ElectroForce® 9210 Drug-Eluting Stent Test Instrument

Accelerated Pulsatile Distension for Coated Stent Durability

Ten-year FDA accelerated bench testing of coated stents can be performed in weeks with the ElectroForce® 9210-12 drug-eluting stent test instrument. This application of ElectroForce high bandwidth linear motors provides the capability to test more stents faster. The modular design allows the stent developer to acquire additional test capabilities as they are needed. The test modules consist of:

- The ElectroForce 9210-12 pulsatile fatigue instrument
- The automated particle capture module
- Interface to real-time particle counters.

The base **ElectroForce drug-eluting stent/graft test instrument** provides several test capabilities to the stent developer, including:

- Accelerated 10 to 15 year (400-600 million cycles) fatigue durability testing at relevant physiological distensions
- Accelerated fatigue to fracture testing at greater than physiological distensions
- Demonstrated performance bandwidth to perform physiological or accelerated (from 1 Hz to >100 Hz*) durability testing of coated stents.

ElectroForce®
Model 9210-12
Drug-Eluting Stent
Pulsatile Fatigue Instrument

Laser micrometer for measurement and control of pulsatile distension

Features and Benefits

- Accelerated closed-loop servo-control of pulsatile distension
- Up to 12 mock arteries per test
  - This leaves as many as 10 tubes available for testing when using the recommended 'blank' tube and optional 'bare metal stent' tube
- 2.0 mm to 14.0 mm mean device diameter capacity*
- Adjustable tube length for optimal testing of longer or shorter stents
- Programmable control and system monitoring using WinTest® Controls. This provides the user with real-time computer control and monitoring of:
  - Distension control
  - Pressure control
  - Flow rates
  - Filter condition and automated filter changes
- Direct diametric distension measurement using the integrated laser micrometer
- Meets or exceeds international standards such as ISO 25539 and ASTM F2477 as well as related FDA guidance documents.

Maximum distension levels and test frequencies dependent on tube diameter, wall thickness, and length.

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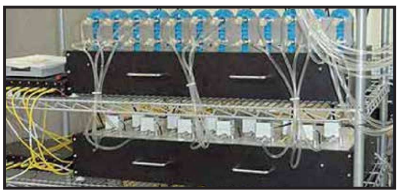
The **automated particle capture module** is designed to simplify the tasks of monitoring and changing laboratory capture filters for each flow loop. The flow from each stent is digitally monitored, and each stent has a laboratory filter element (available in sizes from 1 to 10 micron porosity) in-line and downstream from the stent to capture particulate of interest. The computer monitors the flow and the condition of each filter in use. When a predetermined condition occurs, the computer can change the filter element without the need for stopping the test. Redundant elements for each tube allow the test to continue while the test engineer changes out the first filter. Each filter element is a module that can be disconnected, sealed and labeled to be sent to the lab for particulate analysis.

Real-time particle counting may be added to the system at any time. The ElectroForce® 9210-12 instrument has been tested using commercially available laboratory quality laser counters and counting software. The 9210-12 instrument is also available as an attractively-priced base configuration for those situations where there isn't an immediate need for particle capture or real-time particle counting. The base system provides high-frequency pulsatile distention testing for up to 12 specimens, and then the system can be upgraded in the future. Please contact the ElectroForce Systems Group for more information.



Automated Particle Capture Module

Interface to Real-Time Particle Counting

ElectroForce® Model 9210-12 Product Specifications

Description:	Specification:	Additional Information:
Number of tubes:	12 tubes	Allows two (2) control tubes with ten (10) test samples
Tube configuration:	Straight or curved are available	Other configurations are possible.
Tube length:	Adjustable to 200 mm	
Lumen/tube diameter range:	2.0 mm to 14.0 mm	
Typical distension:	2% to 5% of tube ID	Distensions validated using thick wall tubes
Maximum distension:	10% for 3-6 mm ID	Distensions validated using thick wall tubes
Pulsatile fluid:	Water	Saline (PBS) may be used for fatigue tests. Distilled or deionized water is required for particle counting.
Fluid temperature:	37° C (+/- 2° C)	Instrument incorporates isolated reservoir with temperature controller
Flow rate:	10-250 ml/minute (typically 70-100 ml/minute)	Instrument incorporates isolated flow pump
Maximum mean pressure:	300 mm Hg	Instrument is provided with automated servo-controlled pressure system.
Test control method:	Diameter control or pressure control	Pressure control is run with thin tubes, and diameter control is run with thick wall tubes. Chosen method depends on user test protocol.

Particle Capture Module (PCM) Specifications

Description:	Specification:	Additional Information:
Number of flow paths:	12 tubes	Flow paths are isolated from pulsatile system.
Filter packages:	2 sets per flow path	Filter modules allow easy isolation and transport.
Pore size of capture filters:	1 micron	Filters are consumables and are available in 1, 3, and 5 micron sizes.
Scrubbing filter:	0.2 micron	Bulk scrubbing filter

Dimensions and Power Requirements

Module:	Dimensions (H x W x D):	Power Required:	Weight:
9210-12 SGT	150 cm x 100 cm x 80 cm	100 - 220 VAC single phase (50-60Hz); 10 A	115 kg
Capture module	80 cm x 120 cm x 70 cm	100 - 220 VAC single phase (50-60Hz); 10 A	42 kg

Specifications subject to change without notice

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