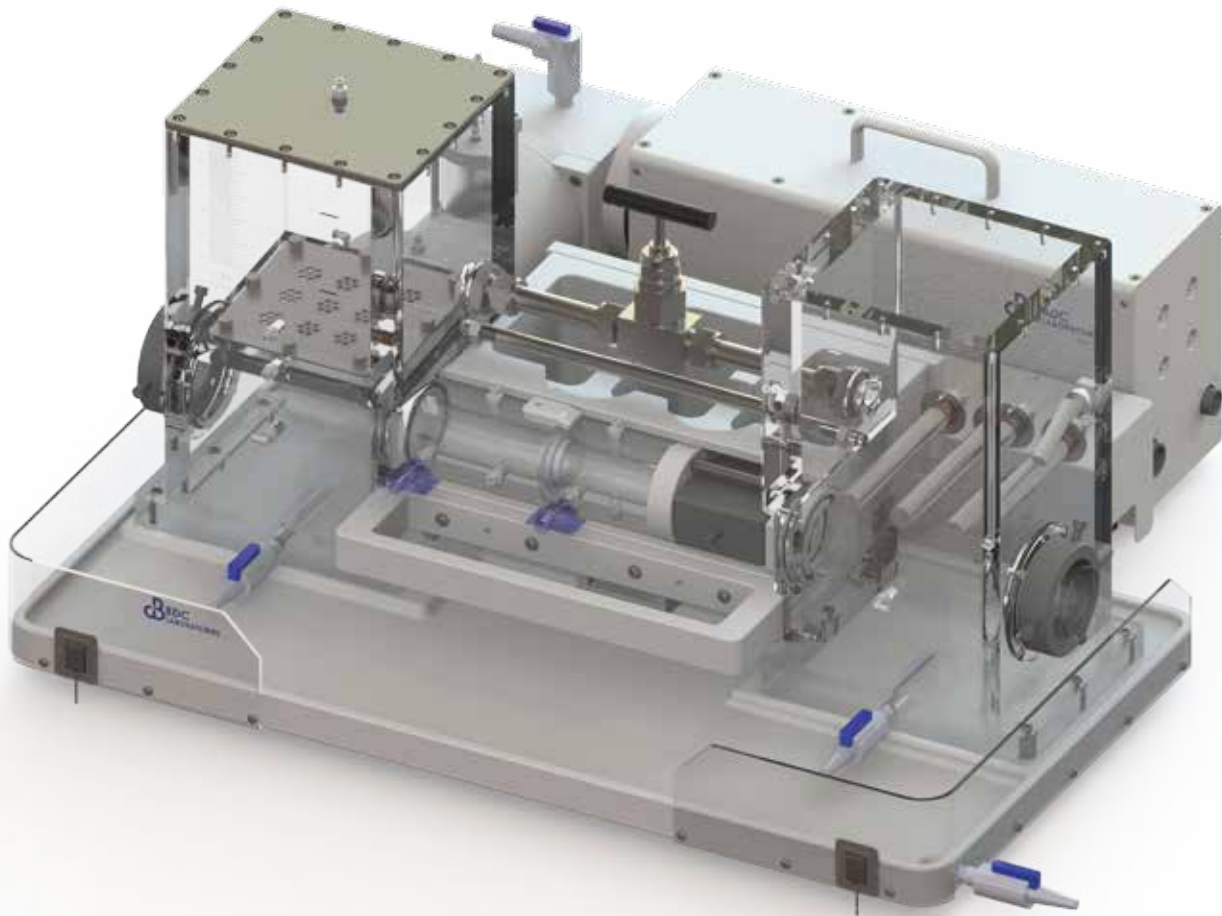


The Next Generation

Pulse Duplicator



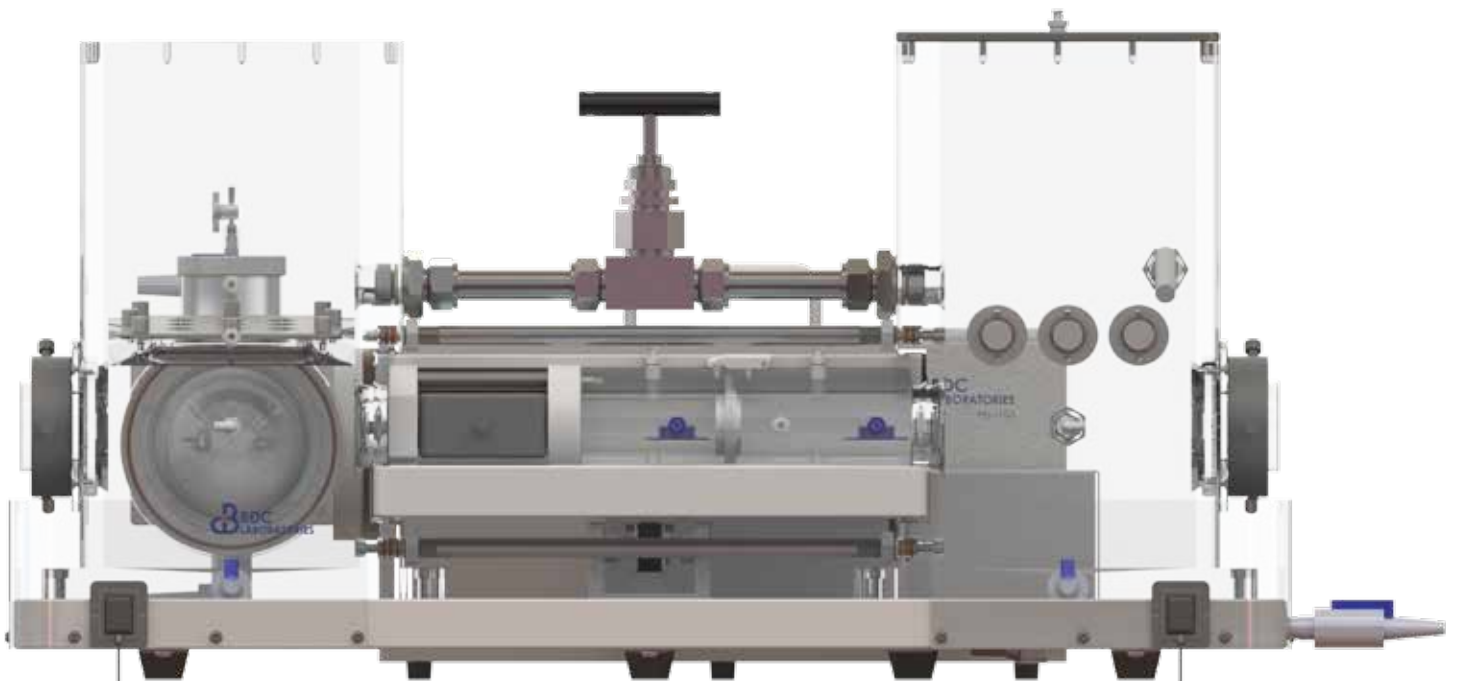
HDT-500



Medical Device Testing & Equipment • Simulation Platforms • Silicone Vessels

Backed by nearly 40 years of experience, the next generation pulse duplicator/pulsatile hydrodynamic test system from BDC Labs offers exceptional flow and pressure control, allowing ISO 5840 testing for heart valve prostheses, consistently and efficiently.

The HDT-500 system consists of four key components: the HDT-500 Test Apparatus, the PD-1100 Pulsatile Pump, the Data Acquisition System and the Statys® HDT software. Together, this fully-integrated system offers a performance level and operator experience unmatched by any other pulse duplicator test system. With its innovative Valve Exchange mechanism, the operator exchanges samples without the need to drain the system. The HDT-500 Test Apparatus simulates clinically accurate in vivo pulsatile flow conditions in a compact, closed-loop system allowing full user manipulation of flow, pressure, resistance, and temperature.



