The Benefits of a Systems Engineering Approach:

How to reduce risks and improve performance in medical device development

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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

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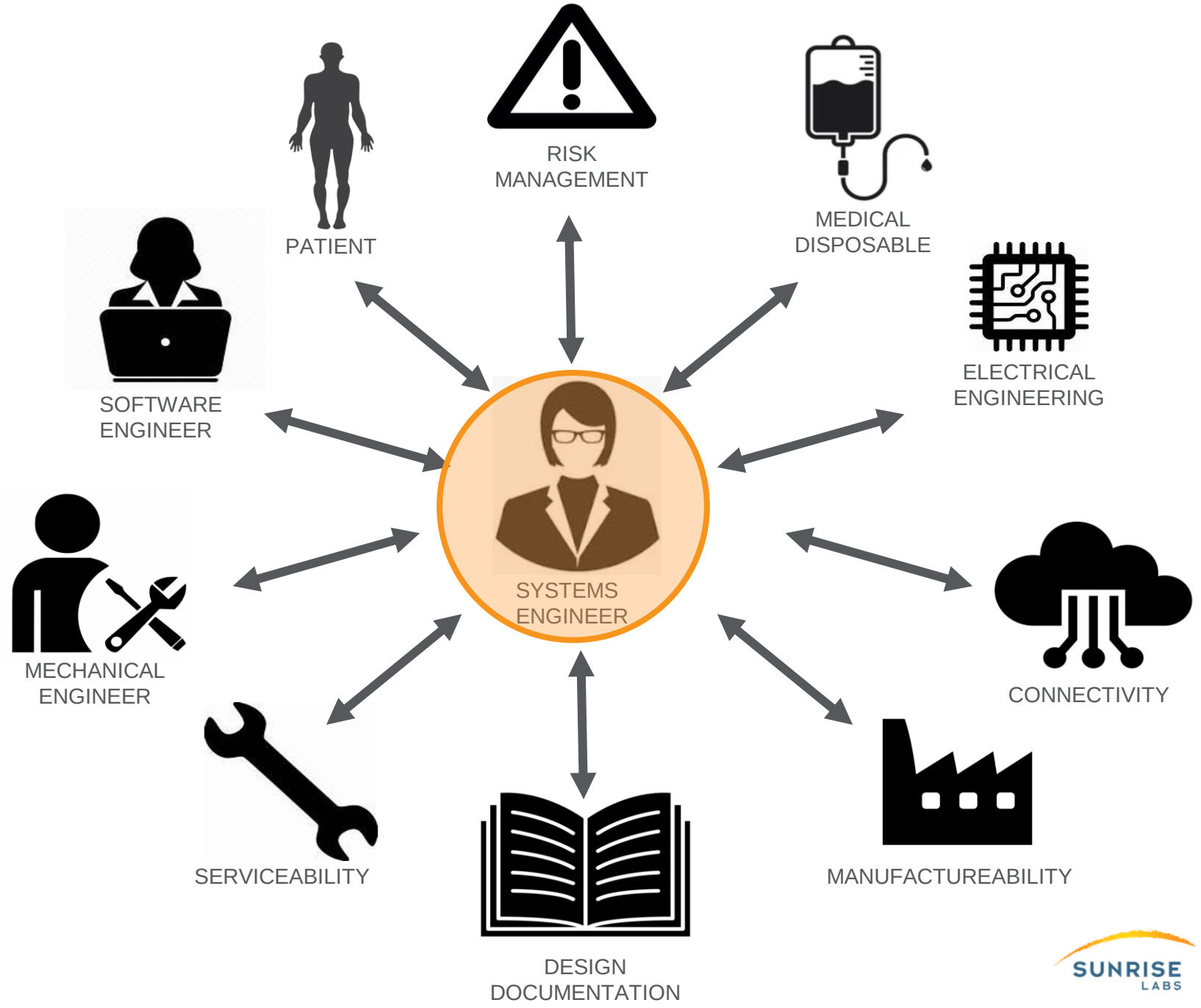
What is Systems Engineering?

