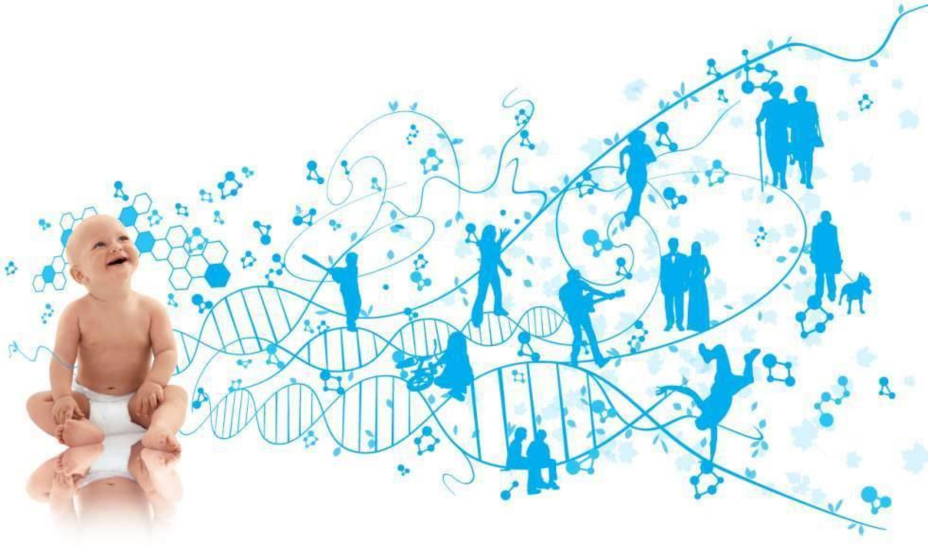
Modeling and Simulation at GE Healthcare



Chris Unger
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Broad solutions for healthcare

Broad-based Technologies

Diagnostic imaging & surgery technologies

Clinical products

Medical diagnostics

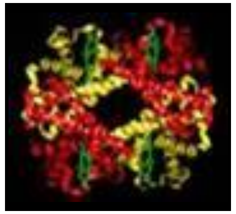
Information Technology

Integrated admin. & clinical

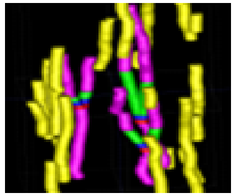
Electronic medical records

Picture Archiving System (PACS)

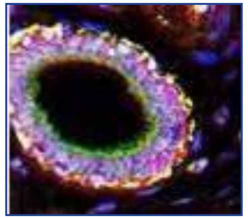
Life Sciences



Discovery tools

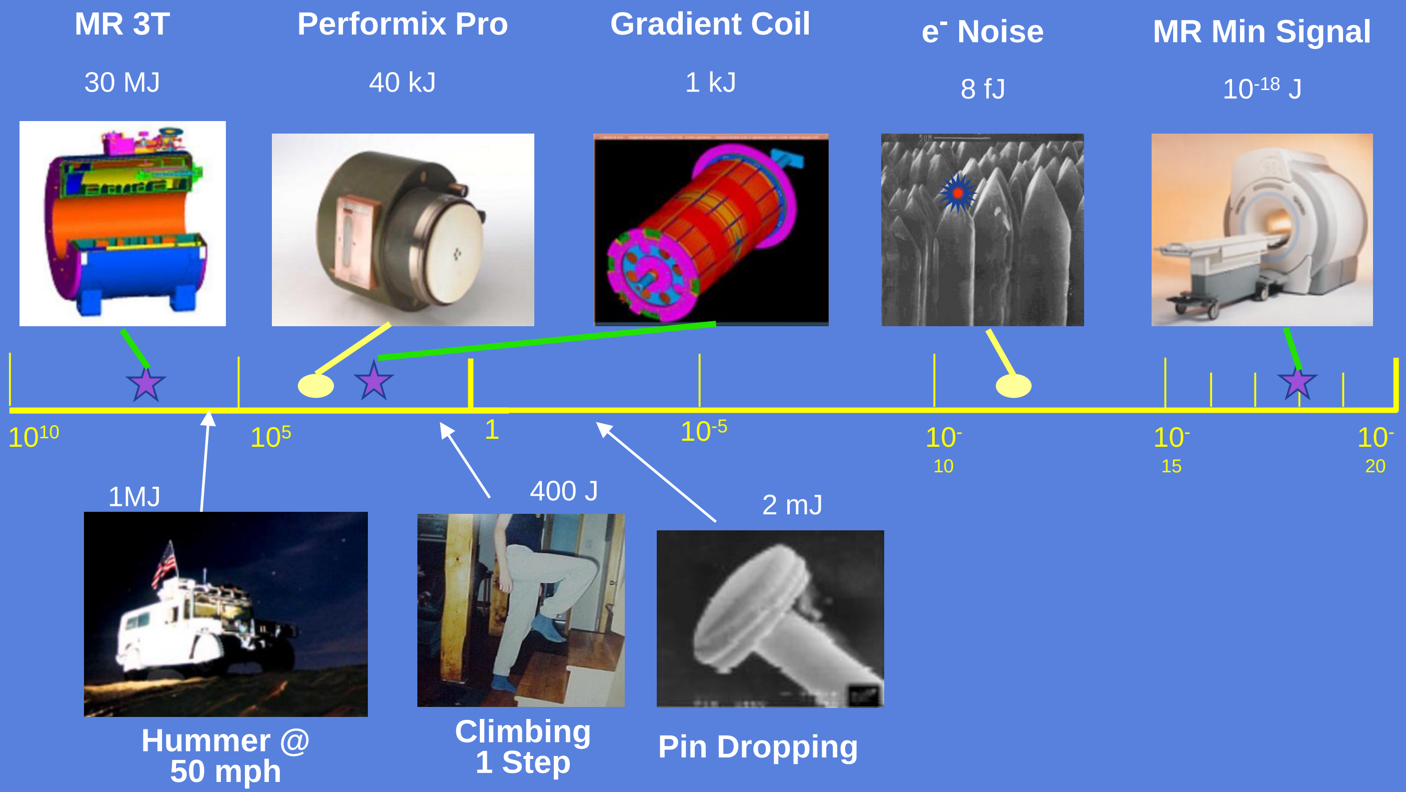


Protein & cell sciences



Clinical tissue biomarkers

The Challenge… Energy Conversion & Detection



Vision

Design is a human activity

Fail early, fail often…in virtual space

Enable greater creativity…

"Predictive Directed Exploration"

Business Outcomes

Reduced Cycle time

Optimal designs (explore design space)

Predictability (better decisions earlier)

