INCOSE Healthcare Working Group
4th Annual Systems Engineering in Healthcare Conference

A SYSTEM DESIGN CONTROL PROCESS FOR MEDICAL DEVICE SOFTWARE DEVELOPMENT

Joseph Akyeampong
(Sr Systems Engineer)

Medtronic

The information presented herein is the personal view of the presenter and not to be taken as an official Medtronic position or endorsement.

AGENDA

- **Purpose**
- **Background**
  - Medical Device SW – What Is It?
  - Medical Device Technology Refresh
- **FDA Design Controls (21CFR 820.30)**
- **System Design Controls Process (SDCP)**
  - Design Inputs
  - Design Outputs
  - Design Verification
  - Design Validation
- **Medtronic Medical Device Software Development Projects**
- **Q&A**

PURPOSE

- Define Medical Device Software & Its Significance
  - *What are the drivers of medical device software development?*
- Describe FDA Design Controls
- Present a Systems Engineering process model (SDCP) for Medical Device Software Development
  - *Why is it needed?*
  - *How does it help reduce cost and improve quality?*
  - *Provide examples of how it has been successfully implemented at Medtronic*

BACKGROUND

Medical Device Software - What Is It?

Software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device [FDA].

Medical device software is used across a broad range of technology platforms

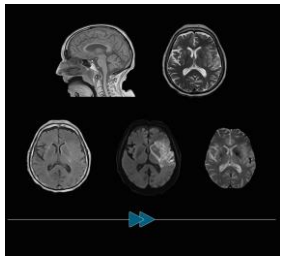
- Medical device platforms (custom-built)
- Commercial Off The Shelf (COTS) platforms (e.g. tablets, smart phones, laptops, PCs etc.)
- Virtual networks (i.e. cloud)

Other names: software as a medical device (SaMD) standalone software, medical device software, health software

BACKGROUND

Examples of Medical Device Software

- Software that controls a medical device e.g. an implantable neurostimulator (pain/brain), insulin pump or pacemaker
- Software that performs imaging and diagnostic procedures e.g. MRI
- Software that controls inflation and deflation of a blood pressure cuff through a mobile platform
- Software that uses the digital camera of medical scopes to diagnose a condition
- Treatment planning applications that supply information
- BMI and body fat calculators, and heart rate monitors