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



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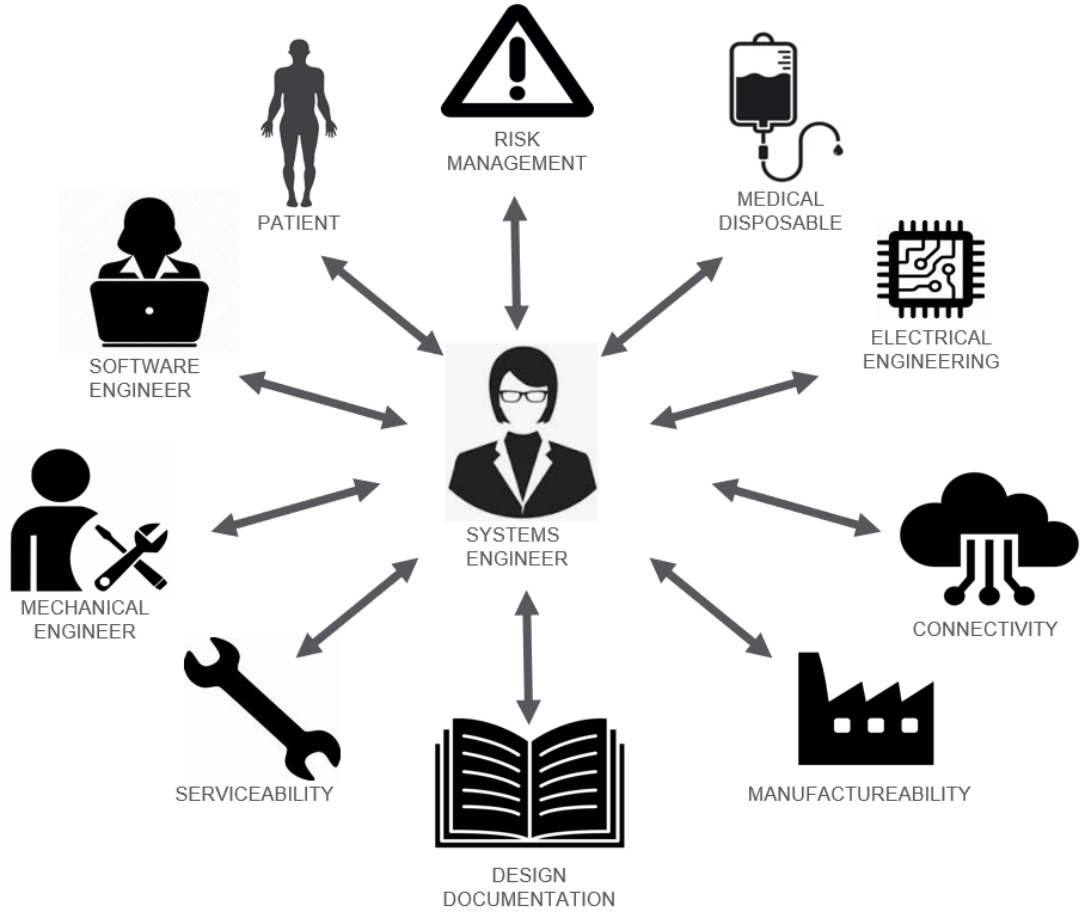
The Role of a Systems Engineer

- 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



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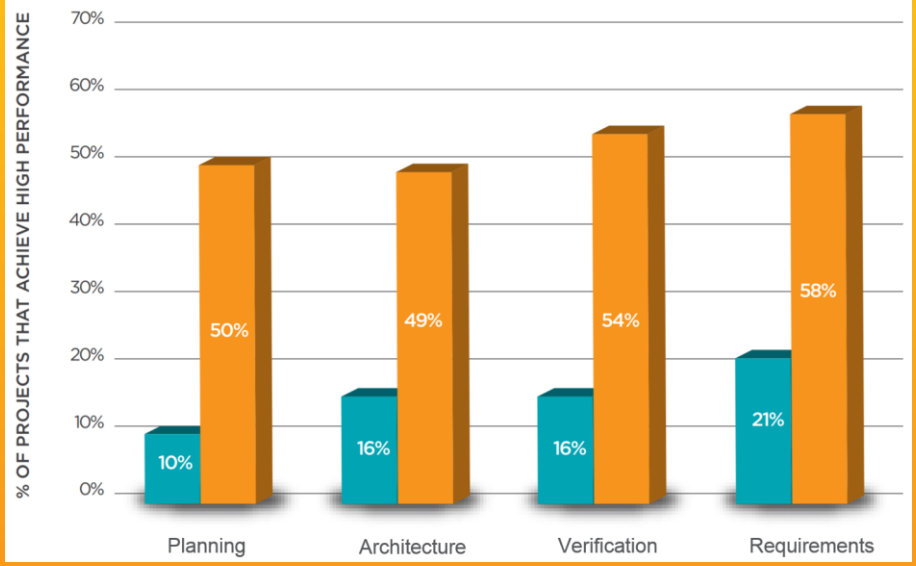
Benefits of Systems Engineering



