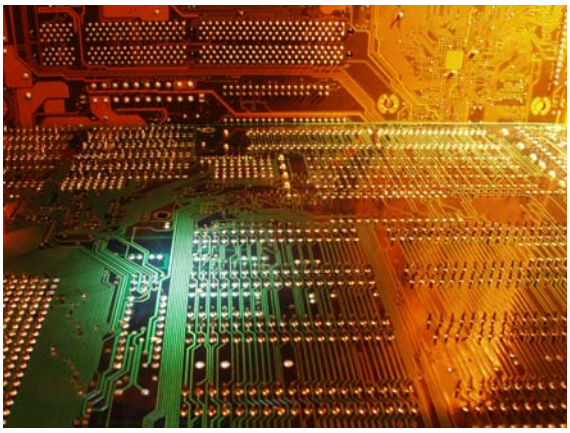
What Medical Technology Marketing Professionals Should Know About Product Reliability

By Alec Alpert

While hospitals provide healthcare services to the public, they are also in the business of making profits, like any other businesses. Naturally, they want the cost of operating medical technology to be as low as possible, especially when it involves expensive technology. When equipment malfunctions, it means downtime and the inability to treat or diagnose patients while waiting for repairs to be complete. This is frustrating to customers and the manufacturer. Frequent breakdowns result in a high number of complaints, high cost of complaints investigation and product repair, a loss of good will, and even product recall or cancellation.

So, what can a manufacturer do to ensure the reliable performance of their medical devices and, hence, customer satisfaction? First, the medical device has to be designed and manufactured with a high sense of reliability in mind, with as few failures as possible over the life span of the product. Ideal reliability would be that a product never fails and lasts forever, which is impossible, of course. Therefore, manufacturers must find that "happy medium," where the failure rate over time is tolerable.



Determining what is tolerable and assuring it is the purpose of reliability science. The definition of reliability is the probability of a product performing, without failure, a specified function under given conditions for a given period of time. A widely used metric of reliability is Mean Time Between Failures or MTBF, which is the average time between successive failures of a repairable product. The higher the MTBF, the higher the reliability of the product. A product that has an MTBF in years has a very high reliability. If a medical device has an MTBF of 15 years, the user will have little downtime, and will likely be quite pleased with the product. The result will be repeat business and a good reputation for the company.

Achieving an MTBF of 15 years, however, requires a dedicated effort by a manufacturer. To start the journey, the ***reliability goal*** has to be spelled out in the product's specifications as one of the deliverables, and ***reliability validation testing*** must be performed to demonstrate that the reliability goal has been accomplished ***before*** a product launches.

Accomplishing high product reliability is a complex and difficult task. It requires the commitment of the company's management and its employees. Product development policies

and procedures have to be geared towards customer satisfaction through robust product design and manufacturing. The best approach to ensuring high reliability would be through the ***proactive*** reliability growth program, where the reliability is designed in from the very beginning of the product development. There are many tools that can accomplish this, such as:

- Reliability assurance plan
- Design reviews
- Six-sigma approach to design and manufacturing
- Management of suppliers
- Failure Reporting and Corrective Action System (FRACAS)
- Failure Modes and Effects Analysis (FMEA)
- Fault Tree Analysis (FTA)
- Environmental Stress Screening (ESS)
- Reliability growth testing
- Hazard analysis
- Reliability acceptance testing

If these tools are used, reliable products will be the result, thereby making a difference to customers and manufacturers. In fact, marketing representatives on product development teams should emphasize the importance of high reliability to the success of the product and make sure that the reliability goal is incorporated in a product's specifications and that it has been accomplished and validated before the product's launch. A good move would be to hire a Reliability Engineer to oversee the reliability assurance program, especially for highly complex, expensive medical devices. If a high reliability goal is accomplished, this can be a **strong selling point** to include in marketing communication, including white papers.