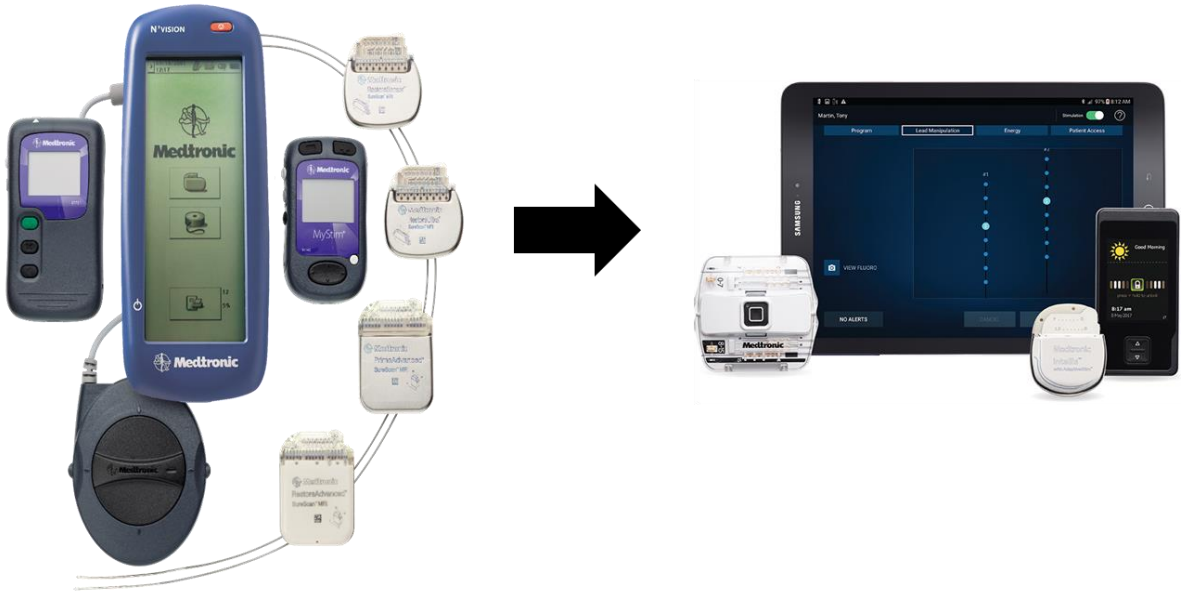

BACKGROUND

Significance of Medical Device Software

- Provides the interface for controlling and monitoring medical devices
- Scalability – allowing expansion of the functional capabilities of medical devices
  - Bodily interaction (i.e. deliver stimulation or a drug)
  - Monitoring and control of therapy
  - Wireless integration
  - System security
- Device/Platform independent – i.e. custom, commercial off-the-shelf, cloud, Windows, iOS, Android etc.
- Accessibility – i.e., downloadable or pushed apps
- Efficient and effective diagnoses and treatment of disease conditions

BACKGROUND

Medical Device Technology Refresh



Drivers

- Accessible healthcare
- Personalized treatment
- Advancements in electronics

Benefits

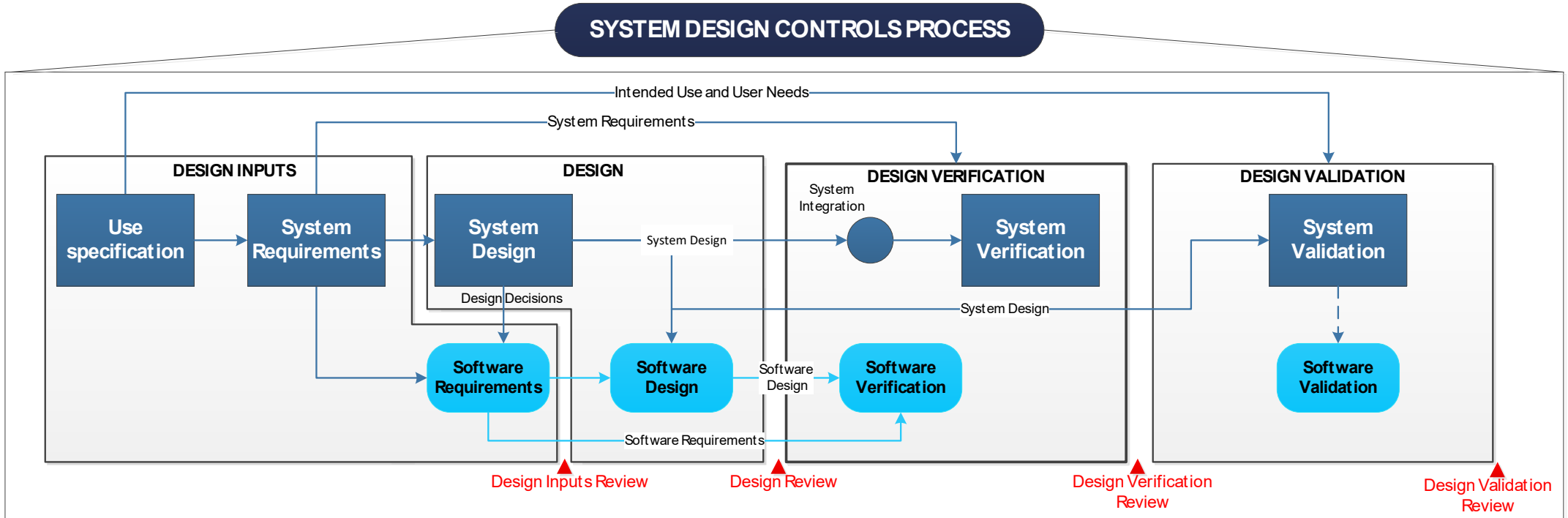
- Competitive advantage
- Reduced cost
- Familiarity/ adoption
- Improved user experience

SYSTEMS DESIGN CONTROL PROCESS (SDCP)

Why SDCP?