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

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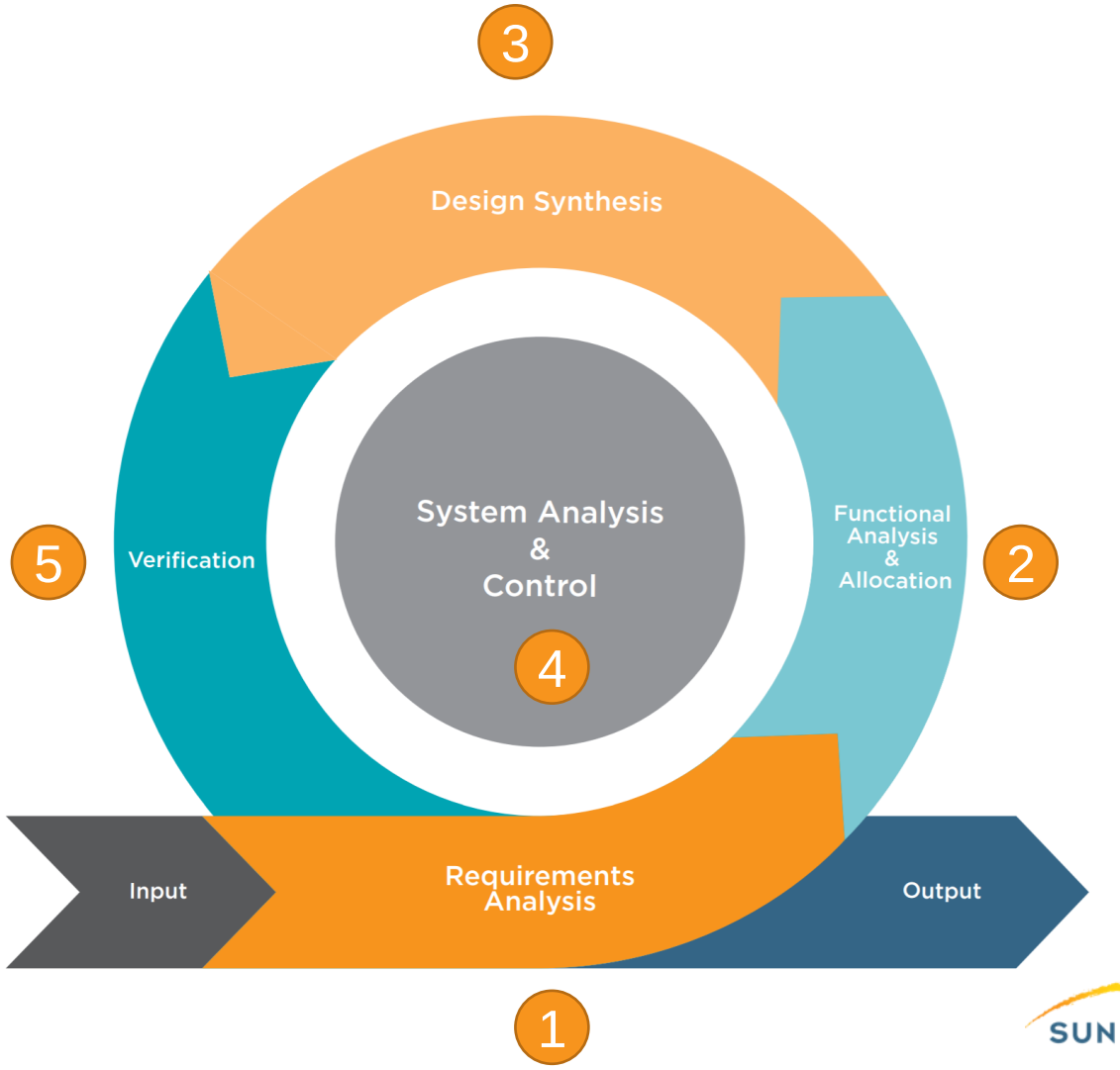
Systems Engineering Processes

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

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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

