

Test Equipment

- TESTING SERVICES
- SILICONE VESSELS
- SIMULATION SOLUTIONS
- CONSULTING SERVICES

BDC LABORATORIES
A Tentamus Company

"BDC is a great, reliable contract laboratory. They exhibited great technical proficiency and tailored the test protocols to our specific samples. The customer service was exceptional as well. They worked with us to accommodate our timelines despite receiving a portion of the test samples last minute."

— Testing Services

"It was amazing to get to work with a responsive and intelligent vendor that can understand the specifications that we needed for this project. We took on a very technically difficult project without much room for error, and BDC put in all the extra effort necessary to delivery on our end project. Despite our tight timeline, BDC maintained a high standard of quality despite heavy pressures to release something quickly, and ultimately we got a better end result because of that attitude."

— Test Equipment

"InnerPulse is a small company engaged in the development of a cardiac rhythm management device implanted in the thoracic cavity. The novel design and implant location of the device meant that standard reliability testing equipment was not applicable. Custom equipment designed from scratch would be required. Working with BDC, we were able to quickly build a test fixture that simulates the thoracic cavity. Our collaboration with BDC was productive from the start. BDC was clearly well versed in the mechanical and electrical design of custom testing equipment, the construction of mock vessels, and the human anatomy relevant to our project."

— Simulation Solutions

BDC LABORATORIES
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CMDC
CARDIOMED DEVICE CONSULTANTS
A Tentamus Company

FROM CONCEPT TO MARKET

Serving medical device manufacturers worldwide, BDC Laboratories and CardioMed Device Consultants deliver comprehensive support across the total product lifecycle of Class II and III medical devices.

UNIQUELY COMPREHENSIVE SERVICE

Medical device manufacturers worldwide have relied on BDC Laboratories and CardioMed Device Consultants to navigate every stage of the product lifecycle, from concept through device approval and market launch. Few partners can offer this breadth of regulatory and testing support under one roof. With more than 200 years of combined experience, our teams support medical device development with a rare pairing of technical precision and regulatory insight — all under one coordinated engagement.

Our collaboration means: We work with your team throughout the full product development cycle.

From early design through submission, CardioMed leads the regulatory consulting and develops a testing approach and plan, drawing on a team of former FDA employees who know the ins and outs of the approval process.

BDC works from initial feasibility testing through regulatory submission and into production tests. Active participation in AAMI, ISO, and ASTM standards committees gives the BDC team unique insight into developing plans and protocols for FDA and CE Mark submissions.

WE BECOME AN EXTENSION OF YOUR TEAM

CardioMed + BDC acts as a force multiplier. With large organizations, this means we work with in-house regulatory and R&D teams. With small companies and startups, CardioMed + BDC become the team that takes care of regulatory strategy and testing services.

Our combined expertise and experience make us agile in bringing novel technologies to market.

Novel devices carry distinct regulatory complexity and can take three to ten years to reach market depending on risk class and device classification. You need a team who has seen it all to help guide you through this complex process.

We serve a wide range of customers, from start-ups to multinational corporations.

Organizations with vastly different resources have different requirements for regulations and testing support. We understand the obstacles you will face and the best ways to overcome them.

COMPLEMENTARY EXPERTISE

CardioMed Device Consultants

- FDA regulatory strategy and submission support
- Guidance on FDA preclinical testing requirements (Class II and Class III)
- Expertise from former FDA CDRH reviewers
- Specialized support for startups and international manufacturers
- Broad spectrum of technologies, including endovascular devices and digital health solutions

BDC Laboratories

- Mechanical and functional device testing
- Regulatory submission testing (Class II and III)
- Custom test protocols, equipment and simulation systems
- Comprehensive device testing reports
- GLP compliant
- ISO/IEC 17025 accredited

VDT-3600i Heart Valve Accelerated Durability



BDC Laboratories' VDT-3600i heart valve durability tester is a patented, accelerated wear test system for evaluating transcatheter & surgical aortic, mitral, pulmonary and tricuspid valves to ISO 5840 requirements. The system has 6 completely independent stations, incorporating 6 drivers that allow each station to be controlled independently. The VDT-3600i system moves fluid through the test valve, producing kinematics representative of clinical response at frequencies up to 50 Hz.

The VDT-3600i system is controlled and monitored by our Statys® VDT software. Among the unique features integrated into the software: complete excitation waveform control; differential pressure loading analyzer; active, closed-loop control on valve loading; real-time monitoring of differential pressure for all stations; and individual station alarms for continual monitoring.

BENEFITS & FEATURES

- Six independent test stations with six independent drivers:
  - Test different size heart valves simultaneously
  - Test different heart valve configurations simultaneously
  - Independently control each station's excitation waveform, frequency and stroke conditions
- Differential pressure loading analyzer for each station to determine adherence to ISO 5840 requirements, with loading criteria cycle counter
- Closed-loop, autopilot control to desired differential pressure loading on each station
- Simultaneous continual monitoring and logging of the real-time differential pressures of all test stations
- Real-time alarms and safeguards to protect both the test samples and test system

KEY SPECIFICATIONS

Sample Capacity	1 to 6
Sample Size	Up to 95 mm
Drive Waveforms	Sine, Modified Sine, & arbitrary (optional)
Frequency*	5 Hz (300 cpm) to 50 Hz (3000 cpm)
Max Differential Pressure	500 mmHg
Fluid Temperature	Room to 50° C

**Actual frequency dependent upon specific test article.*

RWT-4600i Heart Valve Real-Time Durability



BDC Laboratories' RWT-4600i heart valve real-time wear tester possesses the highly unique ability to operate both as a real-time wear and accelerated wear test system, adhering to ISO 5840 requirements in both applications. The RWT-4600i accommodates transcatheter and surgical, aortic, mitral, pulmonary and tricuspid valves. The system has 6 completely independent stations, incorporating 6 drivers that allow each station to be controlled independently.

