

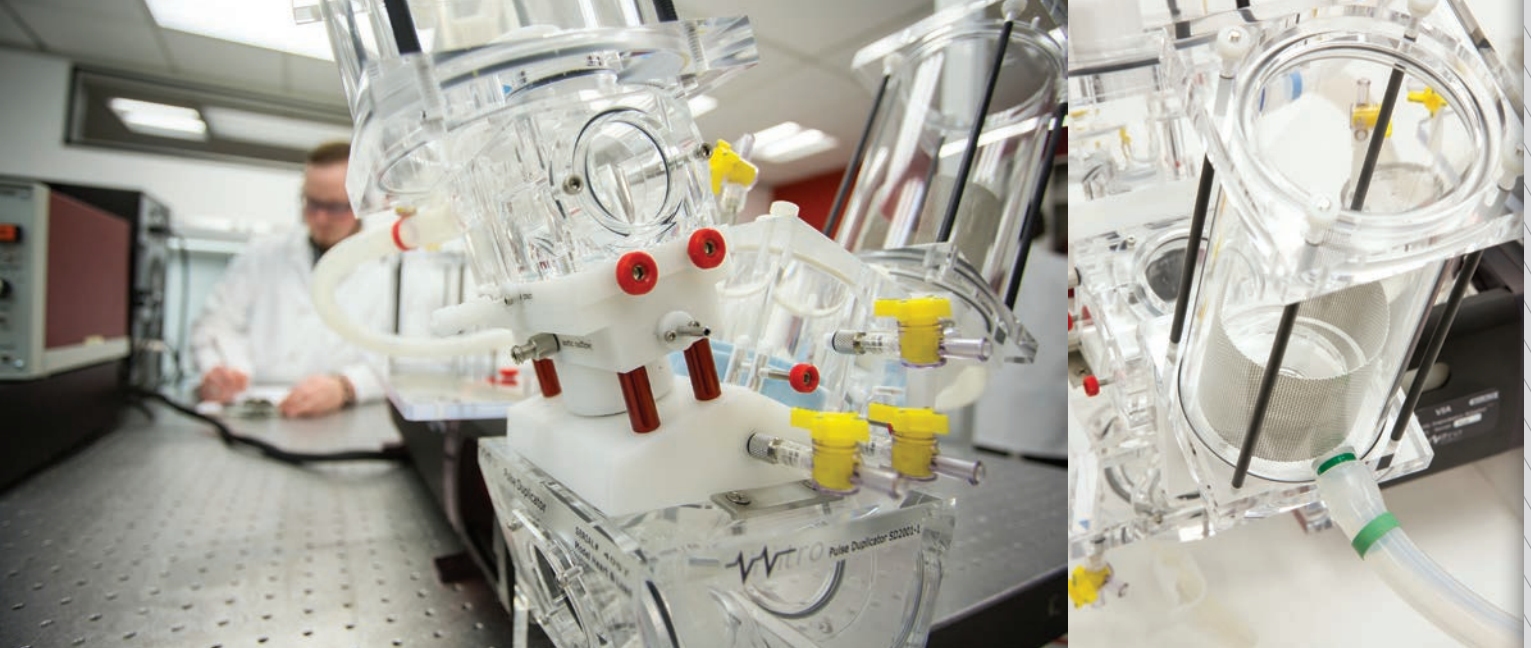
PULSE DUPLICATOR

**Most cited in-vitro cardiovascular
hydrodynamic testing system**

Product Code: 18363

The ViVitro Pulse Duplicator simulates the function of the heart (left or right) by generating pulsatile flow through prosthetic heart valves placed in the Model Left Heart. Powered by the ViVitro SuperPump, it is composed of the ViVitro Model Left Heart, Flow Measuring System and ViVitest Data Acquisition System. The ViVitro Pulse Duplicator System is used by the US Food and Drug Administration and is recognised by regulatory bodies worldwide including TÜV, BSI and the Chinese SFDA.





