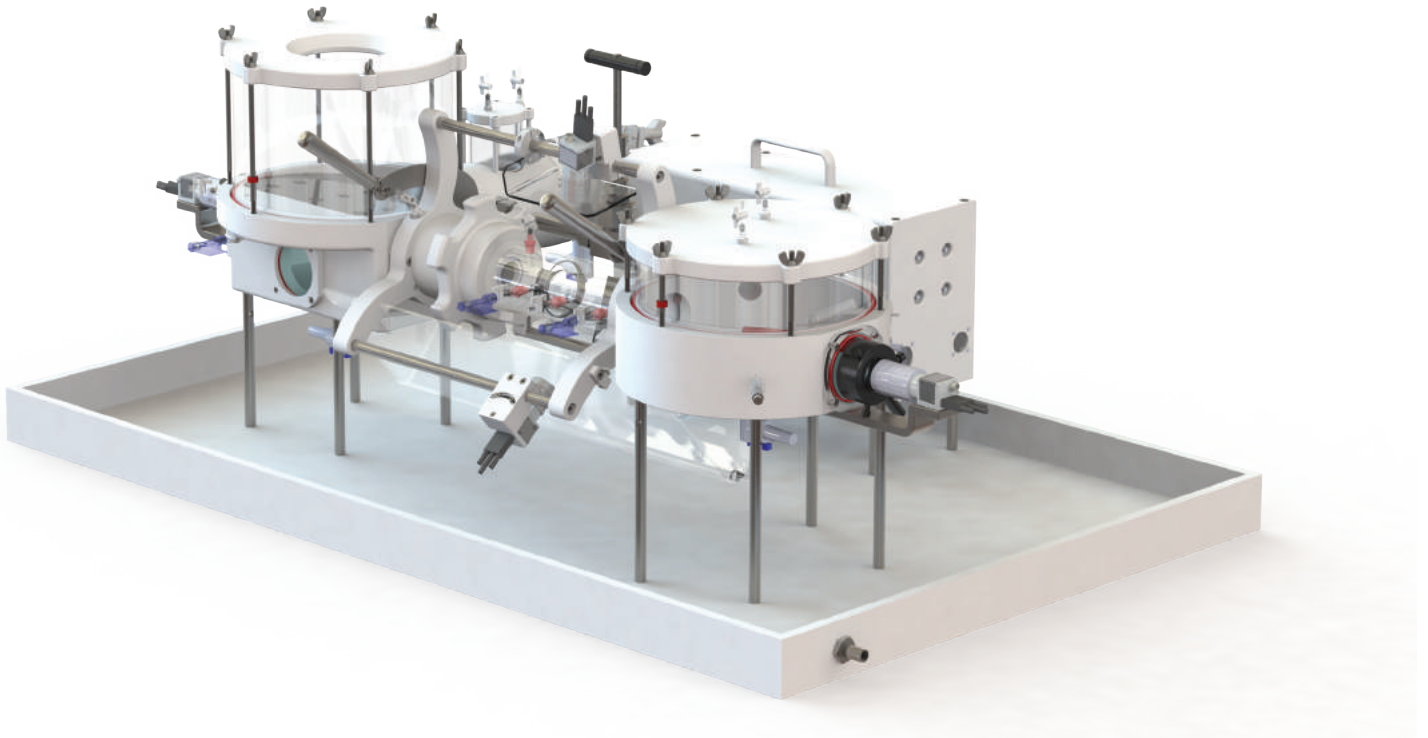


Pure Innovation

Pulse Duplicator



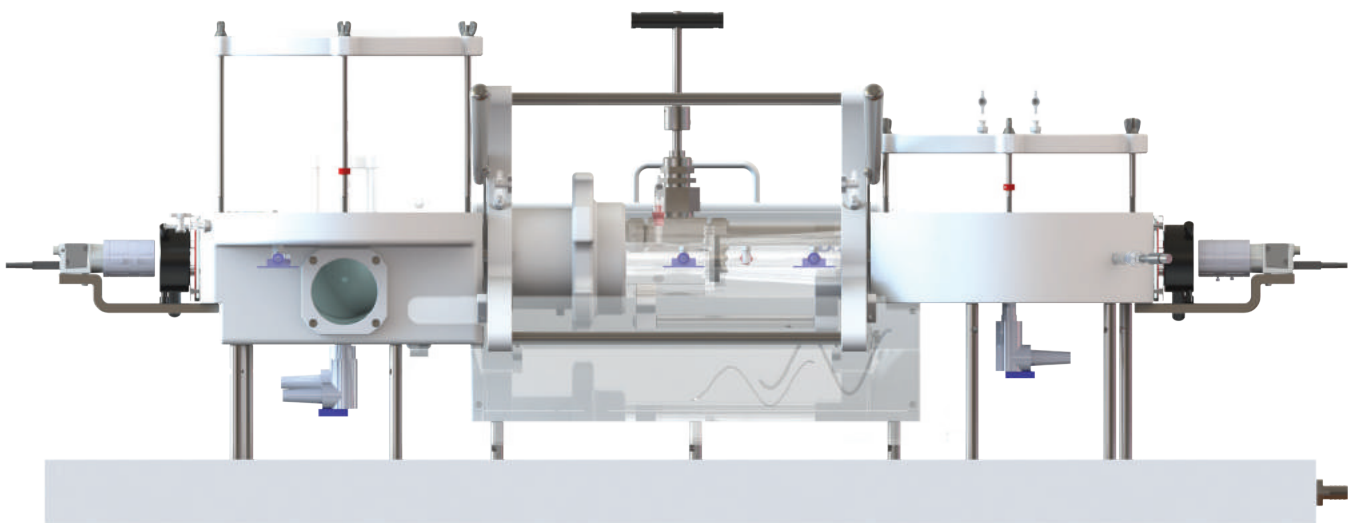
HDTi-6000



Medical Device Testing & Equipment • Simulation Platforms • Silicone Vessels

Building upon a foundation of proven technology, while fully integrating superior cardiac waveform generation with high-speed imaging, the HDTi-6000 Heart Valve Pulse Duplicator is the most innovative pulse duplicator introduced that meets all ISO 5840 requirements.

In a revolutionary fashion, BDC Laboratories' HDTi-6000 heart valve pulse duplicator achieves ISO 5840 pulsatile hydrodynamic performance assessment in a focused and efficient manner, with the added capability of fully integrated high-speed video to facilitate real-time visualization of the heart valve under test. With BDC's proven dual-chamber design, the HDTi-6000 system is easily configurable for either aortic, mitral, pulmonary or tricuspid heart valves with complete adaptability to test mechanical, transcatheter