

ViVitro Labs AWT-V8 System with Dual Control Technology (DCT)TM

For early detection of Heart Valve Prosthesis Fatigue Failure
under constant loading conditions at Valve Closure and Opening



AWT-V8 with true standalone architecture and early detection of valve prosthesis fatigue failure. Plug and Play modules with pre-wired controller for up to 6 test modules

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

The ViVitro Labs AWT-V8 system with Dual Control Technology (DCT)[™] and its True Standalone Architecture is the **first** test system designed to automatically detect the onset of valve fatigue failure before any hydrodynamic inspection points. The **Historical Data View** leverages the advanced dual pressure control technology of the ViVitro Labs AWT-V8 system to offer uninterrupted valve health monitoring during AWT studies, automatically alerts users of potentially undesirable fatigue related events during testing.

The software integrated AWT-V8 Historical Data View allows users to:

- Detect subtle changes in valve behavior by continuously monitoring the ViVitro Labs AWT-V8 system bypass
- Continuously monitor the progression of critical AWT study parameters over time to determine the exact time of event
- Streamline viewing and analysis of large data sets in support of any subsequent root cause analysis
- Monitor AWT system health during studies and efficiently direct system maintenance interventions when required

Features

1. Monitor the behaviour of the bypass valve
2. Monitor system parameters: Bypass restrictor opening/closing, motor % utilization, motor temp
3. Monitor valve performance parameters: Peak different pressure, % cycle above pressure, fluid temperature, Bypass restrictor % opening/closing. Bypass restrictor opening/closing behavior allows users to:
 - a. Pinpoint a failure event on the valve
 - b. Pinpoint continuous subtle degradation of the valve
 - c. Identify a potential cause of odd bypass behaviour, i.e. a bubble in pressure transducer
4. Combine long-term views of valve performance parameter to support root cause analysis on events leading to valve failure
5. Facilitate inspections of study parameters to confirm compliance with ISO requirements
6. Advance plot navigation tool to assist user to inspect data or region of interest
 - a. Long-term data plots against time or cycle
 - b. Default display set to 24 hrs and auto-refreshes to show the most recent data trends
7. Conveniently analyze long term trends from large data sets without requiring users to post-process large amounts of data



ViVitro AWT-V8 System Historical Data View during valve failure – 1 module view



ViVitro AWT-V8 System Historical Data View during valve failure – 3 modules

First AWT test system to generate constant loading conditions at valve closure and opening while bringing 100% confidence that cycles have achieved ISO 5840 requirements

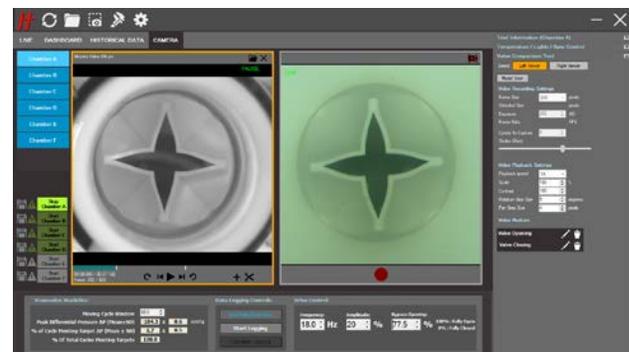
The advanced differential pressure technology of the ViVitro Labs AWT-V8 system with DCT™ provides a unique opportunity to device manufacturers to mitigate the impact of costly test artifacts generated by older generation AWT systems. Unlike older generation AWT systems on the market, the Dual Control Technology (DCT™) of the ViVitro Labs AWT-V8 system protects valve samples from being subjected to variable loading conditions at valve closure and opening, and at the same time maintains repeatable valve kinematics regardless of wear on the leaflet.

