

VIVITRO LABS PULSE DUPLICATOR CHARACTERIZATION VALVE KIT

Product Code: 56466 - REFERENCE VALVE ASSEMBLY, SJM MECHANICAL, 19MM
Product Code: 56468 - REFERENCE VALVE ASSEMBLY, SJM MECHANICAL, 25MM

ISO 5840-2:2021 and 5840-3:2021 now require performance characterization of pulse duplicator system performance. The ViVitro Labs Pulse Duplicator characterization valve kit includes a ISO 5840:2021 ViVitro Labs Pulse Duplicator characterization test method and St. Jude Masters' valve with certified results for the ViVitro Pulse Duplicator.

Features:

- St. Jude Master's Valve
- ISO 5840:2021 ViVitro Labs Pulse Duplicator characterization test method
- Certificate with St. Jude Master's Valve test method results

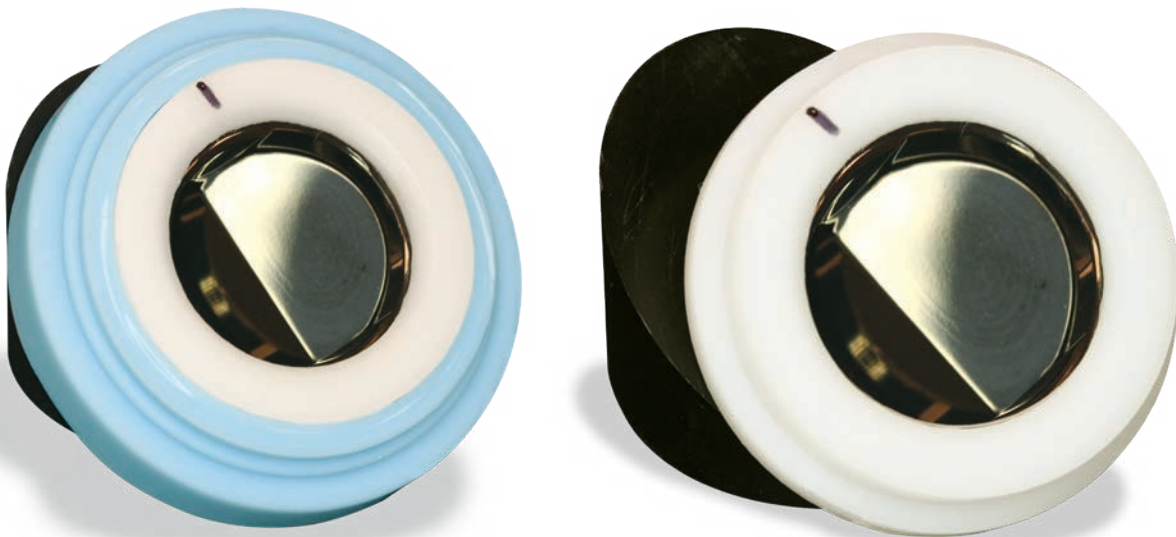


Figure 1: ViVitro Reference valve. Shown with silicone holder (left) and without (right).

Each reference valve comes with a certificate of conformance showing the operating conditions used to test the valve and the results obtained. These demonstrate the valve meets ISO 5840:2021 requirements. Test the reference valve in your Pulse Duplicator system to demonstrate that it gives the expected results and complies with ISO 5840:2021 requirements.

The Valves

ViVitro removes the sewing ring and glues the valve into a rigid holder. This rigid holder can be mounted in a standard ViVitro silicone holder. As the silicone degrades over time, it can be replaced while the valve function remains constant.

The Certificate

The certificate documents all operating conditions required to properly test the valve in accordance with ISO 5840:2021. In addition to controlling cardiac output, beat rate, systolic duration, and mean arterial pressure, our test methods also control the pressure and flow waveform shape, air in the VIA, companion valve, and flow probe orientation. This process enables other to follow and obtain valve results matching those on the valve certificate. The certificate will then show that the valve passes the ISO 5840 acceptance criteria.

Reference Valve Uses

The reference valves can be used to qualify a system in accordance with ISO 5840:2021. They can also serve as ongoing quality assurance samples to ensure consistent data. Ideally, the reference valve should be run with every batch of valves being tested. The results can be applied to on-going proficiency testing that ensures operators are properly trained.

Support

In addition to the valve and certificate, ViVitro includes one hour of technical support to help ensure users can match the results ViVitro obtained. Additional training or system qualification is available for a fee if desired.

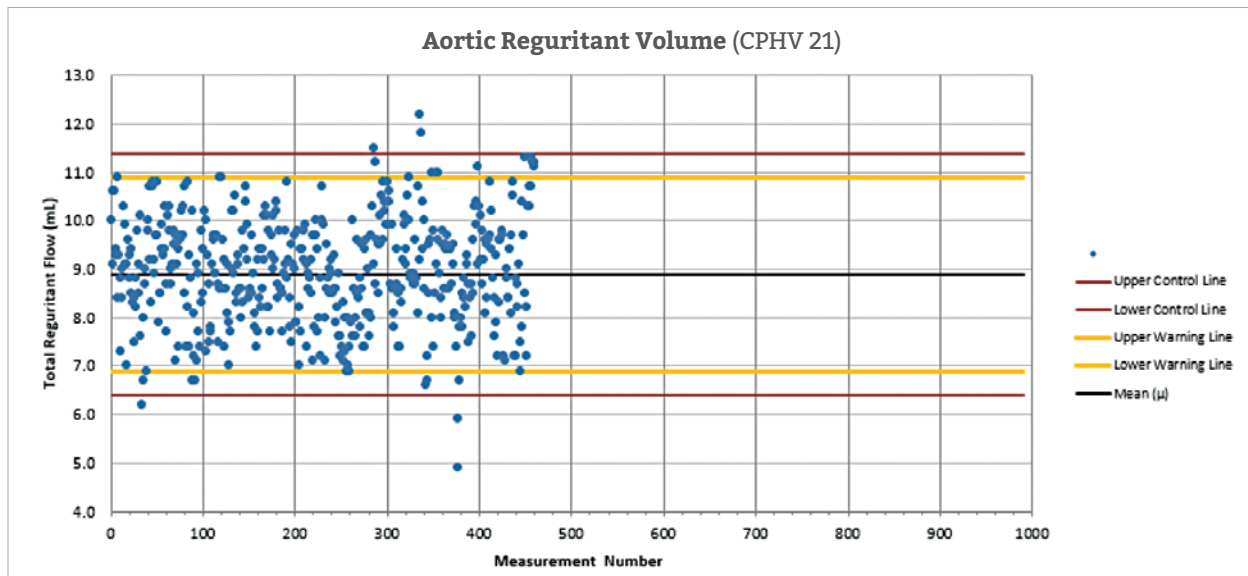


Figure 2: Example reference valve results used for on-going quality assurance and/or operator proficiency