



fast | accurate | experienced

## Pacemaker and Defibrillator Device Testing

### RELIABLE TESTING FOR YOUR DEVICE

PhysioTest tests only medical devices. We provide complete test services including durability, reliability, and materials analysis for medical devices. As an independent testing lab, PhysioTest can serve as your primary, confirmatory and/or overflow test source for developmental testing and Design Verification Testing (DVT). In addition, PhysioTest can assist companies in establishing requirements and a test plan for their device and failure mode analysis on medical devices in the market. We bring a deep understanding of clinical conditions and device applications to each and every project to insure 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 and reporting.

For specialized tests, we develop and validate test procedures and test equipment.

Our focus is in the mechanical durability and reliability testing for medical devices. We also have sophisticated testing capabilities for the electrical testing of implantable or acute use electrodes and connectors.

### Complete testing services

- Test Strategy
- Test reports
- Custom test equipment
- Test protocols
- Standards guidance
- Risk management documentation
- Confidential Database

### Test capabilities

- Durability
- Reliability
- Preconditioning
- Design Verification Testing
- Design Analysis Testing
- Test development
- Failure Analysis

## **ABBREVIATED LIST OF PACEMAKER AND DEFIBRILLATOR LEAD TESTS**

### **Preconditioning**

Thermal cycling  
Accelerated Aging

### **Applicable Standards**

ISO 14708 series  
ISO 5841: IS-1 Connector  
ISO 27186: DF-4 Connector

### **DURABILITY**

Lead Composite Torque Test  
Lead Body Flex Test  
Lead Body Composite Distal Fatigue  
Connector /Transition Flex  
Lead Composite Pull Test  
Fixation Retention Force Test  
Torque Test  
Seal integrity  
X-ray identification

### **IMPLANT ENVIRONMENT SAFETY**

Abrasion Test-Lead to Lead  
Abrasion Test-Lead to Can  
Corrosion

### **IMPLANT TOOL INTERFACE**

Stylet Insertion/Withdrawal Force Test  
Catheter Insertion/ Withdrawal Force Test

### **ANCHORING**

Anchor Sleeve Suture Test