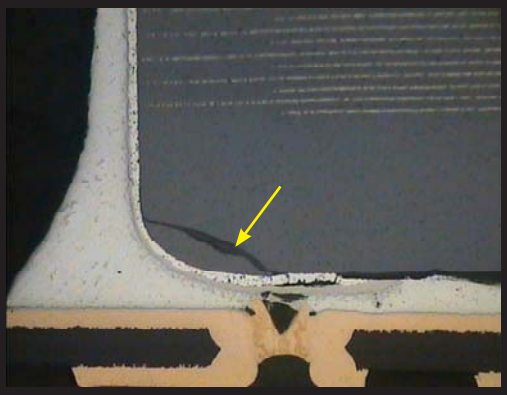
Medical Device Reliability

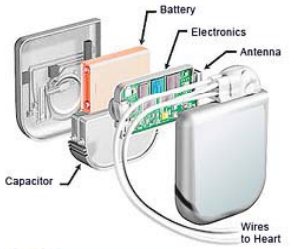
BIOMATERIALS

Objective

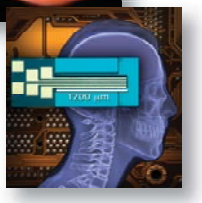
Our goal is to provide medical device manufacturers with critical data, new test structures, and standard test procedures to improve the quality, reliability, and consistency of active implantable medical devices. These devices, including pacemakers, cardiac defibrillators, and neural stimulators, have unacceptably high failure rates. For current devices, we are establishing new test requirements for discrete electronic components, which are often the source of failure. For next-generation devices, we are developing test structures to evaluate alternative packaging materials, which have unproven reliability.



Impact and Customers



- Medical devices represent a significant sector of the U.S. healthcare industry, with annual sales exceeding $13 billion. In the past decade, nearly 3 million life-saving cardiac-assist devices have been implanted. Improved acceptance testing will reduce device failures, improve patient quality of life, and decrease surgical costs.

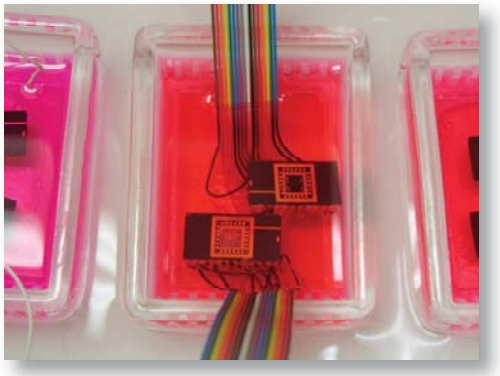


- Next-generation devices will be miniaturized to promote biological acceptance and extend device lifetime. FDA approval hinges on demonstrated reliability. Standard test structures will enable quick evaluation of new packaging materials, allowing more direct comparison between manufacturers and reducing time to market.

- NIST is working with the iNEMI Medical Electronics team to address short- and long-term reliability issues with medical devices. Our collaborators include Boston Scientific, Guidant, Medtronic, St. Jude Medical, Cochlear, Ltd., Biotronik, Med-El, Advanced Bionics, Vishay, AVX, and Kemet.

Approach

Our bodies impose a unique combination of chemical, mechanical, and thermal stresses on implanted medical devices. Current acceptance tests (developed for military, aerospace, and automotive products) do not adequately duplicate these conditions. Failure rates approach 1 %; the goal is less than 0.1 %. To improve acceptance testing, we are assessing a suite of potential acceleration factors and mapping the observed failure modes to those found in explanted devices. Multilayer ceramic capacitors are the focus, as changes in the properties of these components often result in device failure.



We are also gathering critical data on next-generation packaging, where conformal coatings will serve as the primary interface between the device and the biological environment. For example, parylene is already used to coat neural recording electrodes and is proposed to replace metal canisters in implantable cardiac defibrillators. NIST is working with the FDA to develop standard test structures to evaluate the durability and reliability of parylene, and other proposed hermetic packaging, under *in-vivo* stress conditions.