- Establishes a system-driven process for medical device software development
- Identifies the sequence of System and Software development activities for effective/efficient product development
- Emphasizes the need for review at the end of each design control phase to ensure quality outputs
- Built on a foundation of risk management to ensure safety and efficacy of the medical device software

SYSTEMS DESIGN CONTROL PROCESS (SDCP)



1. Identify design input sources
2. Create use specification
3. Define system and software requirements / establish traceability

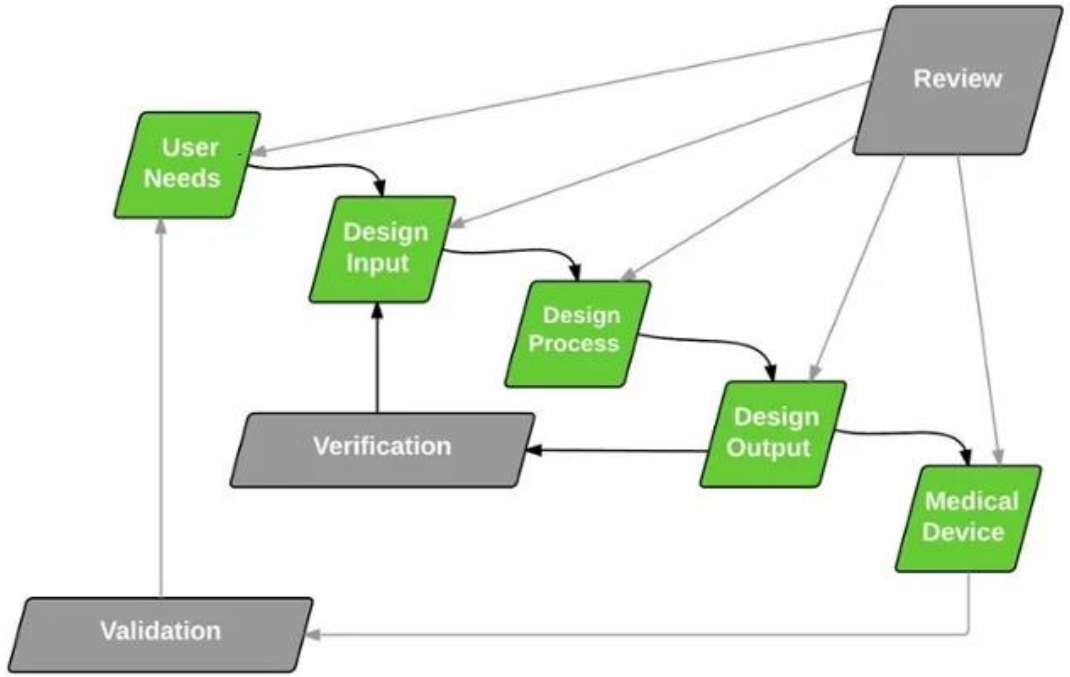
1. Create system/ software architectures
2. Develop system design
3. Perform risk analyses
4. Develop software design

1. Create system and software design verification plan/ protocol
2. Complete SW design verification
3. Complete system design verification
4. Create system and software design verification reports

1. Create design validation plan/ protocol
2. Complete design validation
3. Create design validation report

Quality System / Risk Management

FDA DESIGN CONTROLS(21 CFR 820.30)



Guidance Documents (Medical Devices and Radiation-Emitting Products)
> Design Control Guidance For Medical Device Manufacturers

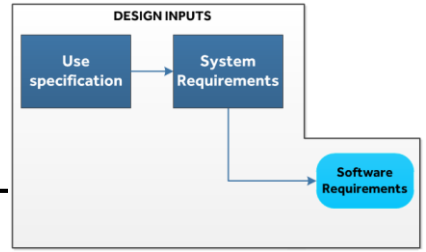
U.S. Food and Drug Administration

Design Controls (21 CFR 820.30)

a) General requirements
b) Design and development planning
c) Design input
d) Design output
e) Design review
f) Design verification
g) Design validation
h) Design changes
i) Design transfer
j) Design history file

12

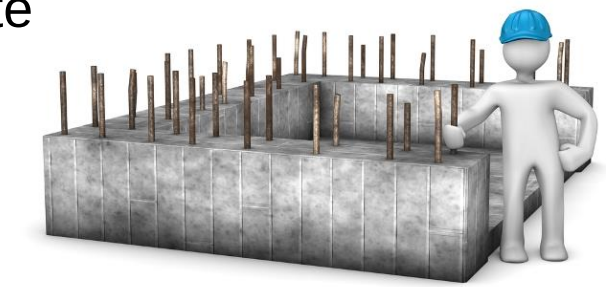
DESIGN INPUTS



Overview

- Design inputs (DI) establish the foundation for medical device product development

