Implantable Medical Device Design for Reliability

"Meet the Experts" Design Forum Event

by
Mike Silverman, Managing Partner, Ops A La Carte
and
Charles Dingus, Senior Reliability Engineer, Intrapace
Confidence in Reliability
Our Company

Our Company is a privately-held professional reliability engineering firm founded in 2001 and headquartered in Santa Clara, California with offices in China, India and Singapore.

was named one of the top 10 fastest growing, privately-held companies in the Silicon Valley in 2006 and 2009 by the San Jose Business Journal.

is a solid company that has been profitable every quarter since its inception due to its outstanding reputation, customer value and scalable business model.
Industry Penetration

We have over 500 customers across 100 different industries, including:

AEROSPACE
AGRICULTURE/FARMING
AIRPORT SECURITY
ALTERNATIVE ENERGY
ARMED FORCES
AUDIO AND VIDEO
AUTOMATION
AUTOMOBILE/TRUCKING
AUTOMOTIVE COMPONENTS
BANKING/AUTOMATIC TELLER EQUIP.
BATTERIES
BEVERAGE INDUSTRY EQUIPMENT
BIOMEDICAL
BOATING
BUILDING MATERIALS
CABLE INDUSTRY
CHAMBER MANUFACTURER
COMPUTERS
CONSUMER ELECTRONICS
CONTRACT MANUFACTURING
CONTROL SYSTEMS
COSMETICS
DEFENSE ELECTRONICS
DESIGN AUTOMATION
DESIGN FIRMS
DISK DRIVES
DISPLAY ELECTRONICS
ELECTRIC METERS
ELECTRIC UTILITY COMPANY
ELECTRIC VEHICLES
ELEVATOR COMPANIES
ENGINEERING AUTOMATION TOOLS
ENVIRONMENTAL EQUIP.
ENVIRONMENTAL TEST LAB
FAILURE ANALYSIS LAB
FUEL CELLS
FOOD INDUSTRY
FOOD PACKAGING PRODUCTS
GAMING INDUSTRY
GENERATORS
GOVERNMENT RESEARCH
GPS INDUSTRY
HANDHELD METERS
KITCHEN APPLIANCES
LASERS
LEGAL INDUSTRY
LIGHTING INDUSTRY
MAGAZINE/MAIL ORDER INDUSTRY
MEDICAL DEVICES
METERS, ELECTRIC/GAS
METERS, HANDHELD
MINING
MOBILE PHONE
MOTORS AND ENGINES
NETWORK APPLIANCES
NETWORK SECURITY
NETWORKING
NUCLEAR
OIL EXPLORATION
OPTICAL COMPONENTS
PET TOYS
PCB MANUFACTURERS
PERIPHERALS
PHARMACEUTICALS
POINT OF SALE DEVICES
POWER STATIONS
POWER SUPPLIES
PRINTERS
RADIO/RF/MICROWAVE
RECREATIONAL/SPORTS
RELAXATION PRODUCTS
RESTAURANT EQUIPMENT
RF COMPONENTS
RFID
ROBOTICS, MEDICAL
ROBOTICS, SEMICONDUCTOR
SATELLITE
SCIENTIFIC RESEARCH
SEARCH ENGINE
SECURITY SYSTEMS
SEMICONDUCTOR
SEMICONDUCTOR MFG EQUIP
SOCIETIES
SOLAR INDUSTRY
SOLID STATE STORAGE
SPACE EXPLORATION
SPORTS EQUIPMENT
SPORTS MEDICINE
STORAGE NETWORKING
TELECOM
TEST & MEASUREMENT
UNDERWATER ELECTRONICS
UNIVERSITIES
VETERINARY
VISION SYSTEMS
WATER PURIFICATION
WEATHER RESEARCH PRODUCTS
WIND
WIRELESS
2011 Specific Industry Focus

Currently, our top six industries are...

