Published on *Medical Electronics Design* (http://www.medicalelectronicsdesign.com)

Get the Lead Out

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Created *2011-10-05 13:51*
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October 05, 2011
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The revised RoHS directive will require medical electronics manufacturers to adopt new reliability testing strategies.

The first Restriction of Hazardous Substance (RoHS) legislation out of Europe, in 2006, provided an exemption for medical electronics. However, a second version that modifies this exemption has been released. Medical devices will be covered as of 2014, in vitro diagnostic equipment as of 2016, and industrial monitoring and control instruments as of 2017. The importance of planning for lead-free products is evident, especially considering the high reliability requirements, long development, and product run times in the medical device field. Many products being developed today will be sold beyond 2014.

Fortunately, the medical electronics industry can benefit from experience gained by other industries that have eliminated lead over the past several years. There are difficulties and risks associated with this significant change, but they can be managed. Experience from the consumer electronics industry shows that it is important to dedicate resources to the lead-free transition effort and to support it from the top down within an organization. Some companies have also used the opportunity to implement other best practices, such as improved process control and more thorough reliability testing. Eliminating lead also provides the chance to clean house and remove old test procedures that are no longer relevant.

This article addresses the reliability testing aspects of a lead-free conversion and provides a foundation for developing a lead-free reliability test plan.

Reliability Testing

To achieve consistent lead-free reliability testing, a well-thought-out document detailing the reliability requirements of the end products is useful. Naturally, many medical device companies have a wide range of products that vary in complexity and may fall within different FDA classes. The levels of reliability testing may be different for each class of products. Additionally, there may be several phases of product development, each with differing reliability requirements. These factors need to be considered when writing qualification requirements for lead-free medical products.

Structure of Qualification Document

One way to structure a qualification document is to recognize the phases of development used within a company and incorporate these into the structure. If phases don't exist today, create them as part of the lead-free transition strategy. There are three key phases on which to focus.

Phase 1—Material Selection. Critical materials to select and optimize for medical electronics include:

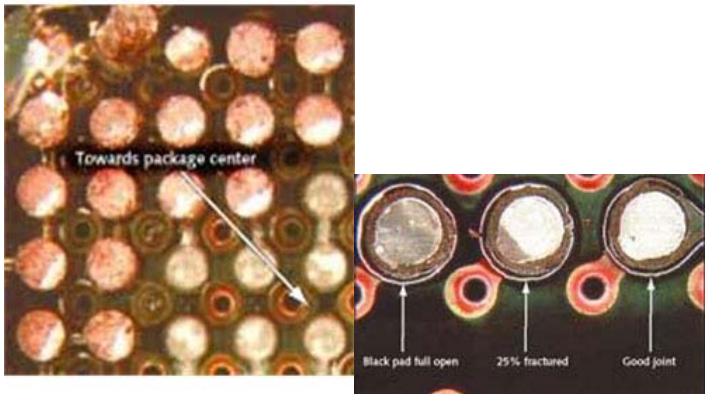
- Solder paste alloy and flux type for surface mount (no-clean, rosin flux, etc.).
- Wave solder alloy and flux (if applicable).
- PCB laminate.
- PCB surface finish.
- PCB copper thickness and via sizes.
- Conformal coating (if applicable).
- Rework materials.

The objective of this phase is to run any experiments needed to select the appropriate materials for the product. These materials give the product the best chance for passing the subsequent reliability testing. Testing in this phase might include interconnect stress testing (IST) of the printed circuit board (PCB) to ensure the laminate and copper thickness values provide sufficient life or temperature-humidity-bias testing to check for conductive anodic filament (CAF) formation. Fluxes would be evaluated with surface insulation resistance (SIR).

Phase 2—Reliability Testing to Validate the Material Selections. This phase involves the use of a test board. Converting a production board (same shape and attach points) into a daisy chain board by modifying the circuitry is ideal. Major components such as ball grid arrays (BGAs), surface mount connectors, quad-flat no-leads (QFNs), large resistors, or other higher risk components would have their solder joints daisy-chained for easy resistance monitoring during testing. This test board would then be subject to test to failure conditions in thermal cycling, shock, vibration, highly accelerated life testing (HALT), and, perhaps, corrosion testing. Testing may take place at the board level or while the board is fixed into the product (for drop testing, as an example).