The ViVitro Labs AWT-V8 system with DCT™ regulates the differential pressure across the valve sample independently of the stroke volume using two separate control mechanisms. By keeping the stroke volume

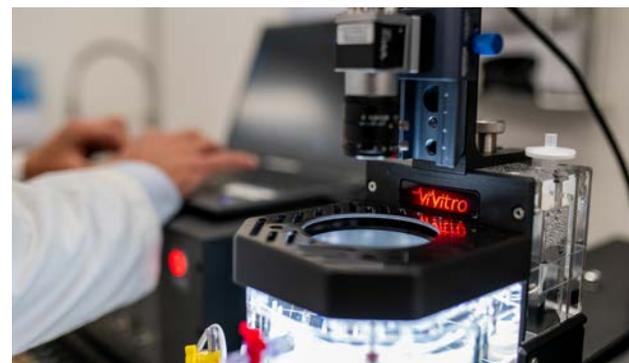
constant, the loading conditions at valve closure and opening can be kept constant and stable throughout the duration of the AWT study. At the same time, to mitigate the effect of the pressure variation due to valve wear, the bypass valve automatically regulates the differential pressure across the valve with minimal impact on leaflets kinematics. By controlling stroke volume throughout the duration of the study, the ViVitro Labs AWT-V8 system with DCT™ locks the driving parameter that affects valve motion and strains experienced by leaflet materials the most. The independent control of the bypass valve optimizes the differential pressure across the test sample with minimal impact on valve motion while optimizing passing cycles. At the end of the AWT study, customers have 100% confidence that cycles have achieved ISO 5840 requirements.

First AWT system to integrate side-by-side live kinematic assessment of heart valve prosthesis during fatigue studies

The ViVitro Labs software integrated **AWT-V8 Valve Comparison Tool** simplifies and streamlines the assessment of valve kinematics to increase the reliability of AWT test results. Users can efficiently and reliably determine which AWT test conditions produce the desired valve opening position by comparing any pre-recorded real-time valve kinematics videos side-by-side with a live High-Speed (HS) camera stream from the AWT system. The ViVitro Labs AWT-V8 with DCT™ combines the action of a High-Speed Camera with an adjustable intensity annular LED light, a Micrometric Rail Support System and an integrated Valve Comparison software interface to simplify video capture and provide uttermost consistency in valve kinematics assessment. The side-by-side comparison allows users to quickly and conveniently compare valve motions between samples at any point during a durability study.



AWT-V8 System with DCT™ with integrated Valve Comparison Tool software interface. Image captured with an industrial silicon valve.



AWT-V8 System with DCT™ Valve Comparison Tool with High-Speed Camera, adjustable intensity annular LED light, Micrometric Rail Support System and software interface

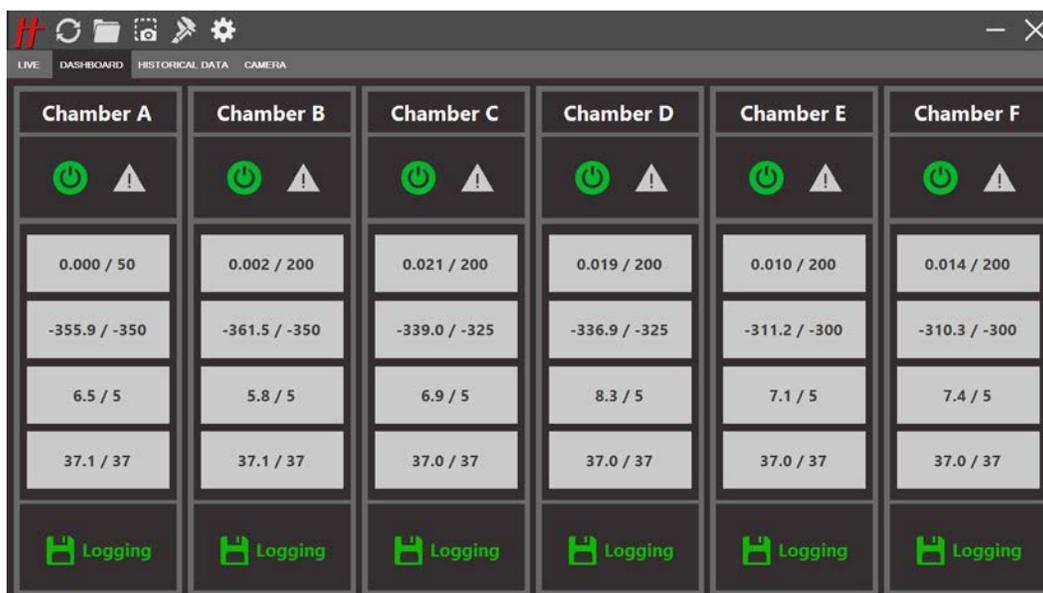
First AWT System to enable smart at-a-glance overview of the status of multiple test modules

