**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLORADO**

Civil Action Number: 1:23-cv-867-SKC

BIOMEDICAL DEVICE CONSULTANTS &
LABORATORIES OF COLORADO, LLC

Plaintiff,

vs.

VIVITRO LABS, INC.

Defendant.

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**DECLARATION OF CRAIG WEINBERG IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION**

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I, Craig Weinberg, hereby declare and state as follows:

1. I am the former CEO and currently the Chief Technical Officer of Biomedical Device Consultants & Laboratories of Colorado, LLC ("BDC"). I make this Declaration in connection with BDC's motion for a preliminary injunction. I have personal knowledge of the facts herein, and if called as a witness, I could and would testify competently thereto.

2. I received my Ph.D. in the area of Mechanical Engineering with a focus in cardiovascular fluid dynamics from the University of Colorado in 2003. In early 2011, I began to serve on the US sub-committee and then, as of January of 2015, began serving on the parent international committee ISO/TC 150/SC 2/WG 1, which is the group that creates the international guidance documents for design verification/validation evaluation of heart valves and heart valve repair devices. As a result, I am very familiar with all the commercially available products that are part of the functional performance evaluation of prosthetic heart

valves, both real-time and accelerated, utilized during the verification/validation testing of the associated devices.

3. In 2006, I joined BDC as its president. In about February 2008, a team of three people—me, Benjamin McCloskey, and Dr. Steven Weinberg—began researching and designing a new prosthetic heart valve and venous valve durability testing system. The dedication of a three person research team to this project was a significant investment for BDC. Though BDC currently has five or six employees devoted to working on its testing equipment development and eight or nine employees working on its test equipment assembly, back at the time of the invention in 2008, the entire company was only on the order of six full time employees.

4. The nature of BDC's business requires that it make these types of significant investments in research and development. BDC's customers are those that wish to test medical devices, often the medical device manufacturers themselves testing the device to obtain regulatory approval. The medical device industry is an innovative industry—new and improved medical devices enter the market all the time. These newer devices often require state of the art testing systems for their evaluation. Prosthetic heart valves have seen significant improvements in the past decades, resulting in larger sizes and different methods for securing devices in place within the human body (*e.g.*, transcatheter heart valves). This has required similar innovations in the equipment available to test the valves. Therefore, to stay competitive, BDC must keep pace with the innovation of both its customers and its competitors.

5. Our research, with respect to heart valve durability test equipment, eventually led to the issuance of several patents, including U.S. Patent No. 9,237,935 ("the '935 Patent" or "the Patent-in-Suit"). I am a named inventor on the '935 Patent, among other patents.

### A. BDC's Innovative VDT-3600i System Was Designed to Accommodate Cutting-Edge Devices Using Superior Technology

6. Before the Patent-in-Suit, heart valve durability testing systems on the commercial market used designs that resulted in minimal control of the differential pressure rate and spikes associated with valve closure that could result in unnecessary early deterioration of the test valves and potential false test failures. To better manage valve closing dynamics and differential pressure spikes, and thus better comply with the durability testing standards, my co-inventors and I developed a novel test system that placed an excess volume area on the outflow side of a test sample valve. In one implementation, a volume of test system fluid was "stored in an excess volume area during a system driving stroke that opens the valved prosthetic device," and "released during a return stroke that closes the valved prosthetic device." '935 Patent at 3:14-18. In this way, the excess volume area aids in controlling differential pressure spikes.

7. One type of "excess volume area" is a "compliance chamber." A compliance chamber is an area usually filled with air or gas within a test system that permits a change in its volume with an associated change in system pressure. In our design, we positioned a compliance chamber downstream of the test sample. It acts similar to a spring and stores pressure in the system during the "drive" phase (the phase the opens the test valve) and then releases it during the "return" phase (the phase that closes the valve). Additionally, our patents describe a variety of types of excess volume areas and compliance chambers.

8. The Patent-in-Suit and the products incorporating its invention revolutionized the market for heart valve durability testing systems by providing an accelerated testing device with an excess volume area on the outflow side of the valve. BDC has commercialized the Patent-in-Suit through a product known as the VDT-3600i heart valve durability tester.

### B. The VDT-3600i System Quickly Rendered Obsolete Competitors' Test Systems to Become the Market Leading Test System

9. The VDT-3600i has been a tremendous success. When it was launched around 2010, it was a unique and differentiated product. It was the only testing system on the market that provided an excess volume area in a return chamber, downstream of the valve to store fluid during the driving phase of the system, *i.e.*, when under compression. This excess volume area and use of a non-regular driving waveform are significant improvements in accelerated test system design. The excess volume area further provided for management of the rate of pressure which improved our system's ability to test heart valves at an accelerated rate in an efficient and controlled manner, helping to avoid and control undesirable pressure spikes.

10. The market for heart valve durability testing systems is highly specialized and therefore is also very small.

11. When the VDT-3600i was released around 2010, the only competitors were Defendant ViVitro Labs and Dynatek Labs. Dynatek's system, however, used old, outdated technology. As a result, it was, and is, not considered a viable alternative in the marketplace for the latest valve technology and currently has few sales, if any.

12. ViVitro's then-current testing system—the HiCycle Durability Tester—had a number of issues that made it unattractive to consumers in comparison to the VDT-3600i.

a. ViVitro's system relied on movement of an artificial heart valve through fluid to create the valve opening and closing, not movement of fluid through a valve, which is thus not testing the valve in clinically representative manner.

b. ViVitro's system was too small to accommodate the larger heart valve products of today.

c. ViVitro's system possessed multiple test stations that were driven by a single motor.

d. ViVitro's system required balanced valves for testing. Specifically, testing could only be performed with a balanced number of valves in the system, and with valves of the same size paired with each other on the system to be on balance.

e. ViVitro's system had only one pressure sensor for all six valves.

13. Once the VDT-3600i entered the market, ViVitro's technology was deemed not as commercially relevant to, or an equivalent of the VDT-3600i.

14. Therefore, as a superior and unique product, the VDT-3600i rapidly (within five years) became the industry standard for heart valve durability testing systems.

15. To the best of my knowledge, there are currently only four competitors in the market: my company BDC, Defendant ViVitro (which until recently was promoting its obsolete technology), TA Instruments-Waters LLC, and Dynatek Labs. To my knowledge, BDC's competitors have a minimal amount of market share.

