

Standard Testing Protocols

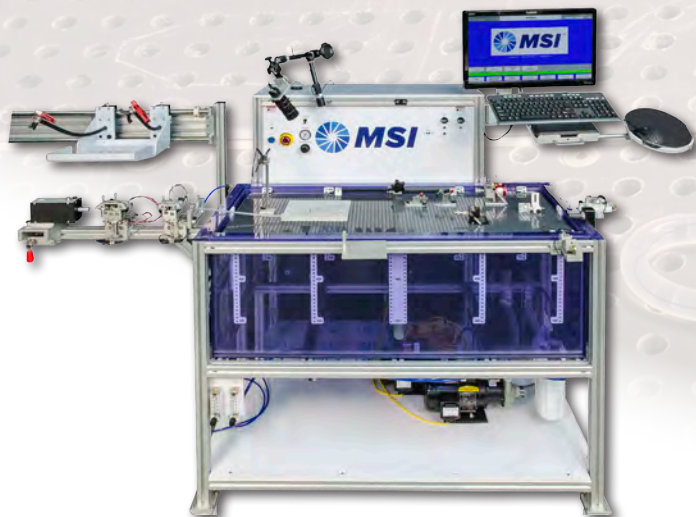
The Interventional Device Testing Equipment (IDTE) from MSI comparatively and quantitatively tests and records the performance features of interventional devices including: catheters, guidewires, stent delivery systems, colonoscopes, endoscopes and scope tools. IDTE's PC controls and versatile test configurations allow for simple and repeatable test setups and instantaneous feedback on device design changes, thereby reducing design timelines. Test results can be used for regulatory submissions, competitive product testing and R&D device evaluation.

The IDTE was designed with several international testing standards in mind. These include: ASTM F2394-07 for preconditioning of the stent on the deployment system prior to retention testing, ISO Standard 25539-1:2003(E) Titled "Cardiovascular Implants – Endovascular Devices" and ISO/TS15539:2000(E) Titled "Cardiovascular Implants Endovascular Prostheses". While still adhering to published guidance standards, the IDTE allows users to distinguish their products from competitors by creating and testing in extremely challenging conditions.

- Trackability – Measures the force needed to advance a catheter, guidewire or other interventional device through a tortuous path using the recommended accessories.
- Retractability – Measure of the force needed to withdrawal the device from a torturous path.
- Pushability – Uses the proximal and distal load cells to measure the amount of force on the distal tip of the product when a known force is being applied to the proximal end of the product.
- Flexibility – Measure of a catheter tip's ability to track over a specified bend in a guidewire, such as a 90 degree bend.
- Crossability – Measure of the force needed to advance an endovascular system through a simulated stenosis/lesion within a tracking model.
- Torqueability – In a tortuous path, measure of the rotational response at the distal end of a device while imparting a rotation at the proximal end.

IDTE3000

Catheter & Stent Testing Equipment



Power Requirements	208-240 VAC
Temp Range	50°C (120°F)
Water Bath Temp Accuracy	(+/-) 2°C (3.6°F)
Proximal Load Cell	600g - 6kg
Product Advance Rate	User Defined (Range 5 - 600cm/min)
Distal Load Cell	1kg submersible
Auxiliary Load Cell (optional)	100g submersible
Proximal and Distal Load Cell Accuracy	(+/-) 3g
Torque Sensor (optional)	5,10,50 oz-in
Units of Measure	Selectable
General Warranty	1 Year

IDTE3000 Machine Dimensions

- Shipping Weight: 850lbs (386kg)
- Machine Weight: 550lbs (250kg)
- Tank Capacity: 32gal (121L)
- Height: 54" (1372mm)
- Width: 47" (1194mm)
- Depth: 37" (940mm)

IDTE3000 Equipment Specifications

Base Equipment Specifications

- Adjustable track configuration with two dimensional and three dimensional testing capabilities
- Semi-enclosed heated water bath system (+/- 2°C)
- Adjustable flow control through the path with luer fitting
- PC with Windows 7 operating system
- Touch screen machine operation
- Catheter holding tray
- Two live roller systems
- Two (2) auxiliary load cell inputs for optional equipment
- One (1) pushability test distal load cell fixture (1kg)
- Spring activated segmental alignment mechanism

Proximal Roller Assembly

- Stepper motor driven flip top urethane roller system for easy product loading
- Micrometer adjustment for various product diameters and repeatable product compression
- Encoder position feedback
- Integrated load cell (600g - 6kg)

PC/Software Specifications

- Indusoft Beckoff controlled PC
- Adjustable testing parameters include: advancement distance, advancement rate, data and direction of motion
- Trackability, Pushability, Cycle and Torqueability testing
- Sequential numbering system for rapid batch testing
- 1000 Profile storage capability
- Password protected user level controls
- Data Acquisition system; data is saved in a CSV (Comma Separated Variable) format and a PDF format for a secure copy

Machine Options

- Integrated video capture system, with data and video linked in time
- Torque measurement package for Torqueability, Torque to Failure and Steerability testing
- Double roller system with 3kg load cell
- High force roller system with 6kg load cell
- Custom size water bath
- Frictionless track system with air bearings and roller supports for products with heavy or large proximal ends or handles
- Touhy borst for side input to the water tank
- Fixed plate paths with customer defined path geometry