The Pulse Duplicator System assesses the performance of cardiovascular devices and prosthetic heart valves under simulated cardiac conditions. It simulates physiological or other complex flow variations while allowing the user to vary the peripheral resistance and compliance of the system. Pressure ports and flow measuring locations allow for data to be collected from aortic or mitral sites. Transparent viewpoints allow multiple viewing angles of the valve including inflow and outflow.

Combined with the ViVitest software control system, it quickly, easily and reliably collects and analyzes physiological flow and pressure data. The ViVitest software also allows the user to easily modify and customize waveforms.

> Features

- Meets ISO 5840 requirements to collect and analyze flow and pressure readings in real-time
- Controls pulsatile fluid flows to simulate cardiac flow conditions including arrhythmia, normal, hypo and hypertensive states at specified cardiac outputs and beat rates
- Measures wall pressures in the atrium, ventricle, and aortic outflow
- Measures flow at the aortic or mitral sites
- Simulates cardiovascular peripheral resistance and compliance
- Ventricle membrane replicates natural chamber flow
- Enables echo imaging, Doppler flow measurements, and PIV for interrogation of flow field regions

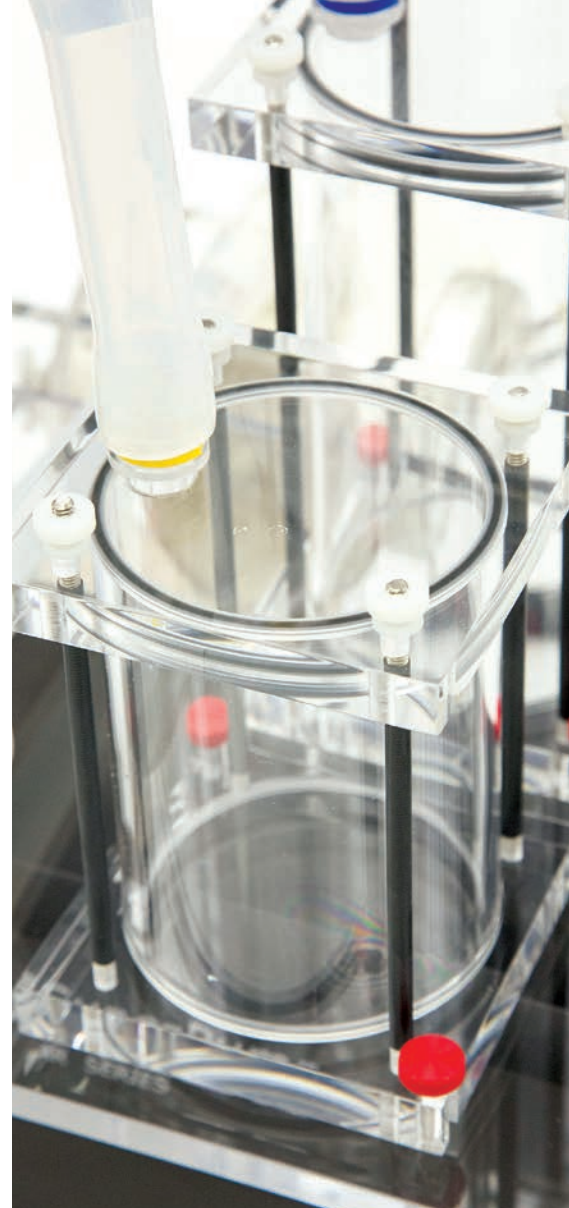
> Testing Capabilities and Applications

- Transcatheter valves (Aortic or Mitral)
- Surgical valves (Mechanical and Biological)
- Stentless valves
- Structural heart and peripheral vascular devices
- Occluder and Closure Devices (with customization)
- Evaluate LVAD or other assist devices (with customization)