The RWT-4600i system is controlled and monitored by our Statys® RWT software. Among the unique features integrated into software: complete excitation waveform control; differential pressure loading analyzer; active, closed-loop control on valve loading; real-time monitoring of differential pressure for all stations; and individual station alarms for continual monitoring.

BENEFITS & FEATURES

- Ability to operate at both real-time (<200 bpm) and accelerated frequencies (5 to 50 Hz)
- Six independent test stations with six independent drivers:
  - Test different size heart valves simultaneously
  - Test different heart valve configurations simultaneously
  - Control of each station's excitation waveform, frequency and stroke independently
- Differential pressure loading analyzer for each station to determine adherence to ISO 5840 requirements, with loading criteria cycle counter
- Closed-loop, autopilot control to desired differential pressure loading on each station
- Simultaneous continual monitoring and logging of the real-time differential pressures of all test stations
- Real-time alarms and safeguards to protect both the test samples and test system

KEY SPECIFICATIONS

Sample Capacity	1 to 6
Sample Size	Up to 95 mm
Drive Waveforms	Sine, Modified Sine, & Arbitrary (optional)
Frequency*	2 Hz (120 cpm) to 50 Hz (3000 cpm)
Max Differential Pressure	500 mmHg
Fluid Temperature	Room to 50° C

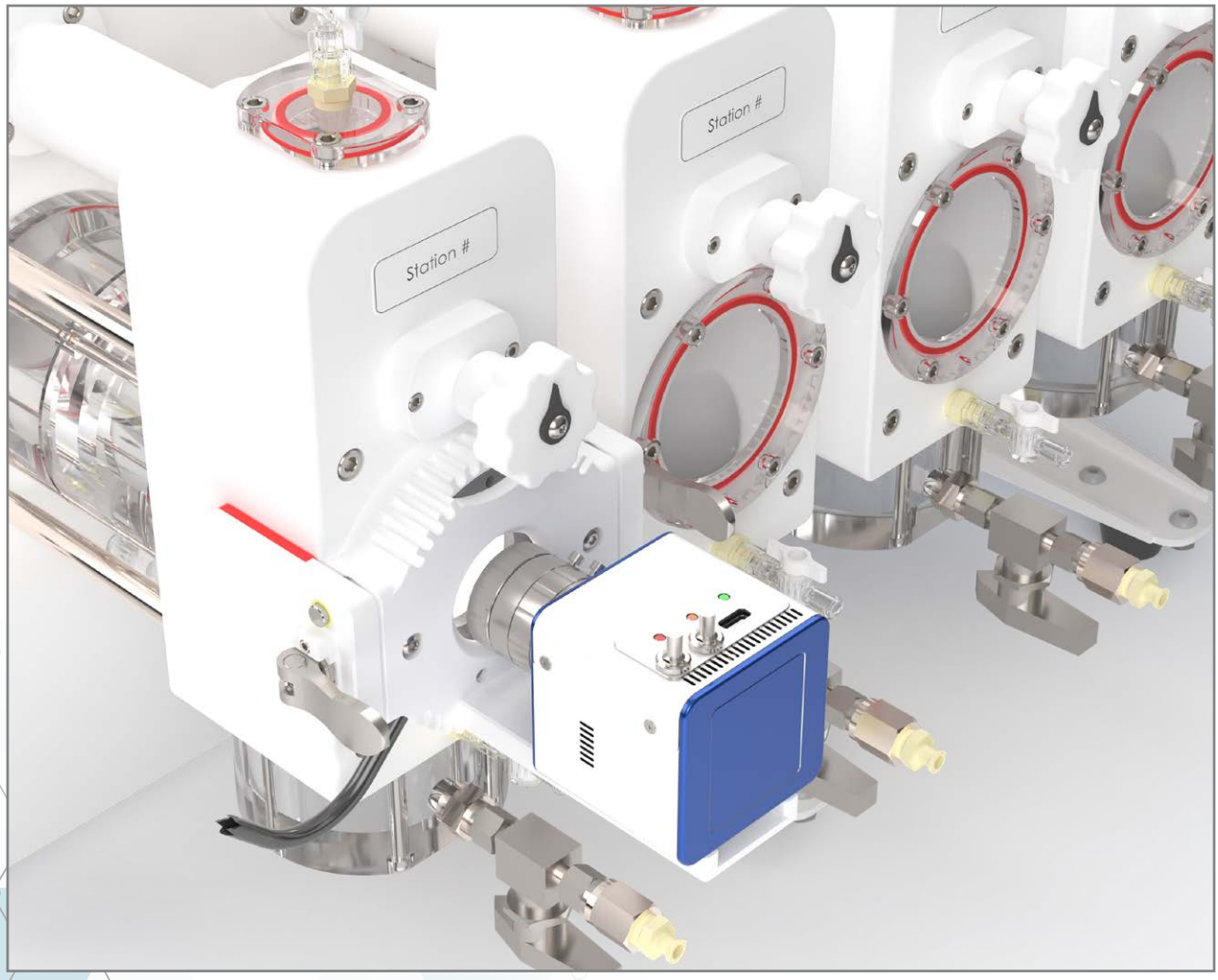
**Actual frequency dependent upon specific test article.*

Integrated Imaging and Real-Time GOA Measurement (Optional)

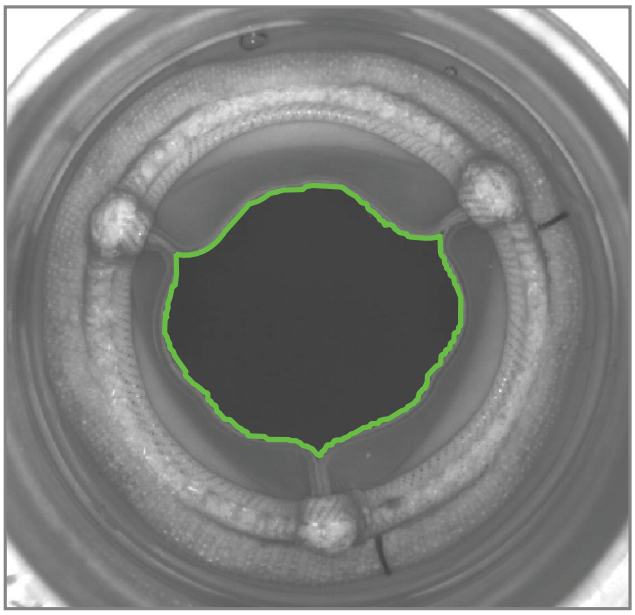
This software option for the VDT-3600i Heart Valve Durability System and RWT-4600i Heart Valve Real-Time Wear System improves test setup and initiation, data processing, data management, and reporting.

