

Revolutionary

Heart Valve Durability Tester



VDT-3600i



Medical Device Testing & Equipment • Simulation Platforms • Silicone Vessels

The revolutionary heart valve durability tester from BDC Labs offers the most clinically accurate test platform for artificial heart valves.

Designed from the ground up, the VDT-3600i heart valve durability tester is a patented accelerated wear test system designed for the evaluation of modern transcatheter and surgical aortic, mitral and pulmonary valves to meet ISO 5840 requirements. The test platform has six completely independent test sections, each test section featuring a dedicated electromagnetic driver which in turn allows both displacement and frequency to be adjusted independently for each station. The VDT-3600i moves the fluid through the test valve using our patented RB-5™ driver technology to produce the opening and closing dynamics representative of in vivo clinical performance at accelerated frequencies up to 50 Hz.



Modular design for ultimate versatility

The VDT-3600i is available in several configurations, thanks to its innovative modular design. You can acquire the VDT-3600i as a one, two or more test station platform up to six stations to meet the current throughput of your internal testing requirements.

Alternatively, you can acquire a six-station chassis that features one (or more) test stations active to begin with, and then you can field-upgrade with more test stations as your requirements change. Advantage? The VDT-3600i is the most compelling heart valve tester solution for startups and high-throughput companies alike!

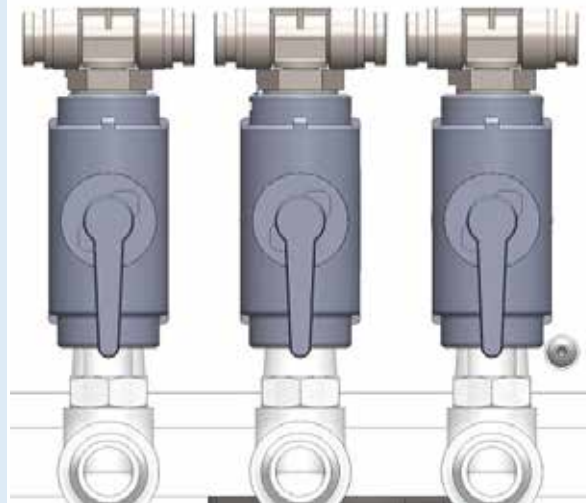
Precise and accurate, for maximum clinical confidence.

The VDT-3600i features the most accurate adjustment system available in any heart valve tester: digital stroke control and micrometer-based resistance. Every test station on the VDT-3600i features this uniquely combination that allows fully independent and accurate adjustments of valve loading pressure to comply with ISO 5840.