The **ViVitro Labs AWT-V8 Dashboard View** increases the efficiency of laboratory resources dedicated to the management of AWT systems by quickly guiding user interventions only when and where they are needed. The ViVitro Labs AWT-V8 Dashboard View provides an at-a-glance overview of the status of each test module

without navigating through multiple system screens and inefficiently searching for study parameters during AWT studies. AWT-V8 Dashboard View is a tool to optimize laboratory resources and boost efficiency in management of AWT studies.



ViVitro AWT-V8 System Dashboard View – At-a-glance system status for 3 standalone modules and 3 disconnected



ViVitro AWT-V8 System Dashboard View - At-a-glance system status for 6 standalone modules

- Patent Pending Dual Control Technology to generate constant loading conditions at valve closure and opening during Accelerated Wear Testing (AWT) and Dynamic Failure Mode (DFM)
- Fully software-controlled system with active bypass valve control to provide 100% confidence that all cycles have achieved ISO 5840 requirements
- Pre-wired controller unit and data acquisition system for easy PnP upgrade of up to 6 test modules to ensure maximum versatility and modularity
- True standalone architecture and independent test modules to avoid disruption to adjacent on-going tests
- Largest stroke volume on the market. 38ml/stroke specifically designed to meet Dynamic Failure Mode (DFM) test conditions with large valve prosthesis
- Large transparent test chambers to provide optimum inflow, outflow, and lateral visibility during test sample inspection
- Patent pending flow loop system to operate system under low hydrostatic pressure conditions and without any external pressure source or compressor