or conduit valve technologies. The implementation of a revolutionary capture mechanism to secure the valve carrier within the HDTi-6000 apparatus allows the operator to exchange samples quickly with minimal effort, while maintaining the fluid within the test system.

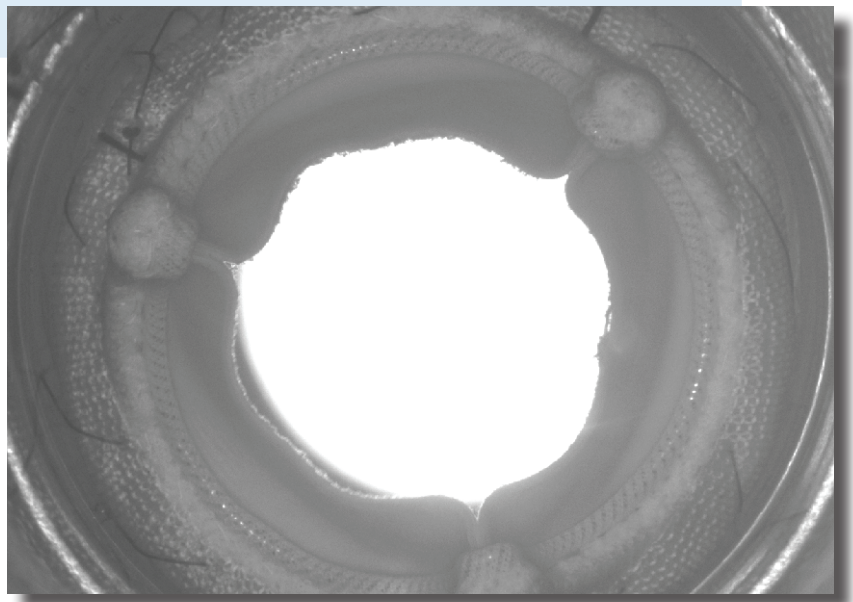


True integration of high-speed imaging

The HDTi-6000 accommodates up to 5 high-speed cameras that are fully integrated into the Statys® HDTi software, allowing simultaneous documentation of the inflow, outflow and each of the three leaflets concurrently with pressure and flow waveforms. After each test, both waveform analyses to determine the ISO 5840 performance parameters and image analyses to assess leaflet kinematics are available. Included with the unique system and software features is the ability to play back high-speed video synchronized with the pressure and flow waveforms, facilitating a comprehensive assessment of the valve at any point in the cardiac cycle.

