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Cleaning Medical Electronics: The Key to Fully Functioning Medical Devices

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Cleaning medical electronics is gaining more attention. As the aging global population rises and interest from developing markets escalate, the increase in innovative medical devices is rising at an astounding rate.

Technology is also driving the pace of advancement in this sector, with designers focused on increasing capability and reducing the size of components. PCBAs (printed circuit board assemblies) are now smaller and more complex than ever before, making it more challenging for electronic device manufacturers to ensure production is completed efficiently and without error. Regulations imposed on the medical sector to ensure superior quality of medical devices is putting further pressure on manufacturers to produce fail-safe assemblies.

Producing anything less than 100% reliable electronic devices is non-negotiable within the medical sector. Let's look at a pacemaker for example which helps to monitor and control a person's heartbeat. If the PCBA within this device were to fail it would be catastrophic. Another example is the cochlear implant. The components inside such devices need to last for many years. They therefore have to contain components that will stand the test of time and function reliably and without fault. When you add to this the continued miniaturization of medical devices, limiting the potential of malfunction can prove difficult.

Contamination – A Main Cause of Device Failure

One of the main causes of electronic device failure is contamination on the PCBA. The smallest contaminant can form a barrier between electrical contacts. Dirty PCBAs are susceptible to a whole host of problems ranging from electrochemical migration and delamination to parasitic leakage, dendrite growth and shorting. It is this reason why cleaning is crucial to ensuring the reliability of a device.

Almost all medical devices require cleaning during manufacture to remove particulate, flux, oils or inorganic contamination resulting from the manufacturing process. The challenge is to identify a process that is suitable for the critical cleaning of complex assemblies, intricate shapes and delicate parts. It must also stand up to the strict regulations put in place by governing bodies. An example of this is the benchmark standard IEC 60601-1. This has been provided by the International Electrotechnical Commission (IEC) and is specifically designed for medical electrical equipment and systems. This covers a wide variety of electronic devices from diagnostic equipment to cardiac defibrillators and patient monitors. It necessitates that the basic safety and essential performance of the medical device be maintained. Cleaning is one of the central practices to help to meet this requirement.

The processes used in the development and manufacture of medical electronics has to be precise and reliable. They must pass tough regulatory requirements because patient safety is always the priority. Therefore, cleaning should always be one of the first considerations for manufacturers. Improved cleaning directly translates to more effective PCBAs, and therefore to better medical electronics.

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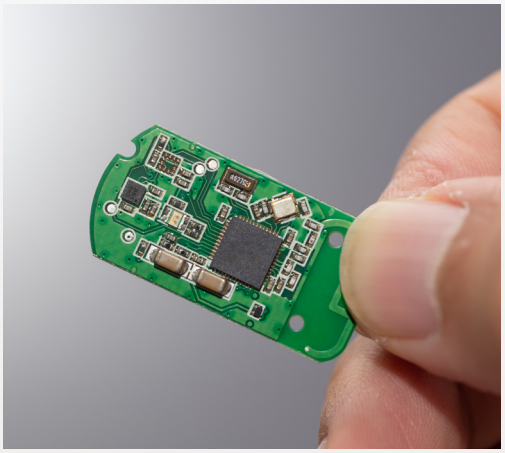
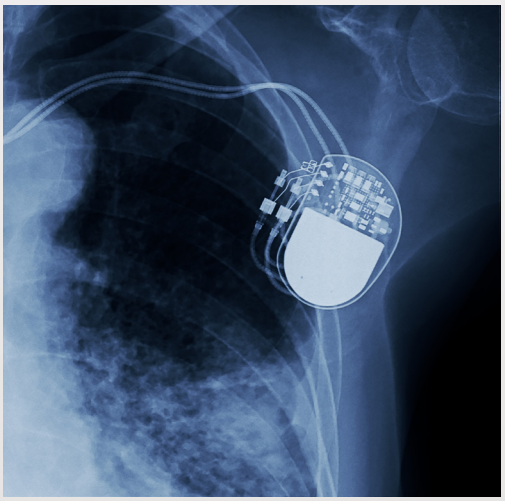


With recent advancements, PCBAs are smaller and more complex.



If the electronics were to fail in a pacemaker, the results could be catastrophic.

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Reliability Calls for Modern Cleaning Methods

We have established that cleaning is key to reliability, but how do you implement effective cleaning processes for electronic devices that contain small, multi-layered, complex PCBAs?

