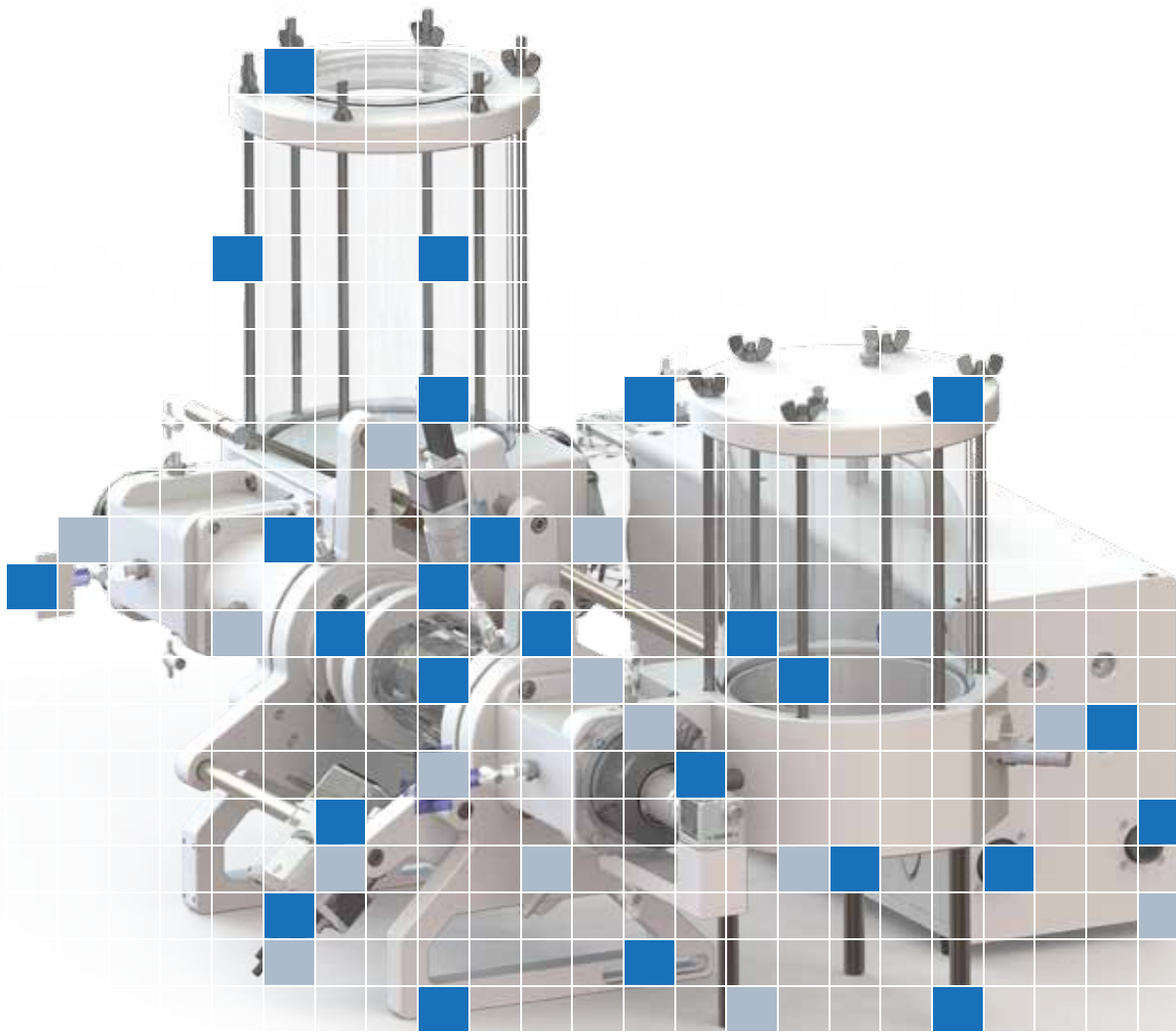


The New Criterion

Heart Valve Production Quality Test System



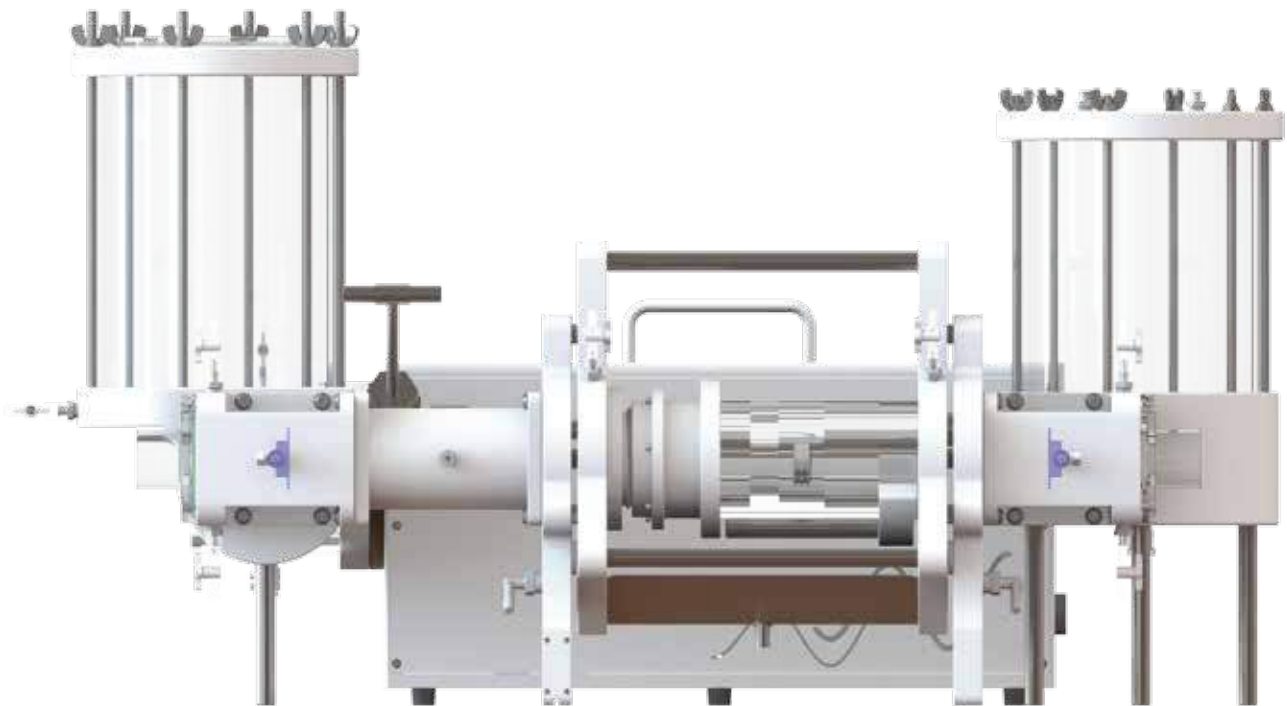
PQT-5000



Medical Device Testing & Equipment • Simulation Platforms • Silicone Vessels

Featuring technology distilled from years of testing the most advanced heart valve prostheses in the world, the PQT-5000 Heart Valve Production Quality Testing System from BDC Labs is the new criterion against which all production QA heart valve testing systems will be evaluated.

The PQT-5000 is a pulsatile flow hydrodynamic system designed to accept a heart valve prostheses for production functional performance acceptance testing. The valves are assessed against a battery of user-defined QA performance metrics, providing a clear pass-fail result for each valve in a rapid, reliable and highly consistent manner.



The PQT-5000 can assess functional heart valve performance and leaflet kinematics through a range of parameters including the following:

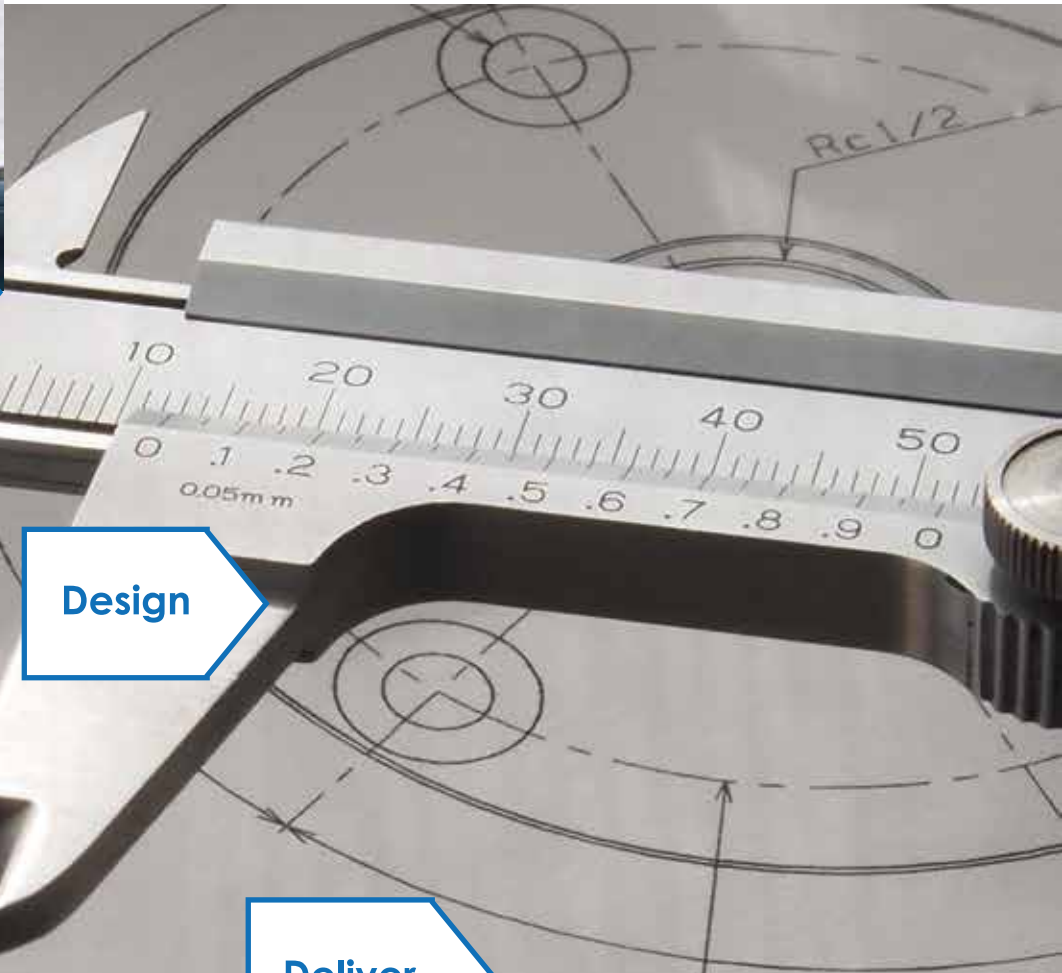
- Forward flow pressure drop
- Regurgitation volume
- Effective Orifice Area (EOA)
- Coaptation center point
- Central jet area
- Leaflet Pin-wheel
- Leaflet coaptation alignment
- Leaflet opening/closing dynamics

Innovative solutions from enlightened collaboration

The PQT-5000 base chassis includes aortic/pulmonary, ventricular and atrial chambers, a compliance chamber, a pulsatile pump, systemic resistance control, rapid valve exchange assembly, drip tray and BDC's proprietary Statys[®] PQT Software package. With each customer, we assess the full spectrum of your functional testing objectives and carefully reflect these objectives, along with our experience in the customization of our PQT-5000. Result? A production testing solution that can test your prostheses accurately, conveniently and rapidly, every day, day after day.

