

# Extend Medical Device Reliability and Mitigate Risk

## Reduce FDA Fees, Restitution Expense and Recall Costs

The most recent numbers for medical recalls and FDA fines and restitution fees indicate that companies are learning the expensive way that legacy product testing is inadequate and inefficient. In their book "Practical Design Control Implementation for Medical Devices", Justiniano and Gopalswamy advise that *Class I-III electronic devices undergo HALT (Highly Accelerated Life Testing) and/or HASS (Highly Accelerated Stress Screening) in order to fully realize operational margins and reliability expectations to meet or exceed the medical industry's geospatially diverse safety and regulatory directives.*

“...in about 20 hours of test time Qualmark identified all major issues that had required hundreds of hours of testing using traditional methods to discover.

**Medtronic**

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The product reliability improvements made possible with Qualmark test systems effectively

mitigate corporate exposure to fees, expenses and costs due to failures in reaching projected product reliability.



**Qualmark's Typhoon 4.0 HALT/HASS Test System**

**Qualmark's QFusion™ 300 Industry's first HASS dedicated test technology**

## Newest Stress Test Technology Increases Medical Device Reliability

Qualmark's Typhoon technology reveals product weak links missed by traditional test methods. Thus, faults can be corrected early in the design cycle - when it's not so painfully expensive.

Qualmark's QFusion™ technology is an industry first - purposefully designed for HASS and HASA (auditing) of medical devices and other high performance electronics. QFusion delivers the *lowest cost per unit tested for production screening*, and can accelerate traditional Burn-in at significantly reduced utility costs.

If you need a fast, effective solution for reducing the field failures of electronic medical devices, place Typhoon technology in the design lab and apply QFusion technology during the manufacturing process.

## Can You Afford Not To?

In 2010, \$690M in warranty claims were paid out by the medical industry. Over the past eight years, warranty costs have run an average of 0.9% of sales. (Sources: *Warranty Week from SEC data.*)

Medical device manufacturers eager to reduce their exposure to recalls, litigation and warranty expenses are turning to Qualmark's accelerated stress test systems to increase reliability and extend operating margins.

Contact Qualmark to learn more about the return on investment impact for medical device ODMs, OEMs, and their supply chains.