16. BDC's VDT-3600i currently has about a 70-75% share of the worldwide market for heart valve durability testing systems, and an 80-85% share of the U.S. market.

**C. The VDT-3600i System Is Vital to BDC's Business Success**

17. Market share in the heart valve durability testing equipment market is extremely important due to the incumbency effects. A single testing system can only test a few devices at a time. For example, both BDC and ViVitro sell systems that test a maximum of six prosthetic heart valves at a time. To bring a new prosthetic valve device to market, however, medical

device manufacturers need testing data from many, often dozens, of sample devices. Therefore, testing system customers need multiple systems. Customers will generally purchase a single testing system and run a short pilot program. If the pilot test is successful, the customer will then purchase more of the same test systems from the same manufacturer as part of a larger testing program for commercial use.

18. Customers generally do not buy testing equipment for a single device from multiple sources in order to avoid introducing additional testing variables (*i.e.*, differences between testing machines from different suppliers) into the test data that would be submitted to the FDA, or international regulatory agencies. The lifespan of valve durability testing equipment is often ten to fifteen years, meaning that once a customer has decided which testing equipment to use, it will likely be a long time before a competitor has the opportunity to usurp the place of an incumbent. Moreover, if the customer buys additional equipment, it is most common for customers to purchase the same type previously purchased, as opposed to creating the variability discussed above with two systems.

19. A company's ability to maintain market share is crucial to its long-term success. As I previously mentioned, research and development is vital to a company in this industry so that it can keep pace with its customers and competitors. In order to fund this research and development, BDC uses part of its revenue from its sales to fund its research and development for new devices.

20. The VDT-3600i is of particular significance to BDC because it is BDC's best-selling test system and is its highest-revenue generating product. Therefore, lost sales of the

VDT- 3600i will negatively impact all of BDC's business because it will have less revenue to fund its research and development across its platform.

21. In this industry, market share is also often linked to reputation for innovation. As I mentioned before, innovation is extremely important. Accordingly, customers often make decisions based on reputation for innovation, and a testing system supplier's long-term success is dependent on that reputation. BDC has a reputation for innovation and associated customer goodwill. For example, the BDC website has numerous customer testimonials discussing BDC's work to innovatively solve problems posed by customers. http://www.bdclabs.com/about-us/client-testimonials/. Contributing to BDC's reputation for innovation is the fact that the VDT-3600i is a differentiated, patented product for heart valve durability testing.

22. In addition to revenues deriving directly from the sale of VDT-3600i Systems, BDC receives revenues for testing services performed under contract with customers where BDC conducts tests using the VDT-3600i.

### D. ViVitro Begins Marketing a Copycat Tester that Infringes the Patent-in-Suit and Presents a Substantial and Unique Risk to BDC

23. However, ViVitro has threatened to change the status of VDT-3600i as a unique product, when it started advertising and marketing at trade shows its copycat tester that it claims will soon be available, the ViVitro ADC Heart Valve Durability Tester.

24. The ADC Heart Valve Durability Tester mimics the VDT-3600i, and moves away from the prior art in the following ways:

a. ViVitro's prior system moved the heart valve through the fluid, but the new ADC Heart Valve Durability Tester moves the fluid through the heart valve (like the VDT-3600i).

b. ViVitro's prior system was too small to accommodate the larger heart valve products of today, but the new ADC Heart Valve Durability Tester has chambers designed to "fit any valve size and geometry" (like the VDT-3600i).

c. ViVitro's prior system was driven by a single motor, but the new ADC Heart Valve Durability Tester has multiple linear electromagnetic motors (like the VDT-3600i).

d. ViVitro's prior system required balanced valves for testing, but the new ADC Heart Valve Durability Tester has independent test modules that can test any number of valves of different sizes (like the VDT-3600i).

e. ViVitro's prior system had only one pressure sensor for all six valves, but the new ADC Heart Valve Durability Tester has independent sensors for each valve (like the VDT-3600i).

f. As described in U.S. Patent No. 9,237,935 and as used in the VDT-3600i, the new ADC Heart Valve Durability Tester uses an excess volume area that can function to counteract pressure spikes.

25. ViVitro's ADC Heart Valve Durability Tester is harmful to BDC in a way that the other competing products are not. As described above, Dynatek's system is obsolete and predates the Patent-in-Suit.

26. TA Instruments' product does not present the same competitive risk as ViVitro's product. TA Instruments is a large company with many types of equipment for testing products not exclusive to the medical device industry (i.e., batteries, biopharma, electrodes, pharmaceuticals and medical devices). To my knowledge, TA Instruments offers only one

product related to testing of heart valves, and does not offer testing services of the type offered by BDC and ViVitro. TA Instruments does not have the reputation and credibility in the heart valve testing industry enjoyed by BDC and ViVitro. For these reasons, although TA Instruments has been on the market for nearly a decade, it has not achieved substantial market share in a way that threatens BDC. Further, ViVitro has a greater reputation for innovation than either of those two competitors. As I stated above, innovation is key to attracting and retaining customers.

27. By contrast, ViVitro is a greater competitive threat because it is well-known in the market for heart valve testing. According to the ViVitro website, it was founded in the mid-1970s and its first development project was to build a heart valve tester. https://vivitrolabs.com/company/. ViVitro has been well-known in the industry since at least the mid 1990s. I am aware of only six pieces of equipment offered by ViVitro, and four of those pieces relate to heart valve testing.

28. Prior to BDC's ground-breaking invention, embodied in the VDT-3600i, ViVitro was a leading provider of heart valve testing equipment, through its HiCycle accelerated durability tester. With BDC's introduction of the innovative VDT-3600i product, it disrupted the industry and captured the vast majority of market share for accelerated durability testers of heart valves, including most of ViVitro's market share. Now, a dozen years later, ViVitro is seeking to recapture this market share by introducing an infringing system.

29. BDC faces a far, far greater risk from ViVitro—a company with a reputation for innovation, and which offers the same testing services as BDC—than it ever has from either Dynatek or TA Instruments. ViVitro's coming out with a truly competitive product will dramatically impact BDC's reputation as the leading innovator in heart valve durability testing

equipment and damage the good will BDC has spent years building based on its patented, innovate product.

