
The Benefits of a Systems Engineering Approach:

How to reduce risks and improve performance in medical device development

Presented by: Phillip Palmer, PhD
Sunrise Labs

-
- What is Systems Engineering?
 - The Role of the Systems Engineer
 - Benefits of Systems Engineering
 - Systems Engineering Processes
 - The Clear Case for Systems Engineering

Today's medical devices need Systems Engineering

Complex architectures and operational environments

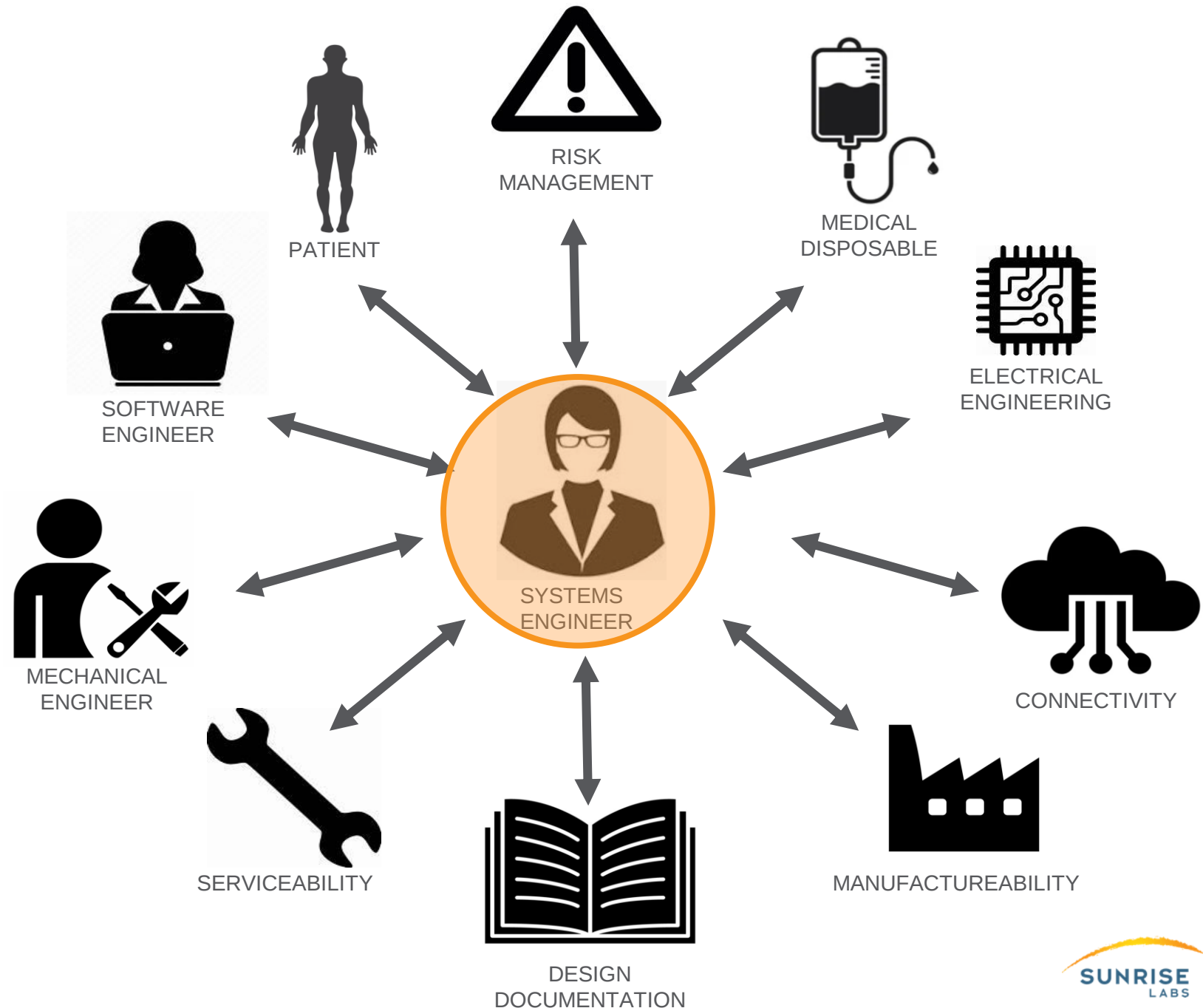
- Patient Connectivity
- Medical Disposable Interfaces
- Distributed Embedded Architectures
- IoT Driven Functionality
 - BLE, Cellular, and WiFi Connectivity
- Ergonomics, Usability, and Human Factors
- Enclosure Design & Branding

Multi-disciplinary engineering teams

- Mechatronics and Motion Control
- Fluidics
- Digital & Analog Electronics Design
- Low Noise Sensing
- Digital Imaging
- Signal Processing
- Power Management Systems & Battery Tech
- Inter-processor Communication Protocols
- Dynamic and Feature Rich GIUs

