

ISO 13485:2016 & ISO 9001:2015 Certified

# SES Medical Technologies

## Reliability for Combination Products

Reliability Definition & Planning / Reliability Modeling & Prediction / Reliability Testing & Analysis / Reliability Estimation & Documentation

### About Combination Products...

Combination products are therapeutic and diagnostic products that combine drugs, devices and/or biological products. As technological advances enable the merging of these product types with historically different regulatory pathways to commercialization, the need to direct attention toward the safe and reliable development of these products has emerged. Stress Engineering Services can help!

### A Great Opportunity... with Unique Reliability Challenges

With the strong growth in personalized medicine, and the recent finalization of cGMPs for combination products by the FDA, opportunities for bringing these products to market have never been greater. These opportunities are accompanied by challenges, which are often found at the interfaces between the subsystems of the components that have been integrated into a single device or delivery system solution. Stress Engineering Services (SES) has the tools, expertise and reputation for designing reliability into devices, drugs and biologics as well as helping clients improve the reliability of existing products.



The SES approach to reliability includes four primary activities:

- Reliability Definition & Planning
- Reliability Modeling & Prediction
- Reliability Testing & Analysis
- Reliability Estimation & Documentation



# Reliability Definition & Planning

Our Reliability Approach starts with Reliability Definition & Planning. In this initial phase, we guide your team through the development of a comprehensive written Reliability Plan that includes:

- Defining Reliability
- Setting Reliability Goals
- Developing a Usage Model
- Writing Strong Reliability-Related Requirements
- Creating a Reliability Allocation Model
- Identifying Reliability Modeling and Prediction Activities
- Launching a Reliability Testing Approach
- Obtaining a Preliminary Reliability Estimate
- Establishing a Documentation Plan

A Project-Specific Reliability Definition is developed. This working definition is refined to eliminate ambiguity and updated to reflect changing project goals.

## Sample Reliability Goal Statement

- "With a confidence of X%, Y% of sensor units will operate for Z time units without a functional failure"
- Where sensor units = under-skin sensor, wireless transmitter, and skin patch
- Where functional failure = the inability of the sensor system to continuously transmit glucose levels to the monitor with specified accuracy

## Reliability Allocation Model Excerpt

A spreadsheet-based Reliability Allocation Model is a useful tool during the Reliability Definition & Planning activities.

