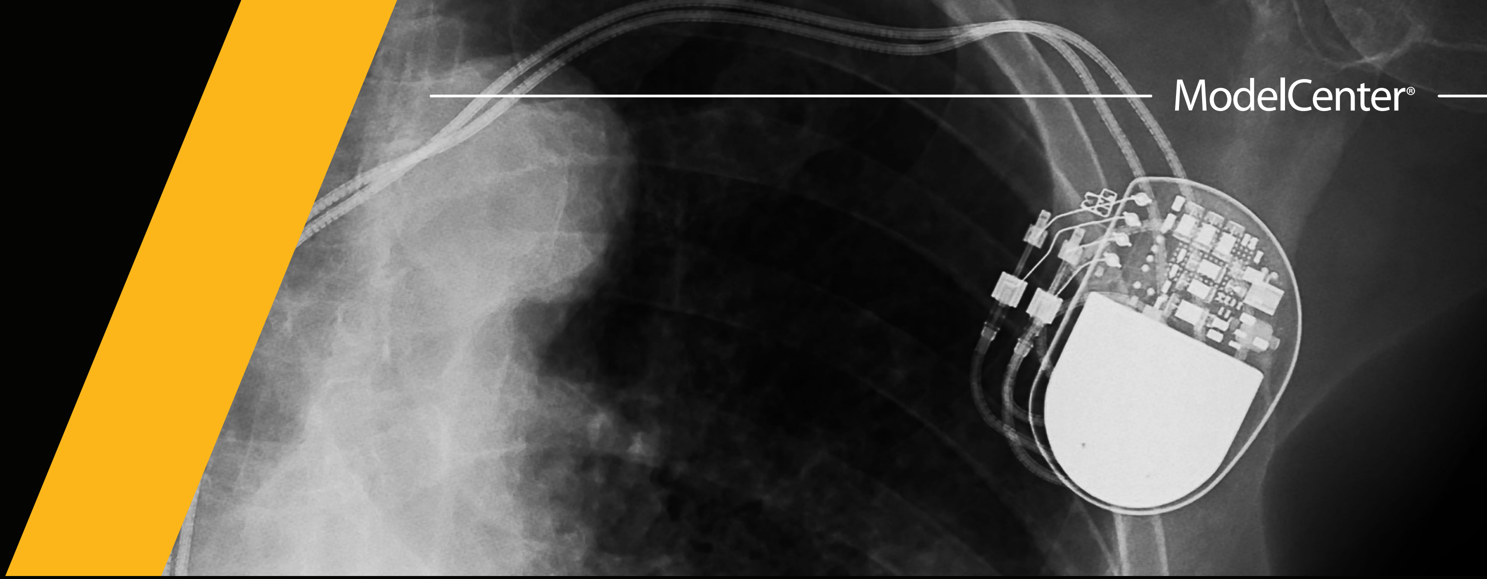


CASE STUDY /

ModelCenter + Johns Hopkins University

Johns Hopkins University explores how Model-Based Systems Engineering (MBSE) can address medical device developmental challenges and improve device communication

"Since these devices deal with biological applications, we need to be **concerned about safety, performance and of course efficiency**."

Kerron Duncan
Ph.D. Candidate / Johns Hopkins University

Implanted medical devices are helping doctors monitor patients' health as they go about their daily lives. It shows the impact of physical activities, rest, and environmental factors on their health that helps doctors better diagnose the condition and choose the appropriate medical treatment. Over the last decades, medical professionals and biomedical engineers have researched and developed medical devices that have improved or saved lives.

Even with the strides in technology, implanted medical devices still come with risks and potential for device failure. To improve device performance, engineers are utilizing technologies and approaches developed from aerospace engineering; model-based systems engineering (MBSE).

MBSE is a methodology that uses models as the primary source of information. When this information is connected with simulation tools, it allows engineers to conduct early architecture trade studies and make better device design and construction decisions. Resulting in safe biotelemetry devices that perform and consume power efficiently.

This case study will show how ModelCenter® helped Johns Hopkins University to examine 6,000 different design options in a relatively short period to find the best solution. Users were able to explore "what-if" analysis connected to models and data that aligned with systems requirements.

ModelCenter®

CASE STUDY

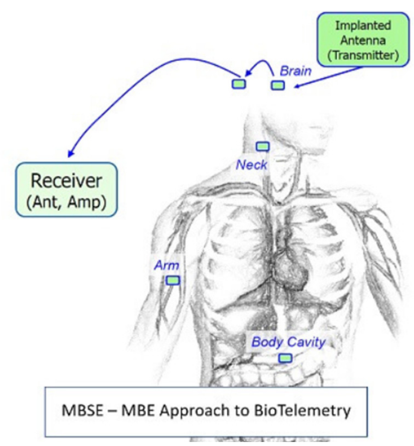
MODEL-BASED SYSTEMS ENGINEERING (MBSE) / INTEGRATING SYSML WITH ENGINEERING SIMULATION
MODELCENTER® INTEGRATE / MODELCENTER® EXPLORE / MODELCENTER® MBSE

/ Background

Implanted wireless devices have become an initial tool for medical professionals to measure, monitor, and record real-time physiological parameters through radio frequencies. These devices have saved thousands of lives a year. For implanted cardioverter-defibrillator (ICD), researchers have seen a 55% reduction in total mortality and a 75% reduction in sudden cardiac death (SCD). Which is estimated to contribute to over three million deaths in the United States each year.

