and sample status at all times. Silicone O-rings ensure that the valve test chambers remain completely leak-proof.

Below each valve chamber is one bellows made of a proprietary alloy that is mated to each valve test chamber with a silicone O-ring seal. The bellows sit on the pistonless swash plate drive system. As the swash plate moves up and down, the bellows are compressed or extended causing fluid to flow through each valve test chamber. This allows for test fluid to be driven into the valve test chambers, enabling durability testing of the test valve in each chamber.

Innovative Test Chamber Design

The M6's test chambers are machined from a solid block of acrylic. These test chambers are always custom-made, based on the user's heart valve design. Unlike competitive heart valve testers, the M6's test chambers do not move; instead, the test fluid moves through the chamber, just like blood moves through the heart. Advantage: since there is no reciprocating movement of the chambers, there is no possibility of leakage of fluid around the test chambers due to leaking sliding seals.

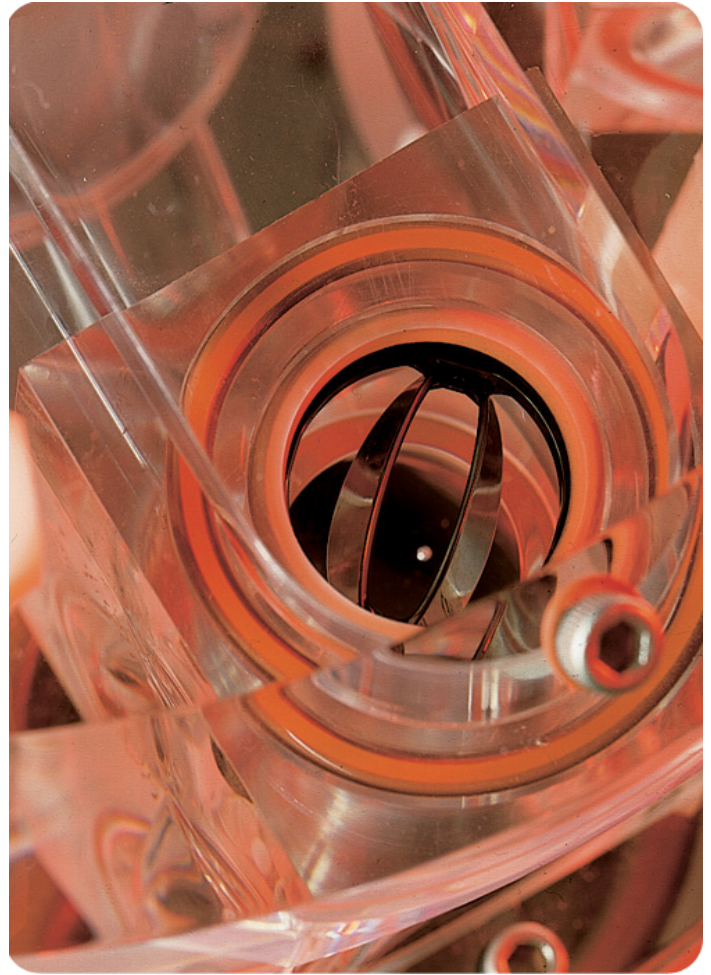
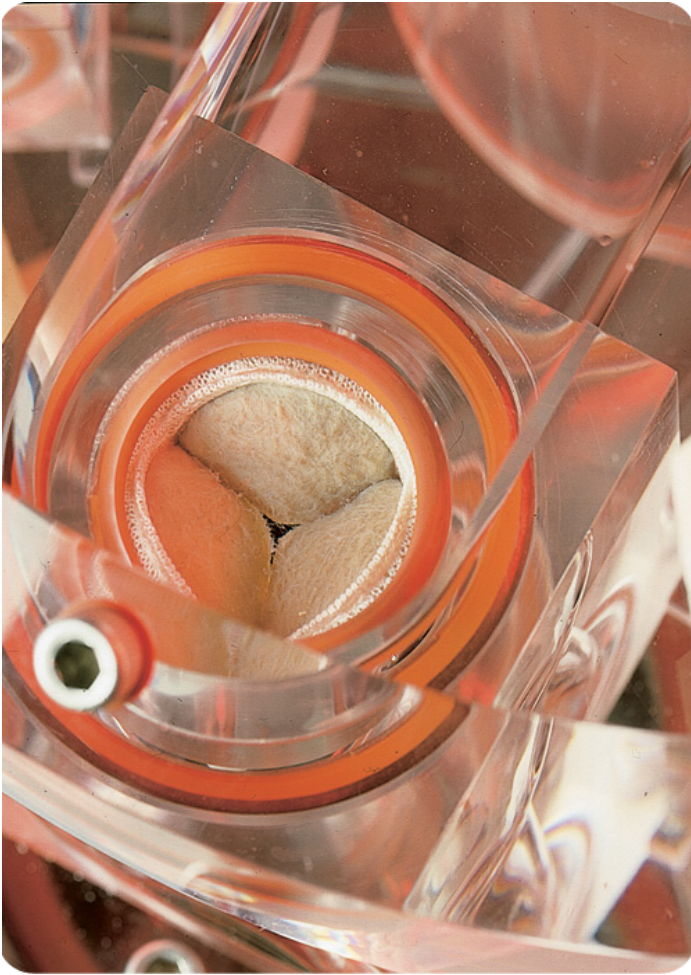
The M6's test chambers are sequentially pressurized, which means that the failure of a heart valve in one chamber does not lead to significant pressure fluctuations in other test chambers or worse, the shutdown of the whole unit. The M6 is the only heart valve tester in the world that utilizes this principle, known as tuned fluid oscillation. This allows the heart valves to be opened and closed fully while attaining targeted closing pressures in the most biologically relevant way.