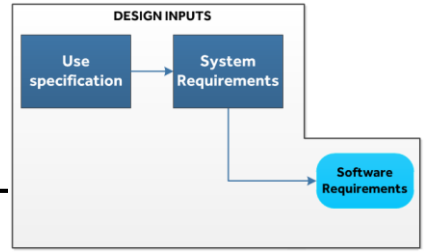
- Defining DIs can be time-consuming
  - Requires a disciplined approach to identifying appropriate design inputs



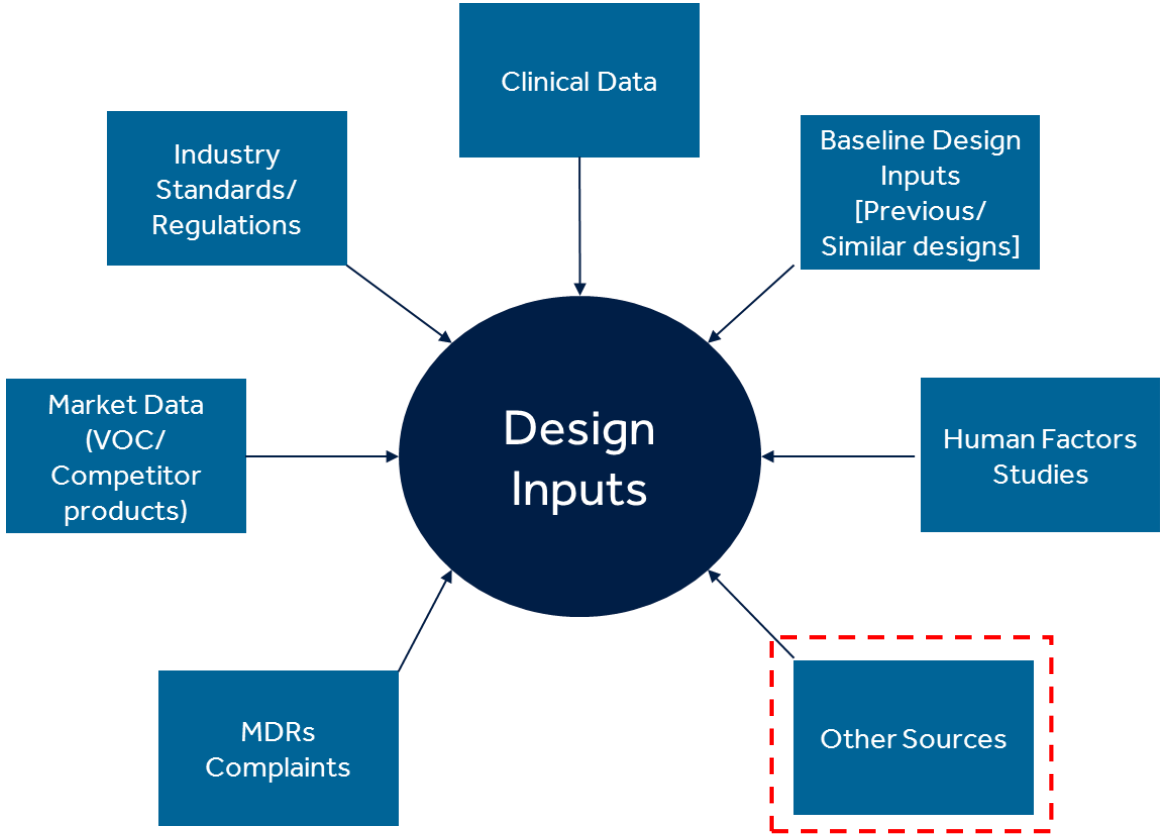
Goals For Defining Design Inputs

- Appropriately capturing all user and stakeholder needs
- Adequately capturing applicable requirement types – (functional, performance, usability, regulatory etc.)
- Ensuring DIs are clear, unambiguous, non-conflicting, verifiable, “validatable”

