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Long Term Reliability Concerns
Philips Medical Systems

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Agenda

- Performance Requirements of Medical Products
- Reliability Analysis of Medical Products
- Impact of RoHS on Medical Products
- MRx Qualification and Reliability Tests (DVD)
- Project Proposals

Performance Requirements of Medical Products

- Medical Products need to have
  - Longevity
  - Long Term Reliability
- Medical Products need to perform in all types of environmental conditions

Performance Requirements of Medical Products

Medial Products have the highest reliability requirements because they are designed to not only support life, they save lives

Performance Requirements of Medical Products

Medical Products

- ***Must*** **work 100% all the time and can not fail in the field**
- ***Must*** **perform under the most extreme conditions**
- ***Must*** **be durable and rugged and**
- ***Must*** **deliver high quality performance**

Reliability Analysis of Medical Products

Medical products contain all or some of the following materials

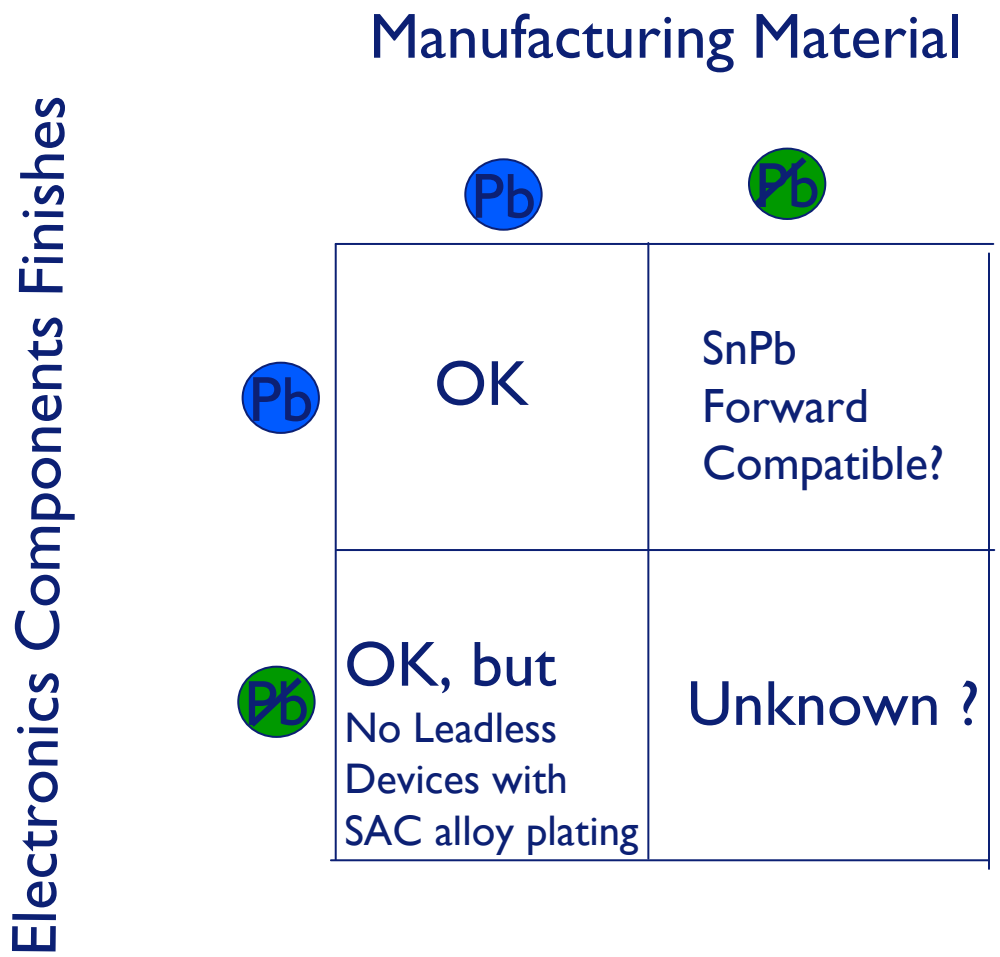
Printed Circuit Boards (PCBs)
Electronics Components
Solder (Wave or Reflow)
Power Supply
LCD Display
Motors
Cameras
Transducer Cable Assemblies
OEM Products
Metal Enclosures