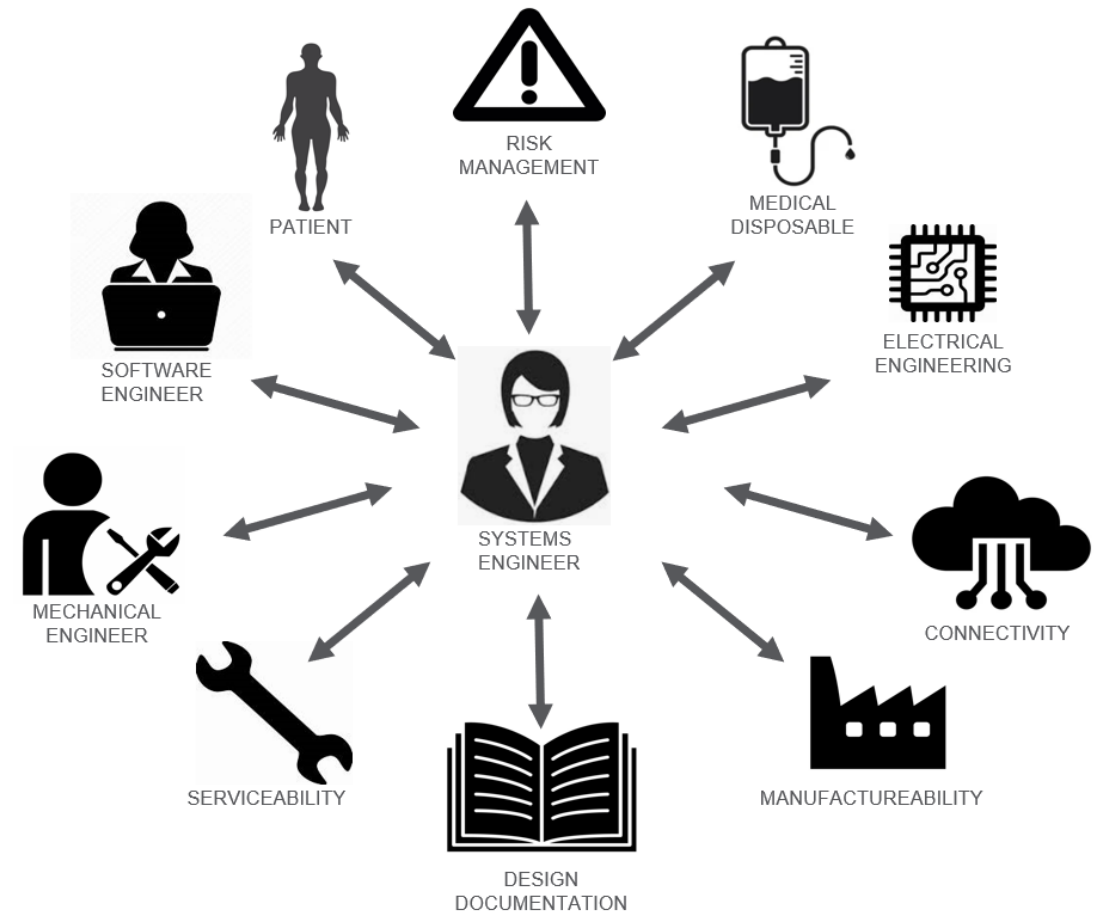
What is Systems Engineering?

- Provides the glue that binds the individual engineering disciplines together
- Enables systematic progress from conceptualization to commercialization

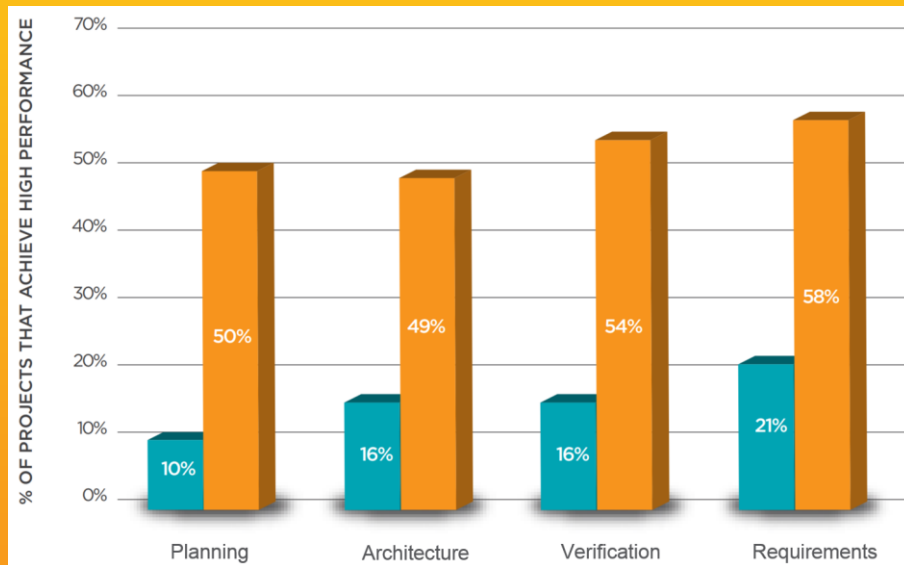


The Role of a Systems Engineer

- Oversee Risk Management
- Facilitate technical decisions
- Coordinate multi-disciplinary team
- Act as gatekeeper of design intent and resulting product realization
- Supervise creation of design documentation



Benefits of Systems Engineering



By applying Systems Engineering processes and resources projects will achieve:

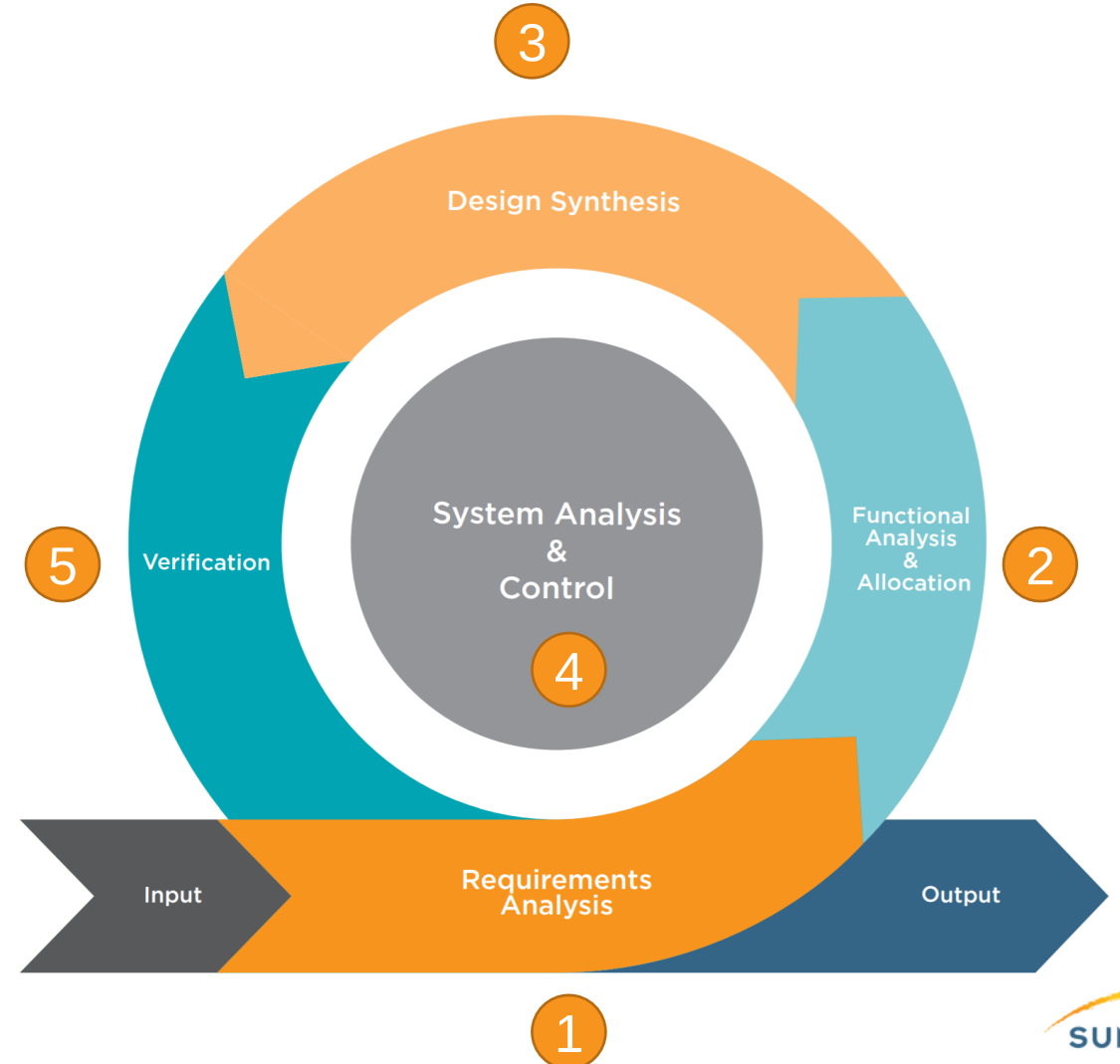
- More predictable budget and schedule performance
- Lower product costs
- Enhanced product performance
- Greater quality, maintainability, serviceability, and extensibility
- Conformance to medical device design control requirements (FDA, MDD, etc.)
- Greater adaptability to unforeseen change

Systems Engineering Processes

1. Requirements Analysis & Management
2. Functional Analysis & Allocation
3. Design Synthesis
4. System Analysis & Control
5. Verification

SEPE

Systems Engineering Process Engine



Systems Engineering Processes

Requirements Analysis & Management

1

For medical devices, Design Inputs most relevant to Medical Devices include:

- Market Requirements
- User Requirements
- Human Factors Evaluations
- Risk Analyses
- Industry Standards
- Regulations

Systems Engineering Processes

Requirements Analysis & Management

1

A good requirements is: The “WHAT”, not the “HOW”.

- Unique
- Complete
- Consistent
- Unambiguous
- Viable
- Traceable
- Verifiable
- Implementation Agnostic