The optional integrated imaging upgrade adds a high-speed camera, dedicated lighting and mounting, and image-processing capabilities for real-time geometric orifice area (GOA) measurement. The software and hardware work together to incorporate GOA analysis into the active heart valve durability test environment.

The upgrade enables measurement of leaflet kinematics, including fully open and closed states, during durability testing. Engineers can calculate GOA in real time, visualize leaflet response during initial setup, and adjust valve opening to support optimized loading. GOA measurements are also integrated into report outputs, reducing manual data handling and supporting complete study documentation.



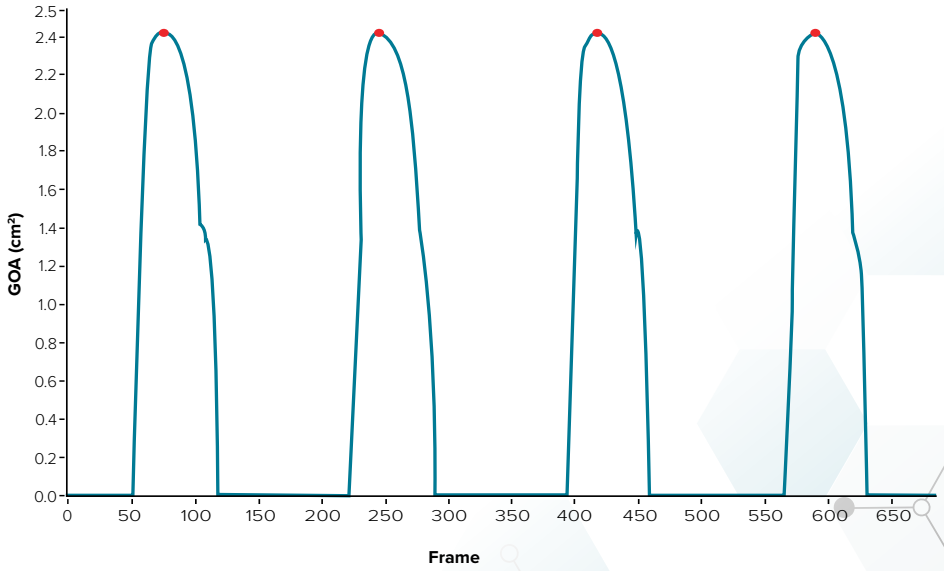
Statys® GOA

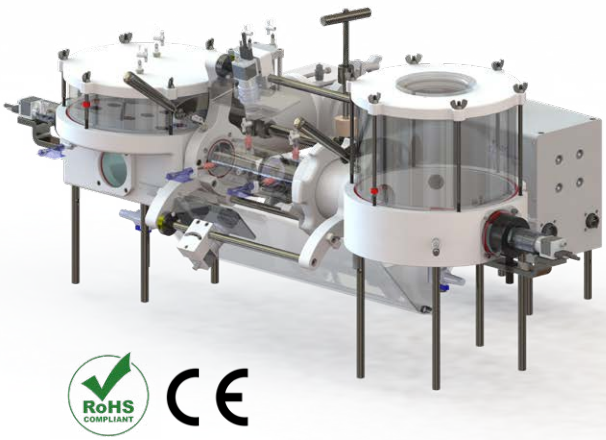


In performance testing of prosthetic heart valves, measurement of Geometric Orifice Area (GOA) is an advantageous tool for characterizing leaflet kinematics in both hydrodynamic and accelerated wear testing. BDC Laboratories' Statys® GOA software takes this technically challenging analysis and packages it in a robust and easy-to-use software program. Statys® GOA imports both high-speed video and static image files, facilitates calibration of the image(s), automatically analyzes all video frames or static images, overlays the identified boundary on all frames, and determines the GOA for all images. With this software, quantitative comparison of heart valve leaflet opening area between pulsatile and accelerated wear testing can be performed efficiently and accurately.

BENEFITS & FEATURES

- Intuitive and easy-to-use software interface
- Automated leaflet tracking throughout cardiac cycle
- Multiple algorithms available to tailor analysis for image quality
- Adjustable masking for fine tuning of GOA determination
- Maximum GOA identified and reported for each cycle, facilitating statistical analyses
- Direct comparison to a user-defined reference GOA for rapid conclusions
- Automated report generation for archiving of analysis and results





HDTi-6000 Heart Valve Pulse Duplicator

BDC Laboratories' HDTi-6000 heart valve pulse duplicator complies with ISO 5840 requirements, while possessing the innovative ability of integrating high-speed video. The HDTi-6000 accommodates both surgical and transcatheter heart valves, configurable to either left-heart or right-heart for evaluation of all valve positions (i.e. aortic, mitral, pulmonary, tricuspid).

The accompanying Statys® HDTi software offers absolute control over the pulse duplicator, while seamlessly integrating high-speed cameras for both live and post-test video review. Included is the highly desirable ability to playback the video, synchronized to the pressure and flow waveforms, to comprehensively assess the heart valve's response at any point in the cardiac cycle. The embedded Statys® HDTi analysis tools provide a simple and effective means to determine all ISO 5840 noted parameters.

