



Medical Device Risk: Is your Power Supply Increasing Your Exposure?

An essential eGuide on how to select a quality power partner

Medical Device Failures

The FDA (US Food and Drug Administration) recall database for medical devices provides a level of insight into the behavior of installed equipment that is unparalleled in OEM markets.

According to the last five years data, there were 25 incidents relating directly to “power supply”. In 2008 alone, there were nine reports: two were end-application issues; while seven were quality concerns with power supplies.

Over the same five year period in the Medical Device Reporting (MDR) database, there are hundreds, if not thousands, of incident reports relating to “power supply” issues with reasons such as “failure to run on AC/DC”, “electrical failure”, “failure to power-up” and “loss of power”.

The existence of the MDR or other venues for reporting adverse incidents on medical devices highlight the problems relating to power supplies beyond the

normal warranty reporting and coverage applicable to other electronic devices. Such reports, especially those resulting in death or injuries, require the medical device manufacturers to implement quickly and effectively the necessary corrective and preventive actions (CAPA).

International Standards and Compliances

A medical device is defined as an object used for diagnostic or therapeutic purposes. A power supply is an important active component of a medical device, converting electrical energy from the electrical wall outlet to some form of electricity that is useful to power motors, heaters, compressors, lasers, computers, ultrasound, radio frequency-emitters, etc.

The power supply use is covered under the international standard IEC 60601-1 for medical devices, defined as Medical Electrical Equipment and Systems or is covered under IEC 61010-1 for electrical laboratory equipment such as in-vitro diagnostic equipment (e.g. immunoassays, clinical chemistry, polymerase chain reaction).

For implantable medical devices, where battery-type power supplies are used, ISO 14708-1 is the prevailing standard used. These standards define the design checklist to ensure basic safety and essential performance of such medical devices by spelling out the design rules and test methods for the medical device.

Various safety agencies, such as Underwriters Laboratories Inc., Canadian Standards Association and TUV certify that products comply with these safety standards and demand a few manufacturing requisites such as high potential (HiPot) and ground-continuity tests, inspection of safety critical components and annual or bi-annual factory audits.

The compliance of the power supply to such safety standards simplifies the eventual approval of the medical device end-product as regulated by appropriate agencies such as the FDA (US), Therapeutic Products Directorate (Canada) and the Ministry of Health, Labour and Welfare (Japan).

These standards define and ensure that the components and systems designed for medical equipment are safe by reducing the risk of electrical shock, mechanical, radiation, fire and other hazards under normal and fault conditions. In particular, the IEC 60601 has historically focused on “basic safety”, not the effectiveness of the medical device.

Later amendments to the standards broadened its coverage to include “essential performance”, defining further requirements referred to as “particular standards” as regards to this medical device’s specific application.

The third edition which was published in 2005 and to be made effective by June 1, 2012 for Health Canada (others may follow suit) includes a new requirement for the manufacturer of the medical device to have a formal risk management system conforming to ISO 14971. This requisite directs the manufacturer to identify the hazards associated with the medical device, assess the risk, implement measures to reduce the risk and verify the effectiveness during all the stages of the device’s life cycle. Risk management is limited to ensuring basic safety and other essential performance requirements as they impact proper function.

Risks and the Life Cycle

Beyond just complying with such international standards, the essential performance of the medical device, and of course its power supply, is critical because patient health - whether directly or indirectly - depends on it. In patient care, therapy, monitoring or imaging applications, a medical electrical device's malfunction due to its power supply (e.g. failure to power-up, loss of power or other errors) can directly affect a patient's health temporarily or permanently.

In analytical laboratory or diagnostics, a power supply problem can lead to

errors or delays in making decisions as regards to a patient's care, not to mention the pain and trouble of securing more specimens to be tested.

The medical device's risk of failure in essential performance, not pertaining to safety hazard, as caused by its power supply should be managed over the life of the product and not just during its design stage.