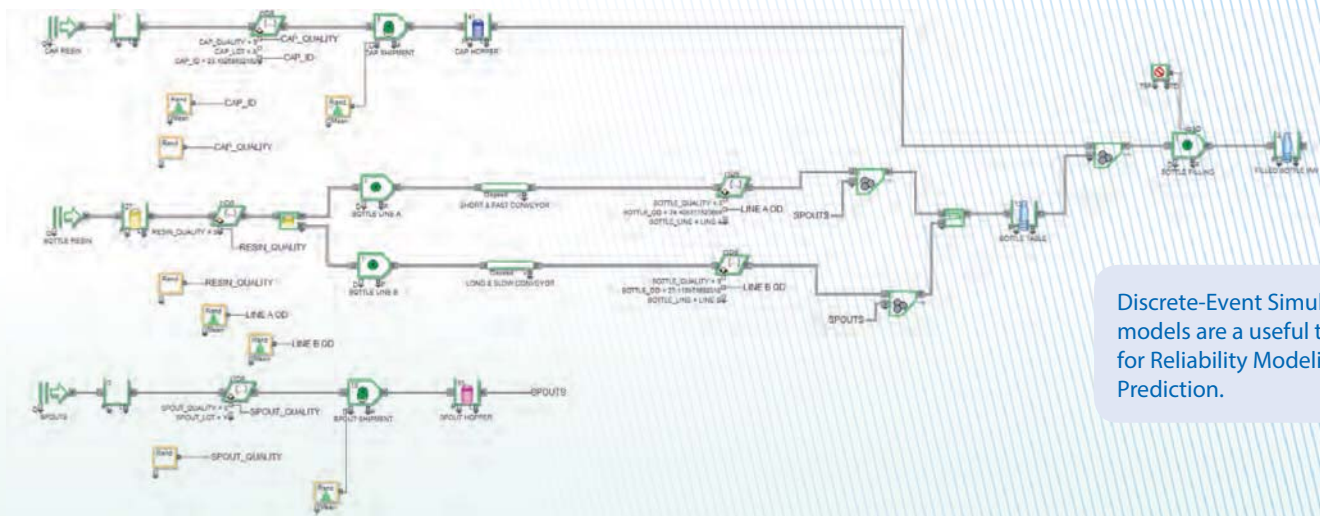
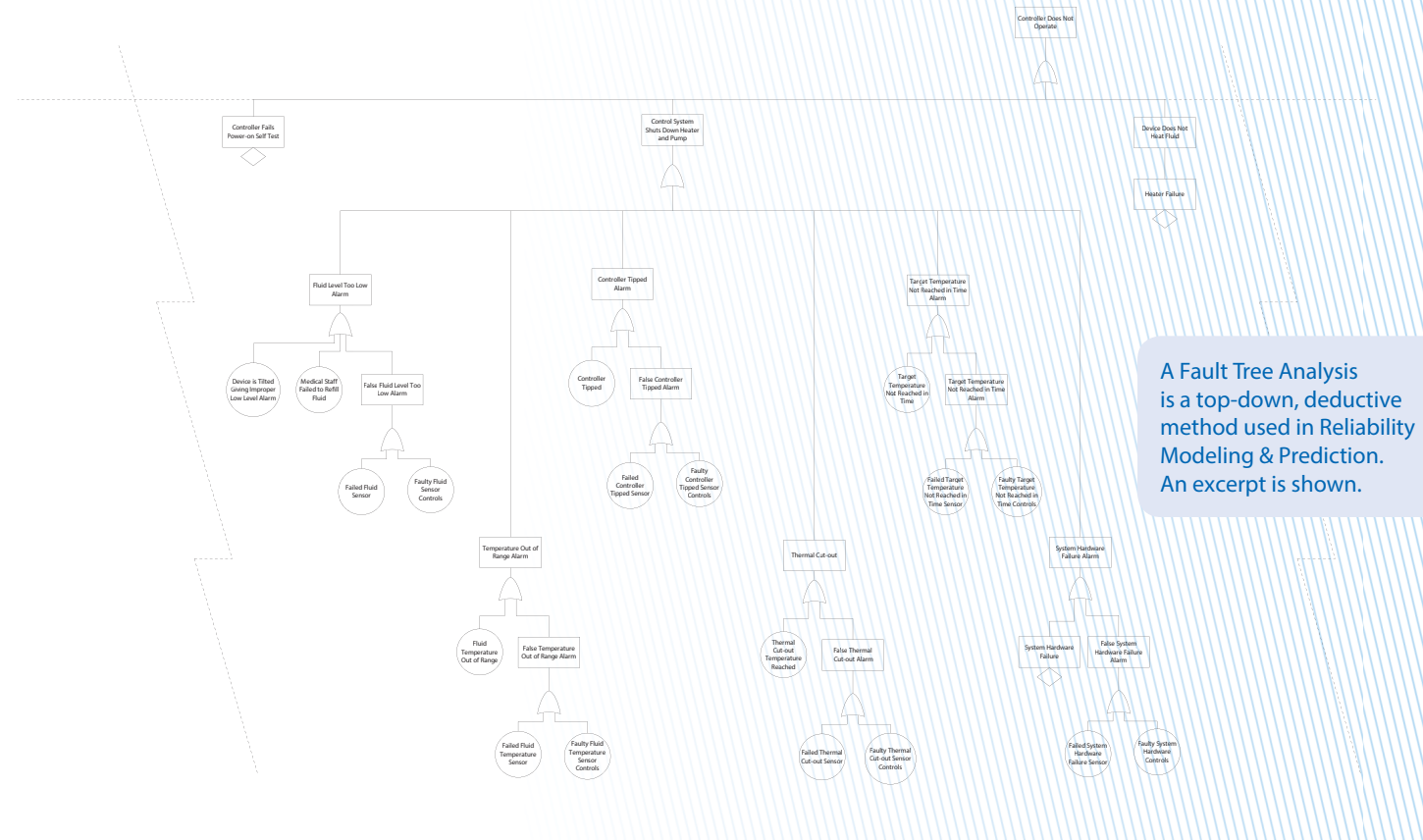
Device	Drug Delivery Device					
	TARGET R	0.900				
	CALCULATED -Subsystem Alloc	0.903				
	CALCULATED -Component Alloc	0.764				
Subsystems	Insertion Mechanism	0.975	Fluid Path	0.990	Enclosure	0.980
	Allocated to Subsystems					
	Calculated from Component Allocations	0.929		0.990		0.950
Components	IM Button	0.980	Fill Port	0.998	Adhesive Patch	0.980
	Introducer Hub	0.999	Fill Port Septum	0.998	Baseplate	0.990
	Springs	0.989	Flex Tubing	0.998	Top Enclosure	0.999
	IM Housing	0.990	Reservoir	0.998	Seal	0.980
	Mechanism Cap	0.990	Supply Tubing	0.998		
	Release Collar	0.990				
	Needle	0.990				
	Catheter	0.999				