Of greater importance is the single fluid reservoir (upper head) that insures that all valves are fed identically. This is vital to insure that each valve is tested under identical fluid dynamic conditions. This is a requirement of all heart valve testing standards and cannot be attained by any "individually tuned" testers.

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DYNATEK LABS
Leading the world in medical device testing



Visualization of Valve Performance

The M6 is an accelerated heart valve durability and fatigue tester and one of its advantages is the ability for the user to easily visualize and confirm the movement of the valve being tested.

ISO 5840 requires visual observation of the test valve at regular and frequent intervals such as daily or weekly. The entire upper head, lower head and all test chambers are made of clear, machined acrylic, allowing you to view both the top and sides of the test valves conveniently.

All test chambers (and therefore the test valves) are stationary in the M6, and you can conveniently use a video camera on a tripod or a stroboscope to easily follow the motion of the valve.

In competitive testers where the test chamber itself is moving up and down at high speeds, it is very difficult to visually follow the test valve's performance with a stroboscope or a high-speed camera, preventing the user from obtaining visual data mandated by ISO.

Negligible Long Term Maintenance Costs

Since the M6 does not use moving test chambers, it does not have moving parts such as sliding seals, gears, and piston arms, and its maintenance costs are negligible, compared to competitive units that have many more parts that are moving. The M6 has a swashplate that compresses the bellows under each test chamber, loading every valve in serial fashion, without the need for sliding seals and gears.



When you're going to run a 400 million-cycle durability test, you want to make sure that you have an absolutely reliable machine like the M6 that will not break down in the middle of a test. With the M6 you just can't go wrong, since it now comes with a 10-year limited warranty, the longest such warranty in the industry!

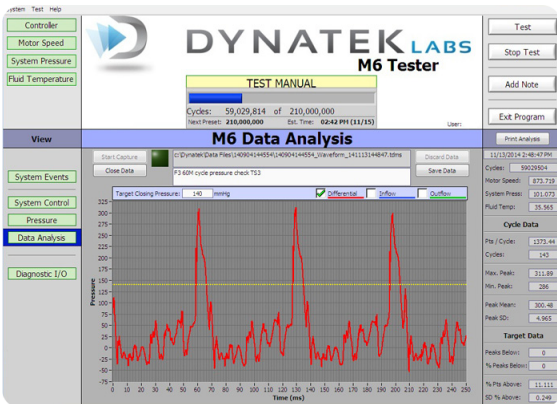


Universal Controller for the M6

Dynatek's new Universal Controller is a powerful controller that has been redesigned to control and monitor Dynatek's six position M6 Heart Valve Tester.

Although the monitoring and control aspects of the UC are impressive, perhaps of equal or greater importance is the time saved setting up or monitoring the "95/5" requirements for the closing pressure of each valve.

The UC can accept 12 pressure transducers, two for every position in the M6. When using all 12 transducers, each valve can be tested simply by choosing each sequentially – no need to change the position of the transducer after each valve is checked.



Key M6 Control Software Functions

The UC Control Software uses proprietary algorithms to offer the following key M6 functions, in addition to those listed above:

- Current cycle number at time of capture
- Motor speed at time of capture
- Date/time of capture
- Number of data points per cycle
- Number of cycles captured
- Highest peak in data set captured
- Lowest peak in data set captured
- Mean of peaks
- Standard deviation of peaks
- Number of peaks below target pressure
- Percent of peaks below target
- Average percent of data points in a cycle above target pressure
- Standard deviation of percent data points in a cycle above target pressure
- Take data
- Recall data
- Export/print data
- Nine modes of operation, including Lockout, Idle, Test, Suspend, Run and Abort

Optional

Catheter-delivered valve test sections for the M6 testing platform.



Dynatek Labs M6 Product Specifications

Description

Specification

Test capacity	2-6 valve samples
Valve test chamber	6; design based on customer requirements
Valve test chamber material	Acrylic, for full visibility of valve status at all times
Sample type	Tissue and Mechanical Heart Valves, Septal Defect Closures, Artificial Heart Bladders, Membranes/sheets, Sutures/clips; Intra-aortic balloons, Percutaneously-delivered Valves
Motor	¼ hp DC (½ hp DC optional)
Volume capacity	1-2 liters
Measured parameters	Cycle count, frequency, pressure, temperature
Fluid temperature	25° to 40°C
Temperature accuracy	±0.3°C of set temperature
Speed	Up to 33Hz (50Hz with the optional ½ hp motor ¹)
Speed control	Closed loop feedback type, user adjustable
Temperature control	Microprocessor based with RTD sensor
Working fluid	PBS, water, blood analog
Pressure transducers	Two optional, up to 12; one each for inflow and outflow
Back pressure on test valve	User adjustable via Throttle Valve
Pump type	Pistonless swashplate, adjustable, with bellows
Controller	Dynatek Universal Controller with proprietary software
Software	Monitors and controls speed, temperature, systemic pressure Calculates 95/5 closing pressure requirement
Capacitance tank	2 liters capacity, to provide air-water interface between the Controller and the M6
Dimensions	12" Dia. X 22.5" H
Power requirement	115 AC
Weight	72 lbs, dry

1 Sample design, size and compliance will determine the highest frequency at which the test can be performed with high confidence.

Specifications are subject to change without notice.

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

