



## MEDICAL DEVICE TESTING

# PHYSIOTEST

Fast | Accurate | Experienced

PhysioTest provides complete test services including durability, reliability and materials testing for medical devices. As an independent lab, PhysioTest will serve as your primary, confirmatory and/or overflow test source for pulse generators, leads, catheters, introducers, guide wires, surgical instruments and other medical devices. In addition, PhysioTest performs DVT and pre-DVT requirements and failure mode analysis on medical devices. We bring a deep understanding of clinical conditions and device applications to each and every project to ensure you meet your test objectives.

PhysioTest has the experience and equipment to perform a wide range of tests per FDA, CE, ASTM and ISO medical testing requirements. With decades of experience in medical device testing, PhysioTest staff will assist you with test feasibility and design, protocol development, test implementation and results interpretation & reporting. In addition, we are skilled in developing test protocols for devices that do not have test standards in place.

Consider PhysioTest as your independent service to validate your testing or as a source for all your testing needs.

### Device Testing

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- Pulse generators/stimulators
- Leads
- Catheters
- Introducers
- Guide wires
- Surgical instruments
- Other medical devices

### Complete Testing Services

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- Test strategy development
- Test reports
- Custom test equipment
- Test protocols
- Standards
- Risk management and documentation
- Confidential database

### Test Capabilities

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- Durability
- Reliability
- Tension/compression
- Lead flex and fatigue
- Thermal cycling
- Accelerated aging
- Force and torque
- Failure analysis

## Capabilities and Expertise

### ACTIVE IMPLANTABLE DEVICE TESTING

- **Preconditioning**
  - Thermal cycling
  - Accelerated aging
- **Applicable Standards**
  - EN 45502 series
  - ISO 5841: IS-1 connector
  - ISO 11318: DF-1 connector
  - ISO 27186: IS4/DF4 connector
- **Durability**
  - Lead composite torque test
  - 10-year longevity cycling
  - Lead body flex test
  - Lead body composite distal fatigue
  - Connector flex
  - Lead composite pull test
  - Fixation retention force test
  - Header-to-can strength
  - Seal integrity
  - X-ray identification
- **Implant Environment**
  - Abrasion test: lead-to-lead
  - Abrasion Test: lead-to-can
  - Clavicle-first rib compression test
  - Abrasion Test: lead-to-valve
  - Corrosion
- **Implant Tool Interface**
  - Stylet insertion/Withdrawal force test
  - Catheter Insertion/ Withdrawal force test
  - Lead-catheter compatibility
- **Anchoring**
  - Anchor sleeve suture test
- **MR Compatibility**

### INTRAVENOUS DEVICE TESTING

- **Preconditioning**
  - Thermal cycling
  - Accelerated aging
  - Shelf-life
- **Durability**
  - Catheter bond strength
  - Kink resistance
  - Twist integrity
  - Wire bond strength: proximal and distal
  - Catheter body fluid ingress test (gas pressure)
  - 3-point body deflection
  - Catheter integrity: tensile force
  - Catheter integrity: torque at each unique section
  - Catheter integrity: torque for working length of catheter
  - Tip stiffness
  - Side force
  - Corrosion
- **Steerability**
  - Actuator hold force
  - Actuator slide force
  - Steerability: spring back
  - Steerability: linearity
- **Dimensional**
  - Shaft diameter
  - Catheter length
  - Tip electrode dimension
  - Distal tip radius
  - Electrode spacing
- **Distal End Characteristics**
  - Catheter reach
  - Steering deflection
  - Temperature sensor accuracy
  - Temperature sensor operating range
- **Electrical Characteristics**
  - Catheter impedance
  - Ablation energy transfer
  - DC isolation resistance
  - RF isolation impedance
  - DC lead resistance
  - RF lead impedance
  - RF leakage current
- **MR Compatibility**

## A Comprehensive Resource

PhysioTest is a subsidiary of Evergreen Medical Technologies. Evergreen Medical provides complete product research, design, development and manufacturing of class II/III devices for cardiac, vascular, neurology, gastroenterology and diabetes applications. Both PhysioTest and Evergreen bring a deep understanding of clinical conditions and device applications to insure your product and clinical objectives are met.



1350 Energy Lane, Suite 100  
 St. Paul, Minnesota 55108  
 651-646-7700  
[evergreenmedtech.com](http://evergreenmedtech.com)  
[info@evergreenmedtech.com](mailto:info@evergreenmedtech.com)