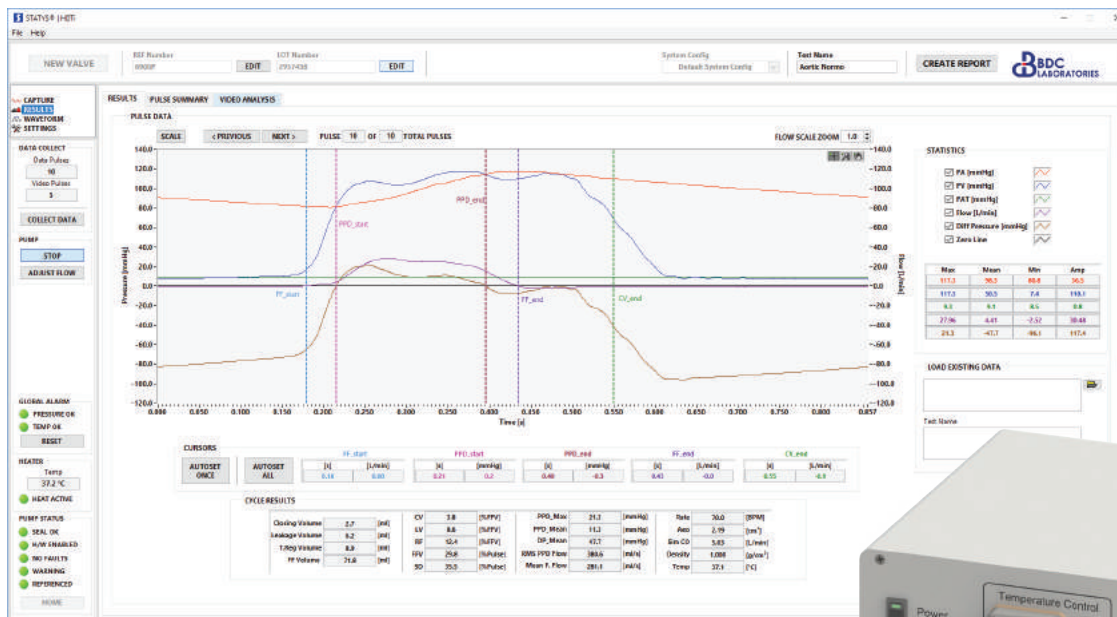
Key Benefits of the HDTi-6000

- Fully integrated high-speed video with multiple cameras
- Simultaneous and synchronized waveform and video acquisition
- Test aortic, mitral, pulmonary & tricuspid valve technologies
- Adaptable for all manners of valve carriers and conduits
- Exchange of samples without system draining
- Precise waveform control with high repeatability / reproducibility
- Rapid valve exchange for high test throughput
- Statys® HDTi software with integration of all control & monitoring attributes
- Test LVAD technologies with minor customization



Presenting the ultimate experience: The Statys[®] software

The Statys[®] HDTi software presents a fully integrated solution for controlling the HDTi-6000, acquiring pressure / flow waveforms and high-speed video, analyzing all waveforms and video, and then generating formal reports after each test. The true power of Statys[®] HDTi is in its user-focused experience and simplicity in accessing numerous complex features and analyses.



Repeatability and reproducibility

BDC Laboratories PD-1100 pulsatile pump is the fluid driving source for the HDTi-6000 pulse duplicator yielding high repeatability, reproducibility and dynamic configurability. With the ability to utilize sinusoidal or user created driving waveforms at flow rates up to 10 L/min and heart rates up to 240 bpm, the HDTi-6000 is capable of achieving accurate cardiovascular representation for all test conditions and valve locations.

Accessories

High Speed Cameras

The HDTi-6000 accommodates up to 5 high-speed cameras with 1280×1024 resolution. The cameras can be oriented for inflow, outflow and each of the three leaflet aspects for complete documentation of the heart valve under test.

Flow Meter with Probe

Optimized Transonic System Ultrasonic Flow Meter with Probe gives precision volume flow measurement. The probe can accommodate up to four calibrations for various fluid types and temperature combinations.

Calibration Reference

A custom designed calibration reference is available for all cameras to establish the image conversion from pixels to physical dimensions (e.g. millimeters).

Adjustable Lighting Source

An optimal, adjustable LED lighting system that includes ring or panel lights to achieve the best video imaging.

Heating Circulation Valve

The heating circulation valve is a directional valve that is deployed as a test article within the valve carrier to facilitate efficient fluid heating during the warm-up of the test system.

Drip Tray

A specially designed drip tray that encompasses the full HDTi-6000 system to capture any fluid that may fall from the system during use.

Software Options

Automated Image Analyses

In addition to manual measurements from acquired video, the Statys® HDTi automated image analysis package provides means to determine key attributes automatically through established software algorithms.

HDTi-6000 Specifications:

Valve type	aortic, mitral, pulmonary, tricuspid
Valve size	up to 95 mm
Frequency	2 – 240 bpm
Flow rate	1 – 10 L/min
Test fluid	water, PBS, blood analog
Driving waveforms	sinusoidal, arbitrary
Fluid 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	



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