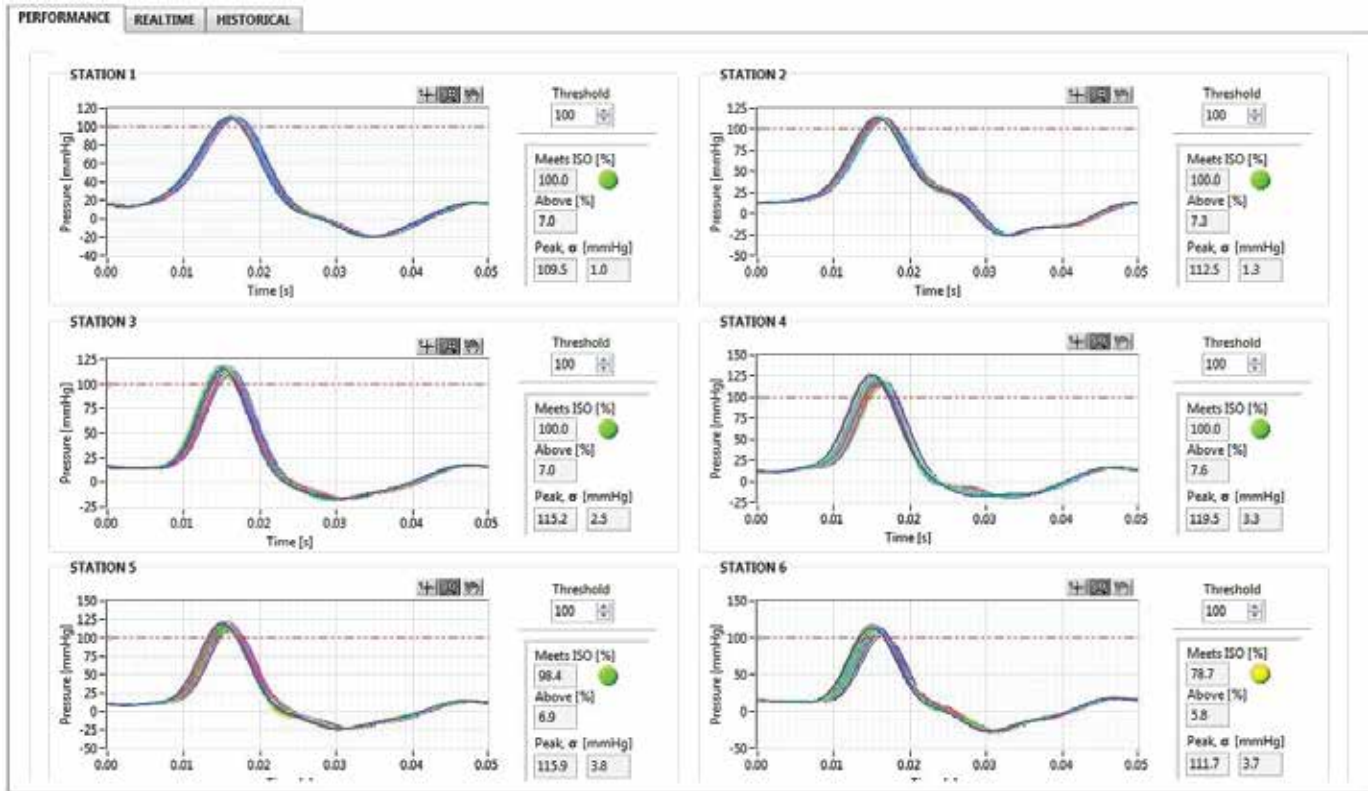
Key Benefits of the VDT-3600i

- Test any number of valves of differing sizes simultaneously, up to six at a time.
- Modular configuration allows you to configure the system with only the number of test sections you need on the VDT-3600i.
- Patented RB-5™ Drive system features enhanced loading performance at accelerated frequencies.
- Bellows-free design eliminates corrosion and contamination concerns with metal bellows.
- Individual micrometer-based throttle valves on every test section allows individual control of hydrodynamic load conditions on every valve.
- Every test section features an inflow and outflow pressure transducer for real-time, continuous measurement.
- The fluid of every test section is isolated from the others; if one or more prostheses fails or is due for inspection, you can continue testing the other valves uninterrupted.
- Statys® VDT Comprehensive Test software offers continual real-time monitoring, control and data logging of test parameters with a full suite of alarms and safeguards for every station. Alarm email notification is standard.
- ISO Count Accuracy provides an estimate of the actual number of cycles meeting the user set loading criteria during a test for each station, rather than just the motor count that is seen in competitive units.



Powerful, fully integrated software makes the VDT-3600i easy to operate.

The Statys® VDT software program offers an intuitive user interface that allows you to start, configure and run a test rapidly.



ISO Criteria Waveform Analyzer showing the status of each station loading to the required criteria

Key Software Highlights

- General motion control at each station
- Arbitrary waveform control (optional)
- Temperature monitoring
- ISO Criteria Analyzer (optional)
- Test alarms
- Alarm email notification
- Data logging
- Real time data acquisition

Accessories

Large Valve Configuration

While the standard system configuration accommodates up to 80 mm valve carriers, the Large Valve Configuration is capable of accommodating a 95 mm valve carrier or annulus), making it by far the largest Valve Configuration available among heart valve testers.

