Cost Effective Reliability Analysis and Testing of Medical Devices

Lori Lucke, John Whitehurst, Minnetronix, Inc.

1635 Energy Park Drive, Saint Paul, MN, www.minnetronix.com

Introduction

Medical Devices and Reliability

Cannot tolerate field failures

- Patient safety
- Regulated environment
- Business financial ramifications

FDA Regulations: 21CFR Part 803, 21CFR Part 820

- Require tracking of all device failures
- Provided guidance that reliability should be part of the device requirements
- Do not set specific reliability targets

Medical Devices

- Reliability testing is inconsistent
- Low volumes and complex devices drive small sample sizes

Methods

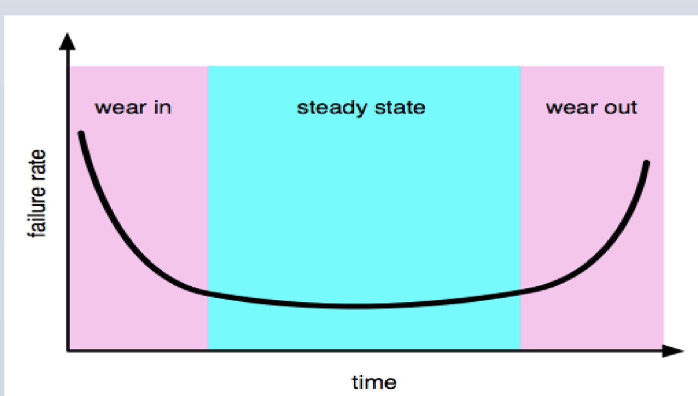
Learn About Reliability Early

Design Phase

- Determine reliability goals.
- Use a combination of reliability assessment and reliability testing to increase confidence in small sample sizes.
- Generate a reliability plan.

Production Phase

- Use stress screening of a device as part of the manufacturing process prior to shipping the device.
- Use trend analysis to remove sources of failures.



Bathtub Curve Demonstrating Infant Mortality

Case Studies

Case Study 1: Design Reliability - Single board computer as part of a blood analysis device

1. Determine reliability goals - The requirement was a stated reliability goal as follows "A mean time between failure (MTBF) of 5 years or approximately 20,000 hours of continuous use will be achieved." Given a MTBF goal of 20,000 hours and confidence level of 90%, could lead to required test times of 5,000 hours for 10 devices. To reduce test time and allow for smaller sample sizes a mixture of reliability analysis and short term testing was used.

2. Generate a reliability plan

Step A: Apply finite element analysis to predict MTBF and identify mechanical weaknesses.

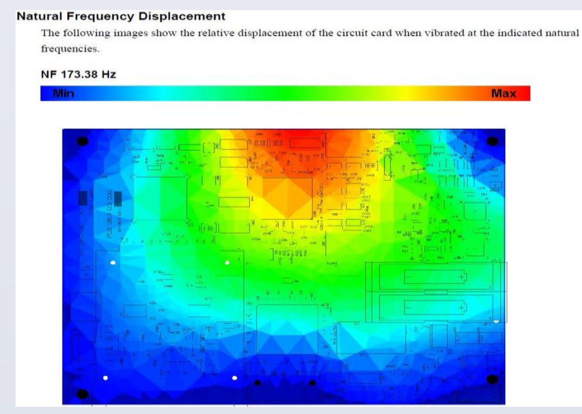
Step B: Perform highly accelerated life testing (HALT) to improve design margins and validate FEA predictions..

3. Results

Step A: Using a tool capable of doing finite element analysis (FEA) it is possible to predict electro-mechanical weaknesses in the design of an electronics subsystem. By adding in information about the circuit board configuration and mounting and individual electrical component characteristics it is possible to predict the MTBF. The analysis is much less expensive than traditional testing.

Step B: HALT Testing at 5 to 45grms and -10 to 90C with a sample of N=3 and SBC connected to test fixture so that it could be powered up and monitored during testing. All samples reached limits. X-ray inspection of boards showed no cracked solder joints.

