PULSE DUPLICATOR

Most cited in-vitro cardiovascular hydrodynamic testing system

Product Code: PD2010

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

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pump &amp; MLH</td>
<td>53 x 92 x 45 cm</td>
</tr>
<tr>
<td>DAS &amp; Flow System</td>
<td>48 x 33 x 32 cm</td>
</tr>
<tr>
<td>Dry Weight: Actuator + Model Left Heart + VIA</td>
<td>18 kg</td>
</tr>
<tr>
<td>Temperature Range</td>
<td>Ambient up to 40°C ± 1.0°C</td>
</tr>
<tr>
<td>Flow Rate</td>
<td>0 – 15 L/min</td>
</tr>
<tr>
<td>Heart Beat Rate</td>
<td>3 – 200 BPM</td>
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<tr>
<td>Valve size</td>
<td></td>
</tr>
<tr>
<td>Aortic</td>
<td>Up to Ø 35mm</td>
</tr>
<tr>
<td>Mitral</td>
<td>Up to Ø 35mm*</td>
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* Ø 55mm with Large Atrium Accessory
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)

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 is part of the ViVitro 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 Data Acquisition System (DAS)
Product Code: PDA2010

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, 8 & 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 Aortic Conduit Mount (ACM), formerly the Left Ventricular Outflow Tract (LVOT), is used to mount compliant conduit, native or synthetic roots, or percutaneous valves in the ViVitro Pulse Duplicator. Please see the detailed accessory overview on page 9.

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 Transcather 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
The ViViFlow Electromagnetic flow meter accurately measures flow for testing, research and laboratory applications. It can be used as a standalone device or used in the ViVitro Pulse Duplicator. It is compatible with the ViVitro I/O module and Data Acquisition System.

ViViFlow offers the following benefits:

- Improved performance (accuracy and flow measuring range)
- Reduced susceptibility to noise and drift
- Increased reliability
- Easier calibration and faster start-up time
- Supports two flow probes
- Standalone operation for non-ViVitro applications

**Accuracy:**
- ± 0.06 L/Min from 0 - 5 L/Min
- ± 4% of reading from 5 - 40 L/Min

**Flow Range:**
- 0 - 40 L/Min

**Frequency Responses:**
- DC - 40 Hz +/- 3 dB

**Transducer Range:**
- 0 - 40 L/Min

**Transducer Accuracy:**
- ± 0.06 L/Min from 0 - 5 L/Min
- ± 4% of reading from 5 - 40 L/Min

ViViFlow 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).
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°C

The ViVitro 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 ± 0.5°C.

The Heat Bath Temperature Controller delivers rapid fluid heat-up, optimized for the ViVitro 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 ±0.05°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)
ViVitro 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 ViVitro 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 26 French deployment devices and mounts easily to a ViVitro 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

ViVitro 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 ViVitro 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
The ViVitro Function 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 Function Tester quickly captures reliable results for a fraction of the cost of designing an in-house system. In conjunction with QCtest software, the Function 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
- Customizable Quick-Change valve holder