- Clean-Tech
- Consumer Electronics
- Defense/Aerospace
- Medical
- Oil and Gas
- Telecommunications
OUR MEDICAL PRACTICE

- We provide Confidence in Reliability.
- We are the leader in reliability and quality solutions for the medical industry.
- We offer a flexible method of engagement: End-to-end reliability solutions, solving specific problems, or providing individual reliability services.
- We consult in every life cycle phase, train in every aspect of reliability, and test in our state-of-the-art HALT and HASS Labs™

OUR MEDICAL MISSION CRITICAL VALUES

- We are committed to Highly Reliable Systems that save human lives
- We successfully analyze and test critical medical products with confidence
- We deliver accuracy and precision to extend product and human life for each application
- We deliver customized solutions & consultancy to address all program risks
Our Customers in N.America
Our Customers Around the World
Ops’ New Reliability Book

How Reliable Is Your Product? 50 Ways to Improve Product Reliability

A new book by Ops A La Carte LLC® Founder/Managing Partner Mike Silverman

The book focuses on Mike’s experiences working with over 500 companies in his 25 year career as an engineer, manager, and consultant. It is a practical guide to reliability written for everyone in your organization. In the book we give tips and case studies rather than a textbook full of formulas.

Available January 2011 in hardback for $44.95 or ebook for $19.95 @amazon.com or http://www.happyabout.com/productreliability.php

For more info, go to www.opsalacarte.com

We will have a book signing event on March 22 in Santa Clara
Reliability Symposium
May 9-13
Santa Clara and via webinar

TRACK 1: DFX TOOLS
• Design for Reliability (DfR) – May 9-10
• Design for Mechanical Reliability (DfMR) – May 11
• Design for Warranty (DfW) – May 12
• Design for Software Reliability (DfS) – May 13

TRACK 2: REL TOOLS: ALT/DOE/RCA
• Design of Experiments – May 9-10
• Best Accelerated Tests (BART) – May 11-12
• Root Cause Analysis - May 13

Details for all are on the Ops Education Schedule for 2011
Future Seminars/Webinars/Events
ALL ARE FREE

• Apr 6 – Solar Reliability Challenges
• May 3 – Synergy between DfSS vs. DfR (tied with WQC)
• Jun 7 – How to Use HALT with Prognostics (tied with PHM)

Details for all are on the Ops web site www.opsalacarte.com
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Introduction

• IEC 60601 Rev 3 requires that your testing be driven from your risk documents.

• This is true for all medical products but especially true for implantables.
Introduction

• Implantables have a tricky use environment – relatively stable temperature and low vibration but often potentially corrosive environment.

• Also, with implantables, replacement is more difficult so reliability must be higher.
Developing Better Test Plans
Developing Better Test Plans
Introduction

In order to write better test plans, we must first understand;
- the use environment
- the key risks to the design

The best tool for this is FMEA
Developing Better Test Plan

Failure Modes and Effects Analysis (FMEA) is the process by which we explore potential failure modes and then prioritize by key risks.
Once the risks have been identified and prioritized, it is time to develop mitigations.

Often times the best mitigations are with reliability testing.
Developing Better Test Plans

Stated another way, we cannot know what to test for unless we understand the key risks.

Therefore, FMEA is one of the best sources of input for a Reliability Test Plan.
Case Studies

Next we will show 2 different case studies for medical products

1. Inhaler (non implantable)
2. Obesity Mitigation Device (implantable)
Case Study - Inhaler
Developing a Test Plan without FMEA

• What types of tests can you think of for this device?
Developing a Test Plan without FMEA

• We used the IEC standards and came up with a number of solid tests, including:
  – High/Low Temperature
  – Temperature Cycling
  – Vibration
  – Drop
  – Shock
  – Crush
  – Humidity
  – Altitude
  – Did we miss any?
FMEA Generated Tests

• Then we performed an FMEA and came up with the following:
  – Different cleaning solutions
  – Pen test
  – Lipstick test
  – Motor Oil Test
  – Cap Tether Test
  – Battery life test
  – Did we miss any?
FMEA Generated Tests

• As you can see by this one example, we would have missed many of the potential failure modes had we not used FMEA to help drive our test plan/program.
Case Study 2 – Implantable Obesity Mitigation Device
Step 1
Identify relevant Laws/Regulations for your device

- This will depend on where you plan on marketing your product and what it is

In the US CFR-21 (Code of Federal Regulations)
http://www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=200921

- In the EU relevant documents are

90/385/EEC AIMDD (Active Implantable Medical Device Directive)
93/42/EEC MDD (Medical Device Directive)

**Example**
Intrapace, Inc. Obesity mitigation device Gastric stimulation
This makes this device an active implantable, i.e. our device has a battery that delivers energy to the patient

In the EU there are other directives that cover drugs or implantable (no energy source)
In the US you will still use CFR-21 but different parts of the code will apply to your device
Step 2