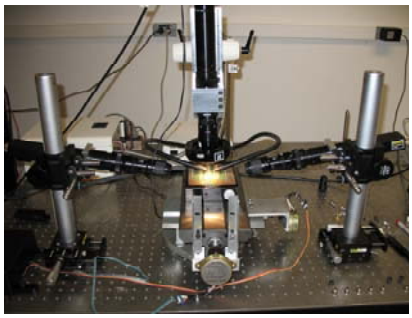
Accomplishments

The iNEMI Medical Technology Integration Group, which includes NIST, has produced a number of documents that advance our long-term goal of better standards for medical device technology. These include a Summary of Use Conditions, an Analysis of Failure Mode Effects, a Definition of Failure Modes, a Pareto of Failure Modes, and a Design of Experiments for measuring and analyzing the lifetime of medical-grade ceramic capacitors.

The Use Conditions Summary and the Failure Mode Effects Analysis are currently under review as potential documentary standards by the Electronic Components Association (ECA, a part of ANSI). Additionally, these formed the basis for a comprehensive study initiated in FY08 at NIST to assess the effects of different stress conditions on component failure, including various combinations of the following:

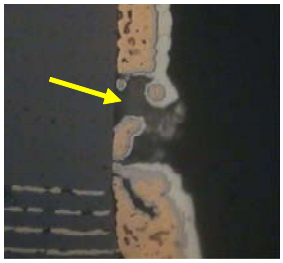
- thermal (hypothermic to febritic)
- mechanical (breathing, bending)
- chemical (corrosive fluids)
- electrical (current, voltage)
- vibration (impacts due to trips or falls)

To analyze statistically relevant component populations, test automation is critical. We have developed an optical imaging system to enable 100 % visual inspection along multiple axes before accelerated testing. This procedure automatically detects potential flaws and initiates manual inspection. Subsequent electrical measurements are correlated with the presence of surface flaws. If the capacitor



Automated optical inspection station

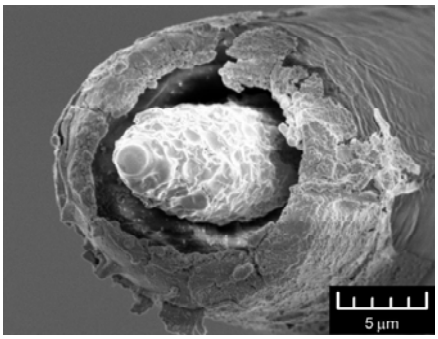
fails electrically, electron and optical microscopy are then used to determine the underlying failure mode (cracking, voiding, delaminations, incomplete base layers, poor adhesion, or plating failure).



Void due to incomplete base layer

We are also collaborating with the FDA to assess the reliability and efficacy of candidate organic coatings for future implantable devices. The FDA is concerned because little data exist regarding the stability of these materials in the biological environment, and existing reports conflict.

To gather additional data, we designed and constructed an electrically-addressable micro-fabricated test structure for applying combined electrical, thermal, and chemical stimuli. The FDA is currently fabricating a series of parylene coatings for NIST with controlled chemistries. Testing these coatings using our active test structure will provide critical stability data under anticipated use conditions, such as applied current and voltage which may be important based on other results.



Degradation of parylene at electrode tip

For example, our studies with parylene-coated neural recording electrodes indicate that coating degradation is a function of both fluid chemistry and applied electric field. With the exception of extremely corrosive chemistries, we found that coating damage was confined to a 40 μm region near the electrode tip. Cracking and separation of the coating were observed over periods ranging from 1 to 26 days, resulting in measurable changes in electrical impedance due to exposure of additional electrode area. These data illustrate the need for further characterization of organic coatings to ensure their reliability for active implants.

Learn More

Grady White
Damian Lauria
David Serrell
Stephanie Hooker

Andrew J. Slifka
(Materials Reliability Division)
303-497-3744
slifka@boulder.nist.gov
http://www.boulder.nist.gov/div853
http://www.inemi.org/cms/projects/medical

Publications

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Anton, JM, Hooker, SA, *Characterization of degradation mechanisms in neural recording electrodes*, MRS Proc. Vol. 1009E (2007)

Primavera A, *iNEMI Statement of Work (SOW) Medical TIG, iNEMI Medical Grade Components Reliability Specifications Project (2006)* http://thor.inemi.org/webdownload/projects/Medical/Medical_Components_Reliability//Med_SOW_Ver%205-0.pdf

Hooker SA, *Reliability of ultra-thin insulation coatings for long-term electrophysiological recordings*, SPIE Vol. 6172, 617218 (2006)