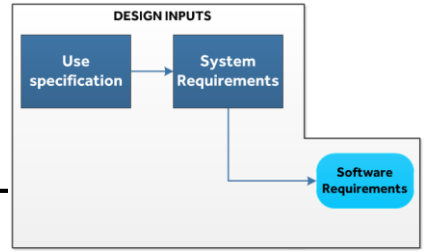
DESIGN INPUTS



Identify Design Input Sources



DESIGN INPUTS



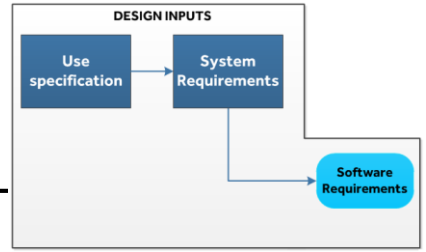
Create Use Specification (IEC 62366-1)

Elements of the Use Specification

- ❑ intended use
- ❑ indications of use
- ❑ user profiles
- ❑ environment profiles
- ❑ user needs
- ❑ use cases/scenarios

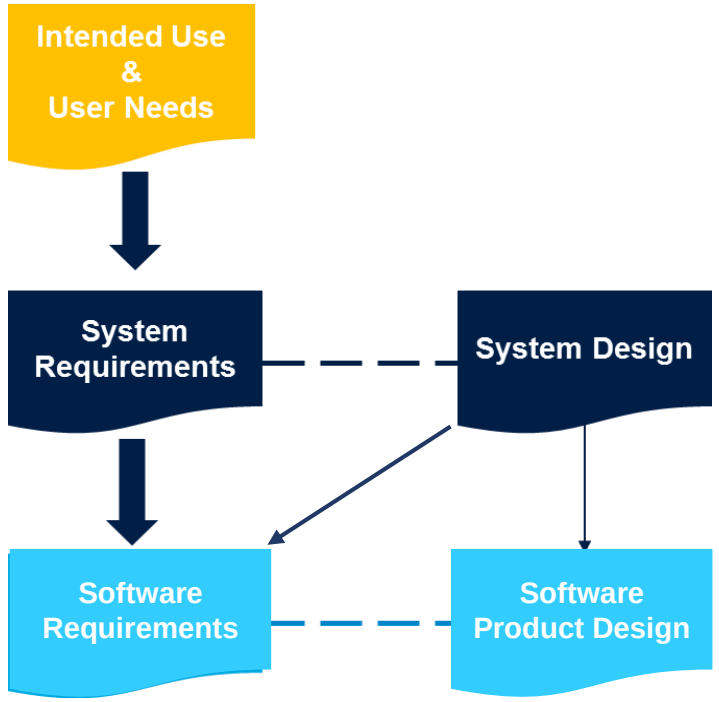
Question	Answer
What will the medical device be used for?	Intended Use
Which medical conditions will the medical device diagnose, treat, prevent or mitigate?	Indication of Use
Who will use the medical device?	User Profiles
Where will it be used?	Environment Profiles
Why is the medical device essential to the user?	User Needs
How will the user interact with the medical device?	Use Cases/Scenarios

DESIGN INPUTS



Define Requirements / Establish Traceability

- System Requirements
  - Functional/performance
  - Operational (including Security)
  - Environmental
  - Usability
- Software Requirements
  - Functional – Capabilities to configure/control medical device
  - Informational - Capabilities to enter, update or view information about the medical device