Life Prediction Curve

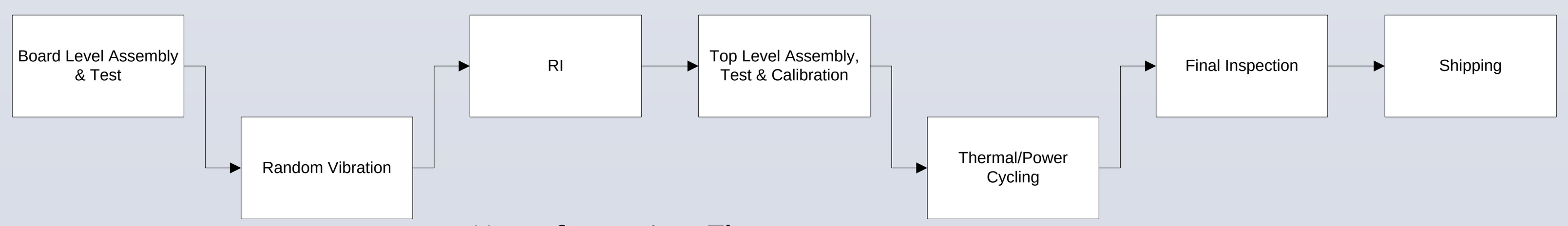


Vibration Analysis

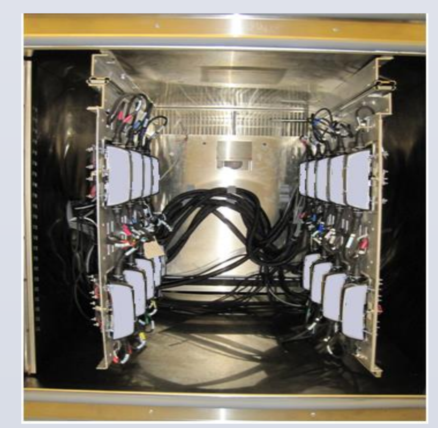
Halt Test Setup

Case Study 2: Production Reliability – Stress screening and trend analysis for a Class III life support device

Use accelerated stress (thermal, vibration, power cycling) to detect latent faults prior to shipping product.

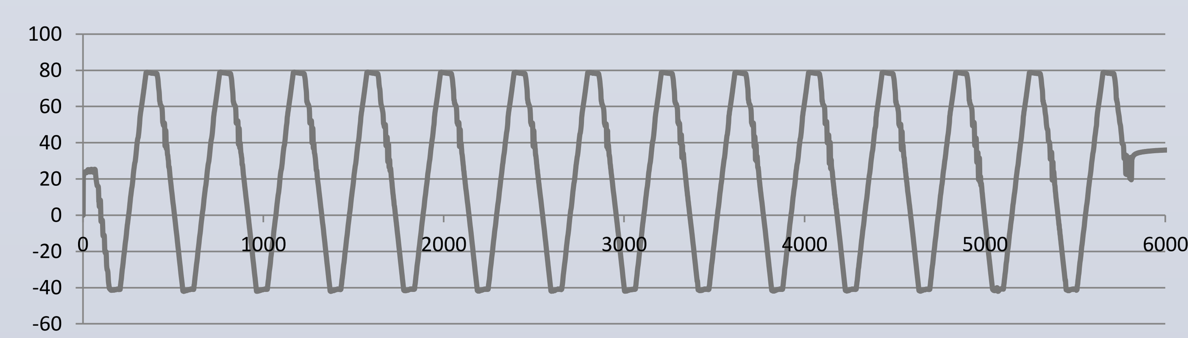


Manufacturing Flow

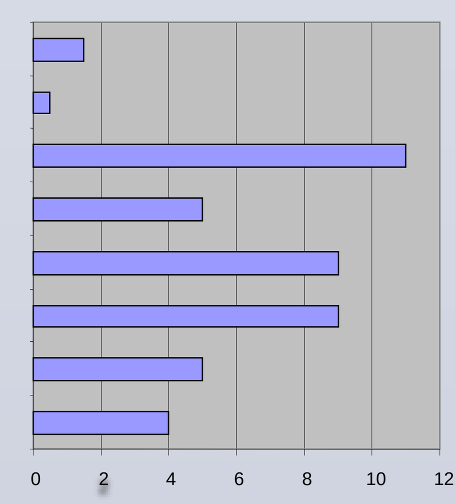


Automated Test Setup

Random Vibration applied to board level – yielded few failures and was later removed. System level thermal/power cycling screen with 12 cycles and continuous monitoring was very effective at detecting latent faults.



Thermal Cycling Profile



Cycles to Failure

Process monitoring showed that devices were failing near the end of cycle test. Increased the number of cycles to 14 to improve the test. Qualified and analyzed test to make sure it was not overstressing the device. Analysis showed less than 1% life consumed.

Faults analyzed for trends included poor solder connections of large components, BGA components, RTC battery, PCB connectors, and open vias. Failed components included RTC, diodes and capacitors, as well as LCDs.

Conclusions

Reliability as part of design

Uncovers design weaknesses

- Effective if done early in design
- Analysis can reduce sample sizes and test times
- Stressing system outside of operational limits can confirm analyis

Reliability as part of production

Done during manufacturing process

- Reduces infant mortality
- Improves process

Uncover faults not caught during board level testing

References

[1] FDA 21 CFR Part 803

[2] FDA 21 CFR Part 820

[3] MDD 93/42/EEC

[4] FDA Guidance: Design Control Guidance for Medical Device Manufacturers, March 11, 1997.

[5] D. Kececioglu, FB Sun, "Environmental Stress Screening" DEStech Publications, Inc., 2003.

[6] Mak, T.M., "Infant Mortality—The Lesser Known Reliability Issue", IEEE International On-Line Testing Symposium, 2007.

[7] Fries, R.C."Reliable Design of Medical Devices, 2nd Ed", CRC Press, 2006.

[8] O'Conner,P. and Kleyner,A. "Practical Reliability Engineering", Wiley, 2012