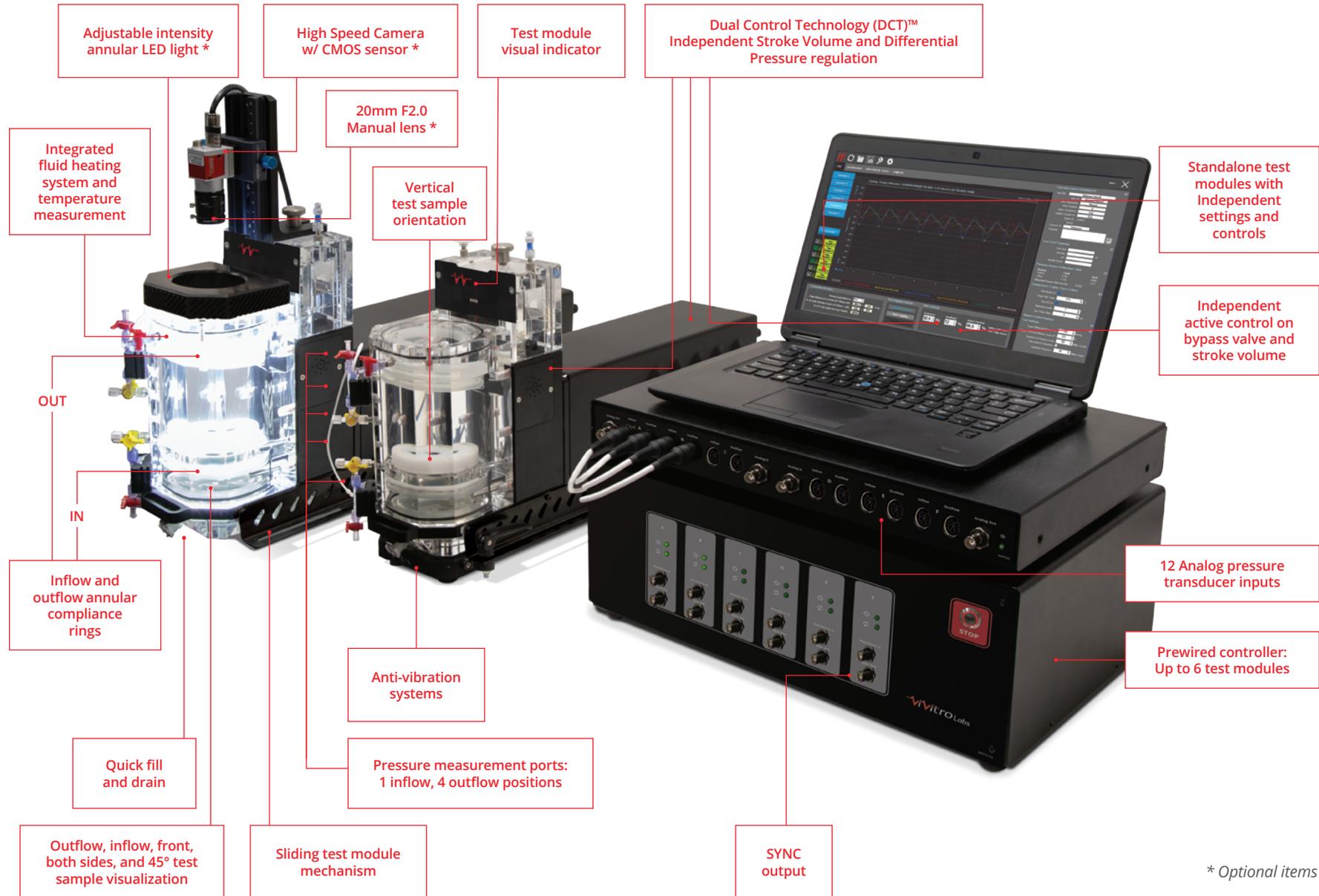
The ViVitro Labs AWT-V8 System with Dual Control Technology (DCT)[™] meets ISO 5840 Accelerated Wear Testing (AWT) and Dynamic Failure Mode (DFM) requirements for all valve types and designs, including but not limited to: transcatheter (TAVI, TMVR, TPVR, TTVR) and surgical valve technologies; aortic, mitral, pulmonary, tricuspid and biological tissue valves; rigid metallic or polymeric valves; and soft polymeric valve technologies for both the adult and pediatric population. The ViVitro Labs AWT-V8 System with DCT[™] can also be used to test many other cardiac implant devices such as cardiac valve repair devices, valve conduits (cardiac, peripheral, venous) and transcatheter cardiac occluders.

More great features essential for AWT studies

- Standalone architecture of test modules with dedicated electronics, linear electromagnetic motors, automated by-pass control, and temperature measurement
- Visual identification for easy recognition of active test modules during test setup and tuning phases
- Modular system to optimize component interchangeability
- True independent test modules to eliminate test chamber fluid interactions
- Independent heaters and temperature sensors for each test module
- Large test chamber designed to fit a wide variety of valve sizes, geometries and supporting structures for TAVI, TMVR, TPVR, TTVR and surgical valves prosthesis
- Low hydrostatic load system designed to increase the lifespan of seals and bellows
- Valve holder designed for optimum chamber seal integrity
- Integrated anti-vibration systems to minimize pressure signal disruptions and improve stability during high-speed video capture
- Vertical test sample configuration to minimize asymmetric gravitational wear effect on valve leaflets
- Customizable valve annulus ring to fit all valve geometries for TAVI, TMVR, TPVR, TTVR and surgical
- Adjustable outflow pressure sensor height to accommodate different valve designs and conduits
- Embedded safety systems for fluid level, temperature change and pressure drop monitoring
- Sliding test module mechanism for optimum test sample inflow visualization
- Sliding test module mechanism for ease of setup and servicing