Behavior

Systems – SysML/UML
Control loops

Physics/Performance

Image/Signal Quality
Acoustics
Reliability

Business Integration

Parts stock/warranty reserve
Workflow
MFG capacity

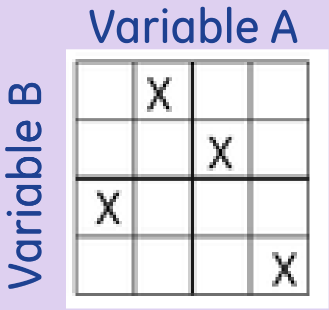
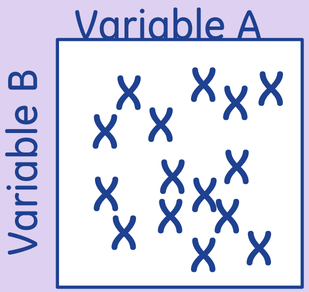
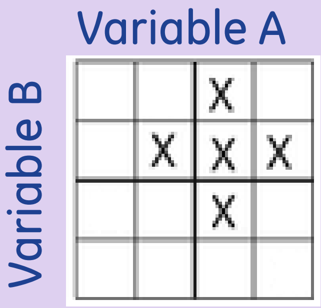
Predictive, **multi-variable design models** enabling characterization, understanding of interactions and margin

Electrical performance
Thermal

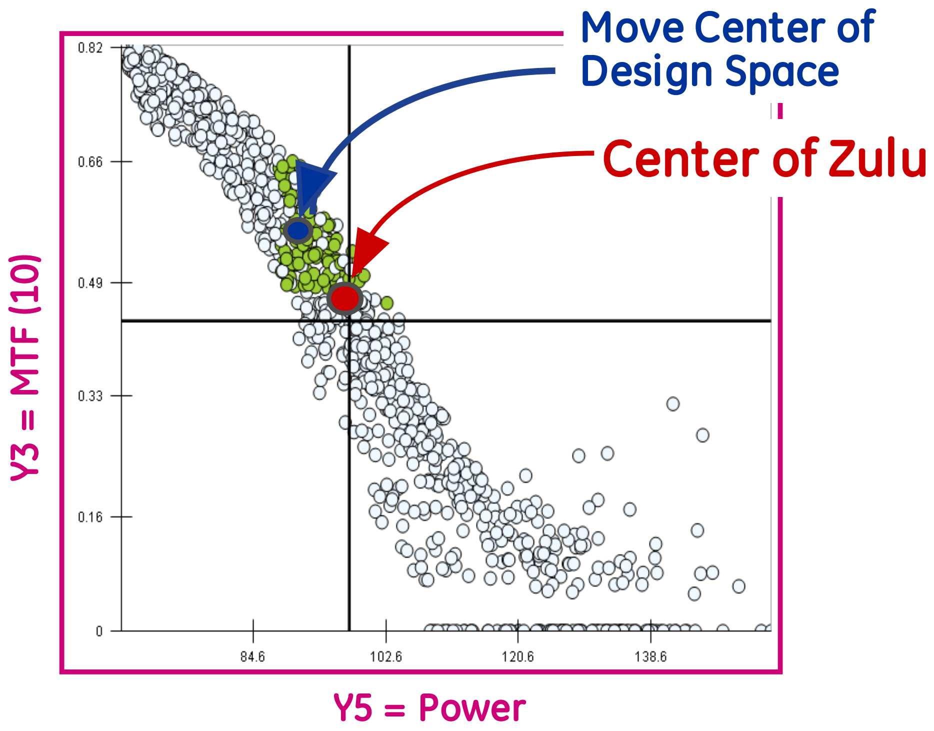
Vibration
Structure/Stress/Stiffness

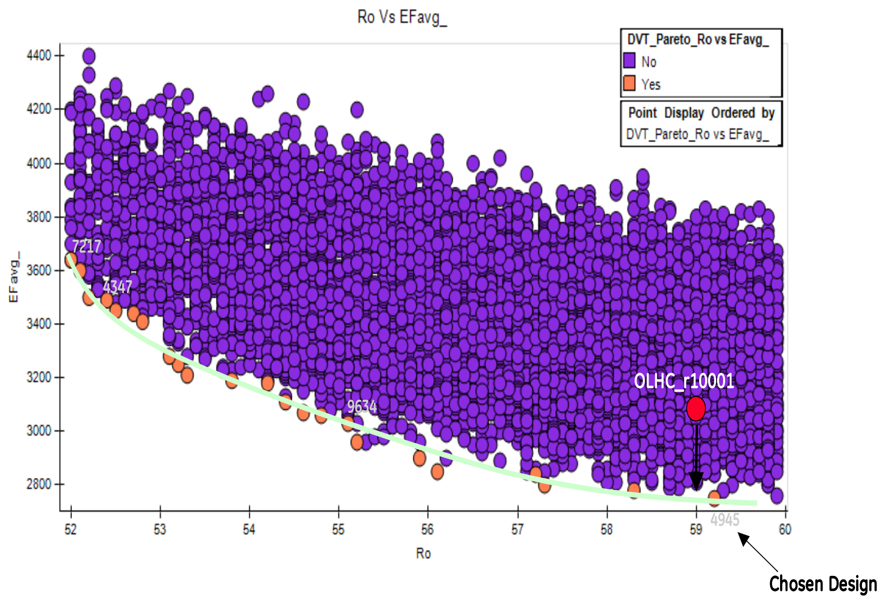
Safety
Lifing

Design Space Exploration

Method	Latin Hypercube Sampling	Monte Carlo	Factorial DOE Full/Fractional
Example			
Cost	Lowest	Variable / Higher	Highest (per space explored)
Where used	Sparsely filling a large design space	Exploring a broad design space	Optimizing response near a design point
Why used	Finds response function	Finding unexpected design optima	Finds local response function
When used	Medium priors Semi-expensive sims	Low prior knowledge Inexpensive simulation	High prior knowledge Expensive simulation

Robust Design using "Space Filling" computer experiments





Robustness: move design to center of feasible range

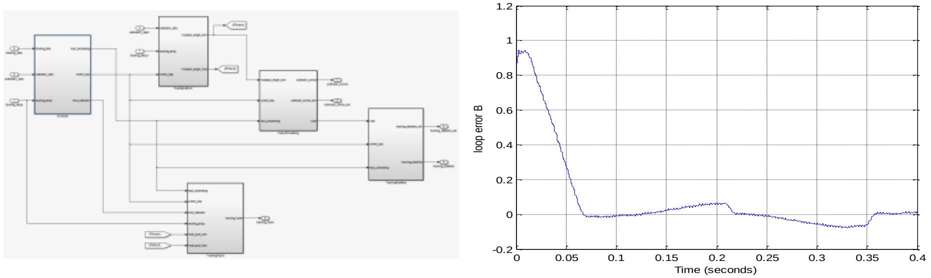
Optimality: move design along Pareto Optimal Edge to maximize a third Figure of Merit