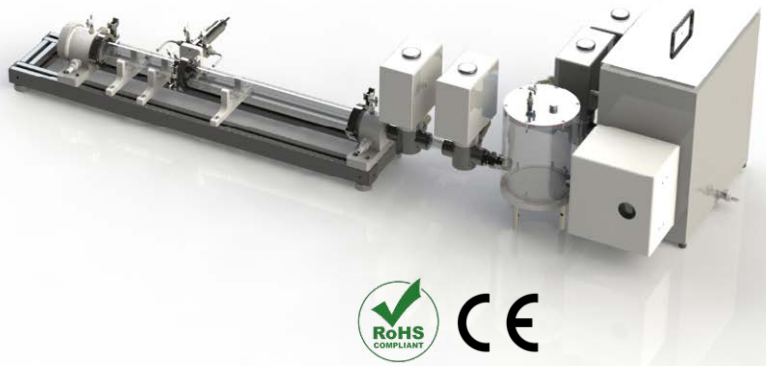
BENEFITS & FEATURES

- Integrated High Speed Video (up to 5 cameras):
  - Integrated high-speed cameras eliminates the need for secondary video systems
  - Video playback with synchronized pressure and flow waveforms provide the ultimate platform for investigation and analysis
- Linear Clamp Operation:
  - Exchanging the heart valve test article occurs without draining the system
  - Facilitates quick and simple exchange of the heart valve test article, increasing productivity
- Integrated data collection and analysis tools to determine all ISO 5840 and FDA required test parameters
- Sinusoidal or arbitrary waveform excitation permits accurate simulation of clinical performance
- System PD-1100 pulsatile pump facilitates precise control with high repeatability and reproducibility

KEY SPECIFICATIONS

Valve Type	Aortic, mitral, pulmonary, tricuspid
Valve Size	Up to 95 mm
Frequency	2 to 240 bpm
Flow Rate	1 to 10 L/min
Flow Monitoring	Ultrasonic technology
Fluid Temperature	Room to 50° C

SFT-1000 Heart Valve Steady Flow



BDC Laboratories' patented SFT-1000 heart valve steady flow hydrodynamic test system achieves all ISO 5840 conditions for both forward flow pressure drop and back flow leakage assessments without the need to remove the valve under test, or change its orientation. This unique ability presents an extremely streamlined and efficient test environment for maximum productivity. The SFT-1000 is available either in a manual configuration or as a fully automated test apparatus.

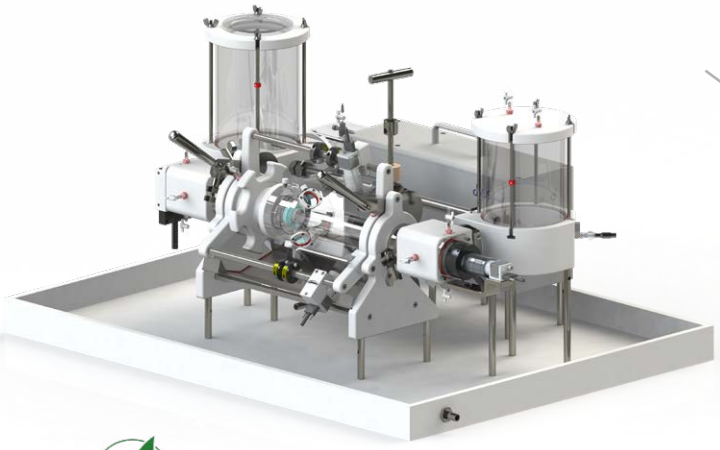
The Statys® SFT software provides a comprehensive interface to program the specific test conditions, as well as present all data real-time throughout the entire test cycle. With high fidelity closed-loop pump control, the SFT-1000 test system will automatically execute each condition precisely, while cycling through all programmed flow rates and/or back flow pressures until the evaluation is complete.

BENEFITS & FEATURES

- Evaluate both forward flow pressure drop and back flow leakage without removing or changing the valve
- Test fluid is maintained within the system and circulated to maintain temperature between tests
- Individual user input test parameters for both forward flow pressure drop and back flow leakage
- Automated execution of all input test parameters with closed-loop control
- Real-time presentation of test results (pressure drop, EOA, back flow leakage rate) for each test condition
- Auto-generated reports with all relevant data for efficient documentation of each test

KEY SPECIFICATIONS

Valve Type	Aortic, mitral, pulmonary, tricuspid
Inflow/Outflow Diameter	25 mm, 35 mm (standard), Custom sizes available
Flow Rate	1 to 35 L/min
Back Pressure	5 to 300 mm Hg
Fluid Temperature	Room to 50° C



PQT-5000 Heart Valve Production

BDC Laboratories' PQT-5000 pulsatile heart valve functional performance test system is designed specifically for the cleanroom production environment. This highly advanced pulse duplicator integrates key attributes such as rapid valve exchange for high throughput, multiple integrated high-speed cameras to visualize leaflet kinematics and quick-release connections for ease of disassembly during sterilization.

The PQT-5000 system is controlled and monitored by the 21 CFR Part 11 compliant Statys® PQT software. Through this state-of-the-art software platform, the heart valve performance is assessed against a battery of user-defined QA performance metrics, providing a clear pass-fail result in a rapid, reliable and consistent manner. The assessment parameters are customizable and can include, among others: forward flow pressure drop, regurgitant fraction, effective orifice area (EOA), geometric orifice area (GOA), central jet area and leaflet pinwheel.