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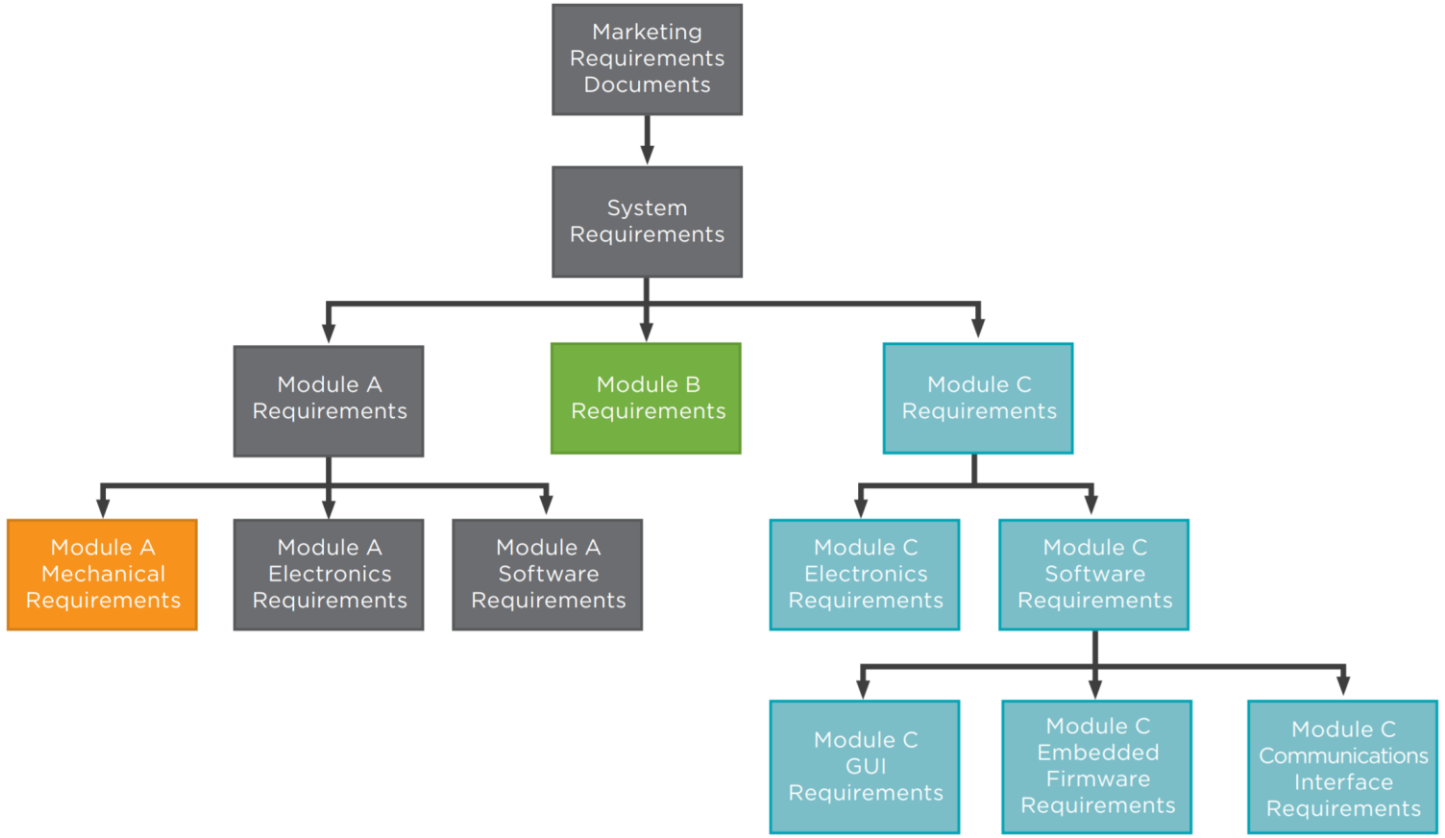
Systems Engineering Processes

Requirements Analysis & Management

1

Design Documentation

Requirement Documentation Structure and Organization



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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 13485
- Medical Device Directive

Determination of Device and Software Classification

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

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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

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Systems Engineering Processes