- **Do a risk analysis**

Documents to use for risk analysis

**ISO 14971**: Medical devices - Application of risk management to medical devices

**CEI/IEC 60812:2006**: Analysis techniques for system reliability – Procedure for failure mode and effects analysis (FMEA)
Step 2 continued

Intrapace Gastric Stimulation System

**Example**
Parts of our system

**Gastric Stimulator**
- Stimulator Hermeticity
- Biocompatibility
- Active Implantable
- Electronics

**System**
- Sterility
- Biocompatibility
- Shelf Life
- Packaging

**Lead**
- Fluid Ingression
- Corrosion
- Leaks at connection
Step 3

• Conduct Reliability Testing

Base your reliability testing on risks identified in your risk analysis. The risk analysis will identify RI levels (Risk Indexes) associated with parts of your device. The level for your reliability testing is driven by the RI level.

Three Types of Reliability Tests we will review
1. HALT (Highly Accelerated Life Testing) for entire Gastric Stimulator
2. RDT (Reliability Demonstration Test) for PCA of the Gastric Stimulator
3. Sterility Testing - all implantables are supplied sterile

ISO 11135-1:2007 Requirements for development, validation and routine control of a sterilization process for medical devices

Packaging tests: Pull test, Pull test

Packaging: Real time and accelerated shelf life testing

Ref: General Aging Theory and Simplified Protocol for Accelerated Aging of Medical Devices
Karl J. Hemmerich
Predicting Shelf Life from Accelerated Aging Data: The D&A and Variable Q10 Techniques
John Donohue and Spiro Apostolou
TIR28:2001 Product adoption and process equivalency for ethylene oxide sterilization
Highly Accelerated Life Test (HALT)

- We performed HALT at Ops A La Carte’s Santa Clara HALT and HASS Labs
- HALT Limits achieved were -90°C to +110°C and 55 Grms vibration
- Why is it important to have large limits, even for an implantable?
- Using Ops A La Carte’s HALT Calculator, we predicted a field MTBF of 2.5M hours
- The result of the HALT helped define design limits of the PCA and helped determine the screen limits for the production screening (HASS)
Background on HALT

1. Exposed 2 units to temperature, vibration, and combined temp/vibration
2. Also included voltage margining and combined with temperature stress
3. Stressed product until we experience a failure
4. Analyzed each failure
5. Performed several rounds of HALT, iterating design
Results of HALT

1. Proved that the product was quite robust
2. Found a few issues with the product during the stressing (at high stress levels) and these were each analyzed for corrective action
3. Developed HASS parameters
Reliability Demonstration Test (RDT)

- Risk Analysis defines Confidence Level and Reliability values for the test
- Time constraints and item costs define sample size
- Functionality defines type of monitoring
- Prior to the RDT a HALT test was done to identify any weaknesses in the PCA design.
Background on RDT

1. Determine your acceleration factor:
   - Select appropriate distribution for the testing that you are conducting
   - Use Chi Squared to calculate the time on test as a function of your number of failures and confidence level (This is a Type I Time censored test)
   - The number of units on test and the acceleration factor determine the actual duration of the RDT

   $$A_f = \exp \left[ \frac{A_e}{k} \left( \frac{T_H - T_L}{T_L T_H} \right) \right]$$

   - Select appropriate distribution for the testing that you are conducting

   For electronics the **Exponential** distribution is used and the reliability is calculated using:

   $$R = e^{\frac{-t}{\theta}}$$

   Solving for \( \theta \) we get the mean:

   $$\theta = \frac{-t}{\ln(R)}$$

   - Use Chi Squared to calculate the time on test as a function of your number of failures and confidence level (This is a Type I Time censored test)

   $$\frac{2T}{\chi^2(\alpha, 2r+2)} \leq \theta$$

   Solving this equation for \( T \) we get the total accumulated time on test:

   $$\frac{\theta * \chi^2(\alpha, 2r+2)}{2} \leq T$$

   - The number of units on test and the acceleration factor determine that actual duration of the RDT
Results of RDT

- The RDT addressed 2 issues with the PCA:
  - The test help identify manufacturing issues associated with the PCA
  - The test also demonstrated that the manufacturing burn-in test was not removing significant useful life from the device
- The test documented that the PCA had the reliability and confidence level values required by the Risk Index identified in the Risk Analysis
Summary

• With all products, the key to reliability is to identify the risks and to then develop a plan to mitigate the risks.

• This is especially true with medical implantable products, given their high reliability requirements.