BENEFITS & FEATURES

- Highly versatile for customization and evaluation of all heart valve technologies
- Integrated High Speed Video (Up to 5 cameras):
  - Integrated high-speed cameras eliminates the need for secondary video systems
  - Provides comprehensive analysis of valve kinematics
- Linear Clamp Operation:
  - Exchanging the heart valve test article occurs without draining the system
  - Facilitates quick and simple exchange of the heart valve test article
- Test system is fully compatible with chemical sterilization
- Three levels of system login & operation: Operator, Engineer and Administrator
- Integrated test article pass/fail/undetermined selectable indicators
- 21 CFR Part 11 compliant with automatically generated test reports

KEY SPECIFICATIONS

Valve Type	Aortic, mitral, pulmonary, tricuspid
Sample Size	Up to 80 mm
Frequency	30 to 190 bpm
Flow Rate	1 to 10 L/min
Flow Monitoring	Ultrasonic technology (optional)
Fluid Temperature	Up to 50° C



RDT-7600i Stent / Stent Graft Radial Durability

The RDT-7600i is a true “set it and forget it” radial fatigue and durability test system meeting ASTM F2477 requirements, with the dynamic diametric strain of each station automatically measured by an optical micrometer. During operation, the micrometer moves to predetermined locations on all test samples to measure and document their strain at a defined number of cycles. Therefore, the RDT-7600i system eliminates the need for an operator to manually interface with the system, rotate manifolds, and measure the diametric strain throughout a 400 million cycle test.

Moreover, the RDT-7600i is the first radial durability system to offer independent test station control to facilitate tuning of each individual sample’s diametric strain. An added benefit of test station independence is that each station can evaluate samples of different diameter and length concurrently.

The test system software that accompanies the RDT-7600i allows the operator to set a test station to its desired conditions. The system will then automatically measure and document the sample’s diametric strain at the desired locations at the prescribed interval. If the strain is found to be outside the target condition, the system software will adjust that station to return it to the correct test conditions before moving to the next sample.

BENEFITS & FEATURES

- Automated measurement and documentation of diametric strain, with automated adjustment of station parameters eliminates the need for operator interactions throughout an entire study
- Independent test stations facilitates individual station tuning and the evaluation of different diameter and length samples on the same test system concurrently
- Integrated, real-time outer diameter to inner diameter calculation based on both ASTM and ISO relationships
- Real-time alarms and safeguards to protect both the test samples and system
- As a self-contained test system, it requires a smaller footprint than existing equipment, maximizing the usage of valuable laboratory space

KEY SPECIFICATIONS

Sample Capacity	1 to 12
Test Frequency*	1 to 80 Hz
Sample Diameter	2.5 to 50 mm
Sample Configuration	Straight, Bifurcated, ‘U’, Angled/Bend, Aneurismal
Diameter Measurement	Optical micrometer
Fluid Temperature	Up to 50° C

**Actual frequency dependent upon specific test article.*



RDTL-0200 Stent / Stent Graft Radial Durability

BDC Laboratories' RDTL-0200 radial durability test system incorporates our patented Dual-Drive Emulator™ technology which produces concurrent pressurization of the mock vessel from both ends with every cycle. Designed for adaptability, the RDTL-0200 system utilizes exchangeable manifolds to facilitate evaluation of smaller technologies (e.g. coronary stents) and large technologies (e.g. thoracic endografts) on the same system to ASTM F2477 requirements.

The accompanying test system software, Statys® RDT, provides a single operator-focused, control and monitoring test interface. Integrated features such as real-time outer diameter to inner-diameter conversion, closed-loop driver control to key test parameters and continual monitored system alarms ensure each test is executed in an efficient and controlled manner.

BENEFITS & FEATURES

- Exchangeable System Manifolds:
  - One RDTL-0200 system can be utilized for many sample diameters, lengths and configurations by simply changing test system manifolds
- Dual-Drive Emulator™ technology pressurizes both vessels ends concurrently with a single test system driver
- Integrated, real-time outer diameter to inner diameter calculations based on both ASTM and ISO relationships
- Autopilot, closed-loop control to maintain consistent test sample diametric strain
- Real-time alarms and safeguards to protect both the tests samples and system

KEY SPECIFICATIONS

Sample Diameter	2.5 to 50 mm
Test Frequency*	1 to 80 Hz
Sample Configuration	Straight, Bifurcated, 'U', Angled/Bend, Aneurismal
Diameter Measurement	Optical micrometer or high-speed imaging
Fluid Temperature	Up to 50° C

**Actual frequency dependent upon specific test article.*



LDT-1800 Uniaxial Fatigue System

BDC Laboratories' LDT-1800 Uniaxial Fatigue System is a test instrument used for mechanical fatigue, durability and dynamic characterization of materials, coupons and devices. The LDT system employs efficient and low friction electromagnetic technology to provide a wide range of test frequencies at displacements up to 30 mm. The system is controlled with BDC Laboratories' Statys® LDT control and monitoring software that provides a powerful and versatile platform for comprehensive test management.

The optional Multi-Station Fixture Assembly is constructed with independent test station adjustability and optional dynamic load measurement that enables the operator to easily preload and monitor each test station independently for general response and fracture detection. Through a standard mounting interface, the Multi-Station Fixture can be configured for numerous test sample configurations and geometries. When combined with BDC Laboratories' TCU-1 Heated Circulator Bath, test samples can be fully immersed in solution and evaluated at a stable 37° C.

BENEFITS & FEATURES

- Cost effective solution for precision fatigue studies
- 50nm position encoder for highly accurate and repeatable cycling
- Moving magnet driven technology for efficient thermal management
- Simultaneous, continual monitoring and logging of all real-time data
- Real-time alarms and safeguards to protect both the system and test samples
- Optional Multi-Station Fixture Assembly with fully integrated individual sample dynamic load measurement for fracture detection and hysteresis characterization

KEY SPECIFICATIONS

Peak Force	1000 225	N lbf
Stall Force	500 112	N lbf
Displacement	30 1.18	mm in
Frequency	0.1-100	Hz
Power Requirements	120/8 230/5	VAC/ A Max VAC/ A Max



TT-2600i Torsion Fatigue & Durability

The TT-2600i torsion fatigue and durability test system applies cyclic, twisting deformation at frequencies up to 50 Hz with independent control of each of the six test stations. Primarily designed for evaluation of vascular stents and stent grafts, torsional fatigue and durability studies can be conducted in full compliance with ASTM F2942.

The unique design of the TT-2600i test system facilitates the evaluation of a wide range of test sample configurations, including straight geometry and curved vessels representative of an aortic arch. When combined with BDC's TCU-1 heated circulator bath, all samples can be immersed in solution and maintained at 37 °C throughout the study.

