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DuraPulse™ Stent Graft Test (SGT) Instrument

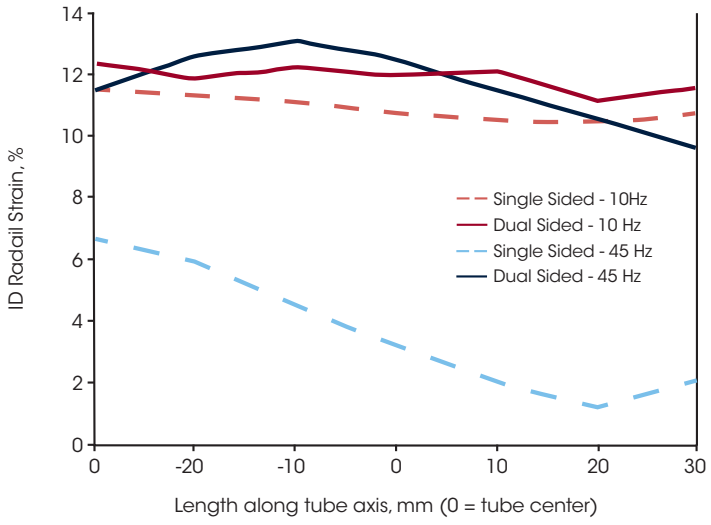
The NEW DuraPulse™ SGT accelerates pulsatile fatigue testing into the future

For more than 20 years, ElectroForce® stent/graft test instruments have been trusted with accelerating pulsatile durability testing for the world's leading vascular device manufacturers. Ten or fifteen year life cycle fatigue tests, amounting to 400 or 600 million total cycles, are shortened to a matter of weeks, resulting in reduced time to market.

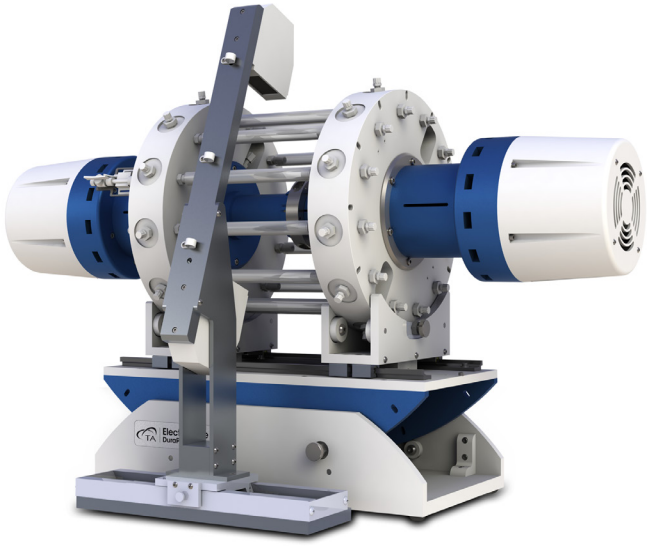
The new DuraPulse™ SGT extends the performance and reliability that ElectroForce SGTs have become known for. A modular manifold design with optimized flow paths, a cradle assembly and cabling scheme that allows full rotation of the manifolds, and an intuitive new user interface that simplifies test set-up and data acquisition, together ensure that the DuraPulse SGT sets a new standard for pulsatile durability testing of stented devices, heart valve frames, occluders, and shunts under simulated physiologic displacements.

The DuraPulse SGT is capable of achieving mock vessel distentions equivalent to test-to-success requirements as defined within testing standards such as ISO 25539 and ASTM F2477. Alternatively, the system may be used to achieve greater than physiologic conditions for fatigue-to-fracture tests. This allows developers to evaluate the fatigue life of a device design under a variety of programmable loading conditions.

DuraPulse SGTs incorporate a **dual-sided pulse design** that provides more uniform strain profiles across the tube than single-sided pulse solutions, particularly at accelerated test frequencies. The fundamental physics of a purely-symmetric dual-sided pulse solution also increases the useful frequency range of pulsatile tests.



Dual-sided pulse profiles demonstrate greater and more uniform strains along the length of the tube, particularly at higher frequencies.



12 Tube DuraPulse SGT with Optical Micrometer Accessory

Proprietary electromagnetic **ElectroForce linear motors** offer the most dynamic performance in the industry, achieving higher test frequencies than competitive systems. This friction-free technology provides unmatched responsiveness, enabling consistent and precise control of volumetric displacements and pressures. ElectroForce motors utilize a flexural suspension, eliminating the need for bearings that wear out over time. DuraPulse SGTs deliver the reliability required for long-term testing and the motors are backed by an industry-leading 10 year warranty.

Small, medium, and large diameter devices can be tested on a single test instrument with the **modular manifold design**. Four interchangeable manifold kits are available and can be utilized to ensure optimal system performance – achieving the highest frequencies for a given device diameter and desired strain. Available in 12, 8, 6, and 4 (bifurcated) mock vessel configurations, the manifolds have been designed to optimize the fluid flow paths, producing the highest frequency and strain combinations available. Each manifold set rests within a **manifold cradle assembly** that facilitates 360 degree rotation of the manifolds and tilts for ease of test preparation.

Testing with the DuraPulse SGT is typically performed at physiologically relevant temperatures (~37°C), however tests can be performed at ambient fluid temperatures up to 40°C with the integrated temperature control system.

The DuraPulse SGT uses an optional **optical micrometer measurement system** to measure real-time strain during testing. The micrometer includes a linear positioning stage that facilitates the movement of the micrometer along the length of the tube to measure strains at different tube positions. The optical micrometer is preconfigured with two modes, yielding higher accuracy and lower signal noise for both small and large diameter devices.