Systems Engineering Processes

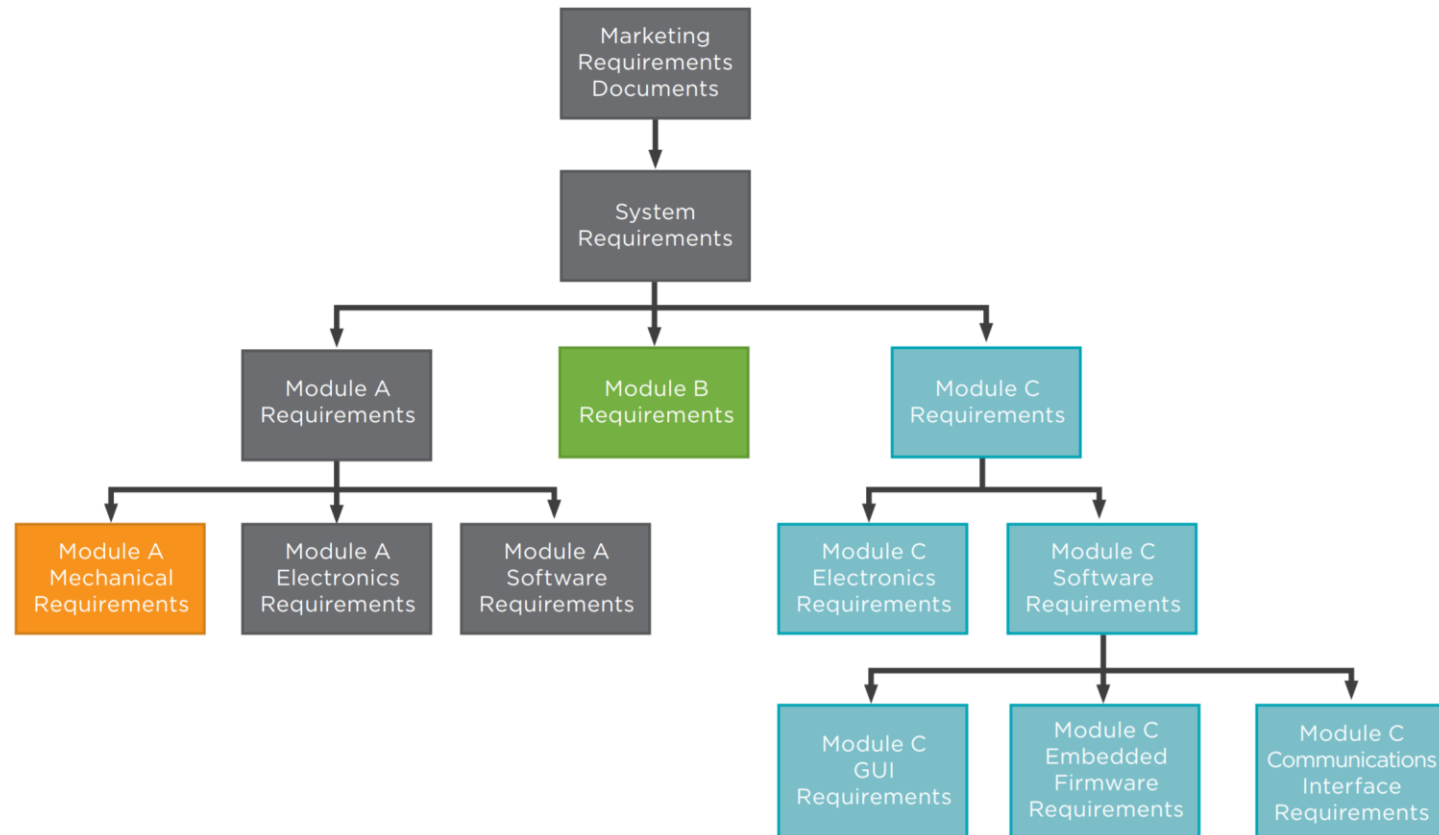
Requirements Analysis & Management

1



Design
Documentation

Requirement Documentation Structure and Organization



Systems Engineering Processes

Functional Analysis & Allocation

2

- Risk Management
- Trade-off Studies
- Functional Block Diagram
- Physical Block Diagram

Risk Management activities are driven by:

- FDA
- ISO 134875
- Medical Device Directive

Determination of Device and Software Classification

- Guide FMEA (Failure Mode Effects Analysis)
- Creation and documentation of risk mitigating requirements

Systems Engineering Processes

Functional Analysis & Allocation

2

- Risk Management
- Trade-off Studies
- Functional Block Diagram
- Physical Block Diagram

Trade-off Studies:

- Evaluate competing design architectures against a set of predefined metrics
- Head-to-head comparison of discrete components
- Make-versus-buy and cost benefit analysis
- Manufacturing and Service support considerations