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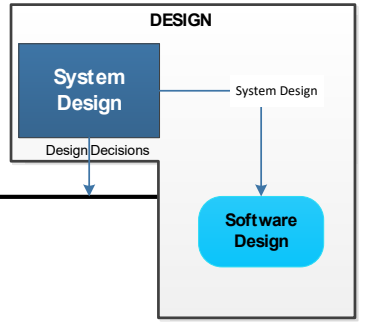
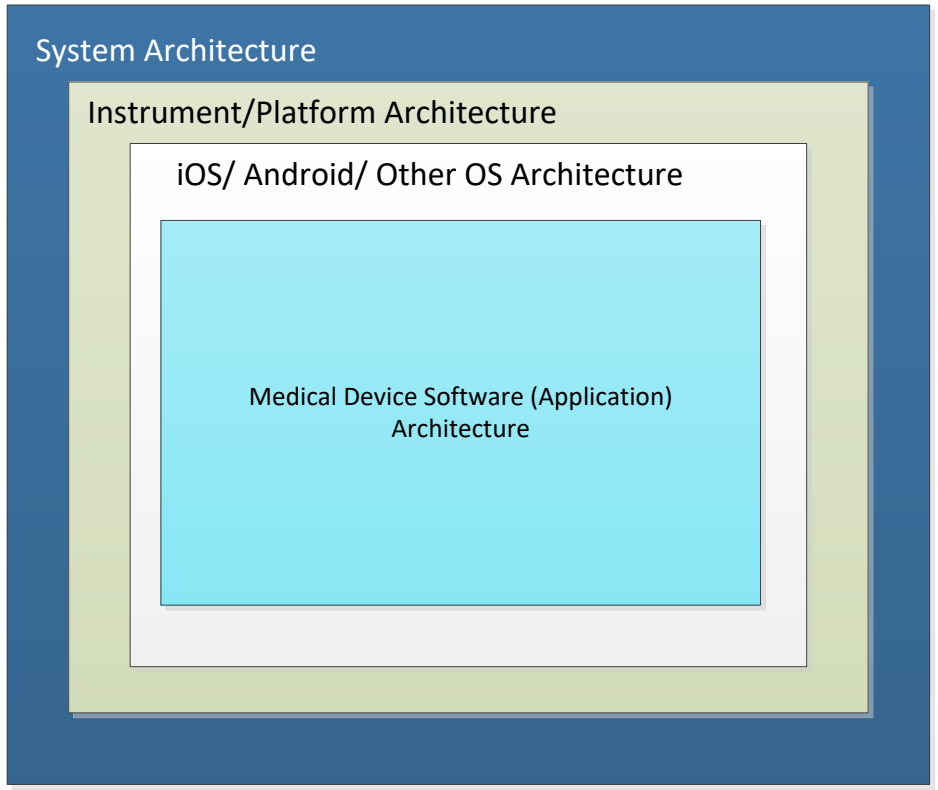
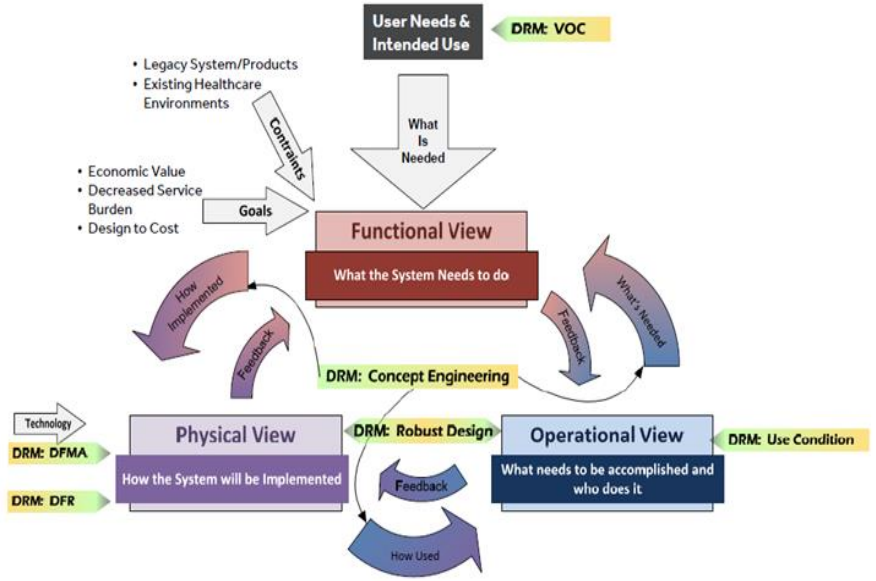


Define Architectures > System Architecture



System Architecture Views

- ❑ Functional
- ❑ Physical
- ❑ Operational



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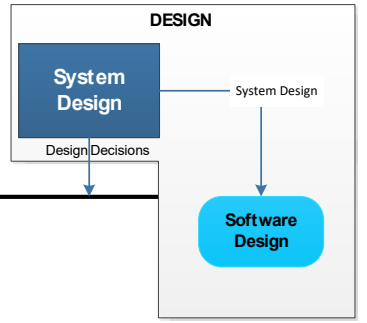
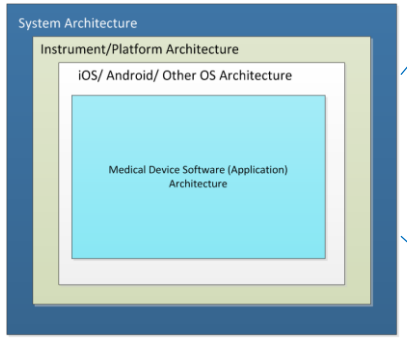