In a survey of medical device manufacturers by Cambashi Inc. (Fig. 1) in conjunction with FDAnews, risk

management efforts come early in a product life cycle and later only when a problem arises as shown in the graph below. Risk levels change drastically during full production as volume of medical device increases, parts become obsolete, vendor sourcing switches and manufacturing changes.

Fig 1. Stage at which risk management becomes a major factor in decisions and activities

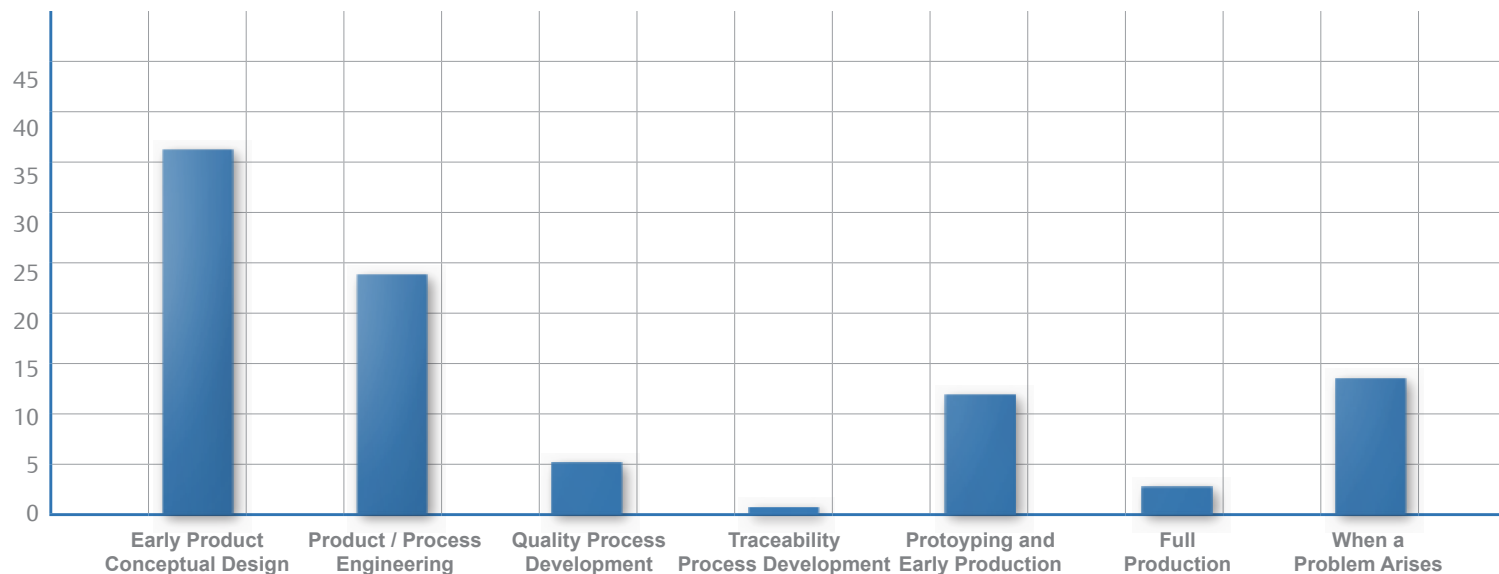


Figure 1 - Source: Risk Management: Best Practices for Medical Device Profitability © 2008 Cambashi Inc., conducted in conjunction with FDAnews and available at www.cambashi.com

Quality Questions for Your Power Supply Vendor

In order to mitigate the risk associated with selecting a component such as a power supply, medical device manufacturers should ensure their supplier has a quality system that at a minimum meets the requirements of the relevant ISO standard. For example, Figure 2 shows the Emerson Network Power quality systems, which goes beyond the usual prescriptions of ISO quality systems and promotes quality from the viewpoint of the customer, focusing on:

- Design Controls - Design Practices, Component Selection and Quality Assurance Verification
- Purchasing Controls - Supplier Qualification and Supplier Quality Management
- Production and Process Controls - Process Control and Quality Assurance & On-going Reliability Testing
- Post-Market Surveillance - Field Support, Automatic CAR System, Field Failure Tracking System

By the same token, the FDA's final rule on Current Good Manufacturing Practice (cGMP) includes design controls and purchasing controls and harmonizes those with ISO 9001³. The goal of design controls is to optimize the quality of the power supply early in the design phase, aiming for minimal failures and better reliability over its life while the goal for purchasing controls is to extend quality control to vendor partners, thereby catching and correcting problems directly at the component sources.