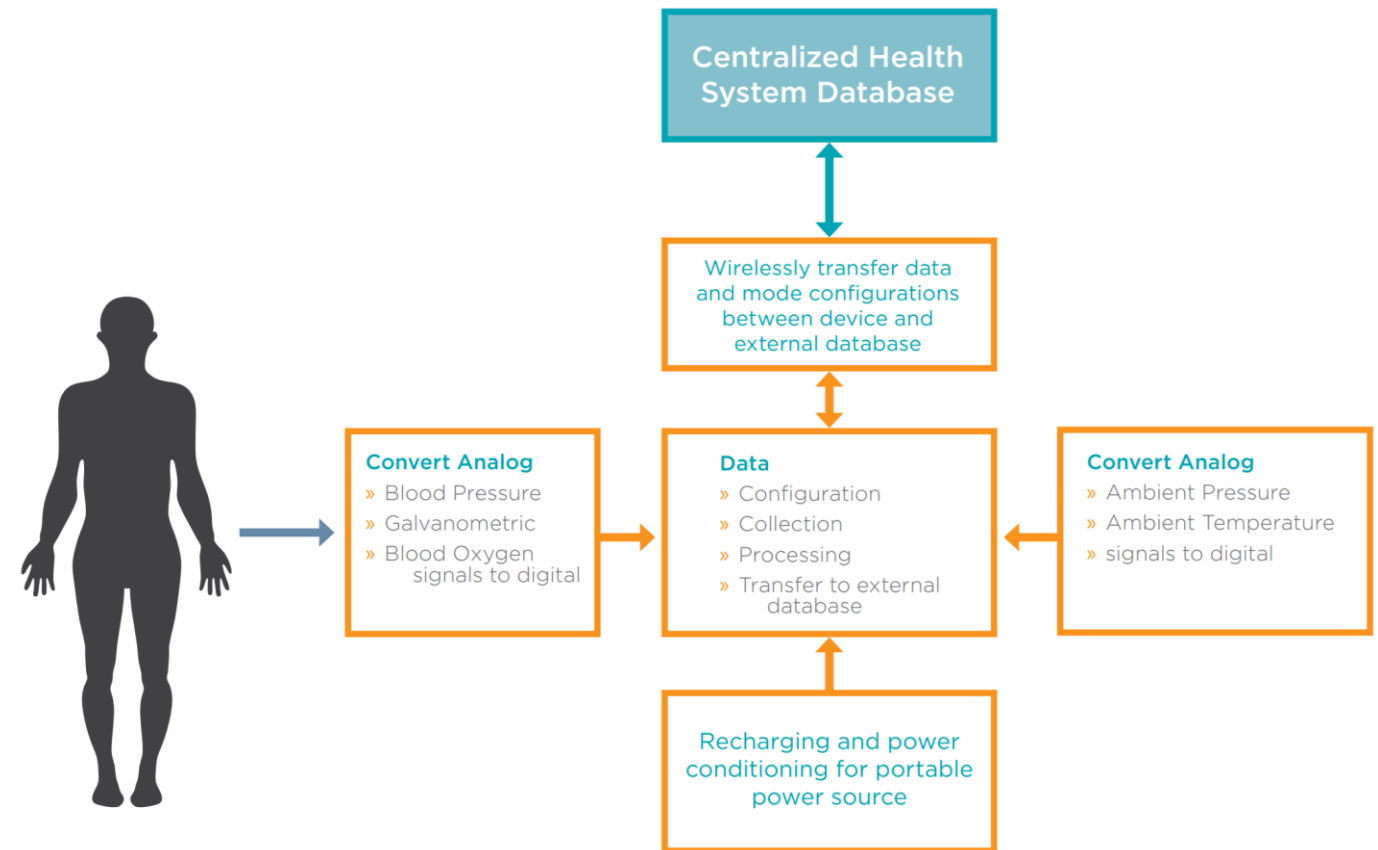
Systems Engineering Processes

Functional Analysis & Allocation

2

- Risk Management
- Trade-off Studies
- Functional Block Diagram
- Physical Block Diagram

