iNEMI®
International Electronics Manufacturing Initiative
Advancing manufacturing technology
Herndon, Virginia • Shanghai, China • Limerick, Ireland
2214 Rock Hill Road, Suite 110 • Herndon, VA 20170-4214
Tel: +1 703-834-0330 • Fax: +1 703-834-2735
www.inemi.org • info@inemi.org

Abstract

Failure Mechanisms, Acceptance Criteria, and Accelerated Test Procedures for Electronic Components Used in Active Implantable Medical Devices: Capacitors

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Active implantable medical devices (AIMDs) (e.g., pacemakers, cochlear implants, defibrillators) have a small, but still undesirably large, failure rate *in vivo*. A significant fraction of these failures can be traced to the failure of individual electronic components within the devices. An industry initiative, organized by the International Electronics Manufacturing Initiative (iNEMI), is addressing this issue. Project participants, which include component manufacturers, device manufacturers, end users, and two federal government agencies — the National Institute of Standards and Technology (NIST) and the Food and Drug Administration (FDA) — have been conducting failure analysis and subsequent accelerated failure testing on specific electronic components.

The first components chosen for study as a proof of concept were capacitors. In Phase 1 of the project, capacitor manufacturers and device manufacturers provided NIST with quantitative breakdowns of identified failure sources observed in the capacitors. NIST combined the information into a single document that listed all the observed failures and their relative frequencies. Simultaneously, the iNEMI group put together a Design of Experiment (DOE) intended to accelerate failures in capacitors.

In Phase 2, capacitor testing, according to criteria defined in the DOE as well as some more aggressive tests, was begun. The goal of Phase 2 is to ascertain which of the DOE accelerated test criteria produce failures consistent with those observed in use. In this presentation, we will describe the failure distribution and the DOE generated in Phase 1 as well as the status of the ongoing measurements in Phase 2 of the project and how those data relate to Phase 1. We will also outline some intended future directions of the project.