As illustrated by Figure 3, such Emerson initiatives have dramatically reduced the overall parts per million failures.

Fig 2. Quality Systems Overview

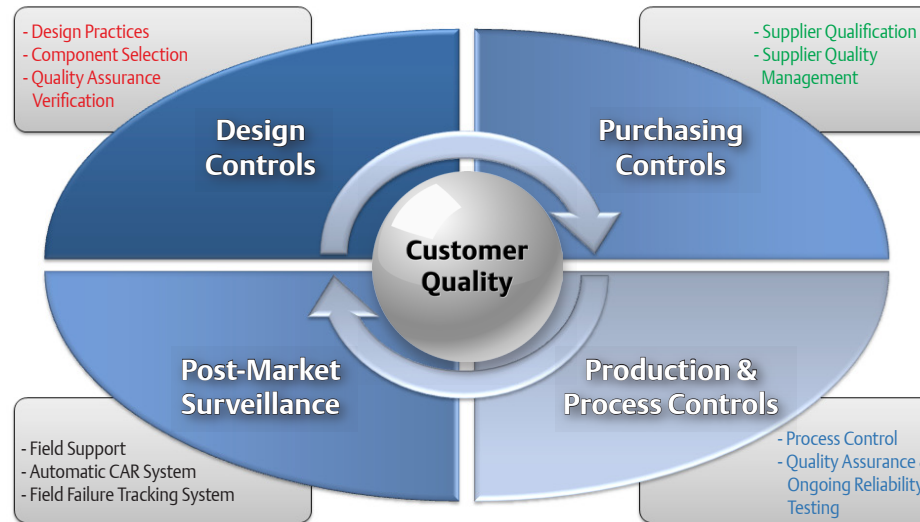
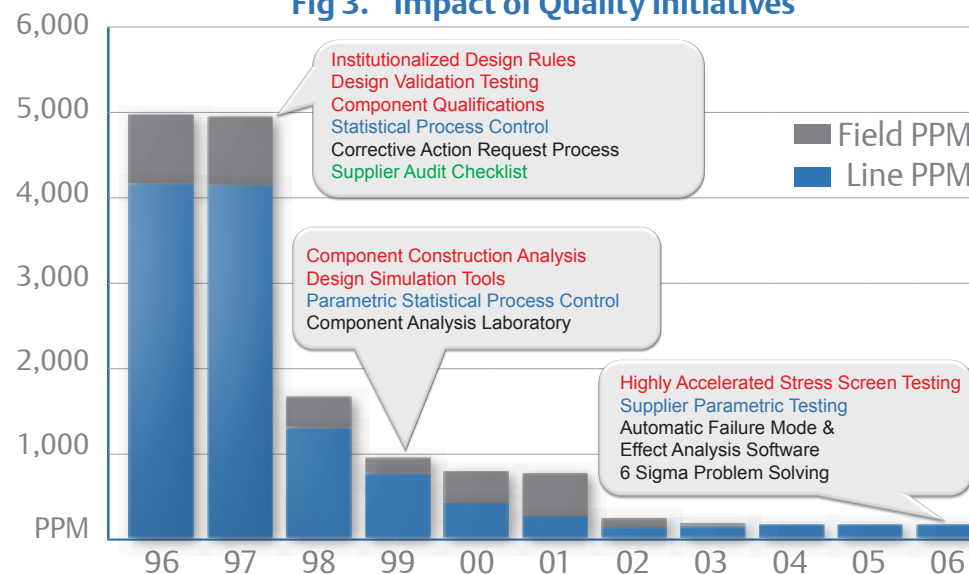


Fig 3. * Impact of Quality Initiatives



*These quality metrics and programs are not a guarantee or promise of reliability or quality performance for any product or customer. These are an accumulation of customers of tens of thousands of product codes, thousands of customers and several factories in varied market applications.

