ISO 5840-2:2021 and 5840-3:2021 reference valves

ISO 5840-2:2021 and 5840-3:2021 now require reference valves to help qualify pulse duplicators. ViVitro Labs offers the valve specified in the standard, mounted in a holder compatible with ViVitro equipment.

Each reference valve comes with a certificate of conformance showing the operating conditions used to test the valve and the results obtained. These demonstrate that the valve meets ISO 5840:2021 requirements. Users can test the valve in their own system, using the same conditions, to demonstrate that their system gives the expected results and complies with ISO 5840:2021 requirements.

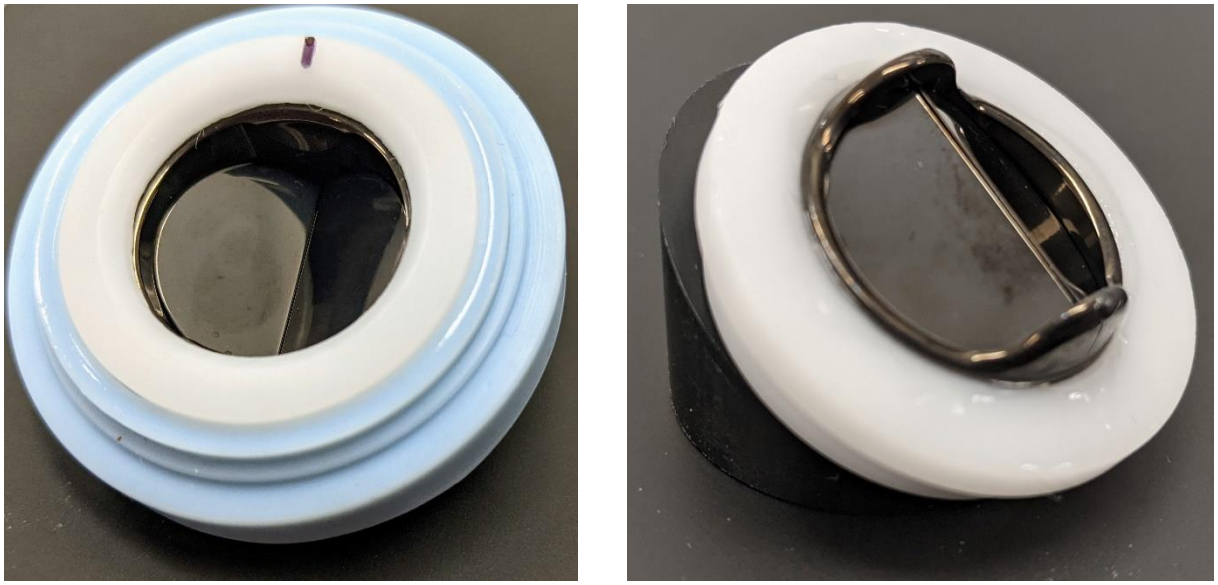

Figure 1: ViVitro Reference valve. Shown with silicone holder (left) and without (right).

The Valves

We remove the sewing ring and glue the valve into a rigid holder. This rigid holder can then be mounted in a standard ViVitro silicone holder. As a result, as the silicone degrades over time it can be replaced, but the valve function should remain constant overtime.

The Certificate

The certificate documents all the operating conditions required to properly test the valve in accordance with ISO 5840:2021. In addition to controlling the cardiac output, beat rate, systolic duration, and mean arterial pressure, with ViVitro systems it is also important to control the pressure and flow waveform shape, air in the VIA, companion valve, and flow probe orientation. This process forms a “cook book” for users to follow and obtain the same results themselves.

The certificate will then show that the valve passes the ISO 5840 acceptance criteria.

How to use reference valves

Users will test the reference valves to qualify their system in accordance with ISO 5840:2021. They can also use the reference valves as ongoing quality assurance samples to ensure consistent data. Ideally, by running this valve with every batch of valves they are testing, or, for on-going proficiency testing, to ensure operators are properly trained.

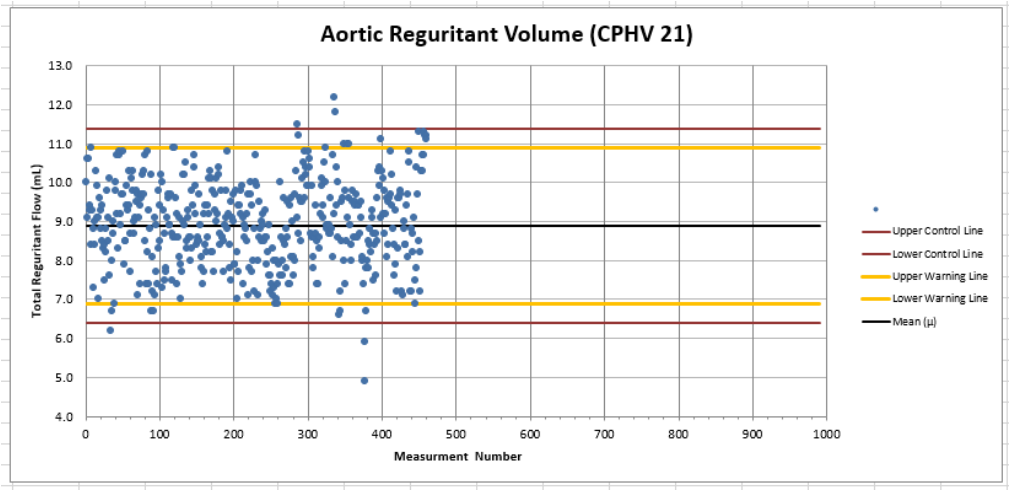

Figure 2: Example reference valve results used for on-going quality assurance and/or operator proficiency.

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.

White Paper

The selection of the reference valves and the acceptance criteria published in ISO 5840 is based on the following publication.

Wu C. et al. **In-Vitro Pulsatile Flow Testing of Prosthetic Heart Valves: A Round-Robin Study by the ISO Cardiac Valves Working Group**. Cardiovasc Eng Technol. 2019, 10 pp.397-422.