Reliability Analysis of Medical Products

Some products are highly complex in design, containing such properties as

- High voltage/current
- Special electro-magnetic interference requirements
- Nuclear materials
- High energy storage
- Extreme robustness – resistance to abusive environment
- RF frequency up to 1.4 GHz and soon to be 5.8 GHz
- Precise impedance and inductance on printed circuit assembly

Reliability Analysis For High Reliability Products



Reliability Analysis For High Reliability Products

Critical Issues with Pb-free Materials

- Impact of printed circuit board (PCB) finishes
- PCB reliability
- Impact of component finishes
- Tin whisker (short) reliability risk
- Component reliability
- Impact of multiple heat cycles + rework
- Solder joint reliability – thermal
- Solder joint reliability – mechanical
- Solder joint reliability – shock & vibration
- Electrochemical reliability
- Reliability tests and acceleration factors

Reliability Analysis For High Reliability Products

Pb-free Material of Most Concern

- **Sn37Pb solder (MP (melting Point) ~ 183^{o}C)**
- **Sn(3-4)Ag(.5-.7)Cu solders (MP ~ 217^{o}C) – SAC current leader**

Reliability Analysis For High Reliability Products

Major Problems with SAC

- **Components and PCB will be subjected to higher temperatures**
- **SnAgCu solder joint reliability data are lacking**
- **Equipment deterioration- huge concern and unknown**

Impact of RoHS on Medical Products

Changes that would have to occur in a Pb-free environment are numerous

- Solder materials
- Component finishes
- Temperature profiles
- Printed circuit board parts (lamination, finish, glass temperature, etc)
- PCB/PCA manufacturing chemicals and equipment
- Design guidelines
- Suppliers

Impact of RoHS on Medical Products

Changes continued….

- Behavioral model of products in the field
- Validation and verification tests and procedures
- Field service support for repairs

Impact of RoHS on Medical Products

- **Transition to Pb-free will require many changes of many aspects of medical equipment**
- **The more aspects that have to change, the greater the risk to reliability and product quality and**
- **The greater the risk to product performance in meeting its intended function**

Impact of RoHS on Medical Products

Most importantly…..

Most common Pb-free substitutes **lack industry knowledge** in solder joint integrity, inter-metallic-compound (IMC) and reliability data when compared to SnPb materials which have 50+ years of data and history of proven reliability and performance!

Impact of RoHS on Medical Products

Most importantly…..

Transitioning to lead-free will necessitate changing many aspects of the products including PCBs, electronic components and the manufacturing processes. All these changes compounded with the unknown reliability data of the Pb-free substitutes will only result in

- *Unreliable medical products*
- *Unreliable delivery of healthcare*
- *A great deal of uncertainty*

Why do we care about so much our medical products?

We strongly believe that the medical products that we design and manufacture will one day operate on someone whom we care for and love and perhaps even on ourselves. It is vital to maintain the quality and reliability requirements of our products for a long long time.

MRx Qualification and Reliability Testing DVD

Philips Medical Systems Projects Requests

- Multiple BGA components plating with SAC alloy on a single assembly (SAC305, 105) reliability analysis
- Cleanliness – No clean Flux vs. Aqueous Wash under Pb-free process
- Overall Leadless devices (BGA, QFN, CSP, WLCSP, etc)reliability performance using Pb-free Alloy plating material
- Reliable Pb-free soldering materials choices for high reliability products
- Backward and forward compatibility analysis on both SnPb and Pb-free components plating under Pb-free Process

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Thank you very much for your attention!


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