DIGICOM ELECTRONICS

Case Study

Transferring a Medical Device to Volume Manufacturing

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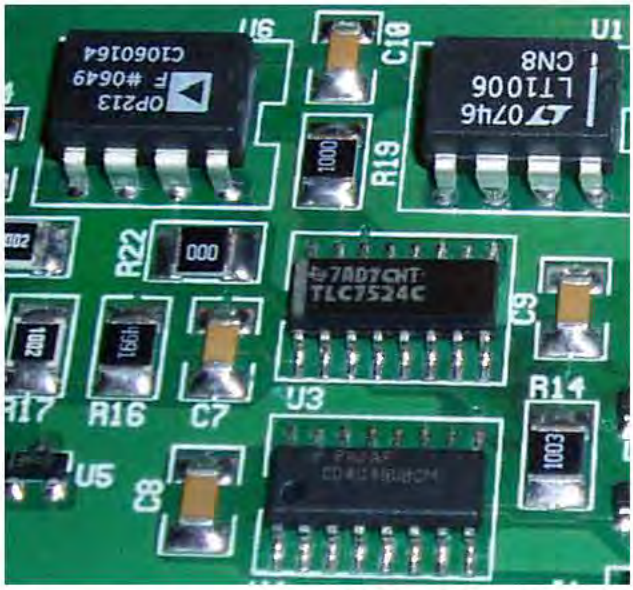
Excitement builds in new product development when the product can move from the lab or small volume manufacturing to a high volume manufacturing environment. High volume manufacturing can be done by the company that developed the product or it can be transitioned to a contract manufacturer. Because equipment and processes often have to be adjusted or changed to accommodate the higher volume and/or speed, problems can arise that hadn't been anticipated.

That was the case with transcutaneous electrical nerve stimulation (TENS) device manufacturer EPRT of Simi Valley, California. As the volumes they were producing increased, they encountered yield problems. Cleaning was another problem they encountered. In addition, since the TENS device is a medical product, they needed certification and process validation. They contacted Digicom Electronics, a contract manufacturer based in Richmond, California. Digicom was selected to improve yield and assist in the development, manufacture, test, and process validation of the product.

The TENS device produces a precisely controlled current which is applied to the surface of a person's skin to overload the nerve and prevent it from transmitting pain impulses, for example in the treatment of lower back pain. This product is difficult to manufacture because it has extremely low output currents of less than 1 millionth of an amp. With a very low current and high impedance situation, any contaminants can cause malfunction or device failure. Building the product is unique and complex, as it requires exact process control.

Because of the negative effects of humidity, it is a factor that must be considered and controlled. There are many variables to consider in the product's manufacture so the product can work as designed.

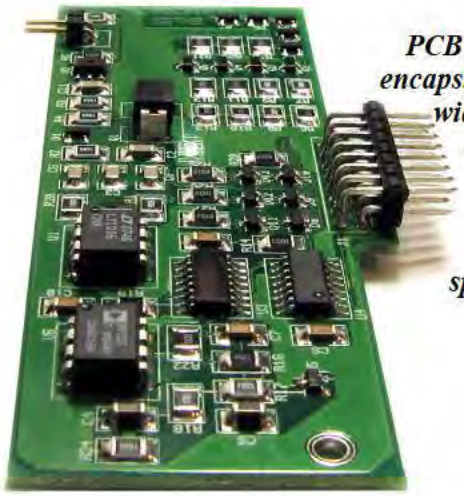


Mix of SMT and Thru-Hole Parts Allow Easy Cleaning Of Board In Key Areas.

When EPRT started to ramp to volume manufacturing, they found they were only getting 80-85% yield. After assembling the modules, they would go through test and they would pass. Then they would go to the epoxy step where they were encapsulated, but after encapsulation, they were retested and failed the self-test.

