

RX575 and RX675 Testing Systems

The Instron® RX Systems are the result of a partnership between Instron, a leading provider of equipment that evaluates mechanical properties of materials and components and Machine Solutions Incorporated (MSI), an innovative manufacturer of proprietary mechanical solutions for the medical device industry. At the core of the Instron RX Systems are Instron's 5900 Series universal test frame and MSI's proprietary segmental compression mechanism. The system can be used to generate standard tensile, compression, flexure, peel data, as well as radial stiffness and radial strength from 12 points of contact with the RX fixture. This data is a critical measurement during expansion and compression of interventional devices.

Features

- Minimal setup time
- High levels of testing repeatability and reproducibility
- Enhanced accuracy and resolution
- RX fixture can be completely encapsulated in a temperature chamber
- Easily calibrated and validated
- Utilizes industry standard Instron Bluehill® Software
- Major testing efficiencies through maximum instrument utilization
- Low maintenance
- The RX575 and RX675 fixtures can be sold separately, as an accessory, on most existing Instron load frames (Bluehill 3 software is required)



Principal of Operation

- The RX575 System is typically used to test smaller interventional devices including: balloon expandable stents, self-expanding stents, collagen plugs, and embolic filters
- The RX675 System is typically used for testing of stent grafts, heart valve products, vena cava filters and other basket type filter products as well as other larger expandable products
- Test results can be useful for regulatory submissions, pre-clinical trial testing competitive product testing and product design
- The fixture can be sold as an add-on to an existing 5500 Series testing Instrument or as a fully integrated 5900 Series with NEW Bluehill 3 Software module that provides radial hoop strength and radial stiffness results, displays, and graphic capabilities. Bluehill 3 is required.



The Instron® RX System was designed with international testing recommendations in mind. These include:

- The FDA guidance document titled “Non-Clinical Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems”
- ISO Standard 25539-1:2003(E) Titled “Cardiovascular Implants – Endovascular Devices”
- ISO/TS 15539:2000(E) Titled “Cardiovascular Implants – Endovascularprostheses”

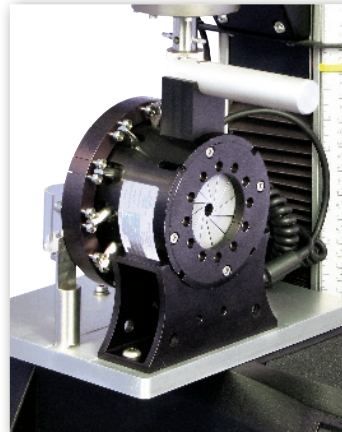
Testing System Options

- 5943, 5944 Single Column
- 5966, 5967, 5969 Dual Column
- Axial speed range 0 to 1016 mm/min (40 in/min)

Since the RX System uses Instron’s Bluehill® software platform, validation procedures, such as IQ/OQ, are simplified for both equipment users and lab managers.

Specifications

Maximum Head Length	mm	60, 120, 220, Custom Sizes
Head Diameters	mm	1 to 14 or 5 to 42, Custom Sizes
Diameter Accuracy	mm	± 0.04
Force Accuracy		± 0.5 % to 1/250 Load Cell Capacity
Power	V	110 or 220
Friction	N	<0.3



RX575 on Single Column System



RX575 Side View

RX575 Head

RX675 Head

Low Maintenance		◆	◆
Stainless Steel Twelve Segment Design		◆	◆
Weight	kg	10.4	32
	lbs	23	70
Size (W×D×H)	mm	305 × 254 × 229	407 × 330 × 381
	in	12 × 10 × 9	16 × 13 × 15
Software		Instron Bluehill 3 Diameter adjustment command utilizing manual setting prescribed ramp or cycle Actual diameter and hoop force are measured displayed, graphed and reported	
Optional Chamber	°C	Clean, lexan enclosure Room temperature to 50 External controller provided	

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