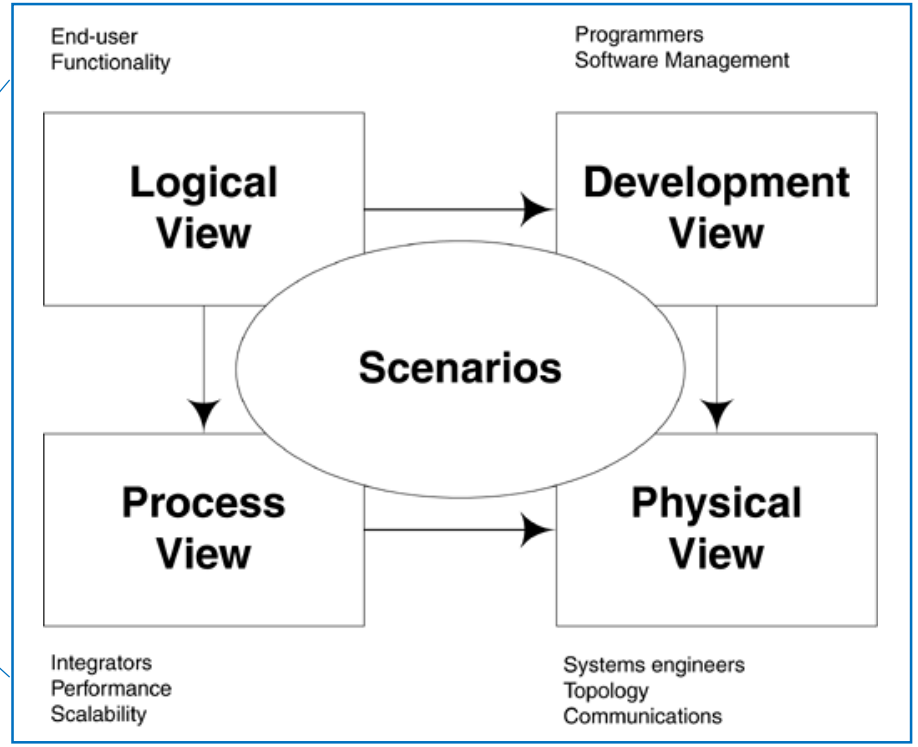
Define Architectures – Software Architecture

Software Architecture Views

- ❑ Logical
- ❑ Development
- ❑ Physical
- ❑ Process
- ❑ Operational (Scenarios)*

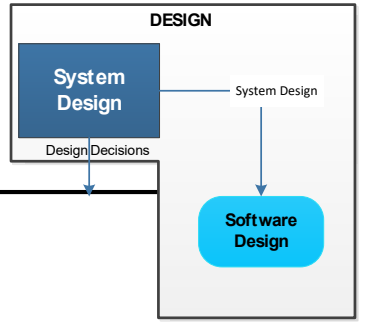


System Architecture



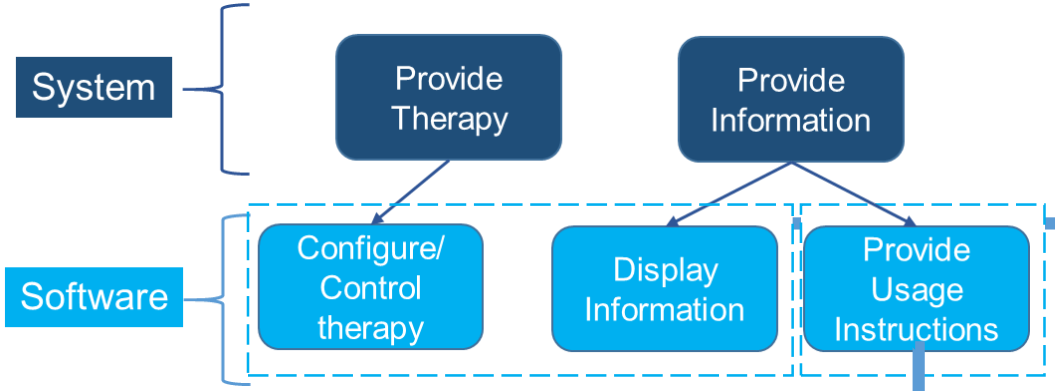
Krutchen 4+1 Software Architectural View Model