Functional Block Diagram - identify functions and interfaces



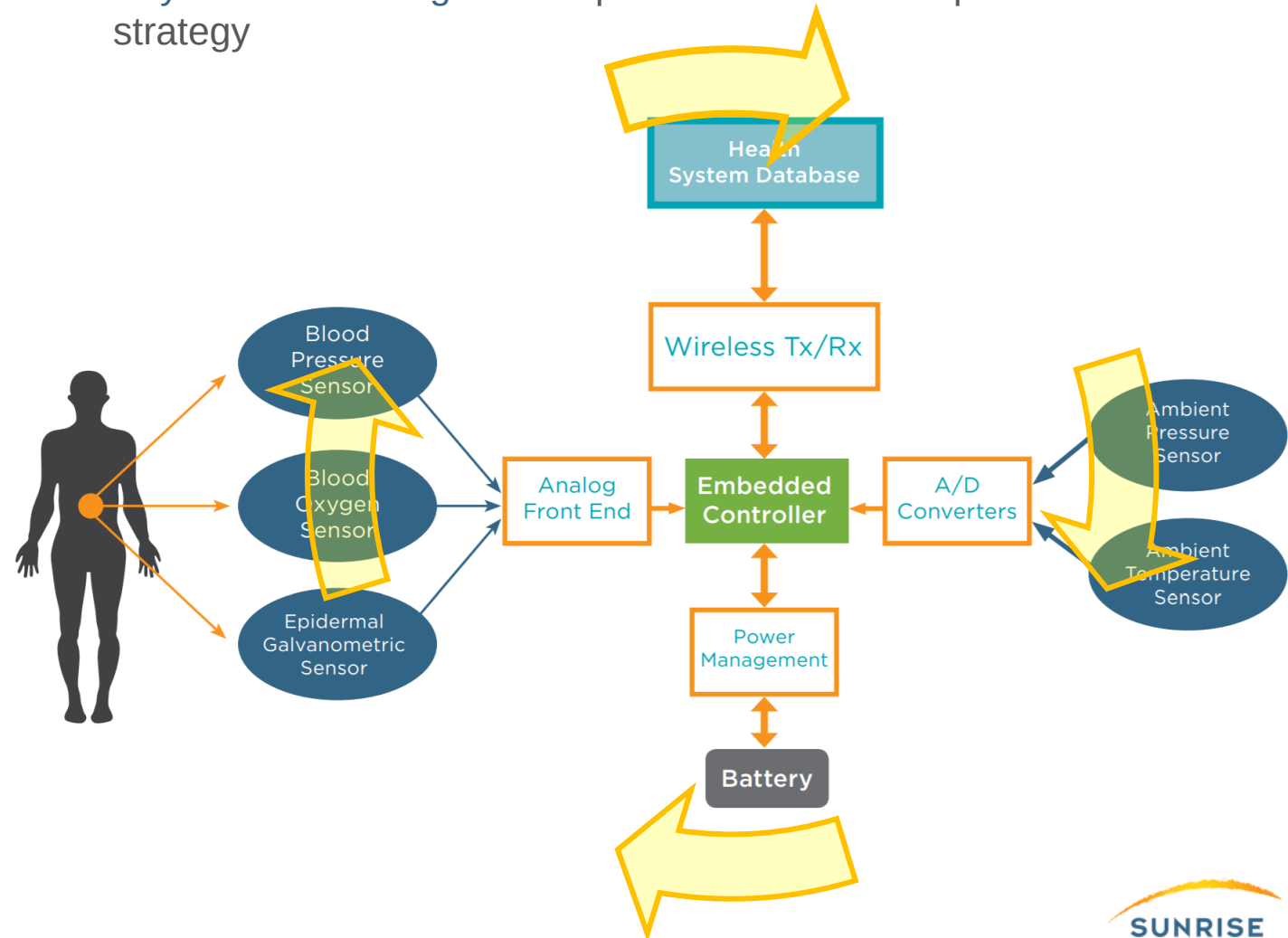
Systems Engineering Processes

Functional Analysis & Allocation

2

- Risk Management
- Trade-off Studies
- Functional Block Diagram
- Physical Block Diagram

Physical Block Diagram – represents intended implementation strategy



Systems Engineering Processes

Design Synthesis

3

- Pugh Charts

Quantitative evaluation of proposed designs

Pugh Matrix			Non-linear quantification can be used to accentuate minor design differences							
Owner:										
Product Owner provides attributes and weighting		Importance Rating	Baseline	Option 1	Option 2	Option 3	Option 4	Option 5	Option 6	Option 7
			Measures CTQ's Factors etc.							
Hard Dollar Savings		7		-	+	-	+	+	+	+
Operating Expenses		7		-	S	+	+	+	+	+
Cost Avoidance		1		+	+	+	+	+	+	+
Ongoing Maintenance Expense		1		+	+	+	S	+	+	-
ROI (NPV)		9		+	+	+	+	+	-	+
Incremental Capital		5		+	+	-	+	+	+	+
Operational Stability		3		+	+	+	+	+	-	+
Brand/Reputation		3		+	+	+	+	+	+	+
Sum of +'s				6	7	6	7	8	6	7
Sum of -'s				2	0	2	0	0	2	1
Sum of Sames				0	1	0	1	0	0	0
Weighted Sum of +'s				22	29	24	35	36	24	35
Weighted Sum of -'s				14	0	12	0	0	12	1
Highest Score Wins				8	29	12	35	36	12	34

Product Owner provides attributes and weighting

Systems Engineering Processes

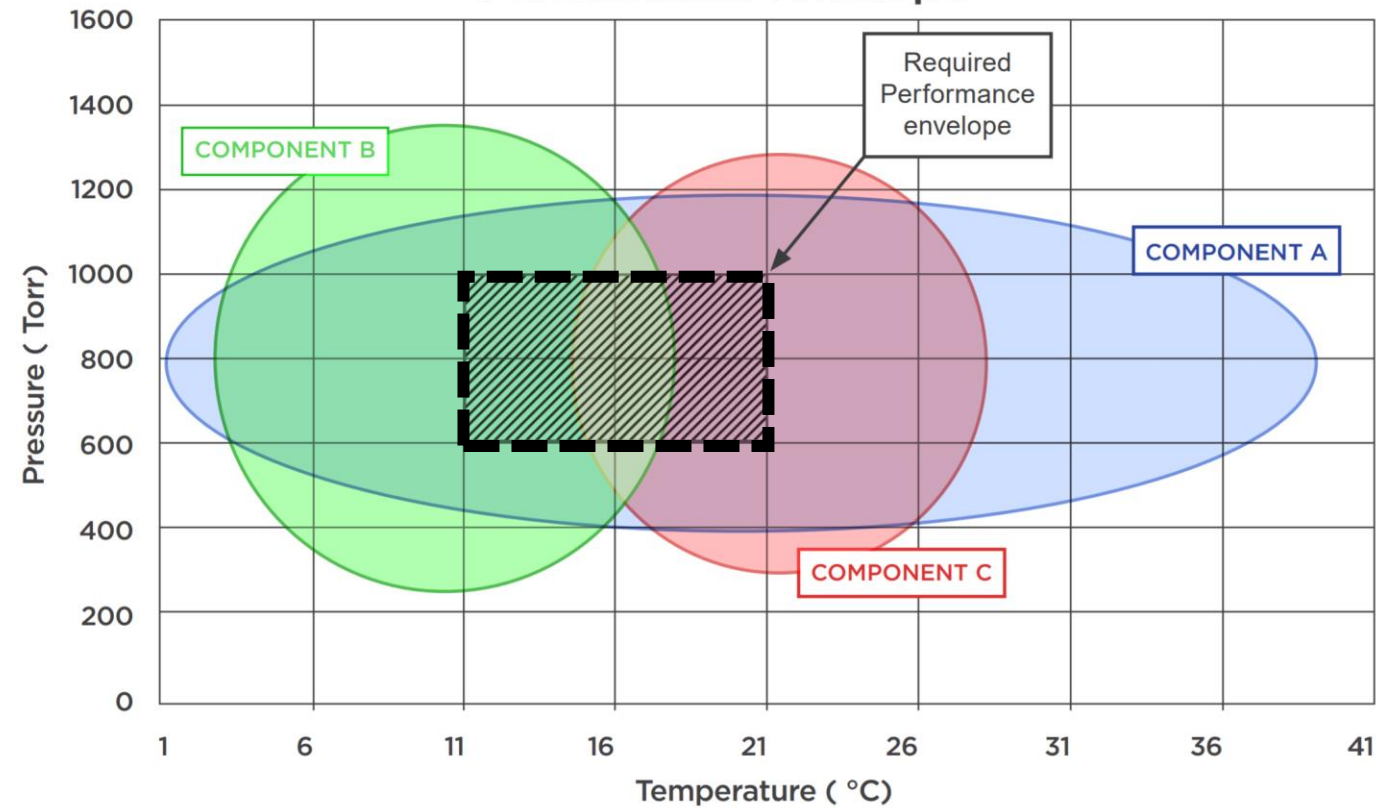
System Analysis & Control

4

- Technical Performance Measurement
- Design Margin Analysis
- Simulation and Modeling
- Traceability
- Technical Reviews
- Configuration Management

