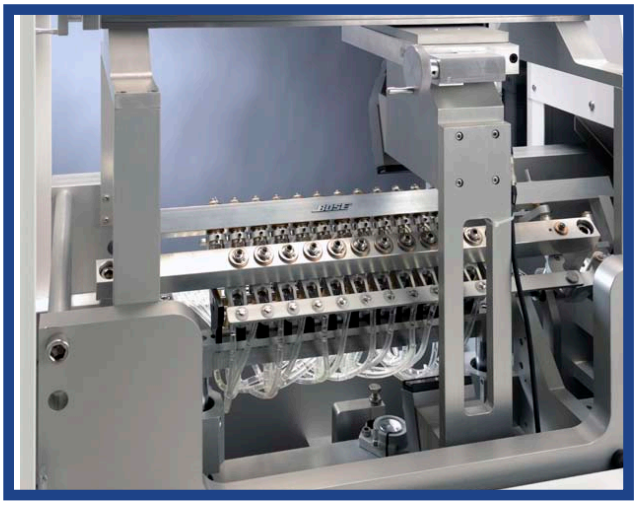
ElectroForce® 9500 Multiaxial Coronary Stent Test Instrument

Advanced Performance to Simulate In Vivo Conditions

Bose Corporation has developed the ElectroForce® 9500 multiaxial coronary stent (MACS) test instrument to simulate the combinations of deflections and displacements that vascular stents experience after deployment into coronary arteries. The 9500 instrument is capable of simulating multiple axes of motion to provide a better representation of in vivo conditions for fatigue and durability evaluation. The system can combine dynamic bending, rotation, extension, and pulsatile distension on multiple stents under controlled conditions.

ElectroForce® 9500 Test Instrument

A New Approach. Coronary arteries have substantial bending, twisting, and stretching motions that are phased with each systolic/diastolic cardiac cycle. In the past, coronary stent developers have had to rely on simple, single motion bench tests and then attempt to combine the loading results into a predictive model for design. These simple bending, tension, torsion and pulsatile fatigue tests have not been appropriate to validate combined motion predictive models, and simulating these motions in an in vitro laboratory test has been difficult for device developers. Agencies such as the US FDA and ISO recommend that new stents being considered for approval be analyzed and pre-clinically bench tested under combined loading conditions prior to regulatory approval.



Multiaxial Angular and Linear Motion Assembly for Multiple Specimens

Multiaxial Test Capability. The ElectroForce 9500 test instrument provides closed loop servo-electric control of the multiple axes of angular and linear motion to simulate in vivo conditions. The motions included are; axial extension (stretch), torsion (twist), bending, and pulsatile distension (inflation/contraction) due to the cardiac cycle. Each of these motions can be combined with each other and adjusted for the proper phase between each other, or run independently. Device manufacturers can now evaluate worst case conditions for a coronary stent design, or program a typical movement profile to perform a simulated 10 year accelerated life test on up to twelve (12) specimens at one time.

The ElectroForce 9500 test instrument from Bose represents a major advancement in multiaxial motion simulation, and provides the coronary stent device manufacturer with a versatile in vitro laboratory testing system. The ability to use representative biomechanical motion data for the evaluation of fatigue durability of an entire stent structure, and then to compare that motion with finite element modeling and clinical studies, is a critical step forward for systematic coronary stent design and validation.

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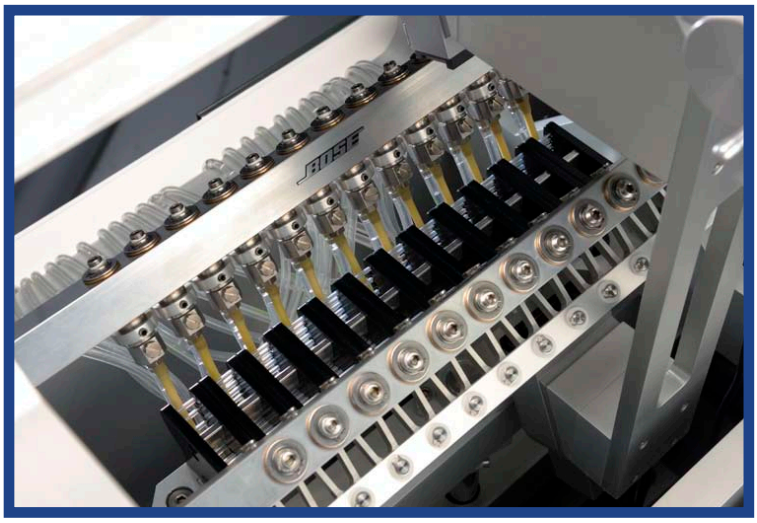
Flexibility and Versatile Software. The ElectroForce® 9500 MACS instrument provides flexible programming to allow the definition of multiple axes of linear and angular displacements in a straightforward manner. For example, the stent developer can choose a prescribed amount of bend at a particular radius, and then combine these motions with a desired rotation and programmed extension. In addition, the motions can be coordinated with the systolic or diastolic phase of each cardiac cycle. Through a motion-predictive model, the system will also automatically compensate for cross-axis motion effects, further simplifying test setup and control.

The ElectroForce 9500 MACS instrument has programmable phase control to allow the developer to program the instrument to meet a variety of worst case loading conditions. The user can also choose to simplify the loading deflection by reducing, or eliminating, an undesired motion by simply programming it into the instrument.



Multiaxial Testing of up to Twelve (12) Specimens Simultaneously

Performance Specifications

Parameter	Specification Rating
Number of tubes	**12**
Working length (maximum stent length)	**Up to 80 mm**
Lumen diameter (mm)	**2.0 - 6.0 mm**
Lumen material	**Standard SGT mock arteries**
Bend (degrees of wrap)	**10° - 120°**
Bend tool radii (measured at tube centerline)	**6 - 40 mm**
Torsion (degrees of twist measured at mechanism)	**± 55°**
Extension (measured at mechanism)	**0 - 12%**
Fluid temperature	**37± 2°C**
Mean pressure	**Up to 200 mmHg**
Stent deployment	**Using standard balloon delivery device, 4mm lumen compatible.** Fittings for smaller ID tubes may have smaller lumen.
Pulsatile distension	**5% to 7% for 2-6 mm lumen diameter**
Pulsatile frequency	**1:1 ratio coupled with mechanical motions**

Specifications are subject to change

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