An important part of this testing is the analytical work performed to evaluate the results and failure mechanisms. Cross-sectioning and dye and pry (D&P) analysis are often required to determine how failures occur and provide guidance on how to improve the product.

Phase 3—Product Qualification. The final phase may be qualification of the product. In this phase, the final production boards are built in the assembly line that will produce the product in volume. Qualification is performed in the traditional “test to meet specification” format. Testing might include thermal cycling (if applicable), HALT, temp-humidity, high temperature operation, shock testing, etc. Some flexibility in these tests might be needed to accommodate the wide range of products and environments required. The pass-fail criteria may be set based on previous qualification testing of similar products or determined based on the specific requirements of the product.



Images of dye and pry analysis

It is important to perform detailed analytical analysis of the product following testing to ensure no failures were missed by the electrical verification testing. For instance, there might be solder joints that are completely fractured but still make sufficient electrical contact. Pass-fail criteria might need to be set on the condition of the solder joints. For example, if D&P analysis reveals cracks of 50% of the solder joint, are these considered a failure? The answer depends on whether the test was meant to cover the full life of the product, such as thermal cycling, or if it was meant to cover shipping conditions, such as a shock-vibration test.

Product Levels

Upon review of the product types to be converted to lead-free soon and in the foreseeable future, a decision might be made to sort them into various product levels. The levels might be separated according to FDA class, or they could be separated further, by the complexity of the electronics involved. For example, there might be three levels.

Level 1 might be defined as:

- PCBs with layer counts < 6.
- PCB thickness is <0.062 in.
- There are no BGAs or flip chip components.
- Expected product life is 3¬–5 years.
- Product is not critical to patient life.

Level 2 might be:

- PCB might be thicker with higher layer count.
- BGAs and/or flip chips might be on board and require underfill.
- Expected product life is 5–7 years.
- Product is not critical to patient life.

Level 3 might be:

- Expected product life is 5–10 years.
- Product is critical to patient life.

The qualification test plan may be different for each level of product. Conductive Anodic Filament (CAF) testing, for example, might be required for Level 3 products only. Or, it might be decided that Phase 2 is not required for Level 1 products.

Reliability Test Plan

Once test structure and strategy has been determined, the complete reliability test plan can be constructed. The test plan will include the test types, parameters, measurement methods, sample sizes, test flow, analytical techniques to evaluate the results, and pass-fail conditions. The tests may include any tests that would traditionally be run to qualify the product, but some tests or analytical techniques might be added due to the change to lead-free solder. Table I illustrates one way to think about the lead-free changes, the areas they impact, and the test and inspection methods to evaluate the product.

Sample sizes used for testing are important and should be decided up front as much as possible. Some flexibility in sample size might be needed to account for different product types and availability of material. If rework is allowed on the final product, then it's a good idea to test the reliability of reworked boards to ensure they meet requirements. In such a case, the rework procedure for each component needs to be predefined, so representative production rework is evaluated.

Additionally, the material supplier matrix needs to be considered when creating the test plan. That is, will all suppliers on the approved vendor list (AVL) be used in the qualification? The most critical suppliers include the electronic manufacturers (EM) and the PCB fabricators. It is important to qualify each EM separately and to include PCBs from all suppliers on the AVL. Other components deemed critical should also have all suppliers on the AVL included in the reliability testing.