Quality Questions for Your Power Supply Vendor

As shown in Figure 4, there is an expected failure rate observed at the customer side. These failures are usually caused by component reliability issues, escaping the normal screens and tests. In the electronics industry, this is simply charged to warranty cost for return and replace. In the medical device industry, such failures, particularly in a power supply, will definitely raise a flag in the MDR or some other adverse reporting database.

The Emerson Network Power quality and reliability initiatives listed above are designed to drive down that failure rate. In particular, as shown in Figure 5, the Test for Significance program at the production level and at certain critical vendors examines power supplies (or components) passing specific parametric tests but performing outside of the normal lot.

Another key aspect in addressing customer quality, particularly for medical device manufacturers, is field support. Either directly or through Emerson's sales distribution partners, field failures are tracked and catalogued. Failed units undergo intensive failure analysis down to the component level at Emerson's component analysis laboratory or trusted third-party centers. The resulting CAPA are implemented and monitored while the corresponding quality metrics and databases are updated to further alert related issues.

Fig 4. **Reliability Programs

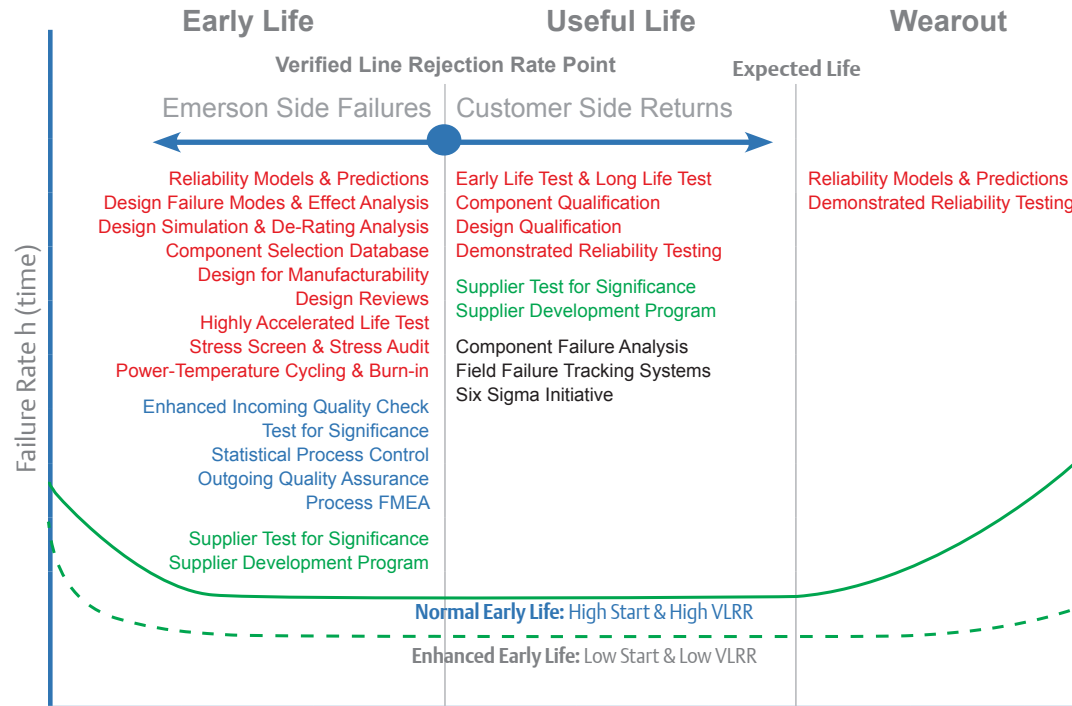
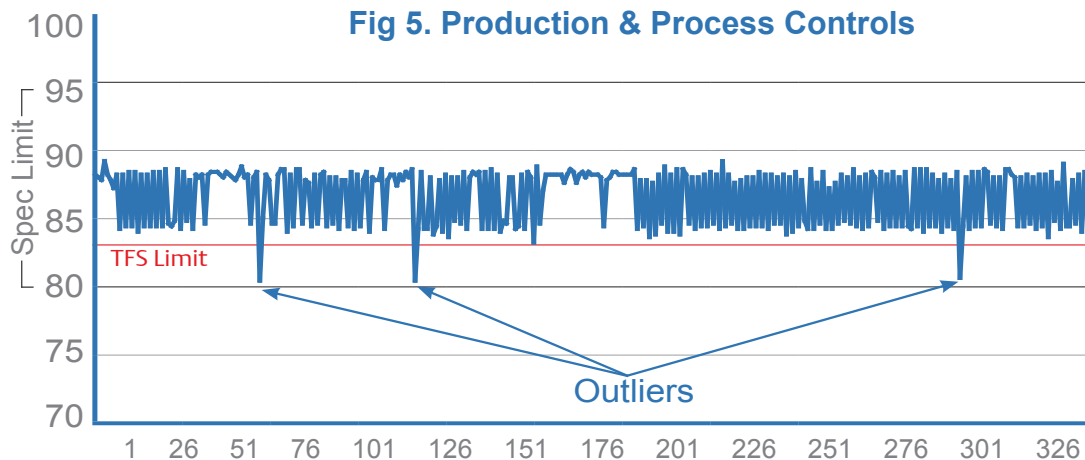