ViVITRO AWT-V8 System with DCT™ - 2 test modules configuration

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* Optional items

Specifications

Test module weight:	Empty = 20.6 kg/module	Full = 22.1 kg/module
Controller and Data Acquisition unit weight:	13.5 kg	
Footprint - 6 modules configuration:	Min Bench Length = 1650 mm* Height = 362 mm (w/out Camera)	Min Bench Depth = 600 mm Height = 400 mm (w Camera)
Footprint - 2 modules configuration:	Min Bench Length = 850 mm* Height = 362 mm (w/out Camera)	Min Bench Depth = 600 mm Height = 400 mm (w Camera)
Computer:	Gen i5 or newer, RAM 16GB (RAM), Display: 15.6" 1080p (1920X1080p), Windows 11 Pro	
High Speed Camera:	Sensor format: 9.2mm x 5.8mm (2/3") Pixel size: 4.8um Resolution: 2.51MP Size: 1024x1024 @ 305 fps, 320x320 @ 1129 fps Lens: 25mm, F2.0, C-mount (Optional with Valve Comparison Tool)	
Controller power supply requirements fully loaded:	1200 W w/ 6 modules, 1 light ring, heaters on, at 100 mmHg	
System operating frequencies:	5 Hz to 30 Hz	
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 AWT-V8 System with DCT™
- 1 test module configuration**

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ViVITRO AWT-V8 System – Proprietary software interface and fully software-controlled system

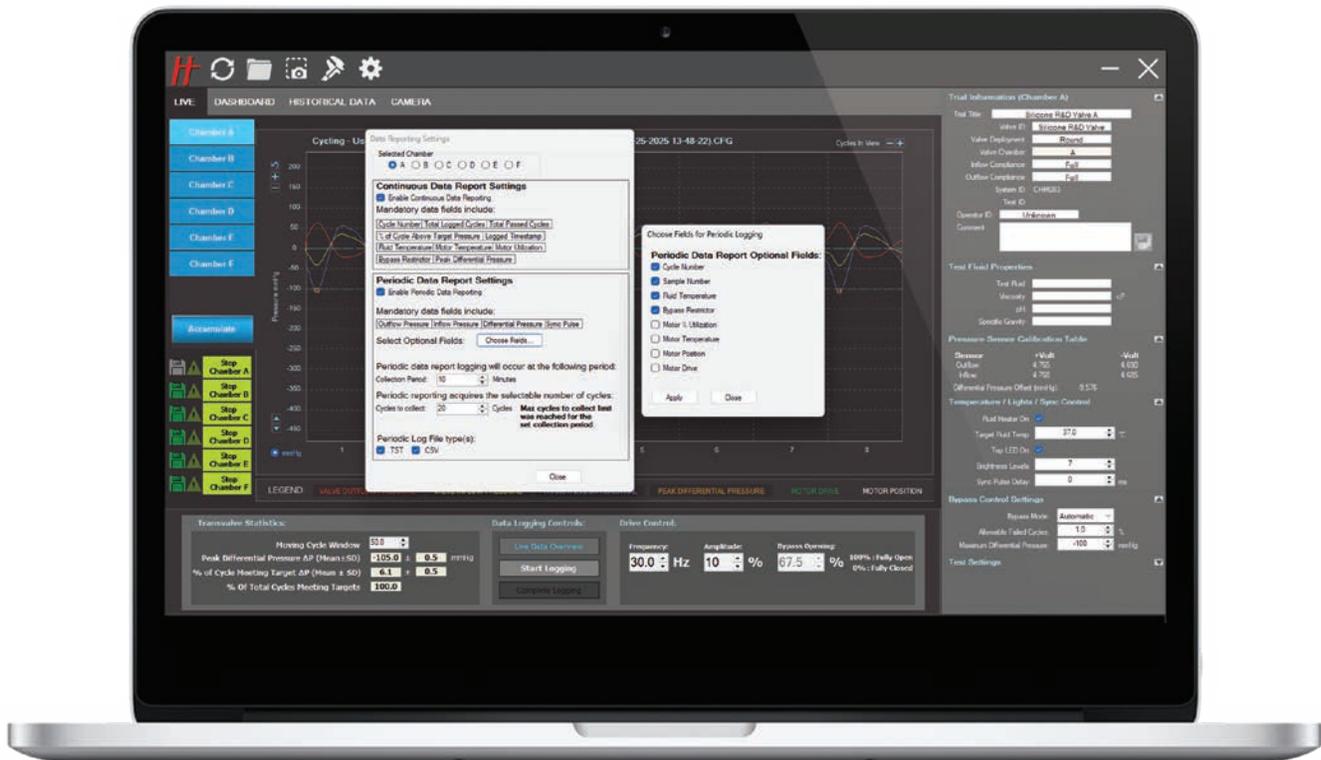
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Content