Area of Concern	Impacted Item	Failure Mechanism	Testing Method	Inspection Technique
Moisture sensitivity	Plastic IC packages, optocouplers, other polymer based components	Popcorn delamination at higher reflow temperatures. Heat damage of IC packages	Moisture sensitivity testing. J-STD-020C	Visual inspection C-SAM
Heat damage	All passive components, circuit boards, Connectors	Cracking, dielectric breakdown (capacitors), PCB delamination, warping, or via cracking	Heat resistance MIL-STD 202G #210F Decomposition temp. Time to delamination Package planarity JESD22-B108A	Visual inspection, functional verification
Poor wetting	All solder joints	Cold joints or weak joints fracture in use environment	Solderability J-STD-002B J-STD-003A	Wetting balance, visual inspection, x-sectioning, lead pull
Solder fatigue	Solder joints, particularly on high CTE components	Cracked solder joints	Thermal cycle JESD22-A104-B, HALT Vibration	Electrical continuity Visual inspection
Mechanical shock	Solder joints particularly on higher mass components	Solder joint failure during shipping or dropping	Shock test	Electrical continuity Visual inspection
Sn whiskers	Sn and SnCu plated components	Shorting	INEMI / JEITA procedures	SEM
Surface mount process control	Insufficient process window creates poor solder joints	Occasional solder joint failures in use environment	Precondition and assembly JEDEC Standard 22-A113D	X-ray, X-section, Inspection, reliability test
Rework process	Poor solder joints, damaged components,	Joint failures or cracked vias in use environment	Rework components followed by reliability testing	X-ray, X-section, Inspection, reliability test
Wave solder process	Incomplete hole fill, fillet lifting, damage to board	Failed through hole, cracked vias, weak joints	Thermal cycle HALT Vibration	Electrical continuity, visual inspection
Electrochemical migration	Board surface with no-clean paste residue	Shorting between biased traces in a moist environment	Bellcore GR-78-CORE J-STD-004 SIR	Visual and resistance after 35C/85%RH exposure at 50V

Table I. Highlighted are areas of concern due to lead-free transition and what test and inspection techniques can be employed to ensure the product quality/reliability has not suffered due to these changes.

Reliability Tests

This section will describe a few of the most common reliability tests and inspection techniques, their purpose, and typical conditions.

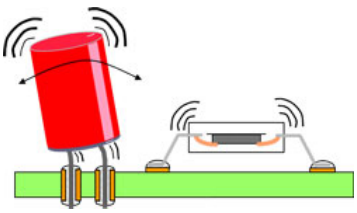
Thermal Cycle Testing

The primary purpose of thermal cycle testing is to repeatedly create thermal expansion mismatch stress on the solder joints, thus fatiguing them. Surviving a sufficient number of thermal cycles provides confidence that the product will survive the required period of time in the field. This is a test where the acceleration factor can be approximated, thus allowing extrapolation of test conditions to use conditions. Thermal cycle test procedure details are outlined in JESD22-A104-B. If different levels and program development phases are used, then a custom thermal cycle test table might need to be created.

An important parameter of thermal cycle testing is the dwell time at elevated temperature, and this is especially true with SAC305 solder. When the solder is given sufficient time to fully creep, the reversal in temperature creates a higher stress on the solder joint. Tin-lead solder creeps rather quickly, so the impact of dwell times greater than 15 minutes are relatively small compared with SAC305, where the creep rate is much lower. Research shows a consistent reduction in thermal cycle life of 40–60% when the solder is allowed to fully creep (long dwell time).[1,2,3] If the product will have long dwell time at elevated temperature in operation, then either recreate this long dwell in the testing (which can be expensive) or compensate for the effect by reducing the results by 50%.

Mechanical Shock and Vibration Testing (S&V)

There are typically two reasons for performing S&V testing. The first is to simulate the worst-case shipping conditions that could occur in delivering the product to the customer. The second is to simulate the S&V conditions that are expected under reasonable use of the product in the field. A good standard for shock testing is JESD22-B104-B "Mechanical Shock." Similar standards exist for vibration testing. The switch to lead-free does not require a change to the shock and vibration parameters that were used for tin-lead products. One aspect that might benefit from additional thought is the pass-fail criteria. Traditionally, a fail is designated as an electrical open following the testing. D



Vibration testing components in resonance

ue to the brittle nature of lead-free solder and the propensity for cratering of the epoxy laminate, there is increased concern for the formation of cracks during S&V testing that might

not become complete electrical opens. If the testing is meant to replicate shipping conditions, a more effective method for evaluating pass-fail might be to perform D&P analysis of major components following the electrical testing. This is a method to identify and measure any cracks that may have formed. The set pass-fail criteria can be based on the percent of a solder joint that is cracked (for example >10% would be a failure). An S&V test meant to simulate the full life of the product might continue to use the electrical open criteria.