Design Margin Analysis

Performance Envelope



Systems Engineering Processes

Verification

5

- Traceability
- Testing Methods
- Configuration Management

Verification vs. Validation

- Verification – Does design output meet design input
 - *Did we design the device correctly?*
- Validation – Does design meet user needs?
 - *Did we design the correct device?*

Systems Engineering Processes

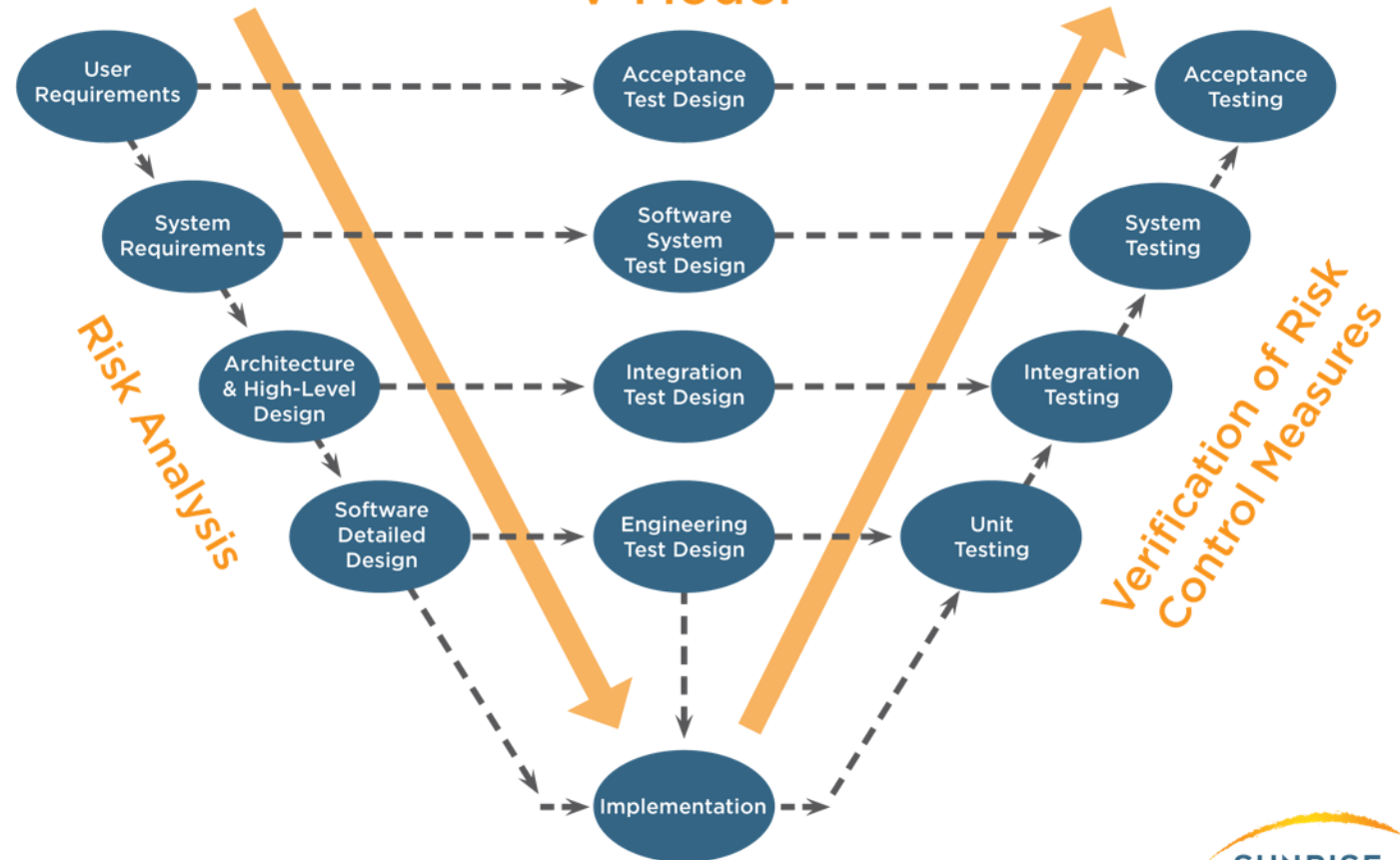
Verification

5

- Traceability
- Testing Methods
- Configuration Management

Traceability

V-Model



Systems Engineering Processes

Verification

5

- Traceability
- Testing Methods
- Configuration Management

Testing Methods

- **Inspection** - nondestructive examination of a product or system using one or more of the five senses. It may include simple physical manipulation and measurements.

Example: visually EXAMINE the car to ensure that it has power windows, power adjustable seats, air conditioning, a navigation system, a tow package, etc.

- **Demonstration** - the manipulation of the product or system as it is intended to be used to verify that the results are as planned or expected.