30. Even before ViVitro introduced its copy of the innovative VDT-3600i tester, it has sought to replicate the testing services offered by BDC. For years, BDC has offered an expanded array of testing services. In or around May of 2021, ViVitro changed its website to provide service offerings that closely mimic the offerings of BDC. The chart below summarizes this shift:

| ViVitro Testing (4/18/2021) - Old | ViVitro Testing (6/20/2021) New (to match BDC) | BDC Testing |
|---|---|---|
| Durability Testing | Stents and Equivalent | Stent & Stent Graft Testing |
| Pulsatile-Flow Testing | Stent Graft and Vascular Prosthesis | Vascular Graft Testing |
| Steady Flow Testing | Catheters | Catheter Testing |
| | Heart Valve Replacement and Repair | Heart Valve Testing |
| | Metallic Frame Based Systems | Coating & Particulate Testing |
| | Circulatory Support Devices | MRI Compatibility Testing |
| | Guidewires | General Testing |
| | Other Cardiovascular Devices | |

31. ViVitro's introduction of the VDT-3600i uniquely threaten BDC's market share and viability, because ViVitro is a recognized player in the heart valve testing market, and is seeking to offer the same services and same products to usurp BDC's customers. By offering a copy of BDC's flagship product that utilizes its patented innovation, especially in addition to the

copycat nature of its new offerings, ViVitro will cause BDC to lose its reputation as an innovator and will take away BDC's market differentiator.

32. ViVitro's sales will not only adversely affect sales of BDC's system, but also BDC's related products and services.

33. Even one lost sale to ViVitro is a significant threat to BDC because the market is very small. Systems are expensive, and BDC only sells between twenty-five and thirty-five systems a year. The market is therefore sensitive to change. With ViVitro on the verge of launching a copycat product, BDC is in immediate threat of losing its market lure as a unique, patented product. This will lead to BDC losing more market share and losing its reputation for innovation.

### E. ViVitro Markets Its Infringing Product, BDC Alerts ViVitro to Its Infringement, and ViVitro Disregards the Notice and Continues to Market Its Product

34. I first became aware of the ADC Heart Valve Durability Tester last summer, when I became aware of literature disseminated by ViVitro. I reached out to ViVitro by email, to politely express my concern. ViVitro responded, but did not allay my concerns or provide additional information on the functioning of the product.

35. On August 22, 2022, counsel for BDC sent a letter to ViVitro notifying it that the ADC Heart Valve Durability Tester infringes at least claim 1 of the Patent-in-Suit and claim 25 of U.S. Patent No. 8,627,708. With this letter, BDC provided a claim chart and a copy of ViVitro's sales brochure with annotations to map it to the patent claim. As of that time, I had not actually seen a product, but understood one would be on display at an upcoming trade show.

36. ViVitro responded, through Canadian counsel. Rather than outright deny infringement, ViVitro noted that "the elevated chamber you identified as 'Feature F'" does not meet the limitations of claim 1 of the Patent-in-Suit.

37. Despite these cautions, ViVitro advertised the ADC Heart Valve Durability Tester on its website, and permitted users to download a brochure. Attached as **Exhibit 1** is a true and correct copy of an archived version of ViVitro's website from last fall, which includes a link to download the brochure. Attached as **Exhibit 2** is a true and correct copy of the ADC Heart Valve Durability Tester sales brochure that I obtained last summer.

38. In mid-September 2022, both BDC and ViVitro attended the Transcatheter Cardiovascular Therapeutics Conference (the "TCT Conference") in Boston, Massachusetts. This conference, which was held September 16-19, 2022, is described as "the world's premier educational meeting specializing in interventional cardiovascular medicine." At the TCT Conference, ViVitro displayed the ADC Heart Valve Durability Tester in its booth. I observed the tester, and generally saw it in operation.

39. At the TCT conference, I spoke with ViVitro's President Karim Mouneimne about the ADC Heart Valve Durability Tester. I explained to Mr. Mouneimmne that BDC developed its products and patent portfolio at considerable expense, and that BDC is committed to protecting its investment and the rights that its patent provides. I asked Mr. Mouneimmne to provide me with further information about the operation of the ADC Heart Valve Durability Tester. He declined, but suggested that a publication would issue in approximately six weeks that would provide additional information about its operation. I have looked for, but been unable to find, any such publication.

40. In early November 2022—*i.e.*, six weeks after my conversation with Mr. Mouneimmne—BDC wrote to ViVitro again, to follow up on ViVitro's letter claiming that BDC had misidentified a feature, in light of "what BDC ha[d] been able to learn about the Vivitro ADC Heart Valve Durability Tester" and the conversation I had with Mr. Mouneimne. BDC provided a revised annotated sales brochure, identifying all of the limitations of claim 1 of the Patent-in-Suit (the '935 Patent).

41. ViVitro then advised it would need to retain a U.S. lawyer to respond. After prodding for a response, nearly three months later—on January 31, 2023—ViVitro provided its substantive response through U.S. counsel. In its response, ViVitro did not try to argue that the ADC Heart Valve Durability Tester does not meet the limitations of claim 1 of the Patent-in-Suit. Instead, it simply argued that the Patent-in-Suit is invalid, while offering clearly different and unrelated prior art.

42. ViVitro continued to market its ADC Heart Valve Durability Tester at the MD&M West conference in Anaheim, California, recently held February 7-9, 2023. I observed the ADC Heart Valve Durability Tester at ViVitro's booth.

43. ViVitro has shown that it plans to continue marketing to U.S. purchasers, both in the United States and abroad. There was recently a technical conference (Heart Valve Society annual meeting) in Malaga, Spain from March 29 through April 1, 2023. ViVitro and many other U.S. companies and customers attended this technical conference. ViVitro's website invited attendees to "Meet with ViVitro Labs at HVS 2023," immediately followed by a product description of the ADC Heart Valve Durability Tester, and a link to download the sales brochure. A copy of this material, accessed on March 21, 2023, is attached as **Exhibit 3**.

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44. Based on my personal observation at trade shows, I have observed ViVitro actively marketing and selling the ADC Heart Valve Durability Tester. I have been informed by other market participants that ViVitro is currently unable to ship functioning ADC Heart Valve Durability Testers to customers, but that it expects to deliver ADC Heart Valve Durability Testers in the fall of 2023.

45. A preliminary injunction is necessary to prevent ViVitro from importing and distributing the ADC Heart Valve Durability Tester to U.S. customers. If an injunction is not granted, BDC will suffer long-term effects and irreparable harm, due to the long-term use of these products, the effect on BDC's reputation, the competitive harm to BDC in light of ViVitro's reputation in the market, and the additional sales and non-monetary benefits enjoyed by BDC as an innovator in this area.