> Specifications

Pump & MLH	53 x 92 x 45 cm
DAS & Flow System	48 x 33 x 32 cm
Dry Weight: Actuator + Model Left Heart + VIA	18 kg
Temperature Range	Ambient up to 40°C ± 1.0°C
Flow Rate	0 – 15 L/min
Heart Beat Rate	3 – 200 BPM
Valve size	
Aortic	Up to Ø 35mm
Mitral	Up to Ø 35mm*

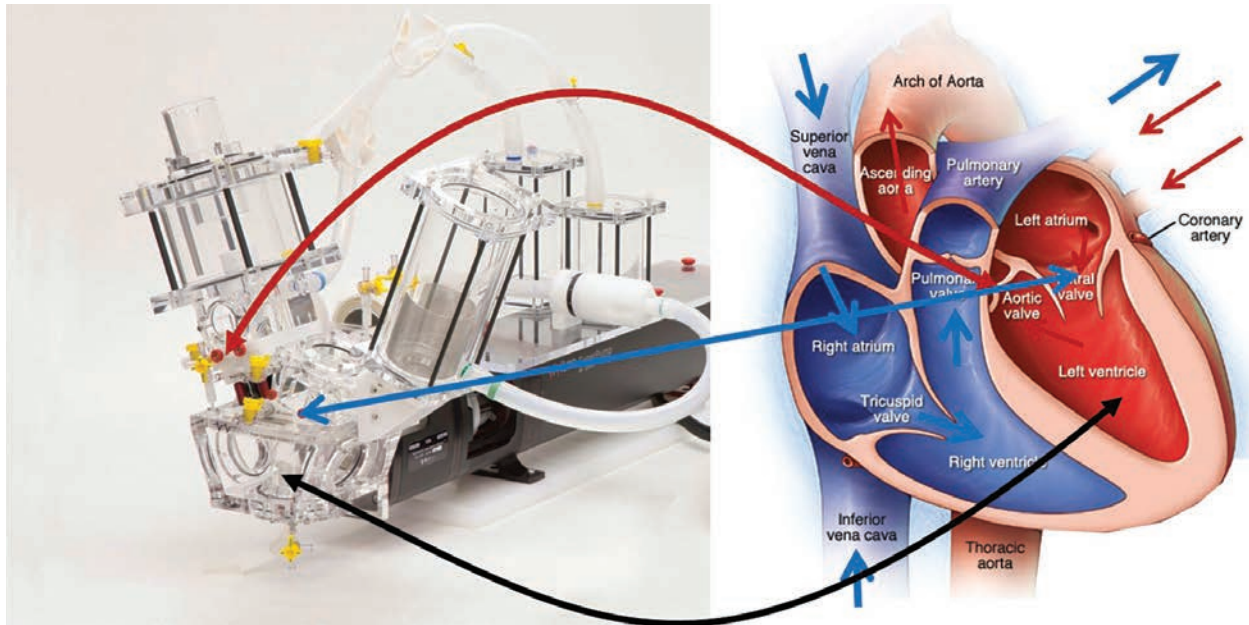
* Ø 55mm with Large Atrium Accessory



Left Heart Model

Product Code: SD2001-1

The ViVitro Model Left Heart emulates the pressures and flows of the left heart allowing insertion of valves and other devices into the Pulse Duplicator system for testing. It includes transparent elements to visualize valve function and adjacent flow fields. Ports are available for transducers to measure wall pressures in the left atrium, left ventricle, aortic outflow tract, and downstream of the aortic valve.