Functional Analysis & Allocation

2

- Risk Management
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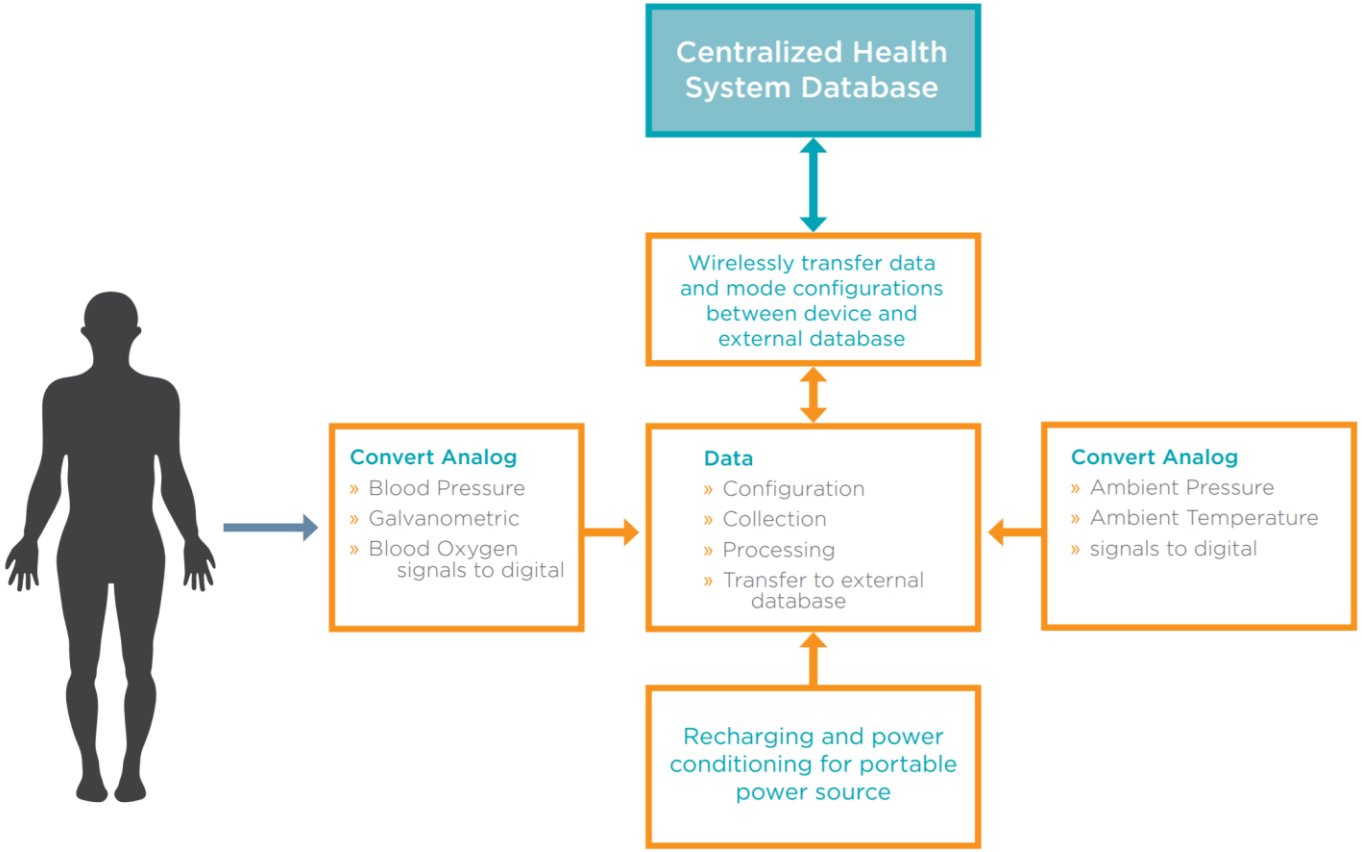
- Functional Block Diagram
- Physical Block Diagram

Functional Block Diagram - identify functions and interfaces



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Systems Engineering Processes

Functional Analysis & Allocation

2

- Risk Management
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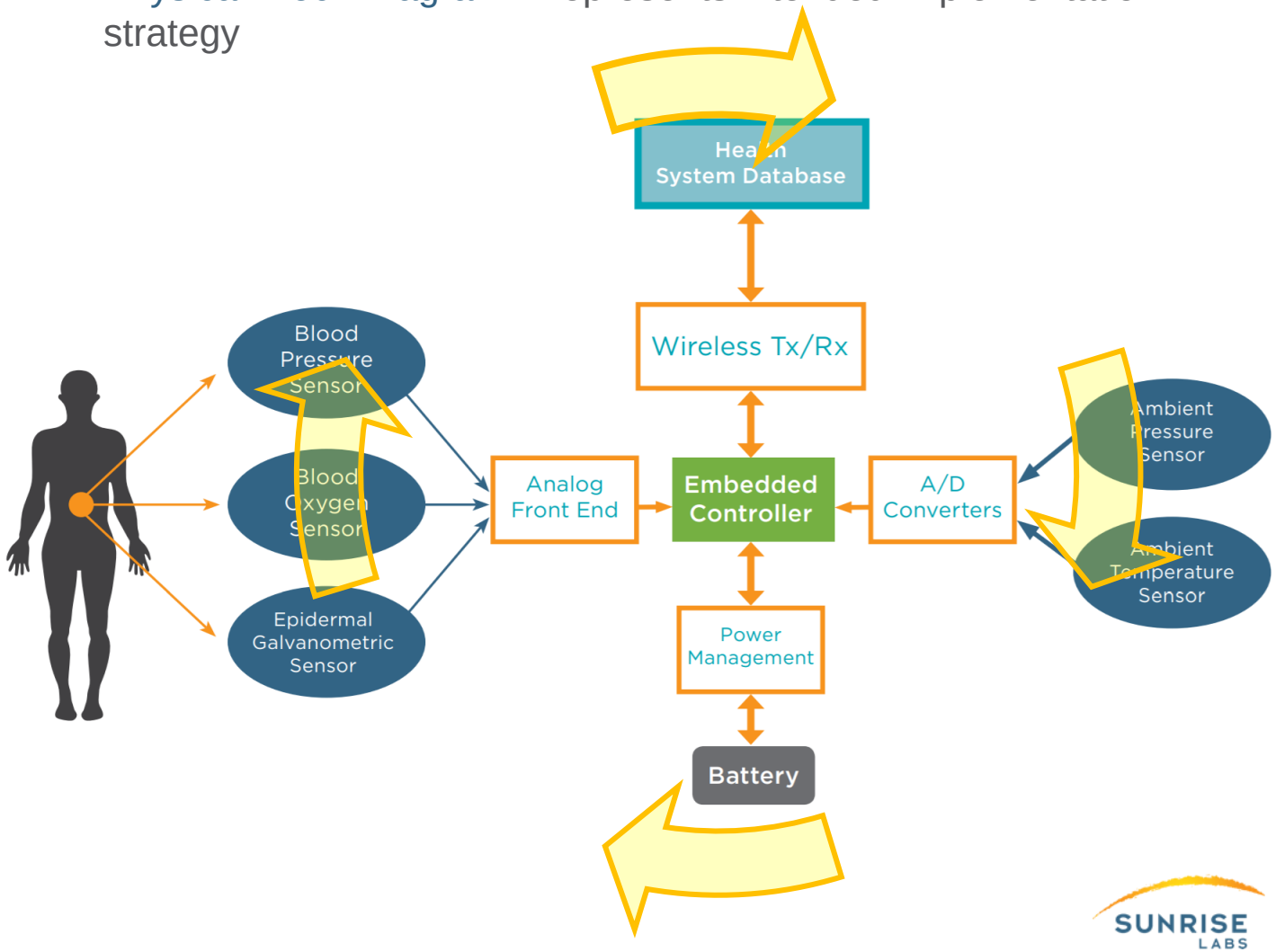
- Functional Block Diagram
- Physical Block Diagram