The accompanying Statys® TT control and monitoring software provides a single interface for closed-loop test system control, monitoring, and data management. The Statys® TT platform presents operator-focused intuitive controls, tabular and graphical data displays, and sample monitoring safeguards to ensure studies are executed with absolute control.

BENEFITS & FEATURES

- Fully independent test stations, allowing separate control of twist angle and frequency at each station.
- Utilization of an optics breadboard platform facilitates testing of countless geometries and configurations.
- Integration of rotational encoders and visual protractors enables precise control and verification of dynamic, real-time twist angle.
- Dedicated software combines test system control, sample monitoring, and data logging in one operator friendly interface.

KEY SPECIFICATIONS

Angular Rotation	0 to 180 degrees
Operating Frequency	1 Hz to 50 Hz*
Sample Configuration	Straight, Angled/Bend
Driving Waveform	Sinusoidal
Number of Samples	1 to 6 samples
Temperature	Room to 50°C**

**Actual test frequency is dependent upon sample size / configuration*
***Elevated temperature requires inclusion of TCU-1 heated circulation bath*



MMT-1200 Multi-Mode Test System

BDC Laboratories developed the MMT-1200 to accurately evaluate stents and stent grafts deployed in regions of complex vascular motion such as carotid, superficial femoral, and femoropopliteal arteries. This 12-station test system delivers dynamic axial compression/tension, bending, and torsion – individually or in any simultaneous combination – at an accelerated rate. Customizable bend mandrels allow for matching the bending radius of curvature precisely to *in vivo* conditions, with the ability to define the location of bending along the sample's length. The MMT-1200 system is compliant with the fatigue and durability requirements of ASTM F2942, ISO 25539-1, and ISO 25539-2 standards for endovascular devices, and can accommodate both non-overlapped and overlapped devices.

The MMT-1200 system is powered by Statys® MMT, an intuitive, operator-focused software interface built for precise control and real-time monitoring. Live tabular and graphical data displays, comprehensive data logging (statistical and temporal), and configurable monitoring alarms work together to ensure every test is tightly controlled, fully verified, and thoroughly documented. As with all BDC test system software, historical test data is displayed alongside real-time data for trending an active study at a glance, without leaving Statys® MMT for a secondary analysis tool.

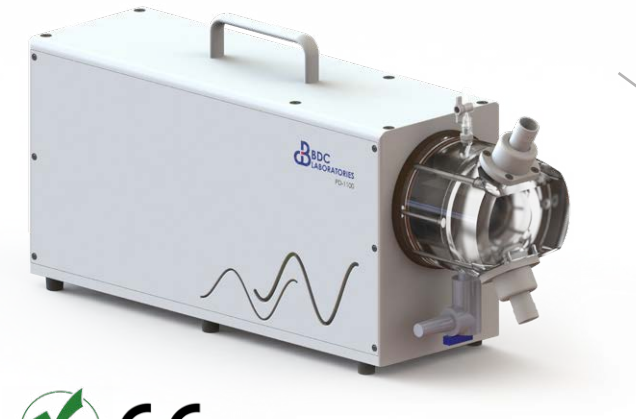
BENEFITS & FEATURES

- **Dedicated Software:** Dedicated software combines test system control, sample monitoring, and data logging in one operator friendly interface.
- **Flexibility:** Test up to 12 samples simultaneously with customizable bend mandrels. verification of dynamic, real-time twist angle.
- **Multiple Conditions:** Replicates dynamic axial compression/tension, bending, and torsion independently in simultaneous combinations.

KEY SPECIFICATIONS

Sample Capacity	1 to 12
Operating Frequency	0.5 Hz to 2.5 Hz*
Test Sample Diameter	2.5 mm to 50 mm
Sample Length	10 mm to 300 mm
Axial Displacement	100 mm-
Bend Angle	±90°
Twist Angle	±60°
System Temperature	Up to 40° C

**actual frequency is dependent upon specific test conditions*



PD-1100 Pulsatile Pump

BDC Laboratories' PD-1100 pulsatile pump system provides a highly versatile, reliable and repeatable pulsatile source for accurately simulating physiological hemodynamics in vitro, in both industry and academic environments. The numerous applications of the PD-1100 include: ex-vivo beating heart models, simulated use platforms, pulse duplicators, particle image velocimetry (PIV) systems, bioreactors and physician training platforms.

The PD-1100 accompanying software, Statys® PD, provides an exceptionally effective, operator-based control and monitoring environment that enables full engagement with all the pump system's capabilities. Integrated in the software is comprehensive driving waveform definition, which is interfaced either through an adjustable built-in controller, or an integrated custom waveform creator tool. Too numerous to list, the extensive hardware and software accessories facilitate tailoring each PD-1100 pump system for its application, yielding unmatched performance in all pulsatile flow applications.

BENEFITS & FEATURES

- Extensive accessories tailor the PD-1100 system to any technology and test platform for structural heart, cardiovascular, endovascular and vascular applications
- Fully digital software-based interface for precise and accurate pump control
- Sinusoidal or arbitrary waveform driver excitation to accurately simulate clinical hemodynamics
- Closed-loop pump control provides superior beat-to-beat repeatability and reproducibility
- Integrated data collection for real-time viewing of test parameters in multiple graphical and tabular layouts
- All measurement signals acquired in high-fidelity for detailed review and analysis
- Operator-focused software environment facilitates ease of system operation

