

**Title:** The Application of Accelerated Stress Testing for Active Implantable Medical Devices during Qualification and Product Development

**Author:** Ping Zhao

Senior Reliability Engineer, Medtronic Inc.

MVN61, 8200 Coral Sea Street N.E., Mounds View, MN 55112

[ping.zhao@medtronic.com](mailto:ping.zhao@medtronic.com)

**Abstract:** Active Implantable Medical Devices (AIMD) are facing tremendous reliability challenges due to their unique usage environments – human body. Although the question of safety and efficacy still need be answered or investigated through long term animal studies and clinical trials, many of the environmental effects on the reliability of AIMD are being verified through in-vitro test setup using the concept of accelerated stress testing. Highly Accelerated Life Testing (HALT) has also been a valuable tool to assess and improve the reliability of finished devices as well as critical components for AIMD.

This presentation starts with the expectation for reliability engineers in medical device field, given today's environments for this regulated industry. Later, the usage of accelerated stress/life testing is introduced by their application in various reliability aspects during the AIMD product qualification. Last, a case study would demonstrate how HALT is applied on the evaluation of a critical component within the device to improve device design reliability.