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

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

Complete Testing Services

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

Test Capabilities

- 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.