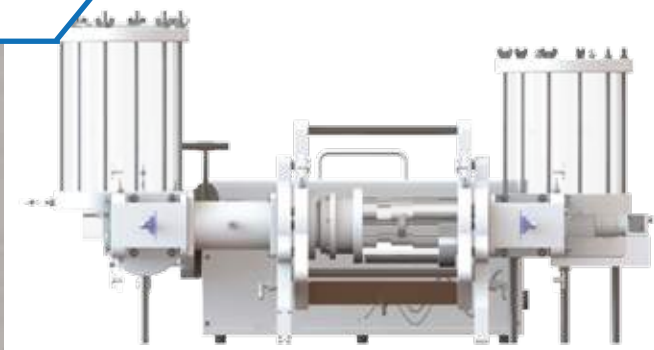
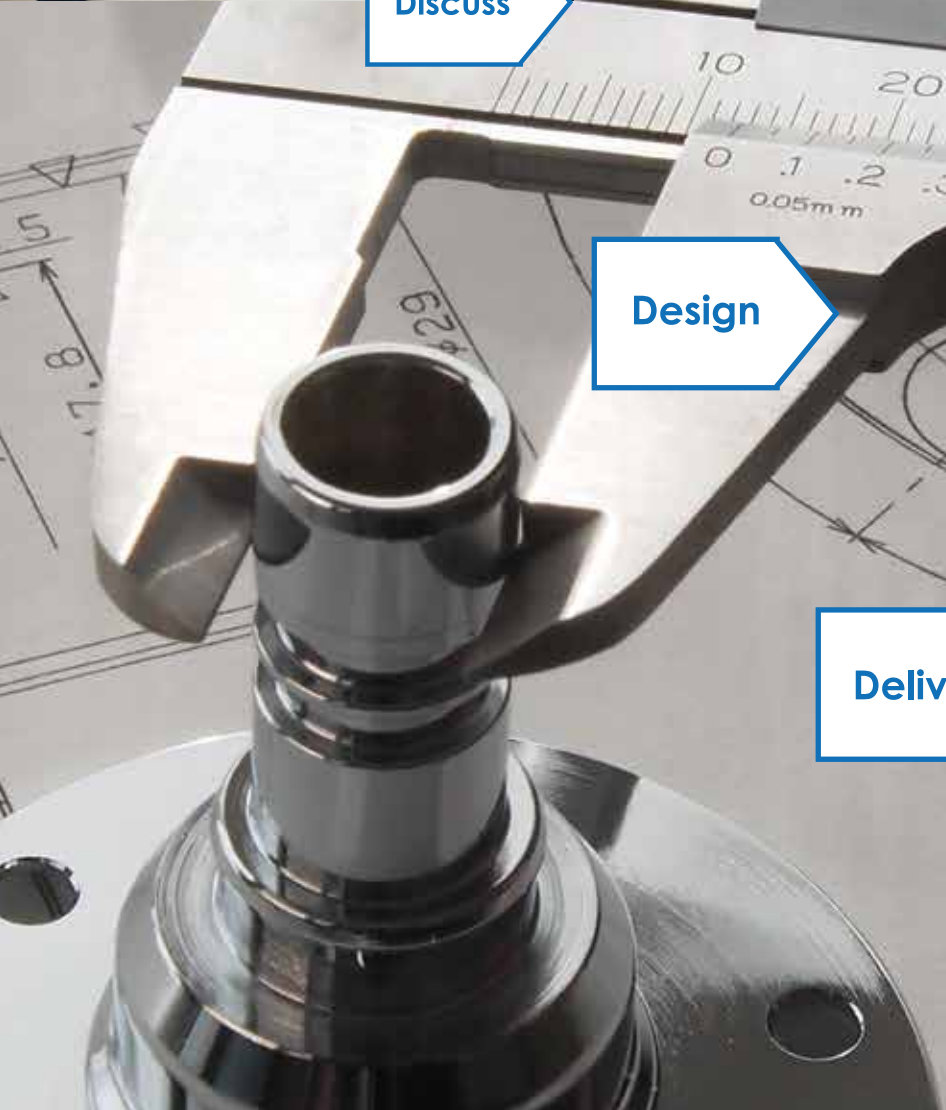


