Can Nitrogen Reduce Failures in Medical Devices?

By David Estes & Mo Ohady, Digicom Electronics

Manufacturers of medical devices must seek every way possible to eliminate failures of those devices. Many major failures result from a weakness in the solder joint that connects the wire bond to the printed circuit board (PCB) or the solder connecting the device or package to the board. Using nitrogen is not an absolute requirement; however, among other things, nitrogen can help to strengthen the bond and improve solder adhesion in the soldering process. As an EMS company, Digicom Electronics seeks to employ technologies in its manufacturing process that can produce products of the highest quality. Towards that goal, we have implemented nitrogen in our manufacturing process. This article explores the use of nitrogen and ways to minimize device failure.

The primary interconnect method of components to the PCB is via soldering. Solder joint quality is largely dependent on the degree of wetting between the solder and the materials to be joined. Lead-free solders have a higher melting point than the traditional lead based alloys. The delta is approximately 100°F for tin/copper/silver alloys. When printed circuit boards are soldered in air, the metal alloy systems used in electronic assembly processes are subject to oxidation. Oxygen from the ambient air that is present in reflow, selective soldering, or hand soldering, permeates the area around the solder joints. Tin oxides form rapidly in an air environment and these oxides inhibit wetting of the molten alloy to printed circuit board lands and component leads which can result in soldering defects. Flux is utilized to inhibit oxide formation and contributes to the wetting of surfaces and allows solder to flow better and produce a higher quality solder joint.

Types of Soldering

Reflow soldering is a process in which solder paste is used to attach one or several electrical components to their contact pads. Solder paste is a mixture of powdered metal and flux. After the solder is applied, the entire assembly is subjected to controlled heat, which melts the solder, permanently connecting the joint. ***(See Figure 1)***

Figure 1. A printed circuit board is placed into the solder reflow oven.

Selective soldering is usually done after reflow and is used to solder through-hole components to printed circuit boards and molded modules that could be damaged by the heat of a reflow oven in a traditional surface mount technology (SMT) assembly process. Parts that are selectively soldered are usually surrounded by parts that have been previously soldered in a surface-mount reflow process. The selective soldering process is very precise to avoid damaging the leads and components. ***Figure 2.***

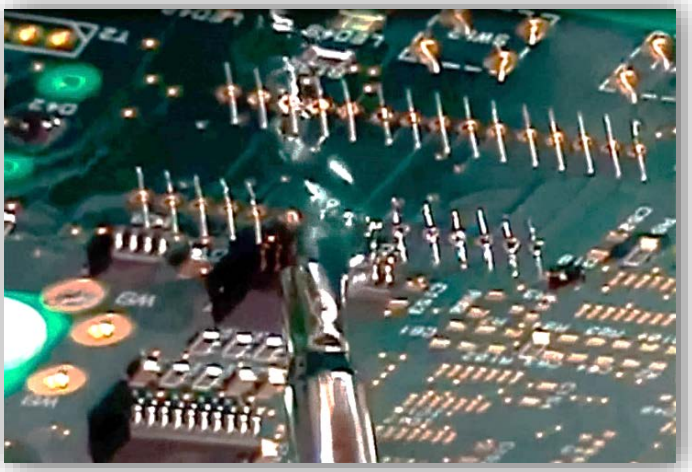

Figure 2. Solder is applied to the leads on the underside of a PCB in the selective soldering process.

Some applications still require hand soldering, especially in the prototype stage and for complex low-volume applications. Hand soldering is also used for touch-up and some rework. ***Figure 3***.

Figure 3. Operators apply solder for touch-ups, rework, and hard-to-reach areas.

Improving Soldering Quality with Nitrogen

Nitrogen is an inert (non-reactive) gas that has low oxygen and moisture levels. It is sometimes used in the reflow, selective soldering, and/or hand soldering process instead of atmospheric air. The use of nitrogen as a process gas provides an inert, reduced oxygen soldering atmosphere. By eliminating the formation of solder oxides, wetting is promoted and soldering quality is improved. Reflow and selective soldering equipment manufacturers are aware of this and sometimes include an option that incorporates nitrogen into these processes.

Nitrogen is used to displace air containing oxygen, diluting the oxygen to a low enough level to prevent or slow the oxidation of metal surfaces during heating. Nitrogen improves soldering quality by reducing oxide formation and creating a higher surface tension across the solder surface. The wetted surface area can increase by 20% to 30%, resulting in increased solder joint strength. Higher surface tension minimizes solder balling when using fine pitch solder paste, and a larger surface tension can hold larger and heavier components on the bottom side of a PCB when performing double reflow. Less oxidation also improves the wetting on NiAu and bare copper solder leads.

Using Nitrogen during Reflow Soldering

In reflow soldering, flux activity, residues, and cleanliness are significant factors to consider when deciding whether nitrogen should be used. According to data cited by TEquipment.net, longitudinal studies provide enough reliable data to confirm that all these factors are improved by the use of nitrogen. In large-scale manufacturing situations, rework defects were monitored over a two-year period, one year prior to a switch to nitrogen reflow and one year after the switch was completed. With the introduction of nitrogen being the only significant change, the proportion of defective joints fell from 82 to 37 dpm, a decrease of nearly half.