Physical Block Diagram – represents intended implementation strategy



Systems Engineering Processes

Design Synthesis

3

- Pugh Charts

Quantitative evaluation of proposed designs

Product Owner provides attributes and weighting

Non-linear quantification can be used to accentuate minor design differences

Pugh Matrix									
Owner:									
Measures|CTQ's|Factors etc.	Importance Rating	Baseline	Option 1	Option 2	Option 3	Option 4	Option 5	Option 6	Option 7
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

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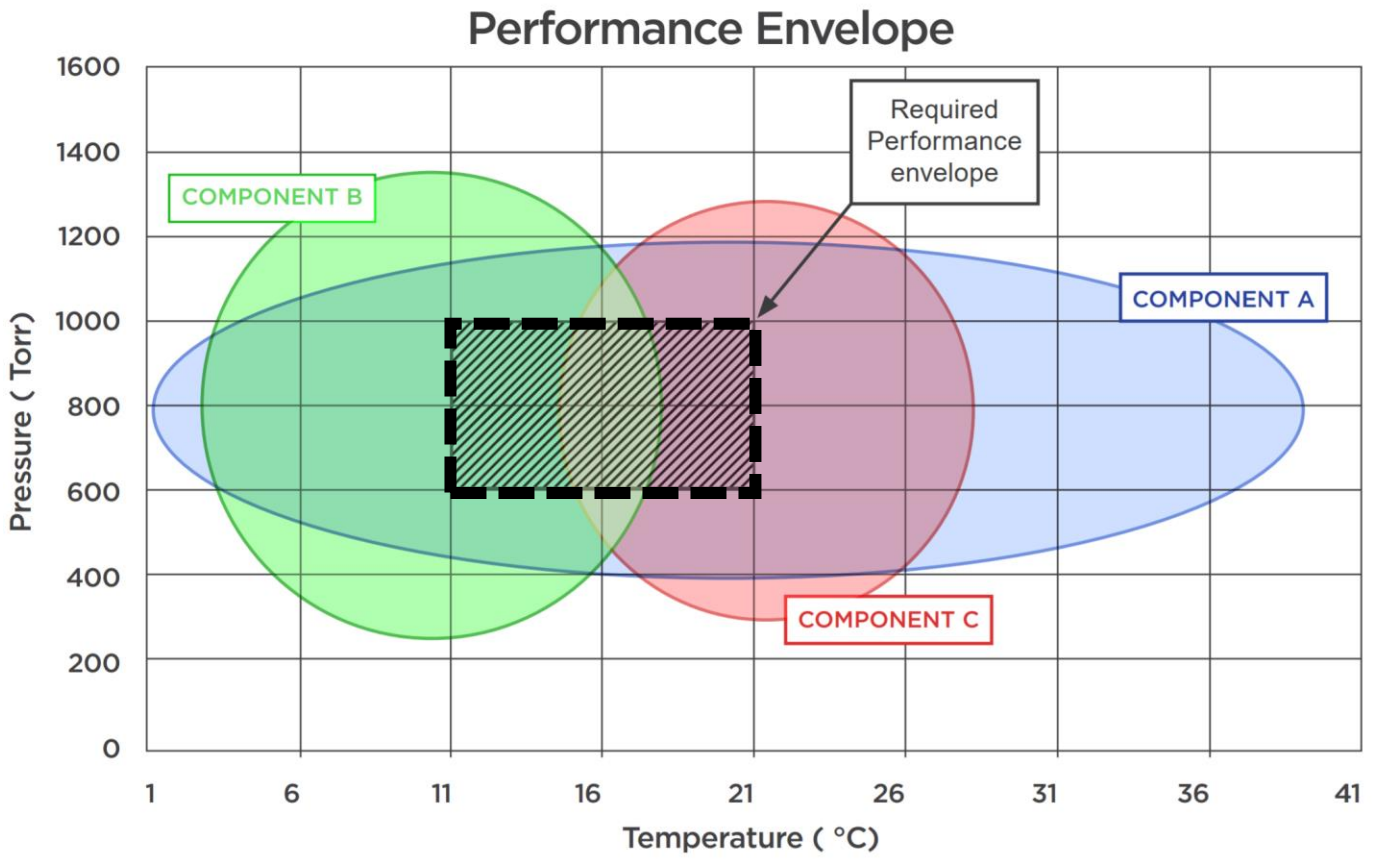
Systems Engineering Processes

