



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, there by 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.

- **Track force** – Measures the force needed to advance a catheter, guidewire or other interventional device through a tortuous path using the recommended accessories.
- **Push efficiency** – 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.
- **Torquability** – In a tortuous path, measure of the rotational response at the distal end of a device while imparting a rotation at the proximal end.
- **Retractability** – Measure of the force needed to withdrawal the device from a tortuous path.
- **Crossability** – Measure of the force needed to advance an endovascular system through a simulated stenosis/lesion within a tracking model.

IDTE2000™

Catheter & Stent Testing Equipment



IDTE2000™ 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 XP operating system.
- Touch screen machine operation.
- Catheter holding tray.
- Two (2) auxiliary load cell inputs for optional equipment.
- One (1) push test distal load cell fixture (1kg).
- Spring activated segmental alignment mechanism.

Proximal Roller Assembly (1kg)

- 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 (1kg).
- Adjustable position to accommodate various introducer lengths.

PC/Software Specifications

- Software written with Visual Basic 6.0.
- Adjustable testing parameters include: advancement distance, advancement rate, data averaging rate, direction of motion, and track, push, cycle or torque testing.
- Sequential numbering system for rapid batch testing.
- Unlimited testing profiles.
- Password protected areas: set-up and calibration.
- 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 Torquability, Torque to Failure and Steerability testing.
- Two live roller systems.
- Double roller system with 3kg load cell.
- High force roller system with 6 or 12kg load cell.
- Custom size water bath.

Summary of Spec Data

<i>Temp Range</i>	Ambient to 50°C (120°F)
<i>Water Bath Temp Accuracy</i>	(+/-) 2°C (3.6°F)
<i>Roller System Accuracy</i>	(+/-) 3g
<i>Power Requirements</i>	208-240 VAC
<i>Product Advance Rate</i>	User Defined (Range 5 – 600cm/min)
<i>Roller System Load Cell</i>	1, 2, 3, 6, or 12kg
<i>Auxiliary Load Cell</i>	100g submersible
<i>Distal Load Cell</i>	1kg submersible
<i>Torque Sensor</i>	5inoz – 50inoz
<i>Units of Measure</i>	Selectable
<i>General Warranty</i>	1 Year

IDTE2000 Machine Dimensions

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