There are several methods to clean PCBAs, from in-line aqueous cleaning, to benchtop cleaning, but the process that comes out on top for its effectiveness to deliver perfectly clean and dry PCBAs every time is vapor degreasing.

In the medical electronics industry, the process of cleaning compact PCBA configurations can be difficult. Consideration has to be given to the solder joints found within these devices. If defective they can cause a large percentage of PCB failures, so removing any harmful contaminant and residue is key to their success. Advanced modern cleaning methods enable engineers to specify stronger, more active fluxes, which results in better solder joints, eliminating problems with cold joints, insufficient wetting, bridging, and shorts. However, these more robust fluxes can be problematic to remove. It is predominantly because of this challenge that vapor degreasing is a favored choice when it comes to cleaning PCBAs.

Vapor degreasing not only ensures the cleanliness of the device but also satisfies the economic and regulatory requirements needed within medical electronic manufacturing. Medical device companies value safety, quality and reliability in order to minimize liability and maximize performance and profits. Many of the challenging production and performance issues encountered can be reduced with the correct cleaning of the PCBAs and mechanical medical assemblies.

Removing contaminant under and around tightly-spaced components is a challenge. The reduction in pitch between conductors collects and traps contaminants like solder balls, making cleaning even more complicated. In some instances, active fluxes or flux residue may also stay on the PCBA after reflow in wave machines or after hand-soldering.

Vapor degreasers offer a simple process that is effective at removing contaminants. The low viscosity and surface tension ratings of modern cleaning fluids used within a vapor degreaser, combined with their volatility, allow them to clean very effectively, especially under bottom termination components such as BGAs, CSPs, MLFs, QFNs, and D-Paks. Vapor degreasing ensures all surfaces of the PCBA will be effectively cleaned and free of contamination. For designers, this means they are not limited in product design, therefore medical electronic advancement can flourish in the knowledge that devices can be cleaned reliably reducing the risk of malfunction.

Modern Cleaning Fluids are Helping to Advance Design

What is really transforming vapor degreasing is the advancement in solvent technology. It is not just the medical industry seeking cleaning methods to ensure device reliability. The use of miniaturized electronics in all industries, from automotive through to consumer electronics calls for better cleaning processes and fluids to deliver quality cleaning results.

Vapor degreasers offer a simple process that is effective at removing contaminants.

Modern, non-flammable, environmentally-progressive cleaning fluids, specifically designed for a vapor degreasing system, can make a substantial enhancement to performance, reliability and longevity. It also has the benefit of reducing the risk of bioburden – critical when it comes to medical devices.

Bioburden is when bacteria remain on a surface that has not been sterilized. This can be challenging within the cleaning process, particularly if aqueous cleaning is used because water is a primary growth medium for bacteria. Water and many detergents are a natural breeding ground for bacteria and mold, meaning bioburden control is an ongoing issue when cleaning devices with any water-based system. Even a minuscule amount of moisture in hard-to-reach areas can encourage the growth of bacteria. If it is not properly addressed, it can result in increased complications during the validation of the product and issues with the reliability of the device. For this reason, medical device manufacturers tend to stay away from aqueous cleaning preferring to use solvent-based cleaning fluids which are hostile to pyrogens minimizing bioburden risk. Vapor degreasing also reduces the possibility of bioburden contamination because assemblies come out clean, dry, spot-free and cool enough for immediate coating or packaging.

Progressive Cleaning is the Answer

Device performance has to be the most fundamental concern for manufacturers. As the trend in circuit board miniaturization continues, the complexity and high density design of PCBAs causes a greater likelihood for cleaning challenges and consistency problems. Within the medical industry this could mean life or death so reliability is of paramount importance.

Vapor degreasing and modern cleaning fluids offer a new answer. It enables a critical cleaning process that ensures contaminated PCBAs are not the cause of any failure. Advances in solvent technology means vapor degreasing not only will be the most reliable cleaning process, without the risk of bioburden, but also the most cost-effective and sustainable solution. Progressive next-generation cleaning fluids allow for better PCBAs to be built and deployed, therefore creating new capabilities for the future of medical electronics.

About the Author:

Emily Peck is a Senior Chemist at MicroCare which offers benchtop and vapor degreasing critical cleaning solutions. She has been in the industry more than 6 years and holds a MS in Chemistry from Tufts University. Peck researches, develops and tests cleaning-related products that are used on a daily basis in electronics, medical, fiber optic and precision cleaning applications. For more information, visit www.microcare.com.

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