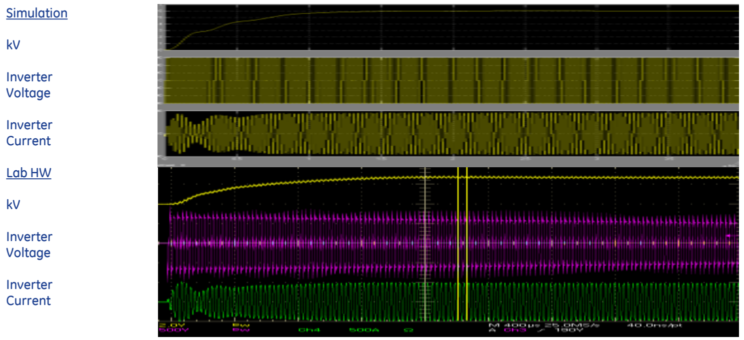
Needs: Efficient Simulation, Automated Parameterization, ***Great*** Visualization tools

Behavioral Modeling in Computed Tomography

Moderately complex system with complex behavior

- ~5,000 parts
- ~5M lines of code
- Triple nested control loops
  - Axial, Cradle, mA/kV



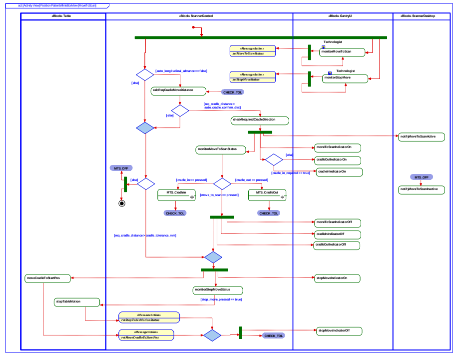


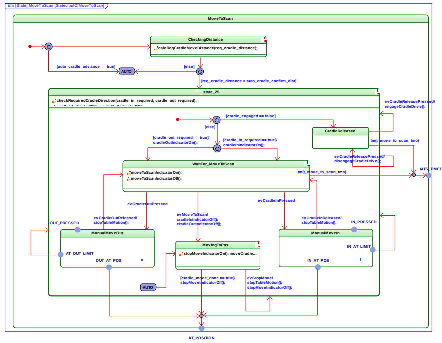
- Feature analysis and simulation in SIMULINK
- Auto-generation of code

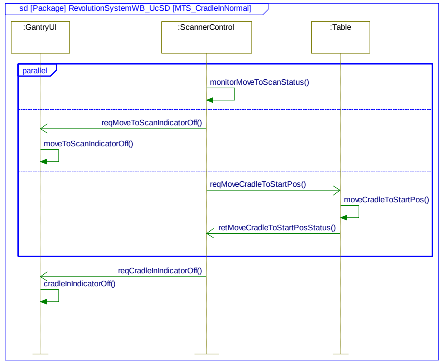
Computed Tomography

MBSE techniques are used to perform behavioral analysis of key system features and functions.

- discover and verify system requirements
- identify and detail subsystem functions and interfaces
- seed FMEA analysis
- develop system test scenarios







Challenges to Adapting MBSE

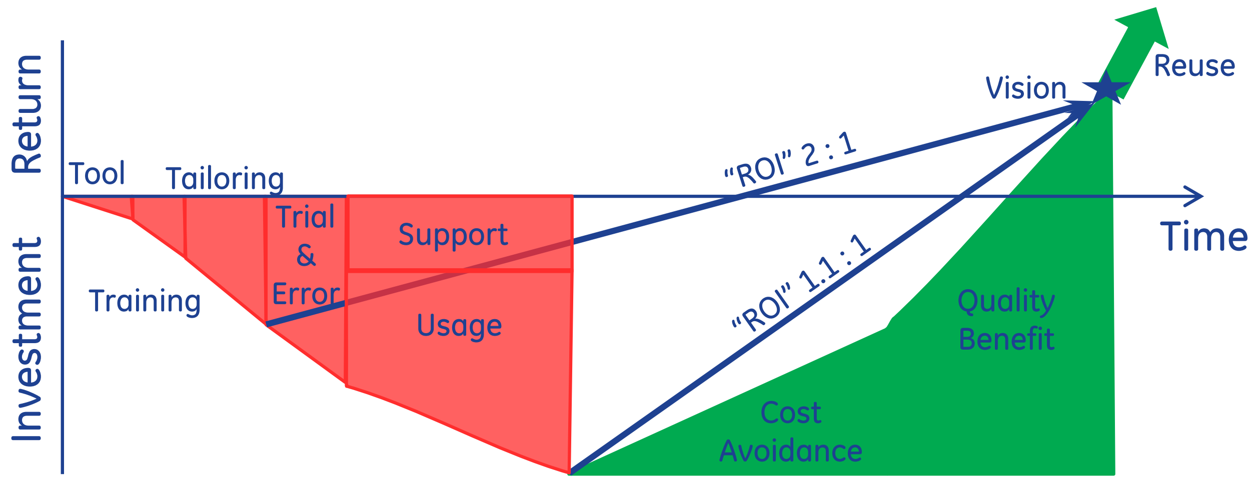
Key Industry Challenges for MBSE adoption

What are the most critical barriers to faster adoption of MBSE?
High barrier to entry with uncertain payback

- ROI – Assured cost, Unquantified return
  - Fear of the unknown – no clear success stories with a business case
  - Many best practices…you pay for the tools and then need to pay for a consultant to tailor a process
  - How to introduce on an existing product – how to start?
  - Many things don't scale…need an incredible investment…hard to justify
- Concerns about regulatory (FDA) acceptance
  - If we have to capture everything in textual requirements anyway (for audits), what is the advantage of the model?
  - Do the tools support validated archive and approval processes?

Lowering the barrier to entry

Management is confronted with many competing priorities for investment



Biggest cost is not the tool…need a way to make 'the pill easier to swallow'

- Big bang: full in on one project, with a complete strategy…needs business case for upper management to justify the investment
- Get your feet wet: partial implementation (one feature, one subsystem)…needs cookbook on how best to integrate a partial MBSE implementation with prior processes and tools

Start small, develop an internal success to build on

Regulatory Acceptance

One concern is that regulations can impede progress toward higher quality processes

- Auditors can be unclear on what is acceptable in a model, and where to poke for quality gaps
- FDA has guidance on computational (quantitative) modelling for industry and
- Gives guidance on what to include…in general, and for four types of models

A consistent approach on how to summarize, review, and document modeling and simulation

- Good reference for internal reports…not just those submitted to regulators!

