

Assurance Delivered for New Generation Electromechanical Medical Device

Challenge

Design and document a safe and reliable medical device for the U.S. market and the reduce number of failures compared to previous generation design.

Solution

Reliability modeling, failure modes and effects analyses, software validation, and reliability test plans provided by Prenscia Solutions.

Results

Timely marketing and launch of device, accurate projection of potential failures, robust manufacturing plans and manage warranty risks.

Client leveraged engineering services and software from Prenscia Solutions to create reliability and FMEA models for making failure predictions to help develop robust design and manufacturing controls to improve reliability while simultaneously, validating the embedded software.



nCode

ReliaSoft

Omnicron

The Challenge

Our client, a medical equipment manufacturer, was developing a second-generation product design that had many high speed moving parts.

Previous designs had higher than expected failure rates in the field, and new design features required software modification, improvements, and validation to ensure improvement.



The Solution

Based on design data, reliability and FMEA software models were created for failure rate prediction at component and assembly levels.

The models determined the probability of failure of various functions to ensure they met the expected life.

Prenscia Solutions partnered with the client to define software and firmware requirements and mapped them to validation activities and test cases to meet ISO 13485 and ISO 14971 requirements.

The Results

Reliability predictions and trends were validated through field return data from the previous generation products for correlation. Accelerated Life Tests of the product continue to validate the predictions and controls put in place.

The models produced by Prenscia Solutions gave the client superior insights, delivering robust predictions for reduced failure rates and the ability to manage risks related to operations planning, warranty, and business forecasts.



About HBM Prenscia Solutions

HBM Prenscia Solutions ensures customer success through value-driven solutions for product and process development, and operational monitoring. We are a multi-disciplinary team with expertise in failure analysis; predictive analytics and modeling for reliability, durability, and deterioration; asset health and usage monitoring; prognostics; development and testing of embedded software and electronics to deliver robust solutions to our global clients. Our team of engineers, analysts, software developers, data scientists, and program managers, many holding United States Government security clearance, are readily available to provide technical expertise and deliver value-driven solutions. For more information, please visit www.hbmprenscia.com/solutions