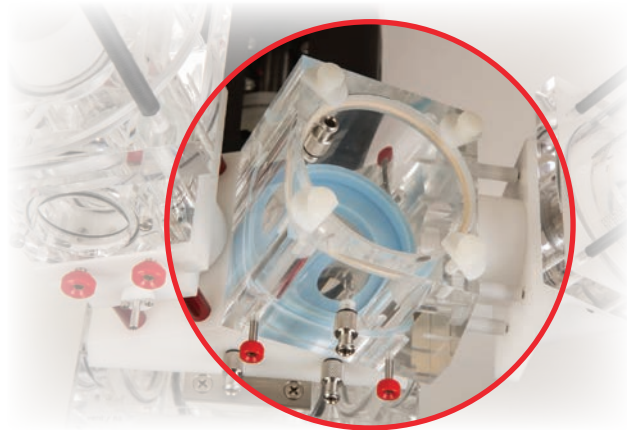


Large Atrium Chamber (Mitral)

Product Code: 21179

The Large Atrium chamber allows devices with an outer diameter of up to 55mm to be tested in the Pulse Duplicator.

- Expands the mitral device testing capabilities of the system
- Quick-release system allows fast device changes
- Accurate flow measurements from flow probe at Atrium inflow
- Enhanced visibility using large viewing window for mitral device inflow
- Customizable Valve Mounting
- Easily added to a ViVitro Pulse Duplicator



ViVitest Data Acquisition System (DAS)

Product Code: 08530 // Related Part Numbers: 08311 I/O Module, AP9991 AmPack



ViVitest is part of the ViVistro Data Acquisition System (DAS) family of software products. Combined with the Pulse Duplicator System it collects hydrodynamic testing data to meet ISO 5840 requirements. ViVitest software controls the SuperPump while simultaneously measuring pressure and flow data. It monitors, processes, and reports data such as regurgitant fraction, effective orifice area (EOA), and other valve performance indicators.

A calibration wizard walks new users through the set-up process for quick system preparation for testing. Output files are available in .CSV format for easy analysis in Excel and MatLab.

ViVitest features an intuitive User Interface

The software is pre-installed on a laptop and tested with all hardware and A-D converters prior to shipment.

Each system includes the following components:

- I/O Module – inputs/outputs signals from the software
- AmPack - Pressure Measuring System including transducers and amplifier
- Connecting cables
- Laptop
- ViVitest Software (compatible with Windows 7 & 10)



> Pulse Duplicator Accessories

ViVITRO Labs offers a wide variety of accessories and equipment to support the Pulse Duplicator. Customization services are always available to meet unique test requirements.

Viscoelastic Impedance Adapter (VIA)

Product Code: VIA7991



The ViVITRO Viscoelastic Impedance Adapter (VIA) works in conjunction with the SuperPump to produce more realistic physiological ventricular pressures. It consists of a fixed resistive element and two adjustable compliance chambers to simulate ventricular viscoelastic behavior.

Please see the detailed accessory overview on page 12.

Aortic Conduit Mount (ACM)

Product Code: 18903



The ViVITRO Aortic Conduit Mount (ACM), formerly the Left Ventricular Outflow Tract (LVOT), is used to mount a compliant conduit, native or synthetic root, and test percutaneous valves in the ViVITRO Model Left Heart system.

The ACM enables valves to be sutured, or Transcatheter valves to be mounted, in an anatomically correct fashion. A variety of ACM sizes are available to accommodate silicone tubes with relaxed tube IDs of 12-29 mm. Custom sizes are available upon request. A compliant conduit may be expanded up to approximately 50mm OD.

Inflator Syringe

Product Code: 26365



The Inflator Syringe includes a plunger lock and fine threaded adjustment for easier pressure calibration of the ViVITRO Data Acquisition System.

- 25 mL barrel volume
- Locking plunger
- Fine adjustment by means of the threaded plunger knob

Pressure Transducers

Product Code: Pulse Duplicator HCM018 // HiCycle 06146



The ViVibro Data Acquisition System includes 3 Utah Medical 6069 Pressure Transducers. Additional Pressure Transducers can be ordered separately. A cable test-port allows for easy verification of monitoring system accuracy and reusable interface cables are available for most every monitor.

- The I/O Module and AmPack provide the interface from the pressure transducers to the Data Acquisition System.
- Suitable for use with the Pulse Duplicator, EV Simulator, Real-Time Wear Tester or the HiCycle (modified connector when used with Scan Valve).