Reporting of computational modeling studies in medical device submissions

Guidance for Industry and FDA Staff, Sep 2016

https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM381813.pdf

Contact: Tina M. Morrison, Ph.D., tina.morrison@fda.hhs.gov.

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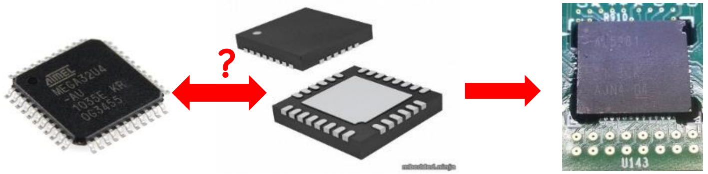
Examples of Modelling

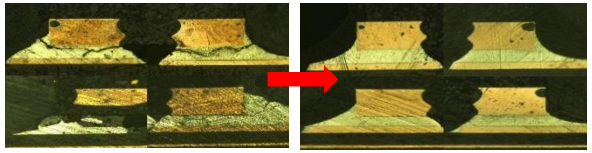
Reliability Modeling

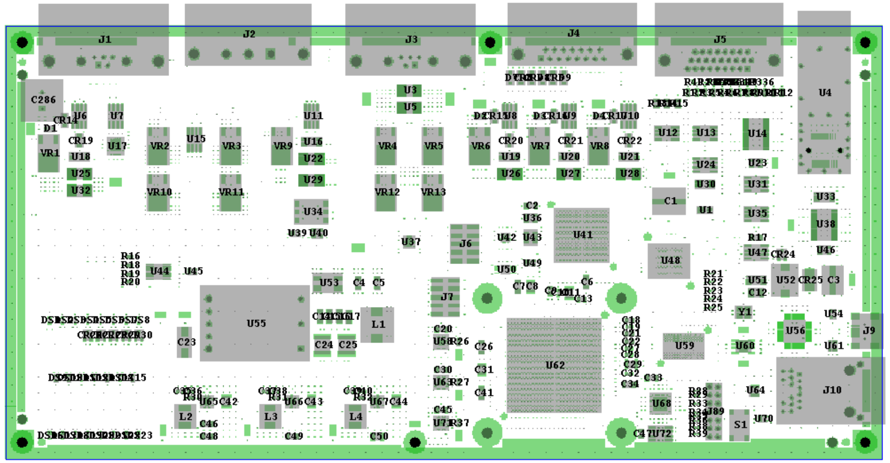
Solder joint reliability

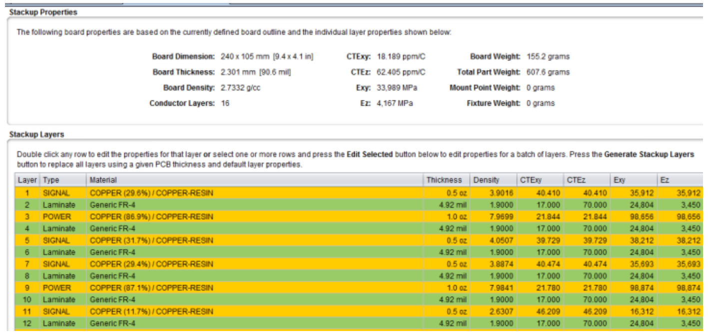
Once a board is designed, what is its reliability?

- Solution 1: perform reliability testing under accelerated conditions (~3 months)
- Solution 2: perform computer modeling (<1wk)
    - Provides quick response to make board changes
    - Choose different IC packages
    - Change component locations









Stackup Properties

The following board properties are based on the currently defined board outline and the individual layer properties shown below:

Board Dimension:	240 x 105 mm [9.4 x 4.1 in]	**CTExy:**	18.189 ppm/C	**Board Weight:**	155.2 grams
Board Thickness:	2.301 mm [90.6 mil]	**CTEz:**	62.405 ppm/C	**Total Part Weight:**	607.6 grams
Board Density:	2.7332 g/cc	**Exy:**	33,989 MPa	**Mount Point Weight:**	0 grams
Conductor Layers:	16	**Ez:**	4,167 MPa	**Fixture Weight:**	0 grams

Stackup Layers

Double click any row to edit the properties for that layer **or** select one or more rows and press the **Edit Selected** button below to edit properties for a batch of layers. Press the **Generate Stackup Layers** button to replace all layers using a given PCB thickness and default layer properties.

Layer	Type	Material	Thickness	Density	CTExy	CTEz	Exy	Ez
1	SIGNAL	COPPER (29.6%) / COPPER-RESIN	0.5 oz	3.9016	40.410	40.410	35,912	35,912
2	Laminate	Generic FR-4	4.92 mil	1.9000	17.000	70.000	24,804	3,450
3	POWER	COPPER (86.9%) / COPPER-RESIN	1.0 oz	7.9699	21.844	21.844	98,656	98,656
4	Laminate	Generic FR-4	4.92 mil	1.9000	17.000	70.000	24,804	3,450
5	SIGNAL	COPPER (31.7%) / COPPER-RESIN	0.5 oz	4.0507	39.729	39.729	38,212	38,212
6	Laminate	Generic FR-4	4.92 mil	1.9000	17.000	70.000	24,804	3,450
7	SIGNAL	COPPER (29.4%) / COPPER-RESIN	0.5 oz	3.8874	40.474	40.474	35,693	35,693
8	Laminate	Generic FR-4	4.92 mil	1.9000	17.000	70.000	24,804	3,450
9	POWER	COPPER (87.1%) / COPPER-RESIN	1.0 oz	7.9841	21.780	21.780	98,874	98,874
10	Laminate	Generic FR-4	4.92 mil	1.9000	17.000	70.000	24,804	3,450
11	SIGNAL	COPPER (11.7%) / COPPER-RESIN	0.5 oz	2.6307	46.209	46.209	16,312	16,312
12	Laminate	Generic FR-4	4.92 mil	1.9000	17.000	70.000	24,804	3,450

Solder joint reliability simulations

Thermal Cycling Solder Fatigue Model
(Modified Engelmaier – Leadless Device)