KEY SPECIFICATIONS

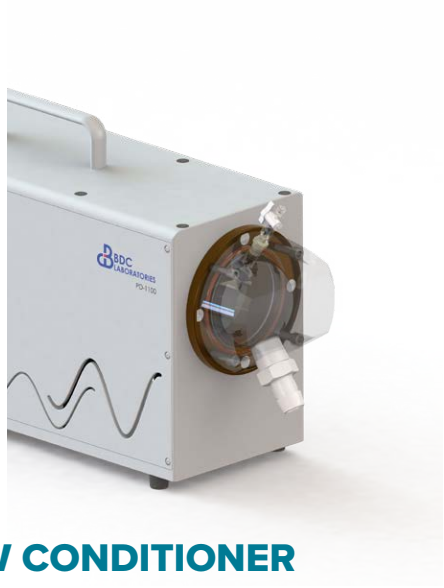
Frequency	10 to 240 bpm
Test Fluid	Water, Phosphate Buffered Saline, Saline, Blood Analog
Stroke volume	0 to 50 ml (small piston) 0 to 290 ml (regular piston) 0 to 450 ml (large piston)
Flow Rate	0 to 2 L/min (small piston) 0 to 10 L/min (regular piston) 0 to 25 L/min (large piston)
Driving **Waveform**	Sinusoidal, Arbitrary
Synchronization	TTL and analog

PD-1100 Fluid Management Options



PULSATILE PUMP HEAD

The Pulsatile Pump Head enables the PD-1100 to function as a positive displacement pulsatile pump. Featuring a barbed inflow and outflow port, both with one-way valves, and self-priming performance, the Pulsatile Pump Head allows convenient inclusion into a fluid loop.



OSCILLATING FLOW PUMP HEAD

The Oscillating Flow Pump Head provides a means for the PD-1100 to function as a oscillating flow source. With a single, large diameter inflow/outflow connection, the Oscillating Flow Pump Head provides the appropriate interface when used with ex-vivo beating heart models.



HEMODYNAMIC FLOW CONDITIONER

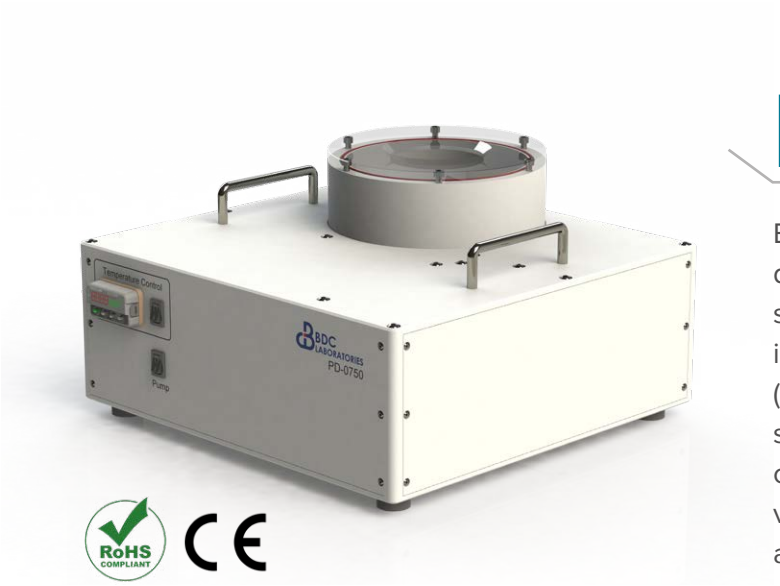
The Hemodynamic Flow Conditioner is an all-in-one addition to the PD-1100 that emulates the vascular bed. The Conditioner has integrated directional valves, a fluid reservoir, a compliance chamber, a resistance element and an optional heater.

HEART FUNCTION EMULATOR, HFE

The Heart Function Emulator is connected to the pulsatile flow pump and serves to emulate the contractile and resistive conditions of the heart, resulting in a more clinically relevant flow and pressure source for cardiac applications. The HFE consists of an impedance element and compliance chambers. The compliance volumes can be adjusted to tune the shape of the flow waveforms.



**Additional options available. Please visit BDCLabs.com*



PD-0750 Portable Pulse Duplicator

BDC Laboratories' PD-0750 portable pulse duplicators provide a compact pulsatile flow source for heart valve applications, with integrated heating and system compliance (mitral & tricuspid models). This portable system presents a partial beating heart that operates in concert with your specific heart valve prosthesis, with PD-0750 models available for aortic, mitral, tricuspid and pulmonary valve applications.

The PD-0750 portable pulse duplicator can be conveniently integrated with BDC Laboratories' simulation solutions or other simulated use test systems requiring pulsatile flow for an extensive array of applications including: device and delivery system testing, marketing and sales demonstrations and physician training.

BENEFITS & FEATURES

- Setup and ready for operation in minutes, with minimal training required, the PD-0750 is very well suited for marketing & sales applications, as well as physician training
- With integrated heating and systemic compliance on some models, the only additional hardware required is the specific test apparatus and collateral valve under test
- Compact and at a modest weight, the system is well suited for applications that require mobility
- Transportation can be accomplished either as checked as luggage for airline travel or shipped in a custom hard-shell case

KEY SPECIFICATIONS

Frequency	60 to 90 bpm
Test Fluid	Water, Phosphate Buffered Saline, Saline, Blood Analog
Flow Rate	1.5 to 5 L/min
Max Pressure	200 mm Hg
Driving Waveform	200 mm Hg
Temperature	Room to 40° C



PD-0500 Portable Pulse Duplicator

BDC Laboratories' PD-0500 portable pulse duplicator provides a compact, left-heart or right-heart pulsatile flow source with integrated heating and system compliance. The PD-0500 is very easy to setup and operate, and designed to drive cardiovascular, endovascular and vascular techology's pulsatile flow systems.

The PD-0500 portable pulse duplicator can be conveniently integrated with BDC Laboratories' simulation solutions or other simulated use test systems requiring pulsatile flow for an extensive array of applications including: device and delivery system testing, marketing and sales demonstrations and physician training.