Example: use the automatic switches to OBSERVE that the windows and seats work as intended, start the vehicle and ensure that the air conditioning produces cold air

- **Test** - verification of a product or system using a controlled and predefined series of inputs, data, or stimuli to ensure that the product or system will produce a very specific and predefined output as specified by the requirements.

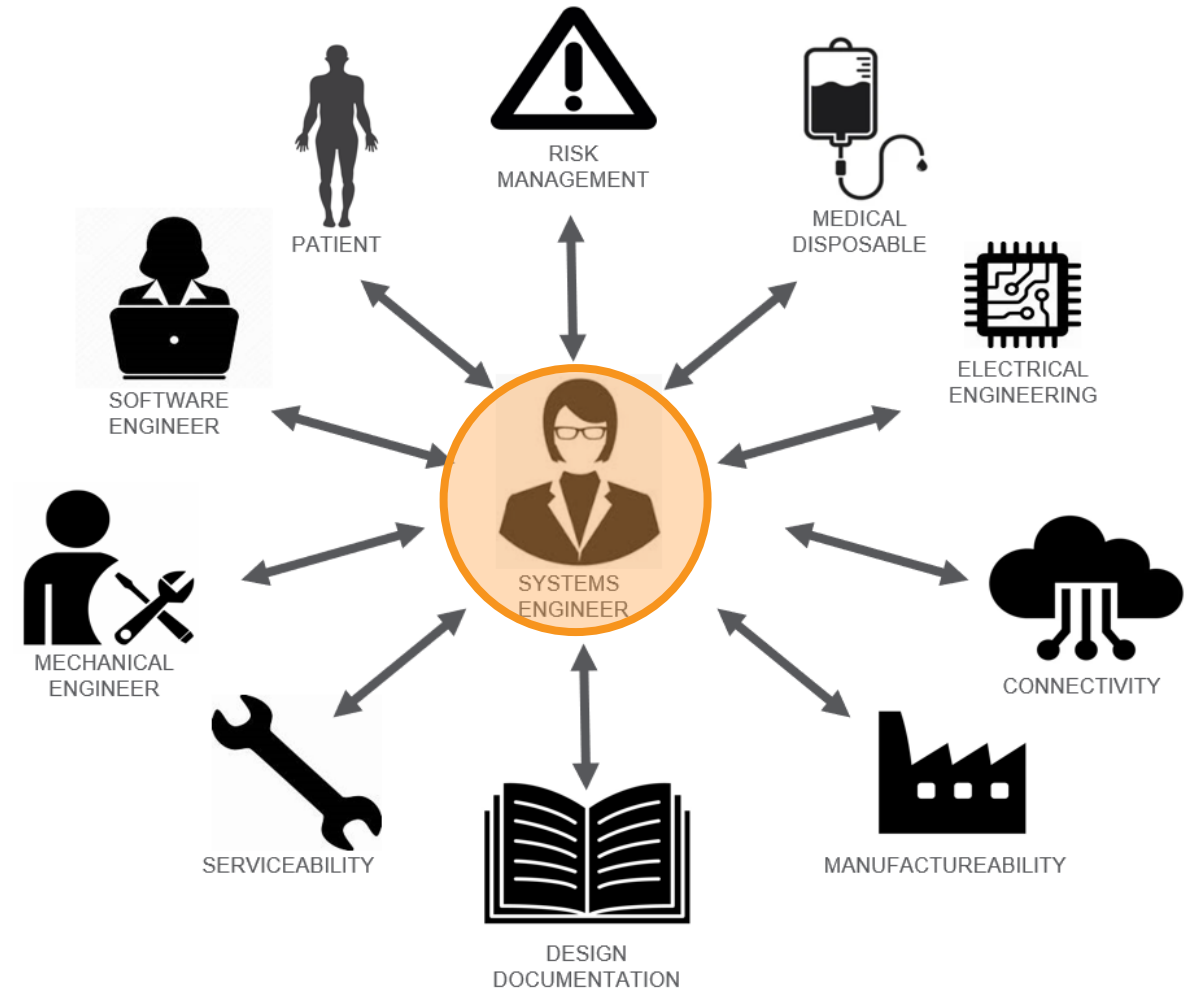
Example: accelerate the car from a complete stop to 60 mph, and MEASURE that it can be done in 5.2 seconds or less

- **Analysis** - verification of a product or system using models, calculations and testing equipment. Analysis allows someone to make predictive statements about the typical performance of a product or system based on the confirmed test results of a sample set or by combining the outcome of individual tests to conclude something new about the product or system.

Example: complete a series of tests which rev the engine at a specific rpm for a set length of time, while monitoring engine vibration and temperature. Use this information to model the failure point of the engine, i.e. max rpm sustained over a specific period of time.

A Clear Case for Systems Engineering

- The medical device industry is trending toward more complex and integrated solutions.
- The demands associated with developing disruptive new technologies, complex architectures, ergonomic and intuitive user interfaces, and multi-dimensional development programs must be balanced with key business objectives.
- Utilizing a holistic Systems Engineering approach is critical to development of commercially viable products.



Q & A



Thank You!

Please visit our website for more information, and to view our portfolio www.sunriselabs.com

Or, contact us directly

603-644-4500

Bgibney@sunriselabs.com

Barbara Gibney, Director of Marketing at Sunrise Labs

We look forward to learning more about your needs and development plans!



25 Constitution Drive
Bedford, NH 03110