System Analysis & Control

4

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

Design Margin Analysis



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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?*

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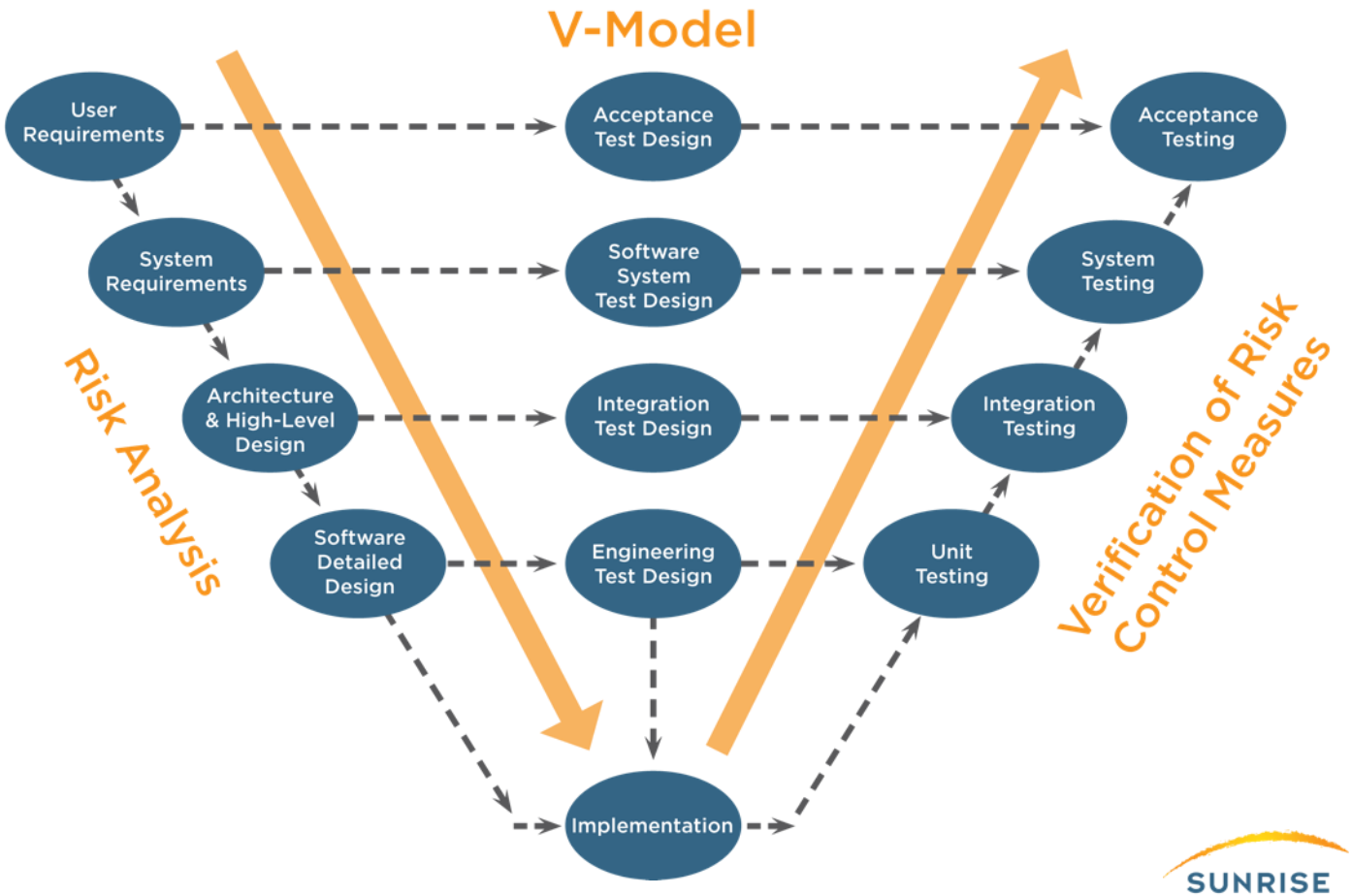
Systems Engineering Processes