PIV Load Assembly

Product Code: 21026



The PIV Load Assembly provides an optically clear, anatomically representative aortic inflow and outflow to enable Particle Imaging Velocimetry studies in the Pulse Duplicator. The PIV Load Assembly replaces the lower half of the standard aortic load assembly and is easily substituted into the ViVibro Labs Pulse Duplicator.

- Optically clear, non-distorting inflow and outflow section
- Interchangeable and customizable silicone aortic annulus
- Anatomical aortic sinuses
- Outflow pressure port
- Easily installed in the Pulse Duplicator

Heat Exchanger and Heat Bath

Product Code: Heat Exchanger - HE9991 // Heat Bath Temperature Controller - 10679 N.A., 10680 Int'l



The **ViVibro Heat Exchanger** allows heating of test fluid with minimal interference of the fluid flow.

- An isolated inflow and outflow metal heat conducting channel transfers heat to the solution
- Maintains testing solution to desired temperature $\pm 0.5^{\circ}\text{C}$.

The **Heat Bath Temperature Controller** delivers rapid fluid heat-up, optimized for the ViVibro Pulse Duplicator. These heated circulating baths feature a long life, high-wattage heater.

- Over Temperature and Low Reservoir level automatic system cut-offs eliminate risk of over heating system components



Reservoir Volume:	6 litres (1.5 gallons)
Temperature Range:	Ambient 15°C to 150°C
Stability:	Digital $\pm 0.05^{\circ}\text{C}$
Work Area Dimensions:	20 x 15 x 13 cm
Overall Dimensions:	23 x 36 x 37 cm
Heater:	1000 W
Pumping Capacity:	12 L/min at 0 psig
Electrical Requirements:	115 VAC, 60 Hz, 15 amp or 230 VAC, 50 Hz 10 amps (specify when ordering)

Digital Thermometer

Product Code: 24086

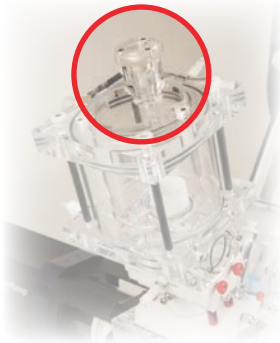


A digital thermometer allows easy fluid temperature measurement in the Pulse Duplicator.

- Traceable to standards provided by NIST
- Accuracy/Resolution: 0.1° from -20 to $+100^{\circ}\text{C}$

Catheter Access

Product Code: Transfemoral Access - 18497 // Transapical Access - 18496



ViVidro offers two standard methods of deploying percutaneous devices into the Pulse Duplicator system; either Transfemoral or Transapical access (Aortic and Mitral). Additional methods can be customized by ViVidro or third party specialists.

Percutaneous Catheter Access enables the deployment of transcatheter devices in an active Pulse Duplicator while the flow loop is operating under pressure. The Percutaneous Catheter Access is designed to accommodate up to 34 French deployment devices and mounts easily to a ViVidro Model Left Heart.

Features:

- Transapical access can be rotated to access aortic or mitral valves
- Catheter insertion with little to no fluid loss during pulsatile operation
- Replaceable valves
- Easy to disassemble and clean

QCtest Software

Product Code: 26066



ViVidro QCtest checks valve performance against user defined acceptance criteria. It is a turn-key, validated function test software system. The software is easy to use and can be paired with a specific Function Tester Load Assembly on the ViVidro Pulse Duplicator, for quick valve change-outs. This combination is a ready-to use solution for one of the most time-consuming aspects of production to validate.

The QCtest software system was developed as a quality control tool for QC performance testing (function testing) of cardiovascular devices such as heart valves. This production tool provides fast, reliable results at a fraction of the cost of designing and validating an in-house system.