HALT Testing

HALT is often used as a screening tool, and it is not a good predictor of life because the acceleration factor is not known. However, it is very effective at driving realistic failures in a rapid manner, thus allowing performance to be compared between product configurations, or to identify weak aspects of a design to enable continuous improvement. If the new product can survive the same or more cycles before failure, it is a good indicator that it will perform as well in the field. For this reason, HALT has often been successfully employed for the lead-free transition of products. A typical HALT test exposes the product to simultaneous vibration and thermal cycling. The product is tested in the operational mode while the vibration stress is increased with each thermal cycle. The test duration is typically less than a week.

Major OEMs have used HALT testing to successfully evaluate new generations of lead-free products and compare their performance with previous generations of tin-lead products. The objective was to make lead-free products as good or better than their tin-lead predecessors. HALT was able to quickly identify the primary failure mechanisms found with lead-free products. These included PCB pad cratering, trace fracture, inner-plane separation, and poorly formed solder joints. These are all failure mechanisms that would likely occur in the earlier stages of a product's life if not corrected. Failure mechanisms that HALT did not find were long-term thermal fatigue issues such as barrel cracking in vias or high-cycle solder-joint fatigue failures of resistors and capacitors. For these failures, thermal cycle testing was most useful.

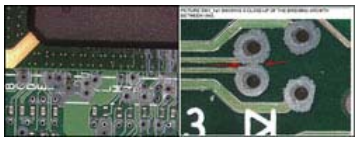
A HALT system

The test parameters depend on the operating temperature limits of the product in question. Note that functional testing is performed while the vibration is taking place. This is important because intermittent opens can be found at this condition. Vibration should start at 0 Grms and step up by 5 Grms each cycle until failure is detected. Failing units should be removed as the chamber is cycling past room temperature. Failing units should be analyzed carefully to find root cause failure. In the event that the PCBA was not the cause of failure, preselected components should be cross-sectioned and the extent of any damage documented.

Corrosion Testing

Electronics continue to be placed into increasingly adverse conditions, and poor air quality and creep corrosion failures are increasing. Such conditions can be found in areas of the world with poor air quality or in industrial environments. Products most affected are those with high airflow and easy access to the electronics.

Existing corrosion testing typically focuses on mixed flowing gas exposure at a 70% relative humidity level. This is a mixture of gases such as sulfur dioxide, hydrogen sulfide, chlorine, and nitrogen dioxide in 20–200 ppb concentration levels. Battelle has established levels for testing, but recent findings show these were not set severe enough to reproduce actual corrosive failures in the field. Because the standard mixed flowing gas (MFG) testing has proven insufficient, there are a number of industry groups currently seeking a better test method (IPC 3-11g and an iNEMI effort).



Creep corrosion on immersion silver

The sulfur clay testing has proven effective in reproducing the creep corrosion observed in high sulfur environments; however, it is difficult to quantify the severity. For this reason, efforts to create an effective test procedure are focused on increasing the hydrogen sulfide levels in the MFG chamber to levels as high as 2000 ppb to cause creep corrosion. The clay test method is an effective way to show if a product is susceptible to creep corrosion. It can then be used to show the effectiveness of any improvements to the product, such as a change in surface finish or the enclosure.

Reliability Audit

Reliability testing commonly occurs on a small sample size of prereleased production product. This practice is necessary but perhaps not sufficient. The first products off the production line were likely built with special attention paid to quality and process control. The true measure of reliability, however, is how well the product is assembled at high volume after a period of time with a stabilized line. This is where ongoing reliability testing (or reliability auditing) becomes important. A common question asked about such testing is, "What do we do with the information if there are failures?" The concern is that a large number of products may have been built and shipped by the time reliability results are known. However, finding and resolving issues late is better than not finding them at all.