With recent applications covering a wide range of products and industries, we can customize a Reliability Approach to fit your product complexity and budget.



# Reliability Modeling & Prediction Activities

SES has experience using both theoretical and empirical data as modeling and prediction inputs. A variety of predictive tools are used, depending on the specific application and objectives. Our staff is experienced in discrete-event Monte Carlo simulation techniques, statistical analysis and classic Reliability Engineering tools. The top-down, deductive Fault Tree Analysis method as well as the bottom-up, inductive Failure Mode Effects (and Criticality) Analysis method are often used as primary tools during this phase of the Reliability effort. When applying these tools to combination products, particular emphasis is placed on failures and functions that occur at the interfaces between the combined items.

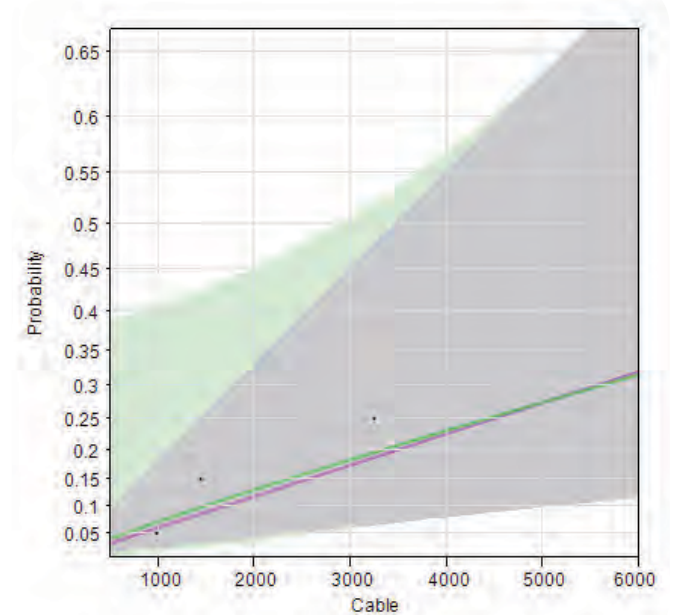


# Reliability Testing & Analysis

Reliability testing can be completed at the client's site or in Stress Engineering's medical and pharmaceutical device testing lab. SES is certified to ISO 9001:2008 for design. SES has experience with the design, planning and analysis of a variety of testing

- System Level Reliability Demonstration Tests
- Component Level Reliability Demonstration Tests
- Failure Screening Tests
- Accelerated Testing
- Multiple Environment Over Stress Testing (MEOST)
- Standards-based Packaging and Transport Testing
- Environmental Chamber Conditioning
- Sequential Probability Ratio Testing (SPRT)
- Duane Growth Testing

By tailoring a custom set of testing approaches, SES is able to balance data requirements with resource constraints.



Sample Probability Curve for Cable Failures

## Reliability Estimation & Documentation

No job is complete until the paperwork is done! Our reliability assessments and estimates are fully documented and ready for inclusion in your Device Master Record and Design History File.

To Improve Reliability & Reduce Risk with Combination Products,  
Call SES Today at 513-336-6701

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