I declare under the penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on April 11, 2023 in Wheat Ridge, Colorado.

By: _____
Craig Weinberg

# Exhibit 1

The Wayback Machine - https://web.archive.org/web/20220926142419/https://vivitrolabs.com/product/a...

1 (250) 388-3531 (tel:12503883531)
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ViVitro Labs (https://web.archive.org/web/20220926142419/https://vivitrolabs.com/)



# ViVitro ADC™ Heart Valve Durability Tester

**Accelerated wear testing for replacement heart valves**

OVERVIEW (HTTPS://WEB.ARCHIVE.ORG/WEB/20220926142419/HTTPS://VIVITROLABS.COM/PRODUCT/ADC-HEART-VALVE-DURABILITY-TESTER)

FEATURES (HTTPS://WEB.ARCHIVE.ORG/WEB/20220926142419/HTTPS://VIVITROLABS.COM/PRODUCT/ADC-HEART-VALVE-DURABILITY-TESTER?TAB=FEATURES)

SOFTWARE (HTTPS://WEB.ARCHIVE.ORG/WEB/20220926142419/HTTPS://VIVITROLABS.COM/PRODUCT/ADC-HEART-VALVE-DURABILITY-TESTER?TAB=SOFTWARE)

SPECIFICATIONS (HTTPS://WEB.ARCHIVE.ORG/WEB/20220926142419/HTTPS://VIVITROLABS.COM/PRODUCT/ADC-HEART-VALVE-DURABILITY-TESTER?TAB=SPECS)

## *Automatic Dual Control Technology (ADC)*
## *Greater accuracy, less manual interaction saves time*

ADC automates individual test module stroke and pressure control.

- Dedicated linear electromagnetic motor utilizes position feedback for consistent heart valve opening.

- By-pass restrictor with patented control algorithm automatically maintains valve differential pressure.

differential pressure.

- Continuous real-time data analysis counts every ISO cycle and yields 0% count error

A prewired controller unit and data acquisition system accommodates any combination of up to 6 test modules.

Transparent customizable test chambers are designed for maximum flexibility to fit any valve size and geometry with optimum inflow, outflow, and lateral visibility on test samples.

ViVitro ADC Heart Valve Durability Tester Independent test modules enable fast, easy interchangeability of test samples and system components with minimum disruptions to adjacent on-going test modules.

Automatic Dual Control technology maintains valve loading conditions throughout the entire test for up to 6 individually controlled chambers.

Flow Loop System autonomously runs under a low hydrostatic pressure head, which decreases the load on all seals and bellows. No external pressure source or compressor is required.

Contact us (https://web.archive.org/web/20220926142419/https://vivitrolabs.com/contact/) to learn more about the ADC Heart Valve Durability Tester and how ViVitro can help you meet your cardiovascular device testing needs.

DOWNLOAD BROCHURE

(https://web.archive.org/web/20220926142419/https://vivitrolabs.com/wp-content/uploads/2022/09/ADC-Heart-Valve-Durability-Tester_Brochure.pdf)

ViVitro ADC Heart Valve Durability Tester meets ISO 5840 AWT, DFM test requirements for all valve types and designs including: transcatheter and surgical valves:
aortic, mitral, pulmonary and tricuspid valve technologies, biological tissue valves, rigid metallic or polymeric and soft polymeric valve technologies.

ViVitro ADC Heart Valve Durability Tester can be used to assess cardiac valve repair devices, transcatheter cardiac occluders, and cardiac implant devices.

Join over 5000 cardiovascular device professionals who receive our testing and engineering insights and tips every month.

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Cited Publications (https://web.archive.org/web/20220926142419/https://vivitrolabs.com/company/cited-publications)

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# Exhibit 2

CONFIDENTIAL PREVIEW

ViVitro Labs

# VIVITRO ADC™ HEART VALVE DURABILITY TESTER



ViVitro ADC Heart Valve Durability Tester
- 6 test module configuration

*Information and images are accurate as of publication, but subject to change.*

## Automatic Dual Control Technology (ADC)
## Greater accuracy, less manual interaction saves time

**ADC automates individual test module stroke and pressure control.**

- Dedicated linear electromagnetic motor utilizes position feedback for consistent heart valve opening.
- By-pass restrictor with patented control algorithm automatically maintains valve differential pressure.

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A prewired controller unit and data acquisition system accommodates any combination of up to 6 test modules.

Transparent customizable test chambers are designed for maximum flexibility to fit any valve size and geometry with optimum inflow, outflow, and lateral visibility on test samples.

ViVitro ADC Heart Valve Durability Tester Independent test modules enable fast, easy interchangeability of test samples and system components with minimum disruptions to adjacent on-going test modules.

Patent pending Automatic Dual Control technology maintains valve loading conditions throughout the entire test for up to 6 individually controlled chambers.

A patent pending Flow Loop System autonomously runs under a low hydrostatic pressure head, which decreases the load on all seals and bellows. No external pressure source or compressor is required.

ViVitro ADC Heart Valve Durability Tester meets ISO 5840 AWT, DFM test requirements for all valve types and designs including: transcatheter and surgical valves: aortic, mitral, pulmonary and tricuspid valve technologies, biological tissue valves, rigid metallic or polymeric and soft polymeric valve technologies.