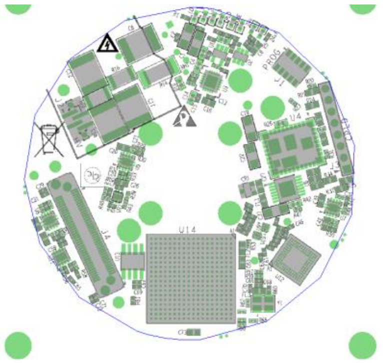
- Modified Engelmaier
  - Semi-empirical analytical approach
  - Energy based fatigue

$$\Delta\gamma = C\frac{L_D}{h_s}\Delta\alpha\Delta T$$

- Determine the strain range ($\Delta\gamma$)
- Where: C is a function of activation energy, temperature and dwell time, L_D is diagonal distance, α is CTE, ΔT of temperature cycle & h is solder joint height
- Determine the shear force applied at the solder joint

$$(\alpha_2-\alpha_1)\cdot\Delta T\cdot L_D = F\cdot\left(\frac{L_D}{E_1A_1}+\frac{L_D}{E_2A_2}+\frac{h_s}{A_sG_s}+\frac{h_c}{A_cG_c}+\left(\frac{2-\nu}{9\cdot G_b a}\right)\right)$$

  - Where: F is shear force, LD is length, E is elastic modulus, A is the area, h is thickness, G is shear modulus, and a is edge length of bond pad.
  - Subscripts: 1 is component, 2 is board, s is solder joint, c is bond pad, and b is board
  - Takes into consideration foundation stiffness and both shear and axial loads *(Models of Leaded Components factor in lead stiffness / compliancy)*



CCA Stackup Information

The following stackup information was used during the circuit card analysis.

Board Size: 71 x 71 mm
PCB Thickness: 91.1 mil
PCB Density: 2.3076 g/cc
Copper Layers: 14
PCB CTExy: 14.013 ppm/C
PCB CTEz: 43.699 ppm/C
PCB Exy: 29,869 MPa
PCB Ez: 3,885 MPa

Layer	Type	Thickness	Material
1	SIGNAL	1.0 oz	COPPER (29.8%)
2	Laminate	.147 mm	370HR
3	POWER	0.5 oz	COPPER (74.2%)
4	Laminate	0.15 mm	370HR
5	SIGNAL	0.5 oz	COPPER (44.3%)

Physics of failure solder joint model → **Electronic circuit design** ← **Material properties**

Life estimation (cycles to failure) based on computer modeling

						ACCELERATED TESTING			USE CONDITIONS		
ID	PACKAGE	MODEL		MATERIAL	PN	CY 0 100C	CY -40 125C	AF1	YRS 20 45C	CY 20 45	AF2
U12	BGA-128	BGA	TOP	LAMINATE-BGA	5505464	1259	329	3.8	88	32061	97.5
U14	BGA-144	BGA	TOP	LAMINATE-BGA	5499296	4106	1071	3.8	286	104244	97.3
U4	QFN-40 (MO-251AFFB-1)	QFN	TOP	OVERMOLD-QFN	5504797	9272	2415	3.8	643	234822	97.2
Y1	QFN-4 (MO-220WEEB)	QFN	TOP	ALUMINA	5437405	21863	5684	3.8	1509	550823	96.9
U3	QFN-20 (MO-220VGGD-1)	QFN	TOP	OVERMOLD-QFN	5455903	95311	24782	3.8	6581	2402109	96.9
U11	QFN-12 (MO-208BBEA)	QFN	TOP	OVERMOLD-QFN	5498573	200956	52239	3.8	13868	5061976	96.9

Buy a tool with embedded physics of failure implemented
- Enter your material properties (from suppliers)

Future: add your parts library into a standard database

Examples of Modelling

Topological Optimization

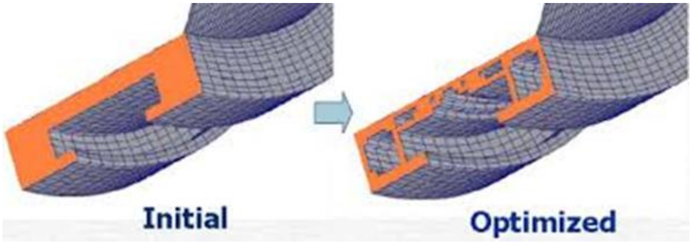
Topological Optimization – What is it?

Definition

- Topological Optimization = automatic, finite element based determination of a structural shape (topology) which optimally satisfies all load and material usage requirements

Benefits

- Maximized strength/weight ratios
  - Reduced cost, improved quality
  - Reduced downstream overhead – effects on other components, manufacturing/service processes, transportation, siting restrictions
- Shortened design cycles
  - Effective, non-intuitive designs
  - Reduce or eliminate iteration
- Compatible with additive manufacturing



External Industry Experience

- Topological optimization fully integrated into aircraft, automotive design processes

The Topological Optimization Design Process

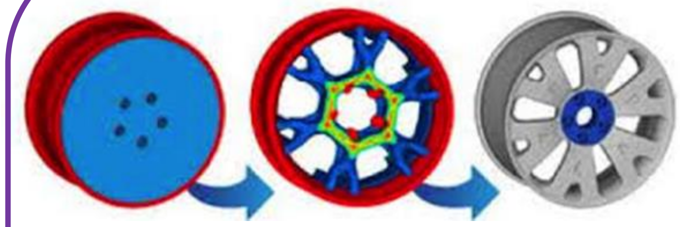
__Conventional Design Process__

Design & Development Iteration

Concept → Design → Evaluate (Test/FEA) → Validate

__Design Process using Topological Optimization__

Design Space OR Existing Shape → Optimize → Design → Validate



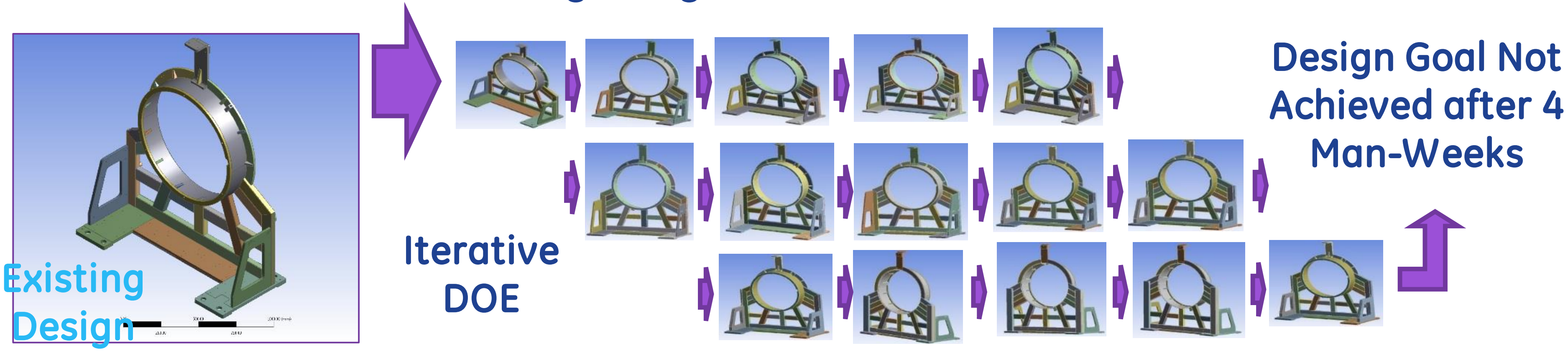
Design Space | Optimized Shape | Final Design