Features:

- Pass or fail criteria definable using a secure log-in
- Automatically saves pass/fail results along with a report of each test and video
- User definable system calibration intervals
- Simple user interface

Production Tester

Product Codes: 26066, 31989 & 31991

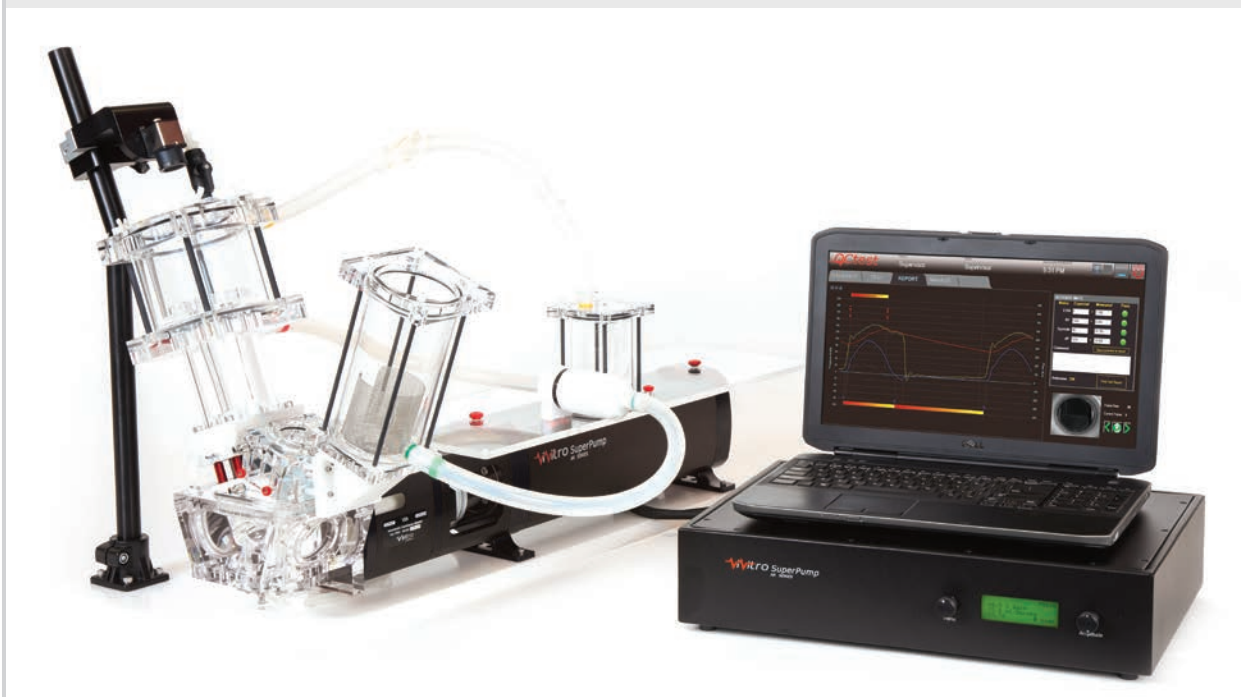


The ViVITRO Production Tester provides a simplified system that assesses valve performance criteria for production quality control. It is an add-on to the ViVITRO Pulse Duplicator and is intended for Production / QC applications.

The Production Tester quickly captures reliable results for a fraction of the cost of designing an in-house system. In conjunction with QCtest software, the Production Tester assesses pressure and flow criteria while recording high speed valve footage via an integrated camera.

Features & Applications:

- Captures pressure and flow data including:
 - Transvalvular Pressure
 - Effective Orifice Area
 - Regurgitant Fraction
- Captures high-speed video with integrated camera
- Provides Pass/Fail results
- Administrators can set individual operation parameters for technicians:
 - Operating conditions
 - User defined Pass/Fail performance assessment
 - Defined calibration expiry intervals
- Test data is tracked by linking result logs to valve model and serial number
- Quick-change valve holder can be custom-tailored to valve design



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ViVITRO Labs Inc.
First in Cardiovascular Device Testing