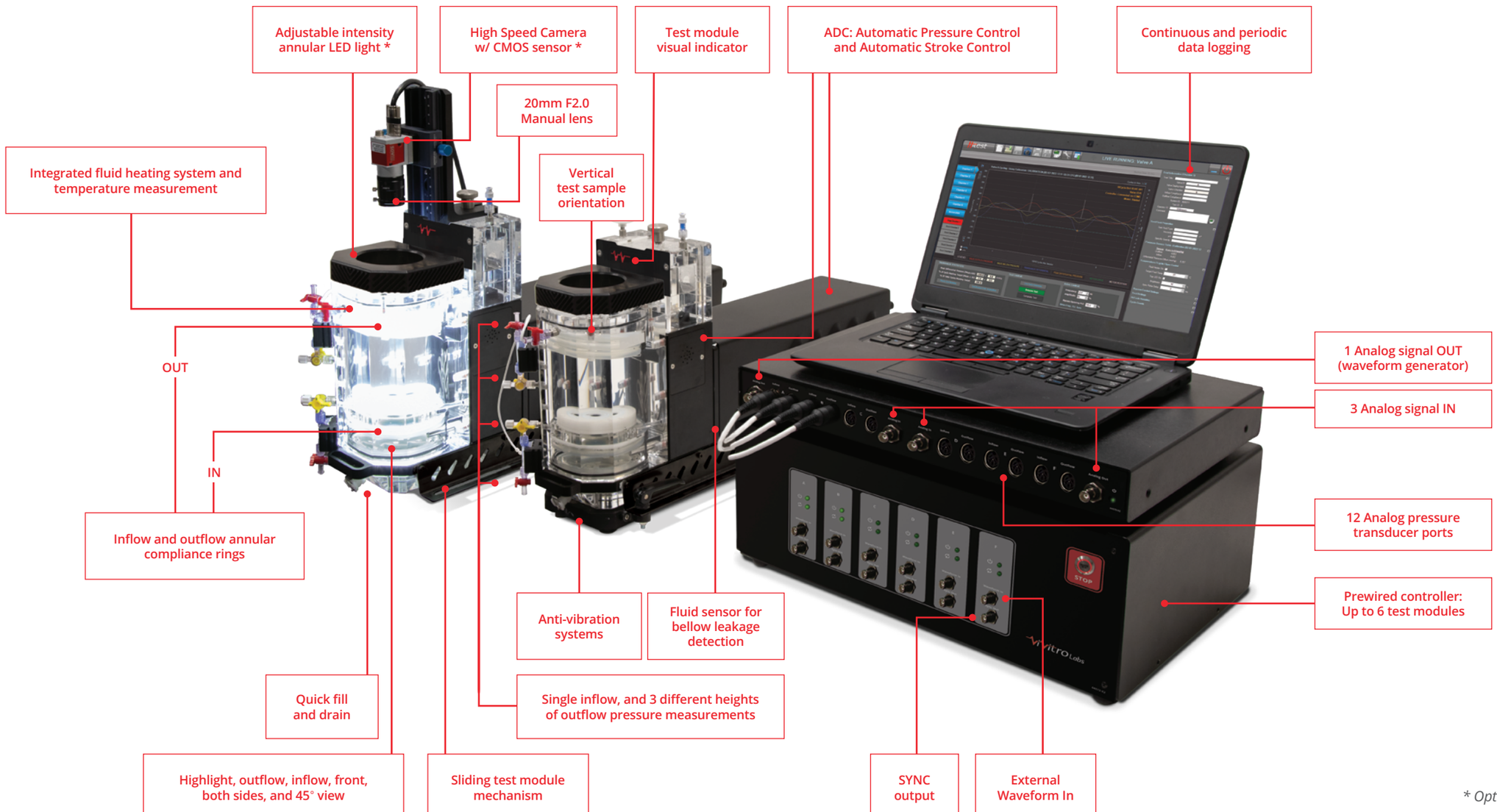
ViVitro ADC Heart Valve Durability Tester can be used to assess cardiac valve repair devices, transcatheter cardiac occluders, and cardiac implant devices.

## More ViVitro ADC Heart Valve Durability Tester Features

- True independent test modules with no fluid connections and dedicated electronics including linear electromagnetic motors, automated by-pass control, and temperature measurement.
- Automatic control system (Patent Pending) maintains optimum valve loading conditions during accelerated wear or real time testing.
- Large, customizable test chamber design fits all valve sizes and geometry and accommodates supporting structure(s).
- Modular system optimizes part and component interchangeability.
- Standalone architecture eliminates neighboring module disruptions.
- Vertical test sample configuration minimizes gravity effects on valve leaflets, leading to symmetric wear.
- Valve holder design facilitates chamber seal integrity.
- Integrated anti-vibration systems minimize pressure signal disruptions and improve high speed video quality.
- Inflow and outflow chamber patent pending annular compliance rings optimize differential pressure waveforms.
- Independent heater and temperature sensors each test module and corresponding test valve.
- Adjustable intensity annular LED light delivers maximum high-speed imaging luminosity with minimal reflection impact.
- Customizable valve annulus ring fits all valve geometries.
- Adjustable outflow pressure sensor height accommodates different valve designs, including valves in conduits.
- Patent pending pressure design features low system mean (approx. 10 mmHg) for load reduction and increased lifespan of seals and bellows. No external pressure source or compressor required.
- Camera holder ensures repeatable high-speed camera positioning, increased test image capture quality and reliability between inspection cycles.
- Embedded safety systems include bellows leakage sensor, fluid level detector, temperature change and pressure drop monitoring.
- Sliding test module mechanism provides test sample inflow visualization and ease of servicing.

## ViVitro ADC Heart Valve Durability Tester - 2 test module configuration

*Information and images are accurate as of publication, but subject to change.*




* *Optional items*

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## Specifications

| | |
|---|---|
| **Test module weight:** | Empty = 20.6 kg/module<br>Full = 22.1 kg/module |
| **Full Controller and Data Acquisition unit weight:** | 8.4 kg |
| **Footprint - 6 modules configuration:** | Min Bench Length = 1650 mm*<br>Min Bench Depth = 600 mm<br>Height = 362 mm (without Camera)<br>Height = 400 mm (with Camera) |
| **Footprint - 2 modules configuration:** | Min Bench Length = 850 mm*<br>Min Bench Depth = 600 mm<br>Height = 362 mm (without Camera)<br>Height = 400 mm (with Camera) |
| **Controller power supply requirements fully loaded:** | 1200 W<br>w/ 6 modules, 1 light ring, heaters on, at 100 mmHg |
| **System operating frequencies[2]:**<br>*[2] Tested w/ calibrated orifice* | 1 Hz to 70 Hz[1]<br>*[1] Test sample behavior and frequency response dependant.* |
| **Test chamber diameter** | Max support OD: 95 mm |
| **Test chamber height & clearance:** | Total Height/clearance up to 113.5 mm |
| **Piston max stroke volume:** | 38 ml/stroke |
| **Test chamber transparency:** | Inflow, outflow, left and right, 1 angle at right 45° |
| **Average hydrostatic pressure head:** | 10 mmHg |

** Minimal distance between units: 30 mm*




ViVitro ADC Heart Valve Durability Tester
- 1 test module configuration

*Information and images are accurate as of publication, but subject to change.*

CONFIDENTIAL PREVIEW




*Information and images are accurate as of publication, but subject to change.*

## Software

The ViVitro ADC Heart Valve Durability Tester with Automatic Dual Control Technology uses a proprietary software platform with a user- friendly interface. All in-software allows individual control of each test module.