Verification

5

- Traceability
- Testing Methods
- Configuration Management

Traceability



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Systems Engineering Processes

Verification

5

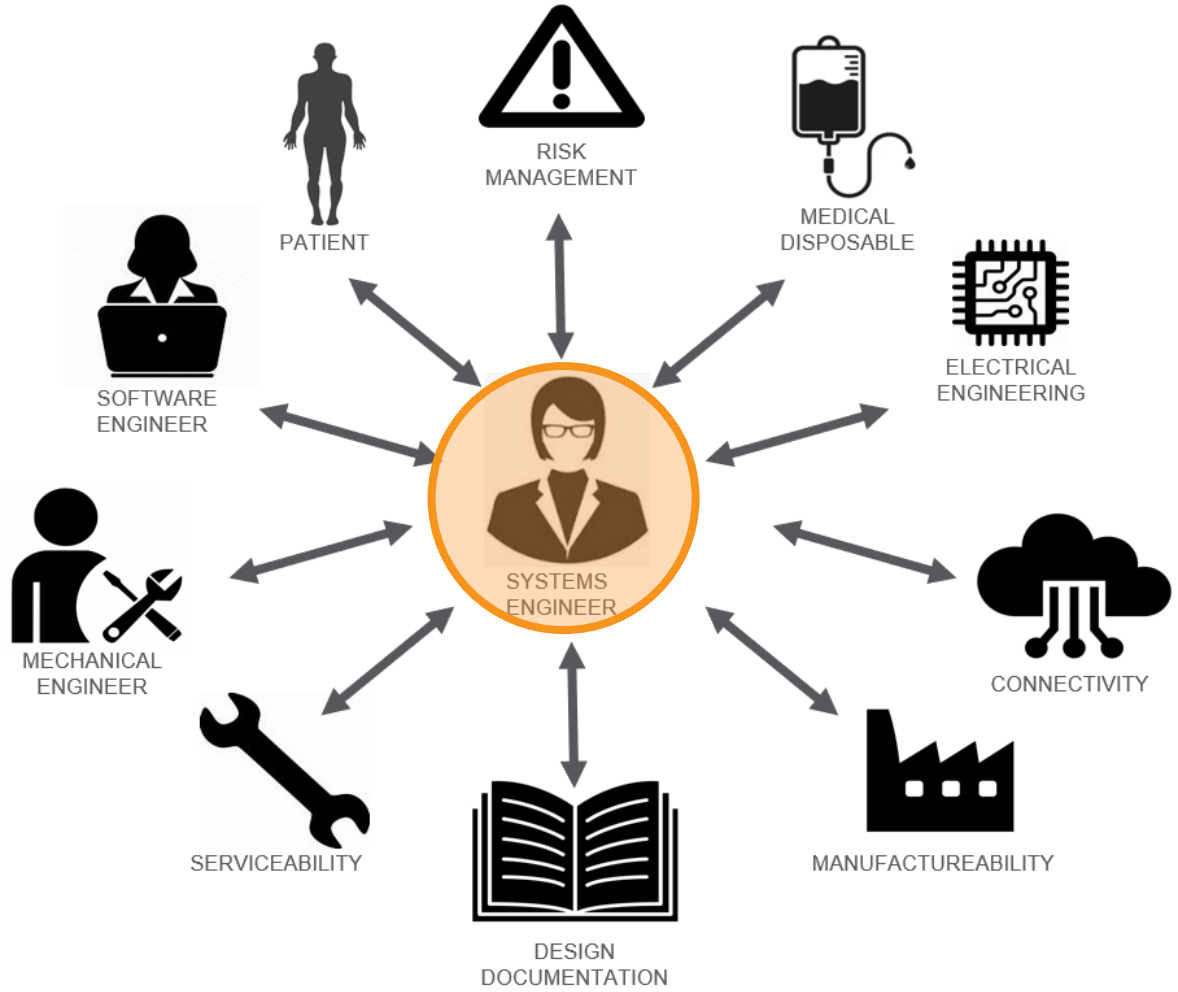
- Traceability
- Testing Methods
- Configuration Management

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.
- **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.
- **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.
- **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.

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.



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Q & A

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

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