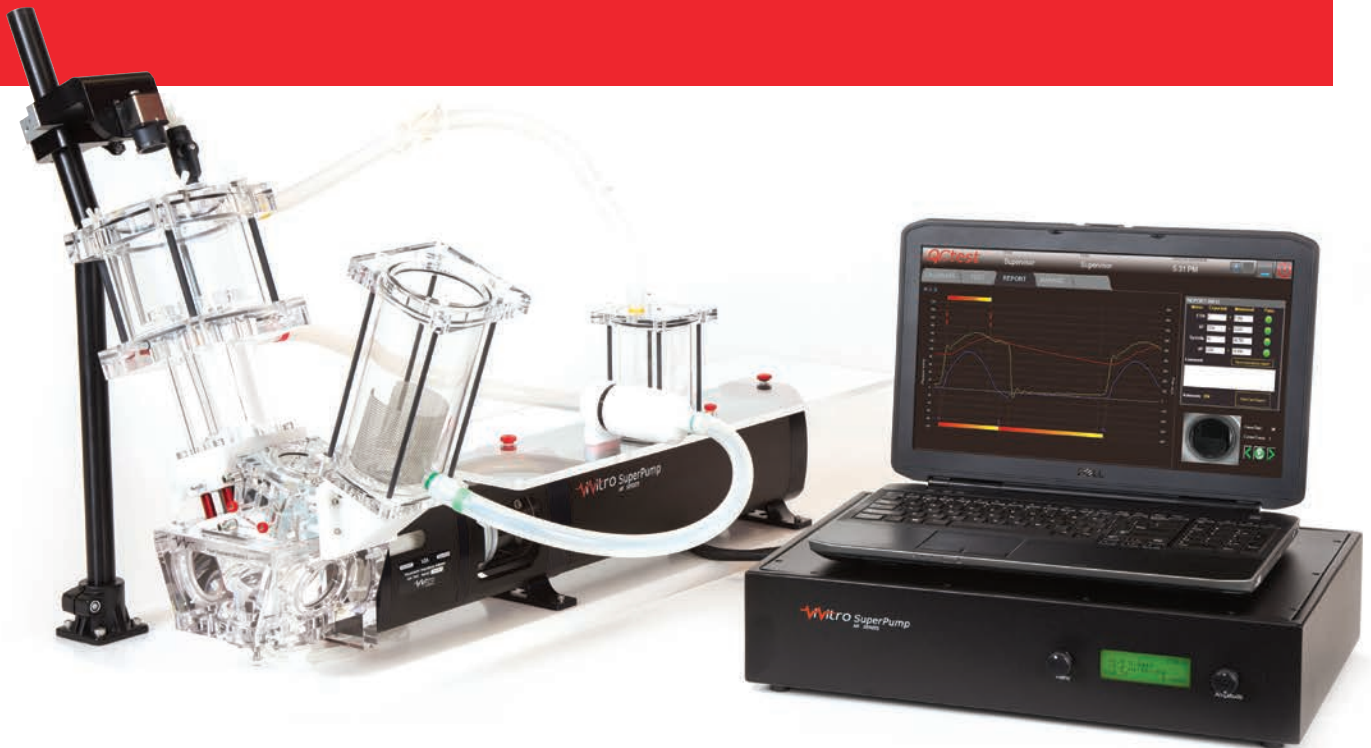


PRODUCTION TESTER QUALITY CONTROL SYSTEM

Product Codes: 26066, 31989 & 31991

The ViVitro Production Tester provides production technicians a simple, easy to use platform to assess valve performance under pulsatile flow. It is an add-on to the ViVitro Pulse Duplicator and consists of a camera with mount, quick change valve cartridge and QCTest software.



Production Quality Control System

The Production Tester quickly captures reliable results for a fraction of the cost of designing an in-house system. The Production Tester can assess valve pressure and/or flow criteria while recording videography of valve operation.

Operator authenticated video and data

The Production Tester Quality Control System is designed to serve in the challenging production environment. The system can be sterilized and run in a clean room environment. Valve exchange is quick, easy and can handle large daily throughput. QCTest software features separate supervisor and operator password protected logins. This allows verification that operators test valves under consistent conditions and provides an objective method of confirming pass or fail results. The system delivers video and output data pressure and/or flow data for a lasting record that valves meet acceptance criteria.