Discuss



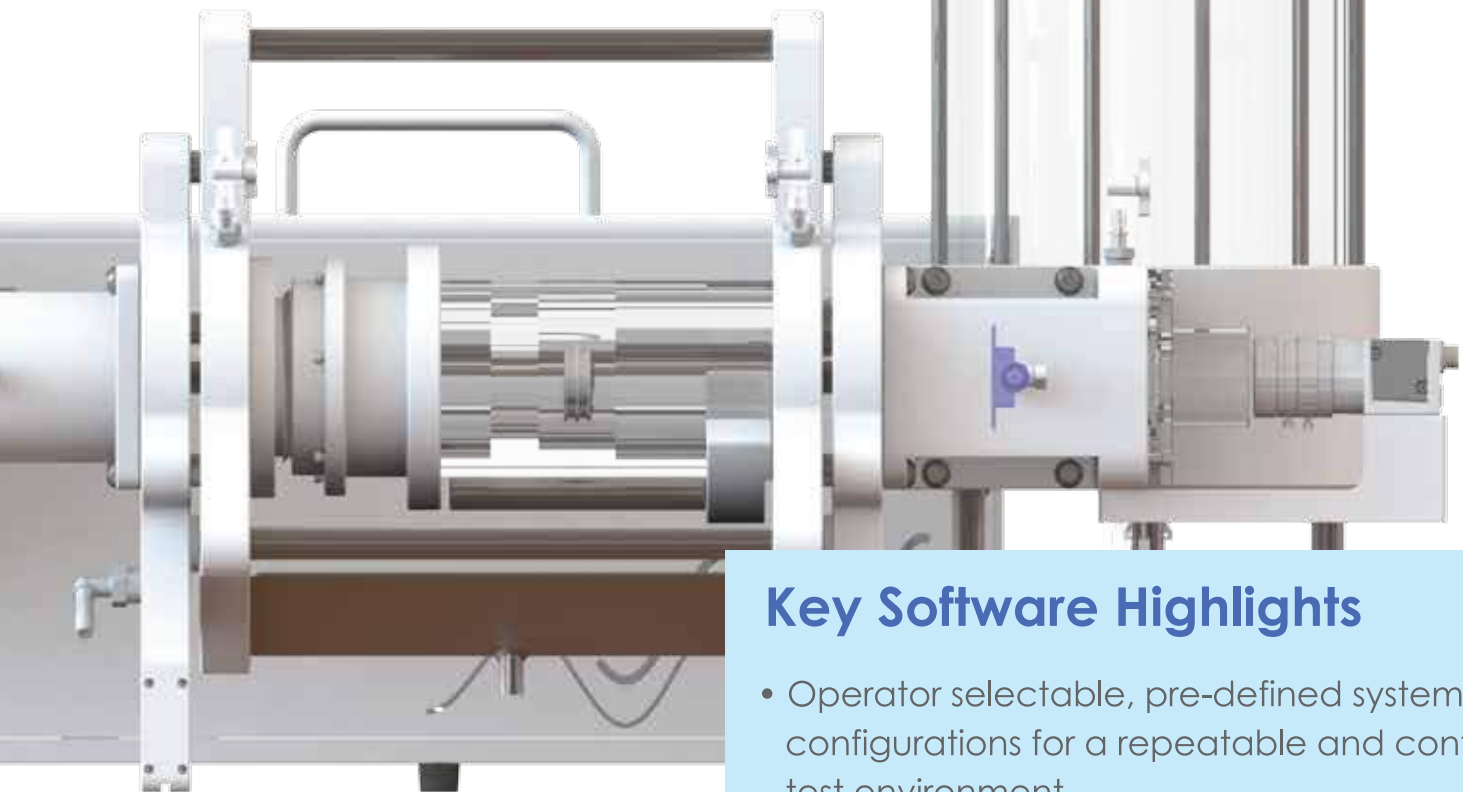
Design

Deliver



Key Benefits of the PQT-5000

- Clinically relevant pulsatile test environment
- Test system is chemically sterilizable
- Rapid reloading of prosthesis in less than 60 seconds for high throughput
- Absolute visibility of heart valve
- Integrated, synchronized cameras (optional)
- High speed camera system (optional)
- Fully customizable solutions available



Key Software Highlights

- Operator selectable, pre-defined system configurations for a repeatable and controlled test environment
- Integrated test article pass/fail/undetermined selectable flags
- Concurrent real-time display and recording of hydrodynamic and video data
- Recording of multiple cycles of both hydrodynamic and video data
- 21 CFR Part 11 compliant with automatically generated test reports
- Online measurement tools for acquired video images (optional)
- Integrated bar code scanner and digital stamping of video images (optional)
- Automated image analysis routines (optional)

Accessories

Standard Speed Cameras

The test system can accommodate up to five cameras to visualize all aspects of the heart valve being evaluated: outflow aspect, inflow aspect and up to three side views.

High Speed Cameras

High speed cameras are available for the system to provide increased temporal resolution when documenting the leaflet kinematics.

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

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.

Software Option

Bar Code Scanner

For absolute traceability, the integrated bar code scanner will acquire the test article identification and document it within the Statys® PQT™ software and test report.

Automated Image Analysis

The Statys® PQT software program offers automated image analysis algorithms that interrogate the captured video to automatically locate the coaptation center point, presence of a central jet with an associated area, and the offset of leaflet edges when in the closed state.

PQT-5000 Specifications

| | |
|-----------------------|---|
| Valve type | Aortic, mitral, pulmonary, tricuspid |
| Valve size | Customer specification |
| Camera System | Standard framerate, option: high speed |
| Frequency | 30 – 190 bpm |
| Flow rate | 1 – 10 L/min |
| Test fluid | Saline or customer specification |
| Driving waveforms | Sinusoidal, modified sinusoidal |
| Fluid temperature | Up to 50 °C |
| Regulatory compliance | Complies with 21 CFR Part 11, ISO 5840, and all applicable European Union directives and standards for safety and EMC. CE marked. |



Medical Device Testing & Equipment •
Simulation Platforms • Silicone Vessels

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