The ViVITRO AWT-V8 System is a fully software-controlled instrument with a proprietary user-friendly interface to control and maintain AWT test conditions specified in ISO 5840.

Features

- Independent settings and controls for each standalone test module, including stroke amplitude and bypass valve control for target differential pressure adjustment, test frequency, % of cycle meeting ISO requirements and total number of passing cycles
- Individual test module parameter displays for live data overview: passing cycles count, operating frequency, fluid temperature, peak to peak differential pressure, % of cycles meeting pressure target, total number of passing cycles and more
- Continuous and/or periodic data monitoring and records in compliance with ISO 5840 Accelerated Wear Testing (AWT) and Dynamic Failure Mode (DFM) requirements
- Easy control and settings navigation between test modules
- Integrated pressure calibration wizard
- Live real-time waveform display for inflow pressure, outflow pressure, differential pressure, and stroke amplitude
- Individual standalone test module management including system status, connection, cycling, data logging, and error monitoring/logging
- Study parameters and test sample identification data embedded in test log with calibration values
- Fluid temperature measurement recorded for each test cycle
- Visual notification of test module error modes for quick system assessment and ease of management of AWT studies
- Ease of use auto complete feature to avoid total number of cycle overshoot and valve overloading at the end of the study
- Ease of use auto pause feature to avoid total number of cycle overshoot at valve inspection point
- Ease of use auto pause feature when system error is detected
- Final test summary file for each standalone test module at the end of its AWT study
- Data file integrity verification tool for regulatory purposes
- AWT-V8 software HiTest version V8 application verified and validated on Windows 11 OS with certificate of conformity against ISO 5840/2021



Vivitro AWT-V8 System – Continuous and Periodic Data Report Setting with selectable options

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Continuous data log mode

- User friendly and intuitive file naming nomenclature, including time and date of file creation, valve ID, trial name, and standalone test module ID
- Data recording for every test cycle, including total number of cycles, total passing cycles, peak differential, % of cycles meeting target pressure, fluid temperature, motor temperature, motor % utilization, and bypass valve % position
- Data collected for the entire study and saved over multiple .CSV files
- Data recorded in engineering units
- Convenient file sizes for easy handling: Max 10 mb per file

Period data log mode

- Periodically save entire waveform with user predefined output data
- Total 12 parameters: 4 defaults and 8 user-selected
- User determined number of cycles and frequency of capture
- User friendly and intuitive file naming nomenclature, including time and date of file creation, valve ID, trial name, and standalone test module ID
- Convenient file sizes for easy handling



ViVITRO AWT-V8 System – Live data overview for each module

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455 Boleskine Road, Victoria B.C. Canada, V8Z 1E7 | +1 (250) 388-3531
 24-26 Blvd. Gay Lussac, Immeuble Energie, 13014 Marseille, France | +33 4 86 68 68 10

info@ViVITRO Labs.com | www.ViVITRO Labs.com

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