A reliability audit can be a subset of the reliability test plan. Typically the sample sizes are smaller and a number of less critical tests can be left out. HALT testing is an example of a good audit test because the test time is only about one week and the sample size may be three to five samples. Testing to failure will provide a good comparison with the preproduct release baseline and will reveal the weak link in the product.

Mechanical shock and vibration is another useful audit test. Thermal cycle testing typically takes too long, and the sample sizes are too large to be practical. Additionally, the results of this test are most dependent on the thermal expansion mismatch of the components and board, which has not changed. The quality of the solder joints can more easily be measured with the HALT test.

Before audit testing, the assemblies should be thoroughly inspected both visually and with x-ray (C-SAM is an additional option). Following testing, critical components should be analyzed with cross-section and D&P.

It is important that the PCBAs to be audited are randomly selected from the production line. The frequency of the auditing must be made clear, and the roles and responsibilities of the functional groups involved in audit testing must be well defined. The test frequency may taper off and eventually cease if no issues are found. Most organizations are not set up to handle this extra workload, so necessary resources must be made available.

Conclusion

With the recent release of the second-generation RoHS requirements, the medical industry can now make concrete plans for the elimination of lead in affected electronics. Fortunately, other industries have been down this path before, and much can be leveraged from their experiences. At this time, nearly all components are available in a lead-free version, and PCB laminates that can withstand the higher processing temperatures are available. Much more is also known about the reliability of SAC305 solder, which has largely become the industry standard. An important part of the transition is to develop a comprehensive reliability test plan designed to reveal any weaknesses or deficiencies in the lead-free product. Such a test plan should take into account the stresses that the product will experience in manufacturing, shipping, and operation. As discussed, a typical test plan might include HALT, S&V, temperature cycling, and corrosion testing, among others. Just as important as the testing are adequate pass-fail criteria and detailed analysis of the tested products.

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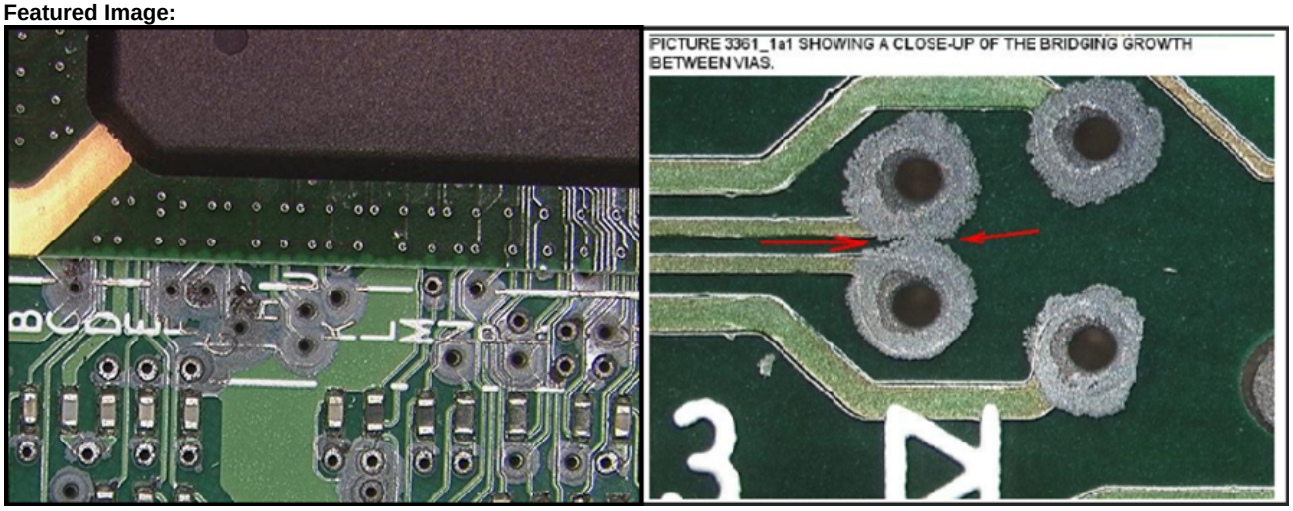

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