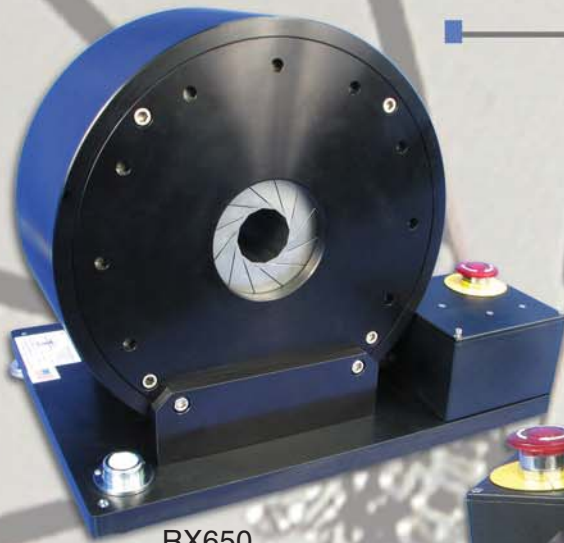
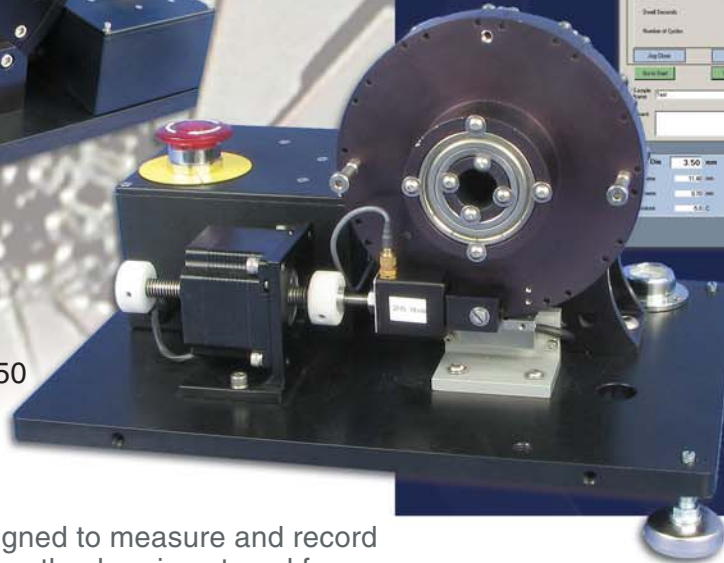


# RX550/650 Radial Expansion Force Equipment



RX650



RX550

The RX550/650 is designed to measure and record radial stiffness and strength, chronic outward force during expansion and radial reactive force during compression of interventional devices such as; balloon expandable stents, self-expanding stents, stent grafts, collagen plugs, embolic filters, vena cava filters, and other radial expanding devices. The MSI RX550/650 radial expansion force gage facilitates knowledgeable and rapid device design changes by utilizing an integrated high speed data acquisition system and proprietary software to generate repeatable and reproducible data.

At the core of the RX equipment is the MSI proprietary segmental compression mechanism which collects data from twelve product contact points providing uniform radial measurement. The RX equipment utilizes an encoder for diameter accuracy, a linear actuator for activation and a precision roller bearing system that is specifically designed to provide a low friction testing environment. Test results can be used for regulatory submissions, competitive product testing, R&D device evaluation and inline manufacturing quality assurance.

The RX equipment 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" and in ISO/TS 15539:2000(E) Titled "Cardiovascular implants – Endovascular prostheses".

## Radial Expansion Features

- High speed data acquisition system.
- Improved motion control.
- Quick set up.
- Repeatable and reproducible data.
- Increased diameter accuracy and resolution.
- Head can be completely encapsulated in a temperature chamber.
- Software capable of replaying multiple data sets for fast and easy comparisons.
- Data output setup for spreadsheet analysis.
- Interchangeable load cells for optimal force resolution.
- Data output includes: lab notes, maximum, minimum and average force.
- Quick and easy software controlled calibration.



# RX550/650

## Radial Expansion Force Equipment



### Summary of Spec Data

<i>Temp Range</i>	Ambient to 50°C (Using Temp Chamber)
<i>Head Lengths</i>	60, 120, 220mm and Custom Sizes
<i>Head Diameters</i>	0.7-11.5, 1-14, 5-42mm and Custom Sizes
<i>Diameter Accuracy</i>	0.2% of Full Scale
<i>Diameter Resolution</i>	0.01mm
<i>Force Repeatability</i>	1.0% of Full Scale
<i>Force Resolution</i>	0.06% of Full Scale
<i>Open/Close Rate</i>	0.01mm/sec - 5.0mm/sec
<i>Power Requirements</i>	110 or 220 VAC
<i>Load Cell Options</i>	10, 25, 50, 75 or 100lbs
<i>General Warranty</i>	1 Year

### RX550/650 Equipment Specifications

#### *Expansion Force Measurement Head*

- Stainless Steel twelve segment design.
- Friction levels <0.3N of Hoop Force.
- Custom head diameter ranges and lengths available.
- Imbedded temperature sensor (accuracy +/- 1.2°C).
- Standard integrated load cell 50lbs (maximum hoop force 33N, 7.5lbs).

#### *Control Module Specifications*

- High speed motion control system.
- Custom cable connection between module and expansion head.
- Integrated control system with monitor, keyboard and mouse.
- High speed data acquisition (100 samples/second).
- Data retrievable via external drive.

#### *Software Specifications*

- Imbedded PC.
- Diameter control command utilizing manual setting, prescribed ramp, cycle or from file.
- Force control command utilizing prescribed ramp.
- Diameter and hoop force are measured, displayed, graphed and written to a CSV file.
- Analyze function replays multiple graphs and saves image as PDF.
- Data interpolation at any specified data point, diameter, force or time.

### RX550 Machine Dimensions

- Shipping Weight: 110lbs (50kg)
- Machine Weight: 23lbs (10.5kg)
- Height: 9" (229mm)
- Width: 13" (330mm)
- Depth: 10.5" (267mm)

### RX650 Machine Dimensions

- Shipping Weight: 170lbs (77kg)
- Machine Weight: 70lbs (31.8kg)
- Height: 15" (381mm)
- Width: 18" (457mm)
- Depth: 13.5" (343mm)

### RX550/650 Control Module

- Machine Weight: 15lbs (6.8kg)
- Height: 17" (432mm)
- Width: 9" (229mm)
- Depth: 15" (381mm)