Design Space = where material <u>could</u> be
Optimized Shape = where material <u>should</u> be

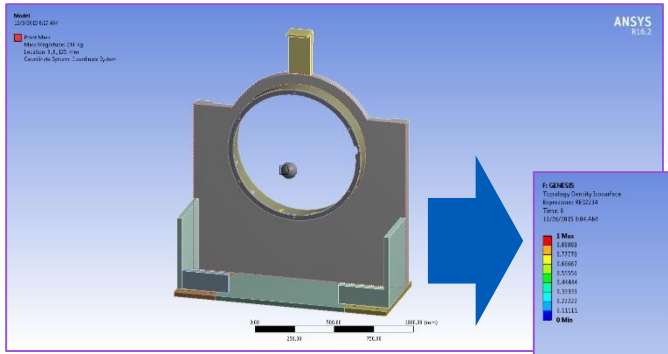
The GE Healthcare CT Design Challenge

An existing design of a CT stationary gantry needed to have its natural frequency doubled to accommodate an operational speed increase.

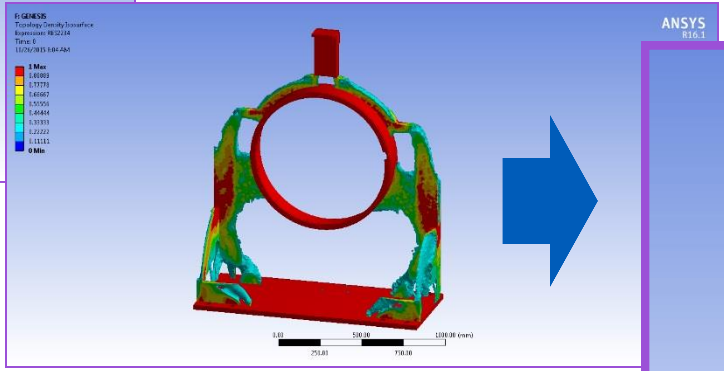
At first, the Design Team spent two weeks applying a simulation-based DOE without achieving the goal.



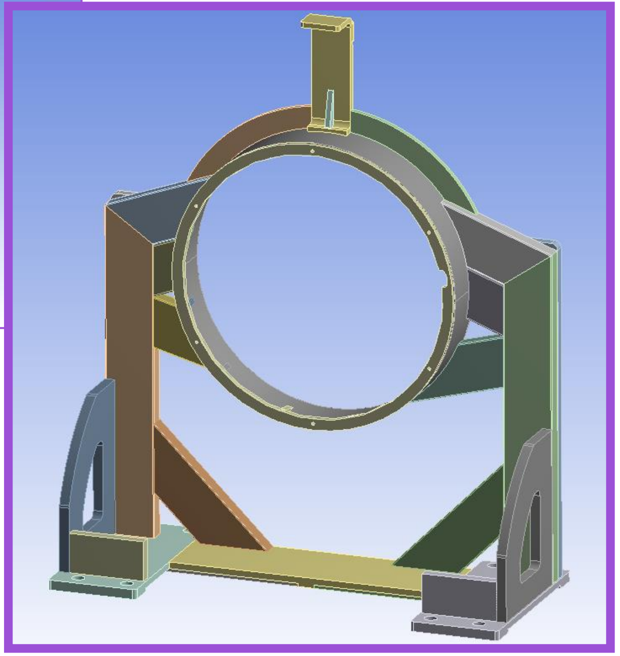
The Topological Optimization Solution



Define the Design Space
(Where Material Could Be)



Determine the Theoretical Optimized Shape that Meets Performance Requirements



Use Theoretical Optimized Shape as Template for Final Design, Proceed to Verification

Total Design Effort = 3 Man-Days

Examples of Modelling

Control Algorithms

Joey Incubator

An incubator maintains a safe environment (heat, humidity, O2…) for a Infant.

Goal - To develop multi-physics, control & system model that will reduce design iterations

<u>Process – Thermal performance:</u>

Develop simplified model & equivalent physical model testing to arrive at heat transfer coefficients for use in CFD

↓

Build system CFD model for various options and downselect 2 options for further physical prototyping and CFD

↓

Final design selection for development using combination of Physical and CFD testing

↓

Develop control algorithms and CFD validation models

↓

Develop Reduced Order Model for arriving at control constants

↓

Refine step inputs for ROM once actual parts are developed
Final control algorithm with refined constants

Benefits

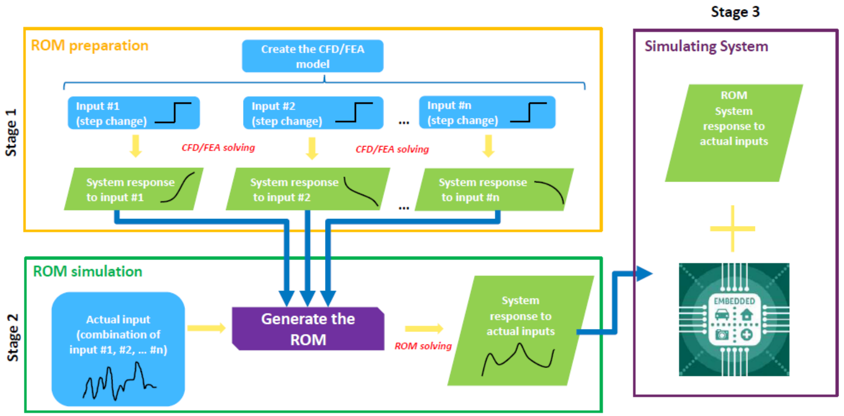
Design cycle acceleration

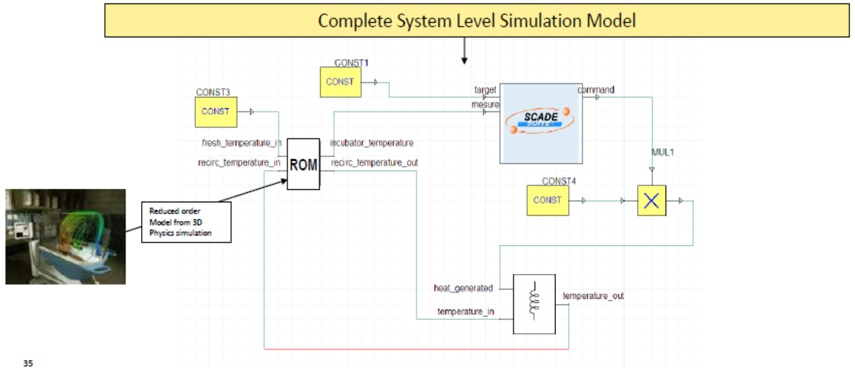
- Electrical: 0 board re-spin
- Control algorithms: Development, virtual testing and Automated design document generation
- Testing and Verification acceleration

