

The RX750/850 is designed to measure and record radial stiffness and strength of self-expanding and balloon expandable devices within a temperature controlled water bath. Many new devices are comprised of materials with mechanical properties that are fluid and temperature dependent. This off-the-shelf solution measures force decay over time and radial strength and stiffness in an aqueous environment. The RX750/850 utilizes the same integrated high-speed data acquisition system and proprietary software as the RX550/650, generating repeatable and reproducible data to facilitate knowledgeable and rapid device design changes.

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 RX750/850 system has an optional dual tank base for testing consecutively in cold and then warm water to simulate loading and body temperature deployment. 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 is designed with international testing recommendations in mind. These include: FDA guidance document titled "Non-Clinical Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems", ISO Standards 25539-1:2003(e), 25539-2: 2008 and 15539:2000(E).

RX750/850 Features

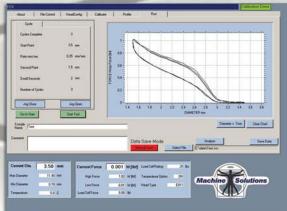
- High-speed data acquisition system.
- Quick set-up.
- Repeatable and reproducible data.
- Software capable of replaying multiple data sets for fast and easy comparisons.
- Software has force control capability for measuring diameter creep over time.
- Data output setup for spreadsheet analysis.
- Interchangeable load cells for optimal force resolution.
- Data output includes: lab notes, maximum, minimum and average force.
- Quick and easy software controlled calibration.



RX750/850

Submersible Radial Expansion Force Equipment





Summary of Spec Data

Temp Range	0°C to 50°C (Using Water Bath)
Head Lengths	120 with 40mm submersible (750) 170 with 70mm submersible (850)
Head Diameters	0.7-11.5mm, 1-14mm (750) 3-50mm, 5-42mm (850)
Diameter Accuracy	0.2% of Full Scale (750) 0.4% of full Scale (850)
Diameter Resolution	0.01mm
Force Repeatability	1.0% of Full Scale
Force Resolution	0.06% of Full Scale
Open/Close Rate	0.01mm/sec - 3.0mm/sec
Power Requirements	110 or 220 VAC
Load Cell Options	10, 25, 50, 75 or 100lbs (50lbs Stardard)
General Warranty	1 Year - Routine Maintenance Required

RX750/850 Equipment Specifications

Expansion Force Measurement Head

- · Stainless steel twelve segment design.
- Standard 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 control 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

- Embedded 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.

RX750 Machine Dimensions

- Shipping Weight: 160lbs (73kg)
- Machine Weight: 70lbs (32kg)
- Height: 18" (457mm)
- Width: 31" (787mm)
- Depth: 24" (610mm)

RX850 Machine Dimensions

- Shipping Weight: 360lbs (163kg)
- Machine Weight: 235lbs (107kg)
- Height: 30" (762mm)
- Width: 31" (787mm)
- Depth: 29" (734mm)

RX750/850 Control Module

- Machine Weight: 15lbs (7kg)
- Height: 17" (432mm)
- Width: 9" (229mm)
- Depth: 15" (381mm)