BENEFITS & FEATURES

- Setup and ready for operation in minutes, with minimal training required, the PD-0500 is very well suited for marketing & sales applications, as well as physician training
- With integrated heating and systemic compliance, the only additional hardware required is the specific vasculature
- Compact and at a modest weight, the system is well suited for applications that require mobility
- Transportation can be accomplished either as checked luggage for airline travel or shipped in a custom hard-shell case

KEY SPECIFICATIONS

Frequency	60 to 90 bpm
Test Fluid	Water, Phosphate Buffered Saline, Saline, Blood Analog
Flow Rate	1.5 to 5 L/min
Max Pressure	200 mm Hg
Temperature	Room to 40° C



PD-0250 Portable Oscillating Pump

BDC Laboratories' PD-0250 portable oscillating pump provides a compact, purely oscillating flow source for applications requiring a dynamic flow environment. When coupled with valved technologies, the PD-0250 is a reliable driver that facilitates highly repeatable opening and closing dynamics of test articles.

The PD-0250 utilizes a diaphragm-based drive mechanism that results in very low maintenance and highly reliability. Applications for this fluid oscillating pump include: physician training systems, production qualification systems and sales demonstration models.

BENEFITS & FEATURES

- The PD-0250 is read for operation in minutes, with minimal training required
- Driven with diaphragm technology, the system operates with low maintenance and high reliability
- Compact and light weight, the system is well suited for applications that require mobility
- Transportation can be accomplished either as checked luggage for airline travel or shipped in a custom hard-shell case

KEY SPECIFICATIONS

Frequency	60 to 90 bpm
Test Fluid	Water, Phosphate Buffered Saline, Saline, Blood Analog
Stroke Volume	30 to 59 ml
Max Pressure	300 mm Hg



TCU-1 Heated Circulator Bath

BDC Laboratories' TCU-1 is a heated circulator bath that creates stable thermal control for any fluid test environment. This saline compatible system has the unique ability to monitor and control to either the fluid temperature within the bath or a remotely measured temperature in the associated test chamber.

Designed for continual operation with an integrated pump, the TCU-1 heating circulator can be utilized for numerous applications that require reliable and tight thermal stability. Common applications for this system include: fluid baths for fatigue test systems, heat exchangers for bioreactors and controlling fluid temperature in simulated use systems and universal tester fluid baths.

BENEFITS & FEATURES

- Compatible with saline solutions to facilitate a wide range of heating applications
- Fluid temperature controlled to either the bath temperature or a remote thermometer located in the test chamber
- As a completely closed system, the TCU-1 can be placed below, at or above the height of the test region without the risk of overflow
- An integrated pump provides for reliable circulation from the heated reservoir to the test chamber without interruption during continual operation over months at a time
- Multiple safety features prevent the bath from exceeding the desired operating temperature

KEY SPECIFICATIONS

Temperature Range	Room to 50° C
Reservoir Volume	1.7 L (0.45 Gal)
Test Fluid	Water, Phosphate Buffered Saline, Saline, Blood Analog
Max Flow Rate	200 mm Hg



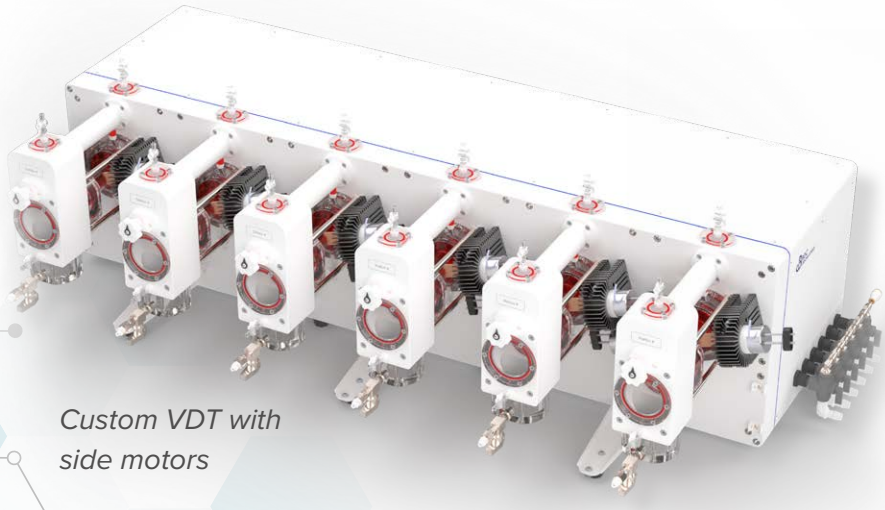
Biosimulator with human shell

Custom Equipment

No two devices are alike, and standard test platforms don't always fit a novel design. When a project calls for something outside our existing product line, BDC Laboratories' engineering team designs, builds, and validates custom equipment — from targeted modifications of proven platforms to fully turnkey systems built from the ground up.

BENEFITS & FEATURES

- Custom design tailored to a specific test article or clinical scenario
- Modification of existing BDC platforms (VDT, RWT, RDT, and others) to accommodate non-standard geometries, loading conditions, or measurement needs
- Full turnkey system design and build for applications with no existing equipment precedent
- Deep working knowledge of human anatomy, physiological loading, and implant environments
- Collaborative process — from concept and specification through fabrication, validation, and delivery
- Experience spanning cardiac, structural heart, endovascular, and vascular applications



Custom VDT with side motors



Eye implant fatigue test system

BDC LABORATORIES
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CAPABILITIES



TESTING SERVICES

Comprehensive ISO/IEC 17025:2017 Accredited testing services for regulatory submissions or R&D on a vast array of medical device technologies



TESTING EQUIPMENT

Cardiovascular, structural heart and endovascular test systems with superior control and adaptability for durability, fatigue and bench testing applications



SILICONE VESSELS

Certified silicone mock vessels for durability testing and silicone models for simulation and R&D activities in all geometries, as well as patient-based datasets



SIMULATION SOLUTIONS

Standard or custom turnkey simulation systems that include clinically relevant vascular pathways and hemodynamics for device development and physician training



CARDIOMED

Regulatory, clinical, pre-clinical and quality system consulting for Class II and Class III medical devices through the complete product life cycle

To learn more about BDC's full range of capabilities and equipment, visit **BDCLabs.com** or call **303.456.4665**

Questions?

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