## Features

- Independent settings and controls for each test module, including stroke amplitude, fluid bypass control for differential pressure adjustment, test frequency, temperature, and many more
- Fully software-controlled system requires no manual adjustments
- Continuous and/or periodic data monitoring records ISO 5840 conformance as required for AWT and DFM.
- Easy control and settings navigation between test modules
- Integrated pressure calibration wizard
- Waveforms display for inflow outflow pressure, differential pressure
- Individual test module parameters display windows show passing cycles count, operating frequency, fluid temperature, peak to peak differential pressure, ¨% cycle pass, % pressure pass, and total number of passing cycles
- Test sample identification data embedded in test log with calibration values

CONFIDENTIAL PREVIEW




*Information and images are accurate as of publication, but subject to change.*

## Continuous data log mode

Cycle to cycle information (peak differential, % of cycle meeting target pressure) can be collected for a predefined periods of time and saved over multiple .CSV files. Data is recorded in engineering units.

## Period data log mode

- Fixed number of cycles captured
- Periodic data report automatically generated based on user predefined parameters:
- Ability to periodically save entire waveform with user(s) defined output data (inflow and outflow waveforms minimum capture, and other test parameters)
- User-friendly field selector for output data

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# Exhibit 3

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ViVitro Labs
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« News & Press Releases (https://vivitrolabs.com/press-releases/?y=2023)

# Meet with ViVitro Labs at HVS 2023

March 20th, 2023

Share this...




(https://heartvalvesociety.org/meeting/)

HVS is an international and multi-disciplinary society which offers global members and attendees education and training in all aspects of heart valve disease and treatment. HVS 2023, the 2023 Scientific Meeting, will be held March 29 thru April 1, 2023 at the Hotel IPV Palace in Malaga, Spain.

*Connect with Jérémie Decressac (mailto: jdecressac@vivitrolabs.com), ViVitro Labs Business Development Manager, Europe, Africa, Israel, at HVS 2023 to discuss your cardiovascular device testing and engineering challenges.*

**Name** *

First

Last

**Organization**

**Email** *

**What would you like to discuss in our meeting?** *

**Multiple Choice**

- Wednesday, March 29
- Thursday, March 30
- Friday, March 31
- Saturday, April 1

Request Appointment

## ViVitro Labs Heart Valve Durability Tester with ADC™ technology



# *ViVitro Labs Heart Valve Durability Tester with ADC™ technology offers greater accuracy, less manual interaction saves time*

ADC automates individual test module stroke and pressure control.

- Dedicated linear electromagnetic motor utilizes position feedback for consistent heart valve opening.
- By-pass restrictor with patented control algorithm automatically maintains valve differential pressure.
- Continuous real-time data analysis counts every ISO cycle and yields 0% count error.

A prewired controller unit and data acquisition system accommodates any combination of up to 6 test modules.

Transparent customizable test chambers are designed for maximum flexibility to fit any valve size and geometry with optimum inflow, outflow, and lateral visibility on test samples.

ViVitro's Heart Valve Durability Tester with ADC Technology has independent test modules that enable fast, easy interchangeability of test samples and system components with minimum disruptions to adjacent on-going test modules.

Automatic Dual Control technology maintains valve loading conditions throughout the entire test for up to 6 individually controlled chambers.

Flow Loop System autonomously runs under a low hydrostatic pressure head, which decreases the load on all seals and bellows. No external pressure source or compressor is required.

Contact us (https://vivitrolabs.com/contact/) to learn more about the Heart Valve Durability Tester with ADC Technology and how ViVitro can help you meet your cardiovascular device testing needs.

DOWNLOAD BROCHURE (https://vivitrolabs.com/wp-content/uploads/2022/09/ADC-Heart-Valve-Durability-Tester_Brochure.pdf)

## ViVitro Pulse Duplicator system




The ViVitro Pulse Duplicator system is the world's most widely cited and most used in-vitro cardiovascular hydrodynamic testing system.

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 Heart (Left or Right). Powered by the ViVitro SuperPump pulsatile pump, it is composed of the ViVitro Model Heart (Left or Right), SuperPump pulsatile pump (https://vivitrolabs.com/product/superpump/), Flow Measuring System and ViViTest data acquisition system (https://vivitrolabs.com/wp-content/uploads/2014/06/ViVitro-Data-Acquisition-Software.pdf). The components work together to assess the performance of prosthetic heart valves under simulated cardiac conditions. The ViVitro Pulse Duplicator System is used by the US Food and Drug Administration and is recognised and used by regulatory bodies worldwide including TÜV, BSI and Chinese CFDA.

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.

**View ViVitro Pulse Duplicator web page.**

**The ViVitro Pulse Duplicator System is cited in numerous research studies throughout the world. Visit our Citation Database (https://vivitrolabs.com/company/cited-publications/?filter=pulse-duplicator) for the current list of applications and articles.**



(https://vivitrolabs.com/wp-content/uploads/2016/02/1764_ViVitro_SalesSheetJuly2018_PulseDuplicator.pdf)

# Cardiovascular Device Testing Services (https://vivitrolabs.com/services/)




(https://vivitrolabs.com/services/)

ViVitro Labs offers cardiovascular device testing services as either ISO 17025:2017 accredited or non accredited to help device manufacturers meet the highest standards in the industry in support of regulatory submissions.

*Connect with Jérémie Decressac (mailto: jdecressac@vivitrolabs.com), ViVitro Labs Business Development Manager, Europe, Africa, Israel, at HVS 2023 to discuss your cardiovascular device testing and engineering challenges.*

Join over 5000 cardiovascular device professionals who receive our testing and engineering insights and tips every month.

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Privacy (https://vivitrolabs.com/privacy)

# VIVITRO ADC™ HEART VALVE DURABILITY TESTER



ViVitro ADC Heart Valve Durability Tester
- 6 test module configuration

*Information and images are accurate as of publication, but subject to change.*

## Automatic Dual Control Technology (ADC)
## Greater accuracy, less manual interaction saves time

**ADC automates individual test module stroke and pressure control.**

- Dedicated linear electromagnetic motor utilizes position feedback for consistent heart valve opening.
- By-pass restrictor with patented control algorithm automatically maintains valve differential pressure.
- Continuous real-time data analysis counts every ISO cycle and yields 0% count error.

