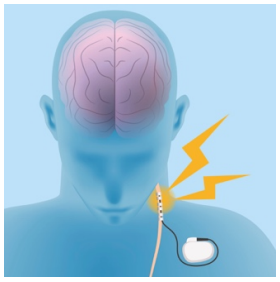
MDT
Medical Device Testing Services
An Element Materials Technology Company

Neurostimulator Lead Testing

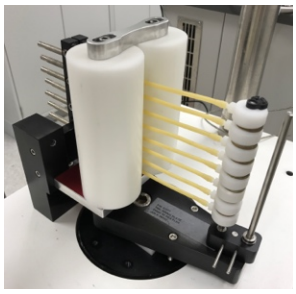


Neurostimulation is a fast-growing field with many recent technological advancements. FDA-approved neurostimulation systems include spinal cord, deep brain, sacral nerve, and vagus nerve stimulation, while emerging technologies such as hypoglossal, gastric, and carotid artery stimulation systems are under development. The neurostimulation devices market was estimated at $3.6B USD in 2015 and is expected to reach $5.8B USD by 2020[1,2].

The recently-updated standard ISO 14708-3:2017 Implants for surgery – Active implantable medical devices – Part 3: Implantable neurostimulators specifies the requirements for active implantable medical devices intended for electrical stimulation of the central or peripheral nervous system to provide basic assurance of safety for patients and users.

MDT has experience testing neurostimulation devices per ISO 14708-3, ISO 14708-1, IEC 60601-1 and IEC 62353[3,4]. Example tests we have carried out are outlined below.

Body Flex Test



The goal of this test is to demonstrate structural integrity by simulating the in vivo mechanical conditions that the device will be subject to. The body flex test is a pass/fail test performed at the center of the electrode using a custom-designed fixture (see left) for a predetermined number of cycles, flexing degrees and test frequency mimicking normal conditions of use using a TA ElectroForce 3300 axial/torsion test system. Samples are inspected pre- and post-testing under an optical microscope for any axial or longitudinal cracks or other anomalies. Electrical functionality testing is also performed pre- and post-testing.

Cannula Insertion Test

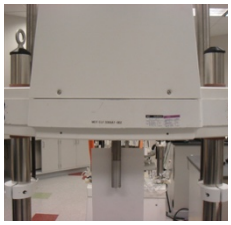
The objective of the cannula insertion test is to meet the customer-defined device durability requirements. A custom-designed fixture (see right) is positioned at a pre-specified angle, and the cannula is inserted and withdrawn for a predetermined number of times in ambient air conditions. The insertion flex angle of the cannula insertion fixture used is verified with image analysis software. Pre- and post-testing optical microscope inspections and current amplitude values for each electrode are also performed.

Durability Test

In durability testing, samples are typically subject to a static tensile load in ambient air conditions without preconditioning using a TA ElectroForce 3300 axial/torsion test system. Test parameters are selected such that they emulate device use. Custom-designed fixturing is used to grip the samples and the following measurements and inspections are performed pre- and post-testing: sample length, electrical functionality, and optical microscopy to identify any sample anomalies or defects.

[1] http://www.grandviewresearch.com/industry-analysis/neurostimulation-devices-industry
[2] http://www.strategyr.com/MarketResearch/Neurostimulation_Market_Trends.asp
[3] https://www.iso.org
[4] http://www.iec.ch/

Torsion Test



The neurostimulator torsion test uses custom-designed adapters (shown on the right) on a TA ElectroForce 3300 axial/torsion test system. Samples are torqued to customer-provided test parameters that emulate device use. Stimulator lead inspections under an optical microscope and electrical functionality tests are performed pre- and post-torsional testing.

Current Leakage Test

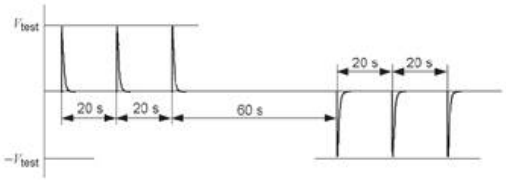
Current leakage testing is performed per IEC 60601-1 using an LCR (inductance (L), capacitance (C) and resistance (R)) meter. Optical microscopy inspection is performed pre- and post-current leakage testing.

Stylet Insertion and Withdrawal Test

The lead stylet is inserted into and withdrawn from the stimulator body while attached to a force gauge so that peak insertion and withdrawal forces can be measured. Number of cycles and acceptable peak forces are determined by the device manufacturer. Samples are inspected pre- and post-testing.

Defibrillation Exposure

Neurostimulators are subject to defibrillation exposure testing in a custom-designed defibrillation exposure box designed to prescribed capacitance, inductance and impedances of the inductor and the defibrillation pulse generator specifications. Timing sequence is described in ISO 14708-1 as shown on the right. Samples are inspected pre- and post-testing for any anomalies or defects.



Dielectric Strength Test

This test measures the dielectric strength of the insulation between the electrode circuits of the stimulator after sample preconditioning (consult IEC 60601-1 and IEC 62353). A custom-designed high potential fixture is used for this test with a Hipot dielectric analyzer. Samples are inspected pre- and post-testing.

Pressure Exposure Test

Neurostimulators are expected to withstand changes in pressure that can occur during transit or normal conditions of use. ISO 14708-1 specifies that the effects of deformation due to absolute pressures at 70 kP ± 3,5 kP and 150 kP ± 7,5 kP applied for not less than 1 h should be investigated to check compliance.

Ultimate Tensile Test

The receiver's ultimate tensile strength is measured using our Instron 5944 tensile tester. Preconditioned samples were inspected prior to testing, attached to the tester with clamp-style grips and pulled to failure in load control at a pre-determined rate and inspected post-testing.

Our engineering team thrives on challenging device testing applications; contact us to discuss how we can help.

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