Digicom engineers investigated the situation. With the modules buried in epoxy, it made it difficult to troubleshoot, so deductive reasoning had to be applied. The epoxy cure process for the TENS process has to be controlled carefully so there isn't too much heat as it damages the components and also causes additional shrinkage with resulting mechanical stresses. The engineers conjectured that perhaps this relay was being damaged by the shrinkage. Further investigation confirmed that was indeed the case. Analysis found that shrinkage of the epoxy when it hardened created a clearance problem for the relay, causing the switching function to be delayed and affecting overall device performance. It was determined that the miniature relay was being deformed slightly during epoxy cure to a degree that the movable contact was dragging on the relay cover. The engineering team found that by putting a small box over the relay to cover it, the deformation was prevented, the problem was minimized, and performance improved.

Cleaning this product was also an issue because residue formed on the circuit board from the remaining solder flux. The circuits in TENS products have to be very clean.



PCB prepared for encapsulation. Note wide spacing of components/ traces to maintain leakage specifications.

Current leakage detection can now be measured down to the picoamp level so leakage that wouldn't have been discerned, and that would have been considered normal in the past, had to be removed.

Digicom developed custom sophisticated cleaning and analysis techniques to ensure that even ultra-low levels of contaminants that were byproducts of the soldering process were removed and to enhance the production of the delicate circuits required in these products. The process included high impedance and low current measuring devices to measure into the picoamp range.

Digicom was also tasked with process validation. A major reason for this is Digicom's ISO 13485:2003 medical devices quality and quality system regulation 21 CFR (Code of Federal Regulations) 820. ISO 13485 was published in 2003 and states the requirements for a comprehensive management system for the design and manufacture of medical devices and ensures that medical devices meet customer and regulatory requirements. It establishes a commitment to quality.

Process validation ensures that a process consistently produces a product that meets its specifications. It is an important component in the design, prototyping and manufacturing process and one, if done correctly, that can save a considerable amount of time, money and resources. In addition, regulatory bodies, such as the FDA, may require process validation.

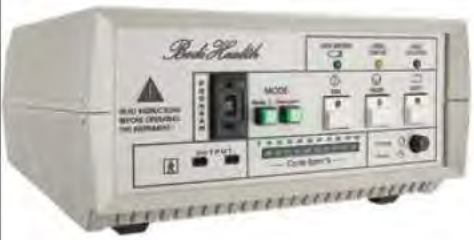
The FDA's Quality System Regulation, 21 CFR Part 820,[1] requires medical device manufacturers to perform a process validation when the process is not fully verified by a subsequent inspection or test. Based on the GHTF (Global Harmonization Task Force) process validation guidance document,[2] a process validation consists of three sequential elements: Installation Qualification, Operational Qualification, and Performance Qualification.

By having the process validated by a company that already has ISO 13485:2003, regulatory bodies know-that certain procedures and requirements will be met, so certification is less labor intensive and approvals proceed more easily.

IMPROVE YIELD, SPEED TIME TO MARKET, AND SAVE COSTS

Transferring volume manufacturing to a contract manufacturer can improve yield, speed time to market, and save costs. Contract manufacturers have the experience to troubleshoot problems incurred in transitioning to volume manufacturing from the design and prototype phase. If it's a medical product, selecting a company with ISO 13485:2003 and 21 CFR 820 speeds the regulatory process and makes it run more smoothly. Contract manufacturers have already invested in the manufacturing, training, process control, test equipment and have people trained in how to maximize their use and integrate them into the manufacturing process. They also have processes in place to handle the entire supply chain.

"This isn't a guessing game. These are calculated steps to get the yield to a point that's acceptable and can lend itself to volume production. Working with an experienced contract manufacturer, especially one familiar with medical devices, has truly been a benefit for EPRT."



~ David Estes
Director of Engineering
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1. *FDA's Quality System Regulation, 21 CFR Parts 820, available on-line at: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=820*

2. *Quality Management Systems – Process Validation Guidance by SG3 GHTF/SG3/N99-10:2004 (Edition 2), available on-line at: www.ghtf.org/documents/sg3/sg3_fd_n99-10_edition2.pdf*

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