Joey Incubator

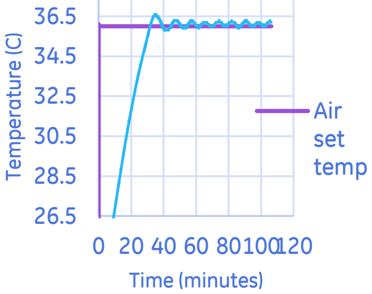
Thermal Control Modeling Goals

- Optimizing the thermal/humidity control loops in weeks (typically takes months)
- Balancing constraints
  - Thermal : Control accuracy, Stabilization time vs overshoot
  - Balancing performance vs. Acoustic noise

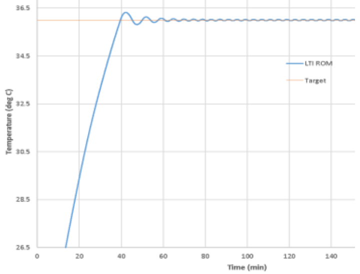




Experimental data



Prediction from ROM



Enabling actions

Do the proper model validation

Tight collaboration between modeling and systems teams

Summary

Benefits

- Faster, more predictable development
- Better designs (higher performance, lower cost, more reliable)

Next Steps

- Improved integration across functions and models
- Better focus on modelling goals, problem formulation, and model credibility

Questions?

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APPENDIX

Joey Incubator - Electrical

Goals

- Electrical 0 board re-spin
  - typically takes 1 or 2 re-spin for clearing electrical safety testing
- Balancing constraints
  - Power, Signal integrity, Thermal, Board and system level EMI / EMC
  - Simulation efforts vs. design confidence

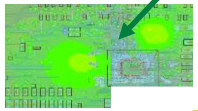
Results

Prototype met functional requirements and pre-compliance in first pass

Enabling actions

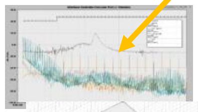
- Engage early with analysis team from component selection)
- IBIS models / Thermal details from component vendors
- Effort for getting simulation right takes long and high – include in schedule