Motor Position and Power Output

The VDT-3600i can be configured with the Motor Position and Power Output option that provides an analog output signal of the motor position and power for each station on the instrument. This optional feature provides the user with the ability to interface and synchronize a secondary measurement system precisely with the valves being tested.

Low Pressure Regulator



The Low Pressure Regulator is a precision pressure regulator designed for applications that require high resolution such as the RDTL-0200 System. The Regulator features control sensitivity of 1/8" water column, a pressure range of 0-10 psi, and a balanced supply valve to deliver consistent and reliable accuracy to maintain the system desired set point regardless of supply pressure changes or flow conditions.

Silent Air Compressor

The optional Silent Air Compressor is a whisper quiet air compressor featuring an inline regulator and moisture trap with a noise level of a mere 30 dB. The Compressor features a convenient carry handle on top with an operating pressure range of 55-85 psi.



Silicone Mock Vessels

BDC Labs offers certified silicone mock vessels in straight, curved or bifurcated configurations for mounting stents, stent grafts and other cardiovascular devices on the RDTL-0200. Our mock vessels can be fabricated based on wall thickness or compliance to suit your requirements. Qualification can be performed at various pulse pressures to meet your specific requirements (e.g., 160 mmHg/80 mmHg).

Instrument Workstation

This rugged, customizable instrument workstation featuring levelers and all-welded 16 gauge metal tube frame for durability, offers the following options for a tailored configuration:



- Full width handle for easy control when casters are present
- Adjustable, full-width 16 inch deep upper shelf for locating electronics away from possible liquid spills
- Steel 6 inch drawer for small accessories and tools
- A 3-way height-adjustable arm to mount the system flat-screen monitor
- Articulating keyboard with mouse tray
- Fixed, full-depth lower shelf for large accessories and fluid containers
- Lockable casters for a mobile workstation

Accessory Rail

An optional Accessory Rail is available, for mounting a camera, strobe or other accessory in front of the valve fixtures to monitor or record valve activity.

Software Options

BDC Labs' Statys® VDT software program offers an intuitive interface that makes running a test simple and rapid. With the following software options, the VDT-3600's capabilities are expanded, improving productivity significantly.



ISO Criteria Waveform Analyzer

The ISO Criteria Waveform Analyzer is a software module that determines whether every waveform of each valve met the *ISO differential pressure loading criteria*. After data have been processed, the statistical results are displayed along with an overlay of the waveforms themselves. Included is a secondary cycle counter that enumerates the total number of loading cycles actually meeting the ISO differential pressure loading requirements.

Alarm Output Trigger

The Alarm Output Trigger option allows the user to configure a digital signal for use in triggering external hardware in the case of a system alarm.

Arbitrary Waveform Creator

The Arbitrary Waveform Creator module enables the user to define and save customized motion waveforms. These waveforms can then be loaded and run by each station motor, allowing the user to optimize the opening and closing performance for the particular test valve.

VDT-3600i Specifications

Sample capacity	1 to 6
Sample size	Std: up to 80 mm, optional: up to 95 mm
Drive waveforms	sine, modified sine, & arbitrary (optional)
Test fluid	Water, saline or PBS
Frequency*	3 to ≤50 Hz
Max. differential	500 mmHg pressure
Operating temperature	up to 50 °C
Regulatory compliance	Complies with ISO 5840, and all applicable European Union directives and standards for safety and EMC. CE marked.

*Actual frequency dependent upon specific test article.



Medical Device Testing & Equipment •
Simulation Platforms • Silicone Vessels

4060 Youngfield St
Wheat Ridge, CO 80033
USA
Phone: 303.456.4665
www.bdclabs.com
E-mail: info@bdclabs.com

Trasonic is a registered trademark of Trasonic.
Statys is a registered trademark of BDC Labs.
© September 2016, BDC Labs. All rights reserved.