Even with the success of implanted devices, there are still many concerns about device failure due to the device's communication components or power supply. Replacing the device exposes the patients to risks of surgery and infection. These concerns point to a need to design better devices.

Johns Hopkins University's Ph.D. Candidate, Kerron Duncan, addresses biotelemetry communication devices' concerns, explores methods used in aerospace design, and applies them to research solutions to device development challenges.



Graphic courtesy of Johns Hopkins University

/ Challenge

Development of a wireless biotelemetry communications system that meets all the constraints of implanted wireless devices in humans and animals and those imposed on short-range, high data rate wireless communications. This biotelemetry system will allow efficient monitoring of people's health as they go about their daily lives. Patient safety is paramount to the success of this solution. For example, the Specific Absorption Rate, which measures the rate at which energy is absorbed by the human body, must be controlled. To assure that the temperature increase from the implanted device is kept within tight bounds. Some of the benefits of using an implant to collect health data are reduced infections and higher fidelity.

The original engineering approach was a document-based method connected to tools such as Microsoft® Word, Excel, and PowerPoint® to describe the entire system. This process provided no way of easily tracking changes. It made it difficult to understand and follow the current state of the implanted system. Engineers could only create a few design alternatives at a time, hindering their understanding of the design space and lowering the number of design options they could consider. Transferring data and files between disconnected models was time-consuming. In addition, engineers could not verify these performance and safety requirements against analytical models, which meant a limited view of the entire system being designed.

Difficult to track engineering changes

Limited ability to explore design alternatives

Time consuming data transferring to models

Limited view on the entire device system

/ Customer's Objectives

Evaluate thousands of implanted device options

Reduce the time to explore design alternatives

Increase efficiency of devices

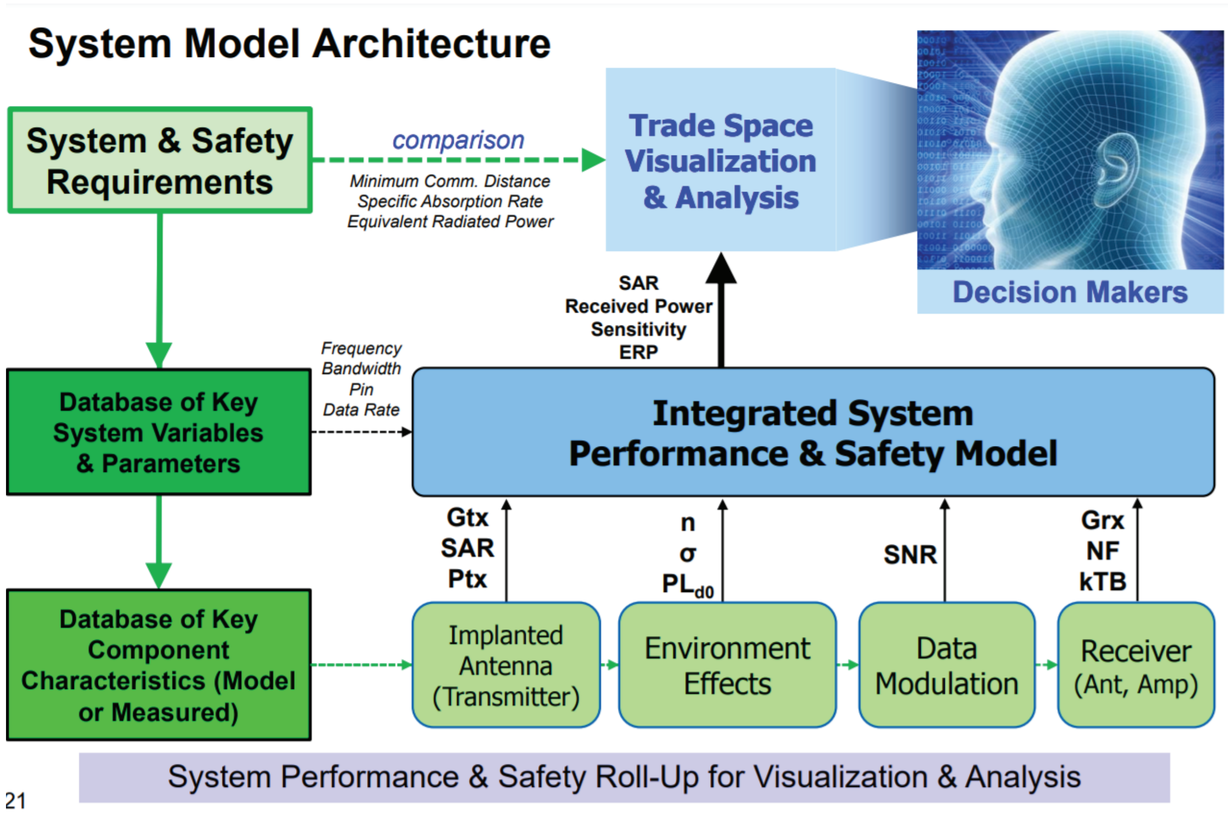
Reduce infection rates due device implantations