HDT-500 Pulse Duplicator, in aortic configuration

Highly repeatable hemodynamic flow conditions

The PD-1100 Pulsatile Pump forms the core of the HDT-500 test platform, acting as the driver for real-time pulsatile hemodynamic assessments of heart valves to meet regulatory requirements. With flow rates up to 10 L/min, the PD-1100 offers highly-repeatable and reproducible sinusoidal and arbitrary waveforms in conjunction with our Statys® HDT control and monitoring software.

All in one: Aortic, Mitral and Pulmonary valve testing

The dual chamber HDT-500 hydrodynamic tester is easily configurable for either aortic, mitral or pulmonary heart valve technologies, made possible by an ingenious Valve Assembly design. The HDT-500 can test the full range of heart valve candidates including mechanical, stented tissue, stentless and percutaneous valves. Real time pressure monitoring is accomplished by pressure transducers strategically located throughout the system and an almost infinite range of flow patterns can be created by the user.

Key Benefits of the HDT-500

- Test aortic, mitral or pulmonary valve candidates
- Exchange samples without draining the system
- Precise waveform control
- Flow measured by ultrasonic flowmeter
- Rapid system tuning
- View ports allow visualization from both inflow & outflow aspects
- Statys HDT control and monitoring software provides absolute control over flow, pressure and temperature
- The Valve Exchange Drawer facilitates rapid valve exchange, allowing high test throughput
- Test an LVAD with customization



Mechanical valve (open), viewed through Multipurpose Port on the HDT-500

Versatile Valve Exchange Drawer, VED

The Valve Exchange Drawer on the HDT-500 allows you to mount or exchange samples conveniently, without draining the whole system. In addition, the VED is the perfect sample mounting system for a variety of test samples and environments beyond classic heart valves. Valve conduits, heart valve repair devices, and technologies deployed within silicone mock vessels can all be conveniently mounted in the VED.

Delivering meaningful results with the powerful Statys® software package

The Statys® HDT Software provides a full suite of functionality for pulse duplicator testing, so you get meaningful answers, not just data.



Key Software Highlights

- Real time valve performance calculations and data monitoring
- Real time data capture with graphic output
- Posttest analysis tools and data archiving
- Pump output waveform control
- Alarm and safety features

Accessories

Multipurpose Ports, MpP

The HDT-500 offers two Multipurpose Ports located in line with the test valve on both the inflow and outflow aspects. These ports are exchangeable and facilitate the insertion of either optional glass viewing windows for exceptional sample visibility/photography, custom magnifying windows, or the implementation of hemostatic valves for real-time valve deployment in the system.

Heart Function Emulator, HFE

The HFE emulates contractile and resistive conditions of the heart, resulting in more clinically relevant flow waveforms and pressure profiles for cardiac valve testing. The HFE consists of an impedance element and compliance chambers.

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.



Sample test fixture with flow probe

Low Pressure Valve Module, LPV

The PVM consists of specific HDT-500 system elements for low pressure applications such as pulmonary valves, tricuspid valves, and venous valves.

Automated Drawer Activation, ADA

The ADA system allows the user to automatically open and close the Valve Exchange Drawer. This option is particularly useful when testing a large number of valves on regular basis.

Large Valve Drawer

The HDT-500 can evaluate a sample up to 65 mm in size. A Large Valve drawer is available for mounting valve samples up to 80 mm.

Extra-Large Valve Drawer

The HDT-500 can evaluate a sample up to 65 mm in size. An Extra-Large Valve drawer is available for mounting valve samples up to 95 mm.



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

HDT-500 Specifications

Valve type	aortic, mitral, pulmonary, tricuspid
Valve size	std: 65 mm; optional: 80, 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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