A prewired controller unit and data acquisition system accommodates any combination of up to 6 test modules.

Transparent customizable test chambers are designed for maximum flexibility to fit any valve size and geometry with optimum inflow, outflow, and lateral visibility on test samples.

ViVitro ADC Heart Valve Durability Tester independent test modules enable fast, easy interchangeability of test samples and system components with minimum disruptions to adjacent on-going test modules.

Automatic Dual Control technology maintains valve loading conditions throughout the entire test for up to 6 individually controlled chambers.

Flow Loop System autonomously runs under a low hydrostatic pressure head, which decreases the load on all seals and bellows. No external pressure source or compressor is required.

ViVitro ADC Heart Valve Durability Tester meets ISO 5840 AWT, DFM test requirements for all valve types and designs including: transcatheter and surgical valves: aortic, mitral, pulmonary and tricuspid valve technologies, biological tissue valves, rigid metallic or polymeric and soft polymeric valve technologies.

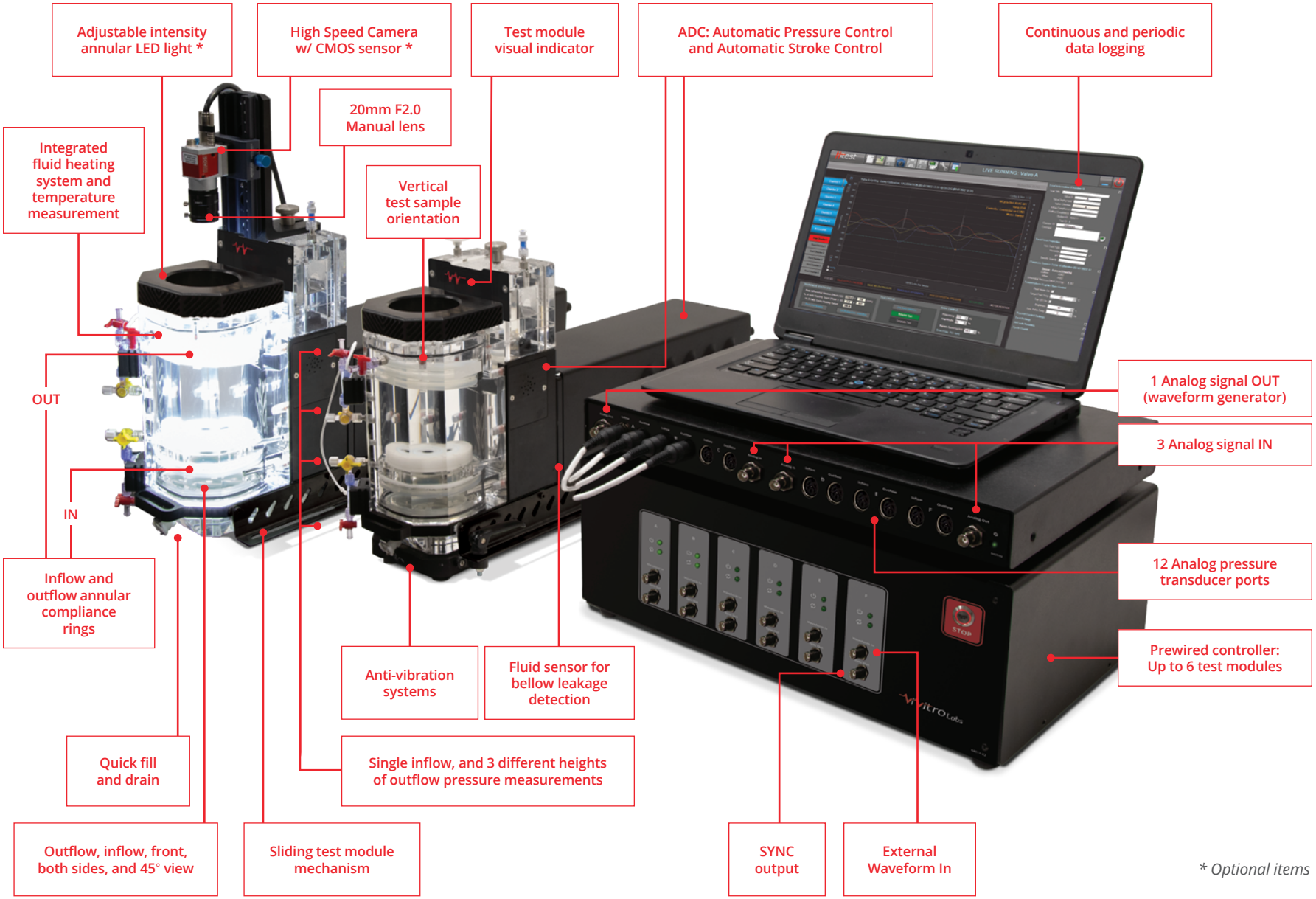
ViVitro ADC Heart Valve Durability Tester can be used to assess cardiac valve repair devices, transcatheter cardiac occluders, and cardiac implant devices.

## More ViVitro ADC Heart Valve Durability Tester Features

- True independent test modules with no fluid connections and dedicated electronics including linear electromagnetic motors, automated by-pass control, and temperature measurement.
- Automatic control system maintains optimum valve loading conditions during accelerated wear or real time testing.
- Large, customizable test chamber design fits all valve sizes and geometry and accommodates supporting structure(s).
- Modular system optimizes part and component interchangeability.
- Standalone architecture eliminates neighboring module disruptions.
- Vertical test sample configuration minimizes gravity effects on valve leaflets, leading to symmetric wear.
- Valve holder design facilitates chamber seal integrity.
- Integrated anti-vibration systems minimize pressure signal disruptions and improve high speed video quality.
- Inflow and outflow chamber annular compliance rings optimize differential pressure waveforms.
- Independent heater and temperature sensors each test module and corresponding test valve.
- Adjustable intensity annular LED light delivers maximum high-speed imaging luminosity with minimal reflection impact.
- Customizable valve annulus ring fits all valve geometries.
- Adjustable outflow pressure sensor height accommodates different valve designs, including valves in conduits.
- Pressure design features low system mean (approx. 10 mmHg) for load reduction and increased lifespan of seals and bellows. No external pressure source or compressor required.
- Camera holder ensures repeatable high-speed camera positioning, increased test image capture quality and reliability between inspection cycles.
- Embedded safety systems include bellows leakage sensor, fluid level detector, temperature change and pressure drop monitoring.
- Sliding test module mechanism provides test sample inflow visualization and ease of servicing.
- Optimum test chamber visibility for image capture in outflow, inflow, front, lateral, and 45° viewing positions.