Quick Change Load Assembly

The Production Tester tests valves under physiological pulsatile flow conditions. Powered by the ViVITRO Pulse Duplicator and ViVITRO SuperPump, the Production Tester consists of an atrium, ventricle, and arterial outflow.

- Measure arterial, ventricular, and atrial pressures upstream and downstream of the valve.
- Measure flow in the semilunar or atrioventricular position.

A quick change cartridge is located in the aortic/pulmonary valve position. The cartridge allows operators to quickly exchange test valves without draining the system. The cartridge can be customized for a specific valve geometry.



Manual processes are designed for minimal maintenance and hassle free operation.

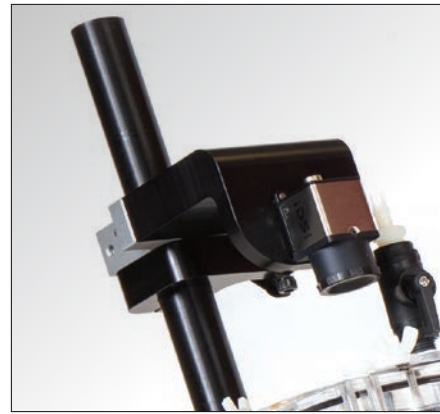
Camera

Specifications

Pump and Model Heart	53 x 92 x 45 cm
Data Acquisition System and Flow Meter	48 x 33 x 32 cm
Dry Weight:	18 Kg
Temperature Control (optional)	Ambient up to 40°C +/- 1.0 °C
Flow Rate	0 – 15 LPM
Beat Rate	3 – 200 BPM
Valve Size	Customizable
Test Fluid	Saline, Customizable
Sterilization	Liquid Chemical, EtO, Customizable

The camera is mounted to remain perpendicular to the valve outflow. It can swing out of the way during valve exchange and quickly returned to a consistent alignment.

The Production Tester Quality Control System uses an [iDS UI-3240CP-M-GL](#) monochrome camera for 60 fps data collection at 600 x 400. A 25mm/F1.4 lens ensures that most valves fill the entire field of view.



The clear quick change load assembly allows additional cameras in other locations. Any additional data collections are not managed through QCTest.

Specifications

Frame Rate	60 fps
Resolution	600 x 400 pixels
Camera	Monochrome

QCTest Software

QCTest software operates and collects data on valves under pulsatile flow in the Production Tester. It includes security and risk management features essential in a production testing environment and is fully validated. A report of each test and video are saved automatically along with immediate pass/fail results.

QCTest software offers separate supervisor and operator password protected login. The software is divided into four main functions: Calibrate, Test, Report and Manage. Operators collect data under prescribed conditions (Stroke volume, Beat Rate, Cardiac Output, Mean Arterial Pressure, and Systolic Duration) in accordance with ISO 5840 and as specified by the supervisor. Data collected

is automatically given a pass/fail indication based on pressure and/or flow criteria (Effective Orifice Area, Regurgitant Fraction, Transvalvular pressure during forward flow) defined by the supervisor.

Calibration of the system contains easy to follow wizards which walk operators through the process step by step. Supervisors specify the required interval calibrations. Data cannot be collected until the system is calibrated.



Customization

Each heart valve is unique and requires a unique production inspection. We offer several levels of customization to meet a variety of budgets and requirements.

Customization of the valve quick change holder to ensure the proper interface with a valve design are routinely performed. Changes to the model left heart to modify workflow or interface with a sterilization process are more involved, but available. Changes to the software or data acquisition system are technically feasible, but are often significant. QCTest is designed to provide supervisors many options in how a valve is evaluated. Customizations are generally not required.



A requirements document is collaboratively developed free of charge for all customization. Upon completion, an estimate is provided for the total cost of the system including the customization.

Service and Warranty

ViVitro Labs equipment for cardiovascular device development and production is used in hundreds of organizations in over 40 countries for 30+ years. We understand how critical production equipment reliability is and fully stand behind our products. We offer a standard 2 year warranty on all products and extended warranties are available.

Global service contracts for IQ/OQ/PQ of the system as well as annual inspection, preventative maintenance, calibration, and onsite spares ensure issues are resolved in an expedited manner regardless of location.

Contact us for a free consultation

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