Level 1: PI SI wave



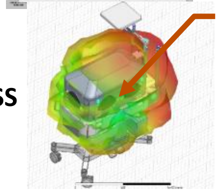
Complete

Level 2: PI/RE SI wave + Cir



Partial

Level 3: PI/RE SIwave + Cir +HFSS

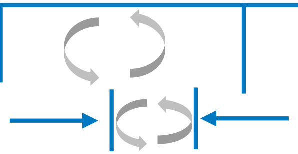


Not completed

Joey Summary

Product Design Cycle

M0 M1 M2 M3 M4

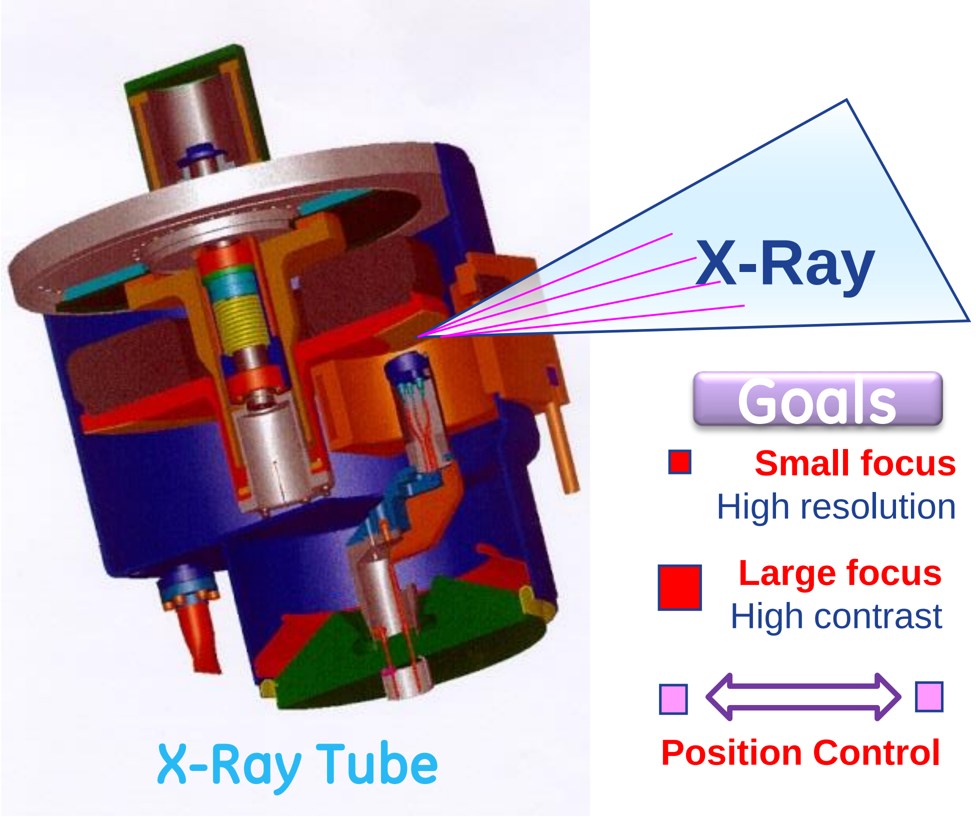


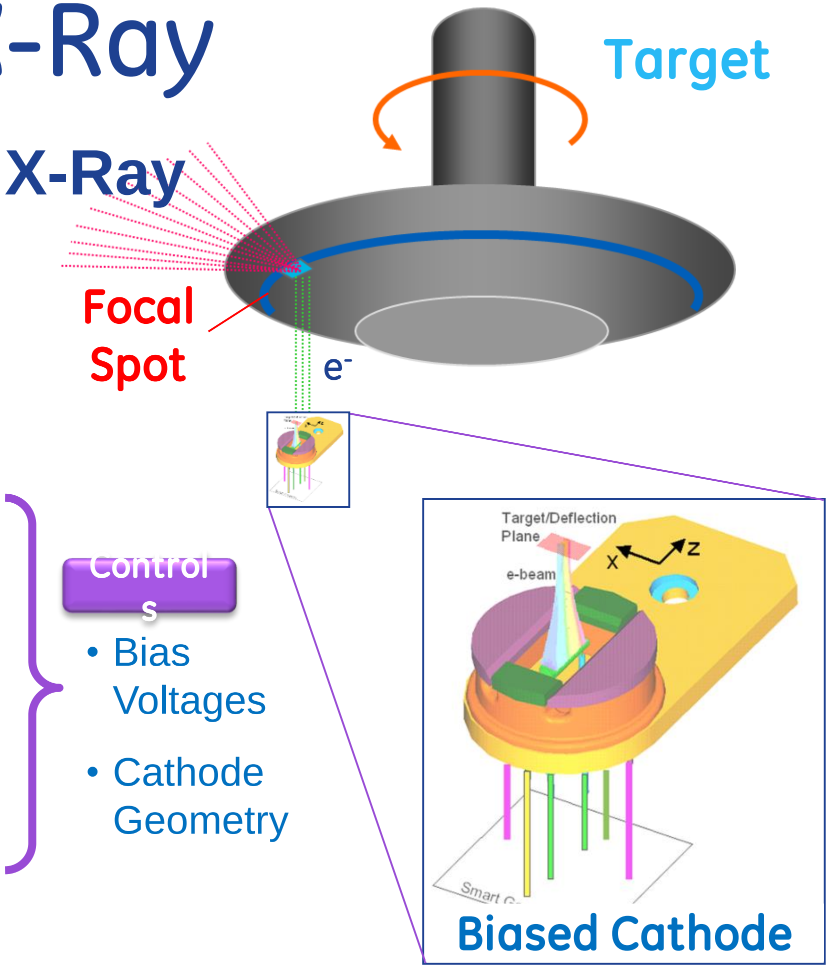
Prototyping Phase Compression Through Simulation and Virtual Prototyping

Examples of Modelling

Physics (Electro-Optics)

Cathode Design for X-Ray





Goals

- Small focus
  High resolution
- Large focus
  High contrast
- Position Control

Controls

- Bias Voltages
- Cathode Geometry

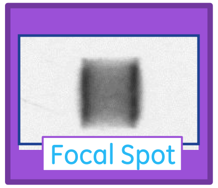
Cathode Optimization

Bias Tank

Focal spot camera mounted on x-ray tube

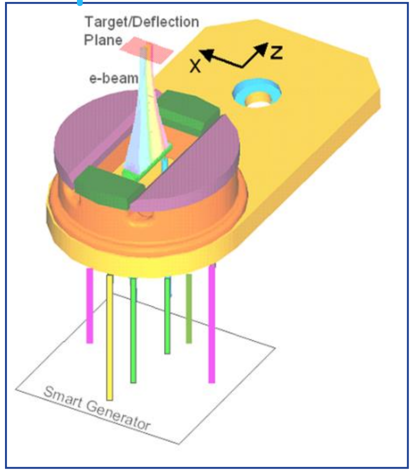
Validation

Simulation

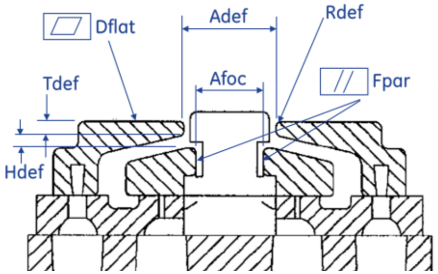


Focal Spot

Electron optics simulation SW



Optimization



Optimization strategies

- Parameterized model
- DOE
- Latin Hypercube
- Genetic Algorithm
- Intuition

Summary – Benefits to Industry of MBSE

Improved Communication: *Pictures, Models vs. Text*

Improved Quality: *Model Analysis, Simulation vs. Reviews*

Improved Predictability and Efficiency (Time to Market)

Questions?

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APPENDIX

Summary – Benefits to Industry of MBSE

Improved Systems Thinking

- Use Case/Performance/Interface Analysis critical for a complete design specification.
- Logical model to provide high level of abstraction for ease of understanding, improved reuse or design sharing

Improved Communication

- Visual vs. Textual leads to Clearer, more precise communication & better reviews
- Visual designs & models are easier for global teams (less language barrier)

Improved Quality

- Verify correctness and completeness of requirements/design – robustness / stress testing of design rather than simply reviewing in quality
- Improved design of test cases, derived from weaknesses exposed in the model

Improved Predictability and Efficiency (Time to Market)

- Verify correctness and completeness of requirements/design – robustness / stress testing of design rather than simply reviewing in quality
- Improved leveling of requirements (efficiency in verification and documentation)
- Auto code generation (no translation errors in implementation)

The industry faces many challenges

The medical industry product developers face problems with ……

- Extreme time to market pressures
  - 1st to market usually gains 80% of that market
- Compliance with regulations
  - FDA, IEC, ISO, HIPAA, ICD-10, ACA, etc.
- Defects are VERY costly to handle
  - Want to avoid audit, decrees, warning letters, recalls, etc…
- Most products are developed in a geographically distributed way
  - Need to communicate and define tasks
- Technology is impacting development and delivery
  - IoT, product variants, Mobile Medical Apps, complex deployment models, cloud

GEHC Approach to New Product Introduction

Tradition NPI process

Program Kickoff	System Req'ts Freeze	Hardware Freeze	Verification Complete	Pilot Release	Full Production	Customer Satisfaction

Traditional artifacts

Requirements = DOORs/Trace (text based)
Systems diagrams in "Visio" (FBD, state machines, activity diagrams, …)
"Quantitative" performance simulations

Challenges

- Lack of customer focus
- Scope creep
- Late integration issues
- Lack of model integration
- Poor requirements leveling (capturing design as reqts)

Recent additions

- Formal Reliability process & team
- Formal Usability process
- Agile methodology (for SW)
- Design for Producibility
- Design for Six Sigma (revitalization)

How Modelling fits in

Systems

- Physics (IQ)

Systems

- *Behavioral*
- *Customer FoM model*

HW: Performance Models

- EE: Cadence/Mentor (Chip->Board)
- ME: Thermal, Structural, Acoustic/Vibration, Life
- Reliability allocations and models
- Should cost modelling

SW: UML models

MFG: Capacity/Cost Models

- Scrap/Cost models
- Capacity/workflow models

GEHC Modelling Maturity Levels

Highly Mature

- Quantitative Modelling
  - Field Strength
  - Air flow
  - Noise
  - Resolution
  - Structure / vibration
  - Electronics
  - …

Developing

- Process map/Utilization
  - Factory utilization simulations
  - Customer workflow productivity
- Customer Task QoS
  - Tumor Visualization
  - Artifacts
- Cost
  - Integrated should cost simulations
- Integrated System Models
  - Image quality from customer to components
  - Architecture model

Needs

- Customer Work Systems
  - Disease state models
  - Interoperability
  - Outcomes (health, economic)