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The optional **Pressure Control Assembly (PCA)** is a convenient way to simplify and automate control of the desired mean pressure in the mock vessels during testing.

System Status Indicator (SSI) lights provide a clear visual indication regarding the operating states of your test instrument such as *System Power On, Test in Progress* or *Test Interrupted*. With a variety of mounting options, the SSI light can be placed in a convenient location that makes it easy to see from wherever you may be in the lab.

WinTest® controls include advanced **WinTest software** and control electronics to provide an ultra-reliable platform for conducting long-term durability testing. WinTest software includes an optional **Advanced Security Suite** to facilitate compliance with current industry standards for data security in the medical device industry and product development.

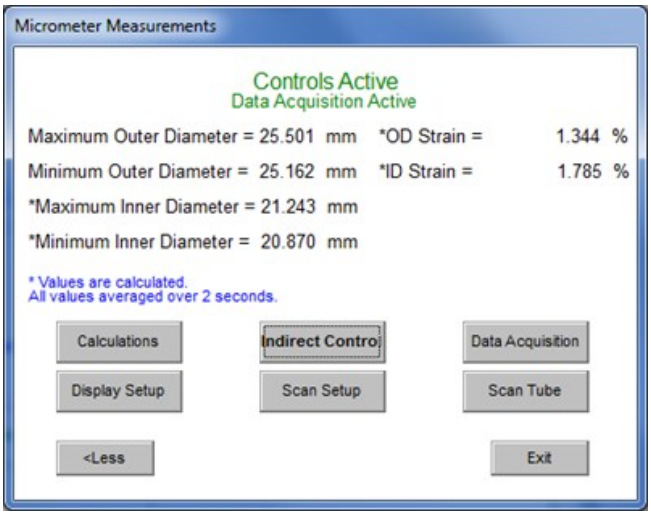
The **DuraPulse SGT Micrometer Measurement and Control application software** ensures easy test protocol development and data acquisition set-up. The application software allows the user to choose between two adaptive control modes; **strain amplitude control and pressure amplitude control.** The control modes utilize amplitude control algorithms to ensure that the test instrument achieves user-defined end levels. Waveform amplitudes and frequency may be adjusted at any time without the need to stop the test. The application software also monitors for unexpected conditions, and may be programmed to automatically stop the test if problems are detected.

In addition to calculating the OD strain of the tube, the application software also determines the maximum and minimum values of the inner diameter of the mock vessel as well as the associated strain percentage. These values are calculated in accordance with the industry standard calculations identified in ISO 25539.

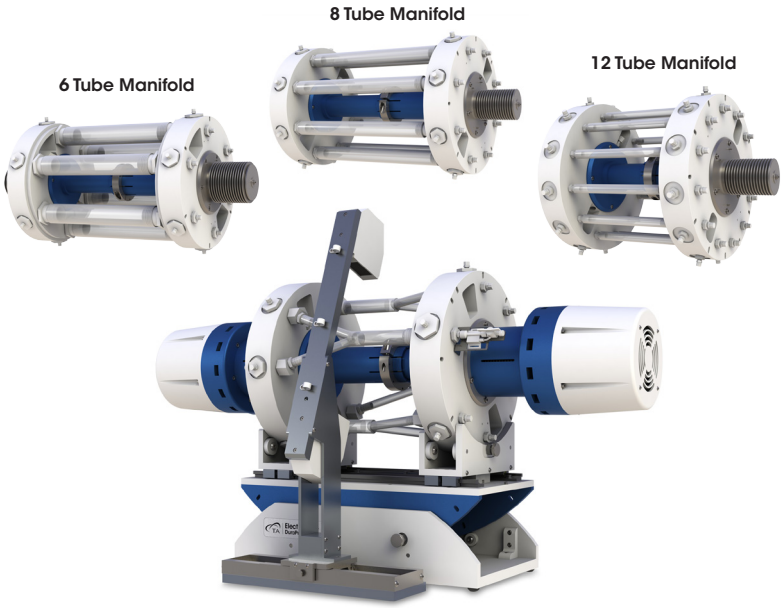
An **intuitive data acquisition** scheme makes it easy to collect maximum (peaks) and minimum (valleys) diameter and strain data over a user-prescribed duration for the length of the test. The data is output into a file format that can be easily imported into a third party analysis software. In addition, a tube scanning feature utilizes an indirect command mode that locks in commanded values and allows the user to move the laser to different positions along each tube and record diameter and strain measurements without stopping the test instrument.

Each system includes an **uninterruptible power supply (UPS)** back-up system to smooth out power bumps and ensure a smooth shut down in the event of an extended power failure.

Specification	12 Tube DuraPulse SGT	8 Tube DuraPulse SGT	6 Tube DuraPulse SGT	4 Tube DuraPulse SGT
Number of Sample Tubes (mock arteries)	12	8	6	4 (Bifurcated)
Sample Tube ID Range	2-10mm	10-25mm	25-50mm	10-18 Iliacs 18-30mm Aorta
Sample Tube length Range (Fitting-to-Fitting)	96-180mm	170-340mm	99-272mm	152-322mm
Operating Frequency	1-100Hz	1-100Hz	1-100Hz	1-100Hz
Dimensions (WxDxH) includes micrometer accessory	1.03 x 0.51 x 0.72m	1.21 x 0.51 x 0.72m	1.24 x 0.48 x 0.73m	1.21 x 0.51 x 0.72m



ID and OD Diameter and Strain Measurements with Optical Micrometer Application Software



4 Bifurcated Tube DuraPulse SGT with Optical Micrometer Accessory and Optional Manifold Kits