ENDEVCO
AN AMPHENOL COMPANY

Medical Design Optimization

Technical Paper 325

Medical design optimization

Are your component providers supplying you with the right testing information?

Device manufacturers are ultimately responsible for the safety and performance of a finished medical device. Therefore, they need to ensure their component suppliers are providing products that meet precise, critical specifications. This article examines the topic of supplier testing and what manufacturers should be demanding from their partners.

Regulatory issues governing the development and sale of medical devices are generally a well understood and necessary aspect of today's global healthcare industry. This ingredient is especially relevant in the United States as applied to long-term implantable medical devices. Historically, government regulatory agencies have relied upon device manufacturers to ensure compliance, as well as to conduct product development and manufacturing activities using accepted industry best practices.

Device manufacturers in turn have relied upon their supply chain of subcomponent providers for components that perform to the standards demanded in the extreme environment known as the human body. But, in many instances, the supply chain is not directly regulated by the same entities that regulate the device manufacturers and, in fact, may be required to answer only for simple performance specifications of their products.

However, this situation has changed dramatically in the last few years. Device complexity continues to increase, and the interrelationship of individual components as they function on a system level has become more critical. In addition, regulatory oversight now dictates that device manufacturers gain a much greater understanding of their supply chain, its capabilities, and the processes and procedures that exist to ensure product quality and robustness. The need for this added level of visibility and the associated infrastructure to support it has been conveyed by the device manufacturers to the supply chain.

One of the major impacts has been in the testing of subcomponents. In the past, when devices were less complex and the regulatory climate less stringent, device manufacturers may have accepted an item for integration into their device based on a manufacturing or performance specification they developed and simply relayed to the supplier. The supplier, as a good business practice, tested their finished product to verify its capabilities, supplied the test data to their customer for approval, and then archived the information. Such records were usually referenced only if a problem arose downstream in the final device manufacturing or testing process.

Today, device manufacturers are requiring much greater depth and scope in testing before accepting a component in order to avoid expensive and time consuming glitches in the production cycle by ensuring quality and performance upfront. In many situations, suppliers have added significant infrastructure and resources to meet these new requirements as a partner in the process. In some cases, the scope of testing can lengthen the product development timeline and should be taken into account in terms of cost and delivery planning.

This challenge is being successfully addressed by innovative and customer-centric suppliers working closely with their device manufacturer partners. In fact, it represents a tremendous opportunity for those with the vision and resources to respond. At Endevco, for example, the company has addressed the need for specialized testing capabilities by developing unique test fixtures and customized testing protocols to provide customers with the data needed to satisfy the requirements placed on them by regulatory agencies. These capabilities enable modification of prototype versions of new sensor designs to allow for pre-launch testing at the customer, leveraging the combined expertise of supplier and manufacturer.

The battery of tests needed to confirm device performance, robustness, and reliability is extensive. Both mechanical and electrical testing are required.

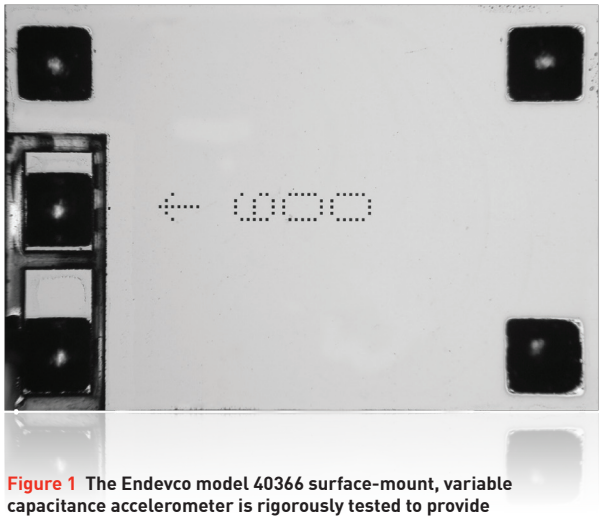

Figure 1 **The Endevco model 40366 surface-mount, variable capacitance accelerometer is rigorously tested to provide consistently high repeatability and high reliability in a small package.**

Some of the basic tests performed on sensing devices for medical applications vary, depending on the core technology (MEMS vs. piezoelectric), but would typically include:

- Capacitance at 0 g
- Capacitance difference between sensor subcomponents
- Sensitivity
- Sensitivity difference between sensor subcomponents
- Stops
- Voltage repeatability
- Electrical isolation
- Series resistance
- Base strain sensitivity
- Thermal transient response
- Cross-axis sensitivity for multi-axis devices
- Shear (destructive and non-destructive) to test internal subcomponent bonds

Figure 2 offers an example of the data generated in a test for sensitivity. In this case, the customer required verification of the interconnect reliability for the Endevco 40366 VC accelerometer for multiple mounting schemes and that it would exceed JEDEC JESD22-A104B, Cond. B thermal cycling conditions. Sensitivity measurements confirmed the interconnect viability and suggested preferred scenarios for the solder mounting technique.

Device manufacturers are facing increasingly competitive market forces and sharing these pressures with the supply chain by seeking cost reductions, increased holding of consignment inventory, and improved response to product demand fluctuations. The supply chain is being challenged with the dual and opposing issues of market driven cost reduction and customer driven increases in infrastructure, costs, and resources.

However, sophisticated testing capabilities present a new opportunity for those in the supply chain willing to step up, with the ultimate result of improving the diversity, health, and long-term stability of the supply chain while meeting the ever increasing demands to support device manufacturers with-in a value-added role. Moreover, society will also benefit, as this trend further enables and enhances the functionality and reliability of the devices many depend upon to improve and extend the quality of their lives.

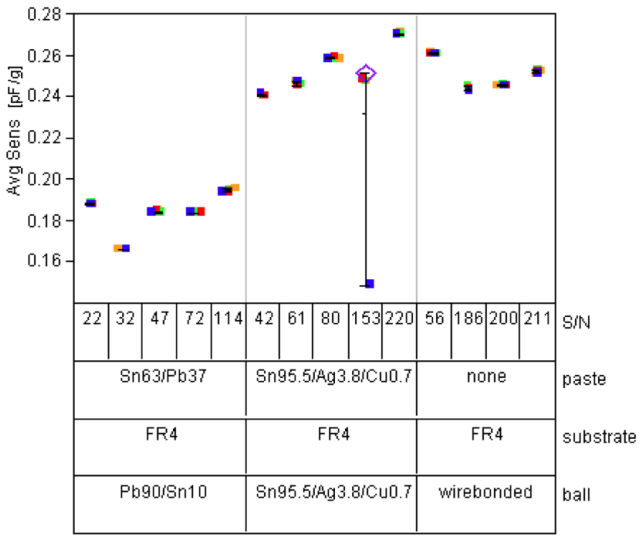

Figure 2 **Device sensitivity before solder mounting (GREEN), before temperature cycling (ORANGE), after 50 temperature cycles (RED), and after 250 temperature cycles (BLUE). Open diamon (◊) indicates desoldered part.**

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