Other operations have shown improvements in first pass yield from five to seven percent, which translates into a reduction in defect levels of 50 to 60 percent. Although not every introduction of nitrogen was equally successful, this could be explained by differences in layout and pitch. Admittedly, the introduction of nitrogen as a cover gas cannot by itself compensate for bad layout. The processes that seem to benefit the most are the ones that have a narrower pitch. In other words, the narrower the pitch, the more that nitrogen use is recommended.

In the reflow soldering process, the choice of the type of flux directly impacts solderability issues as well as the resulting cleanliness of the assembly after soldering. There are, however, other issues also related to flux, such as problems with volatile organic compounds as well as cost. When nitrogen is used, it generally allows the use of milder fluxes. Residues are less objectionable and easier to clean than they are in processes using air because they are not oxidized or as heavily bonded so are less chemically complex. Cleaning flux from PCBs is a significant cost factor in the assembly process. Reducing the effort required to clean boards lowers the overall assembly cost.

If proper layout techniques are in place in the reflow oven, a switch to nitrogen can bring about a sizable rate reduction in defects. Defect rate reductions of 50% or more are sometimes reported. In situations where solderability is reduced below optimum, the use of nitrogen can often enhance the soldering process to allow an acceptable joint to form under less than perfect conditions. It is a bit like having a quality reserve built into the process.

Correctly designed reflow ovens utilize the highest concentrations of nitrogen in the zones of peak temperature, with lower concentrations found in lower temperature zones. This technique maximizes the cost/benefit ratio of nitrogen generation. The wetting characteristic of a flux is a desirable trait, but taken to extremes, it can lead to undesirable bridging between adjacent joints. The increased surface tension from using nitrogen within the solder area minimizes the accumulation of solder outside the pad area and minimizes bridging. This is often the case with low residue (LR) fluxes and resin-containing RMA fluxes. Offsetting the wetting force by increasing surface tension becomes more critical as distances between joints decrease. Nitrogen soldering enhances this balancing. In addition to inhibiting the formation of oxides, a low oxygen environment may reduce the temperature at which solder begins to spread by up to 100°F and also reduce the temperature at which oxides dissolve, thereby producing a win-win situation for a quality solder joint at a lower temperature in less time without the inhibitory effect of oxides.

Nitrogen also improves the visual appearance of the solder joint surface. It will be smoother and shinier, especially for lead-free assemblies, so inspection and rework are simplified.

Medical Device Process Validation

Medical device manufacturers are required to validate the processes used to assemble their products. The FDA's Quality System Regulation, 21 CFR (Code of Federal Regulations) Part 8202, requires medical device manufacturers to perform a process validation when the process is not fully verified by a subsequent inspection or test. This ensures that the process consistently produces a quality product that meets its specifications and is an important component in the design, prototyping, and manufacturing process. The process includes statistical analysis of defects, and failure rates have to meet certain ratios. Throughout the design and manufacturing process, every step must be taken to ensure that the device will not fail. If done correctly, having a validated process can save a considerable amount of time, money and resources. The use of nitrogen in reflow soldering, selective solder, or the hand soldering process can produce a stronger solder bond and reduce the number of soldering defects. This makes process validation for soldering easier to achieve.

Controlling Nitrogen Costs

The cost of deployment of nitrogen has been mentioned as a negative caveat in its use. True, there are always costs associated with attempts to reduce or eliminate the margin of error in favor of a better, predictable outcome, and it is no different in this case. However, there are ways to minimize the cost burden with simple preparations in process control.

1. Reflow ovens can be modified or ordered with sealed heat zones and a seal around the perimeter where there would be air (oxygen) intake. These seals not only help to maintain the level of nitrogen injected in the solder area for a longer period, thereby economizing on usage, but also help keep oxygen from seeping into heat zones where its presence is not desirable.

2. Instead of renting or leasing equipment and dealing with the periodic transportation of nitrogen-containing cylinders and other associated service charges, an initial investment in equipment to generate nitrogen and for nitrogen storage at the manufacturing location can pay back some of the costs in the long haul.

3. Generation and on-location storage of nitrogen will also do away with the need to have it delivered in a very cold, compressed form (which is not suitable for use if you're trying to maintain hot-zone stability in your oven) and the need for increased capacity, cylinders, and tanks.

Conclusion

Nitrogen, itself, is a relatively inexpensive gas. It seems that the incremental cost of its deployment would certainly be overshadowed by the cost savings that resulted from producing higher quality, more durable printed circuit assemblies and finished products. The savings in reduced or eliminated repair and rework costs and the benefits of achieving a higher yield and faster time-to-market, not to mention the positive effects on a company’s brand and reputation, far outweigh any possible negatives. The ever-increasing quality requirements for medical devices portend a bright future for the use of nitrogen in soldering.

DIGICOM Electronics, Inc.
7799 Pardee Lane, Oakland, CA 94621
Phone +1 510-639-7003 Fax +1 510-639-7090
Email info@digicom.org Web www.digicom.org