## ViVitro ADC Heart Valve Durability Tester - 2 test module configuration

*Information and images are accurate as of publication, but subject to change.*




* *Optional items*

## Specifications

| | |
|---|---|
| **Test module weight:** | Empty = 20.6 kg/module<br>Full = 22.1 kg/module |
| **Full Controller and Data Acquisition unit weight:** | 8.4 kg |
| **Footprint - 6 modules configuration:** | Min Bench Length = 1650 mm*<br>Min Bench Depth = 600 mm<br>Height = 362 mm (without Camera)<br>Height = 400 mm (with Camera) |
| **Footprint - 2 modules configuration:** | Min Bench Length = 850 mm*<br>Min Bench Depth = 600 mm<br>Height = 362 mm (without Camera)<br>Height = 400 mm (with Camera) |
| **Controller power supply requirements fully loaded:** | 675 W w/ 6 chambers with controller, 1 light ring, heaters on, at 100 mmHg No DAQ, No PC |
| **System operating frequencies[2]:**<br>*[2] Tested w/ calibrated orifice* | 1 Hz to 70 Hz[1]<br>*[1] Test sample behavior and frequency response dependant.* |
| **Test chamber diameter** | Max support OD: 95 mm |
| **Test chamber height & clearance:** | Total Height/clearance up to 113.5 mm |
| **Piston max stroke volume:** | 38 ml/stroke |
| **Test chamber transparency:** | Inflow, outflow, left and right, 1 angle at right 45° |
| **Average hydrostatic pressure head:** | 10 mmHg |

** Minimal distance between units: 30 mm*




ViVitro ADC Heart Valve Durability Tester
- 1 test module configuration

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## Software

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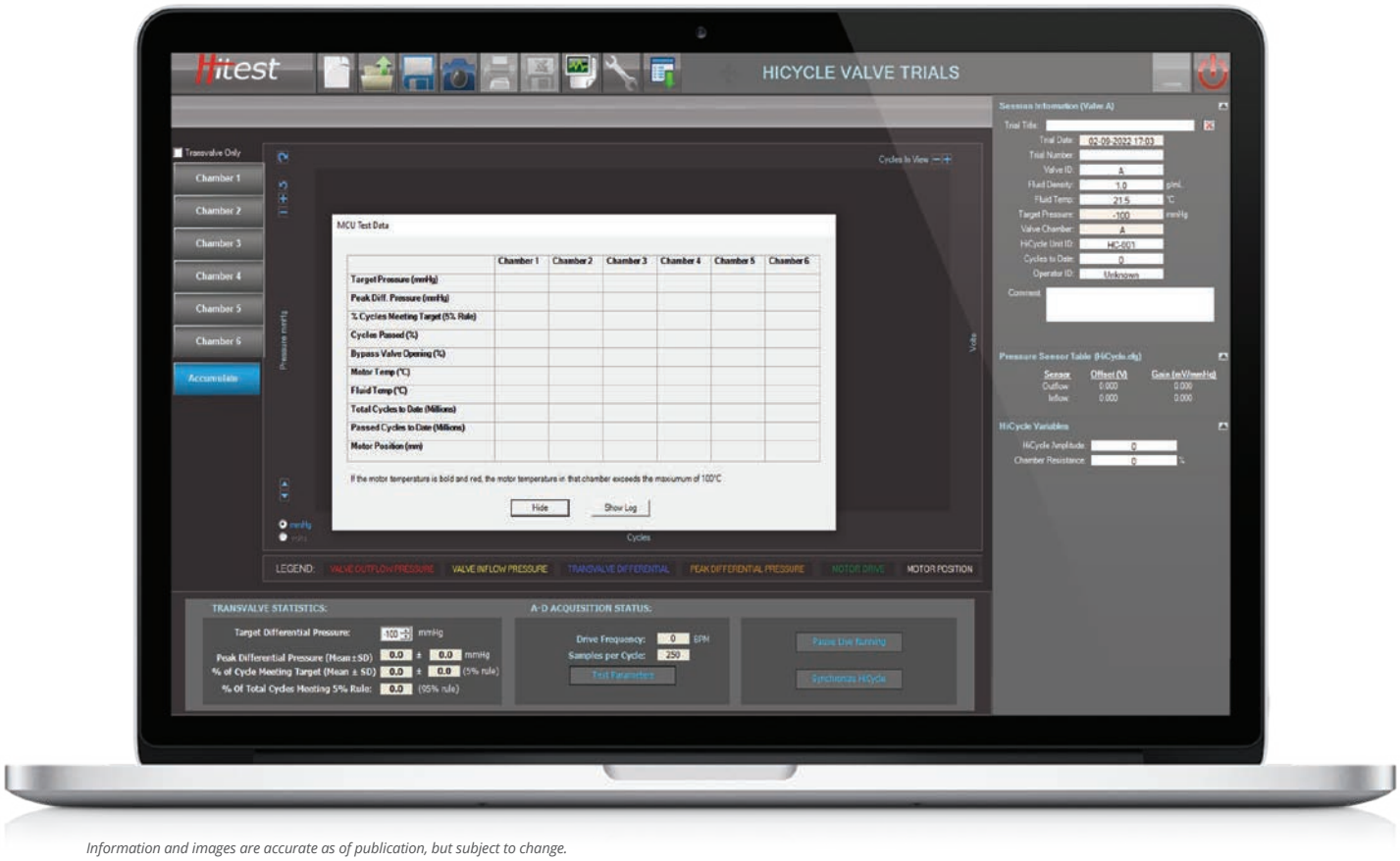
- Test sample identification data embedded in test log with calibration values




*Information and images are accurate as of publication, but subject to change.*

## Continuous data log mode

Cycle to cycle information (peak differential, % of cycle meeting target pressure) can be collected for a predefined periods of time and saved over multiple .CSV files. Data is recorded in engineering units.

## Period data log mode

- Fixed number of cycles captured
- Periodic data report automatically generated based on user predefined parameters:
- Ability to periodically save entire waveform with user(s) defined output data (inflow and outflow waveforms minimum capture, and other test parameters)
- User-friendly field selector for output data

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