/ Solution

Using model-based design approach to the development of the full medical device system helps increase power efficiency while keeping equivalent radiated power in the body within safe limits. This integrated safe-performance system model is constructed using ModelCenter® which enables the digital integration of requirements, architecture, and disparate performance models to determine the optimal solution for an implanted communication system.

ModelCenter® MBSE and ModelCenter's DOE and visualization capabilities, we provided the customer with a solution to integrate all of his analyses, collect data from his model and then visually analyze this data to quickly analyze thousands of system design permutations. Used DOE on integrated workflow to compare 6,000 design alternatives, used charts and plots in MC to analyze Specific Absorption Rate (SAR), Equivalent Radiated Power (ERP), and other factors by varying maximum frequency, input power and transmitter-receiver distance.

ModelCenter® workflow was connected to the system (SysML model) using ModelCenter® MBSE to enable Systems Engineers evaluation of design performance. The systems model now can verify requirement compliance and perform 'what-if' studies.



Graphic courtesy of Johns Hopkins University

/ Results

Using ModelCenter® allowed Johns Hopkins University (JHU) to execute an array of analyses quickly and automated. When they connected ModelCenter® to IBM Rhapsody® through ModelCenter® MBSE they were able to execute analyses through Rhapsody® directly. This reduce the time and accuracy of the data exchange, which original was done manually.

JHU developed a decision support tool that enables a broad trade space of implanted wireless communication system permutations using Model Based Systems Engineering through ModelCenter®. Leveraging system requirements and constraints to prune and explore the results to determine the best solutions from thousands of alternatives for the system in ModelCenter. Users can now simulate numerous alternatives early in the system lifecycle and explore "what-if" analyses.

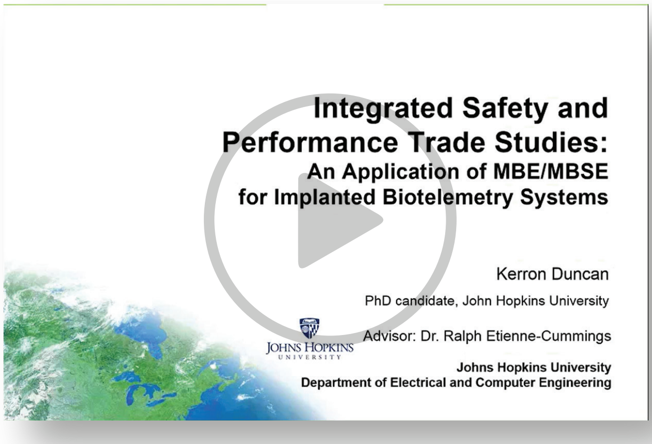
JHU views the new process as a method to save time, increase efficiency of the implants, and reduce the number of infections. Model-based systems engineering has allowed to explore the design space like never before and will be for future device development.

/ Additional Resources

Watch the Presentation On-Demand

An Application of MBE/MBSE for Implanted Wireless Biotelemetry Systems

Presented by:
Kerron Duncan
Manager, Modeling, Simulations and Analysis /
Johns Hopkins University /



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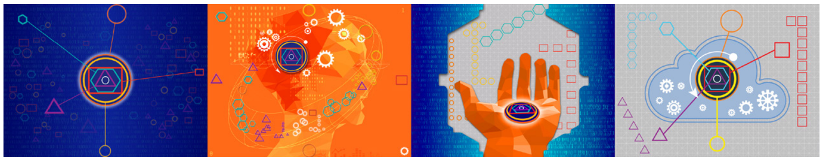

ModelCenter® is the environment for Model Based Engineering.

ModelCenter® is a vendor-neutral software framework for creating and automating multi-tool workflows, optimizing product designs, and enabling Model Based Systems Engineering (MBSE). It is used by leading organizations worldwide to reduce development costs, improve engineering efficiency, stimulate innovation, and design more competitive products. Successful applications can be found in multiple industries, including aerospace, automotive, defense, electronics, energy, heavy industry, and shipbuilding.

Visit www.phoenix-int.com for more information.