Fig 5. Production & Process Controls



**These programs are not a guarantee or promise of reliability or quality performance for any product or customer. Depending on the product, customer and market requirements, these programs are applied when necessary.

Test for Significance (TfS)

- Additional (TfS) limits (tighter than spec limits) are strategically incorporated into the test program to detect outliers
- TfS failures undergo rigid failure analysis and evaluation

Your Trusted Partner in Healthcare Power Supplies

Emerson Network Power has been making power supplies for more than 35 years and is certified by most safety agencies. Emerson serves the healthcare industry's top medical device manufacturers primarily in the medical imaging and diagnostics segments. Emerson gives these medical device manufacturers the opportunity to focus on its core technology, rather than on commodity standard and custom power supplies, which by themselves are comprised of a few hundred and sometimes thousands of electronic and mechanical components.

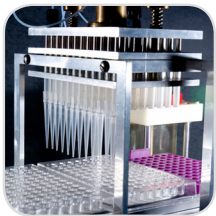
In an interview, an FDA Senior Recall Coordinator pointed out that those problems with supplied components

of medical devices caused a large percentage of recalls¹. The trouble with managing several hundred components versus one part leads many medical device manufacturers to source their power supply needs from Emerson.

Medical device manufacturers are selecting Emerson Network Power as a power supply partner for three main reasons:

1. Experience in the medical industry and expertise in power supplies
2. Highly developed quality systems focused on the customer
3. Processes that are developed to conform to the requirements of international standards and cGMP

As demonstrated by the information above, while medical device manufacturers retain independent responsibility for ensuring that their medical devices, as integrated with the power supply and other components, comply with the FDA's cGMP/Quality System Regulation (QSR), Emerson's focus on manufacturing its components to QSR and other applicable international standards helps facilitate manufacturers' compliance with QSR requirements, including those for appropriate design and purchasing controls.



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1. The Silver Sheet™ Medical Device Quality Control, Vol. 13, No. 2, February 2009.
2. "Risk Management: Best Practices for Medical Device Profitability", Cambashi Reports Industry Directions in Conjunction with FDA News, June 2008.
3. Federal Register, Department of Health & Human Services, Food and Drug Administration. Medical Device; Current Good Manufacturing Practice (CGMP) Final Rule; Quality system Regulation. Vol. 61 No. 195, October 7, 1996.
4. Hill, J.F., Morris, C., Gabriel, R. "An Approach to the Dynamic Detection of Outliers in Electronics Production", International Journal of Production Research, Vol. 45, No. 3, February 2007, Taylor & Francis.



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