DESIGN

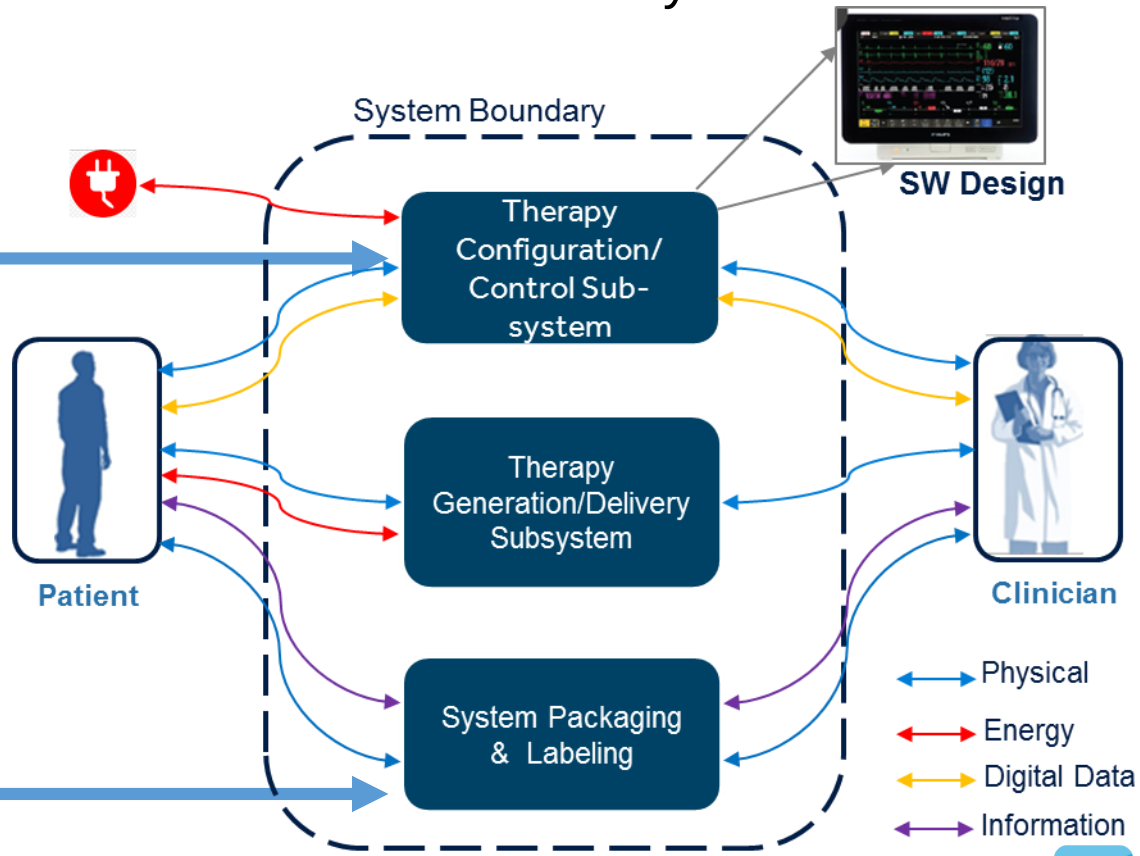


System Design

Define Functions



Allocate Function to Physical Elements



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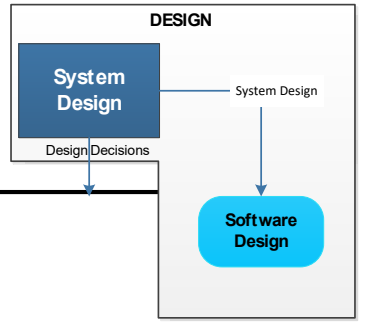


Perform Risk Analysis

Software Hazard Sources

Use Errors

Failure Modes

Risk Assessment

- Define Sequence of Events
- Identify Hazards
- Hazardous Situations
- Determine Severity
- Determine Occurrence

Risk Control Measures

- Inherent Safety by Design
- Protective Measures
- Detection and notification
- Labeling and training

Software Design

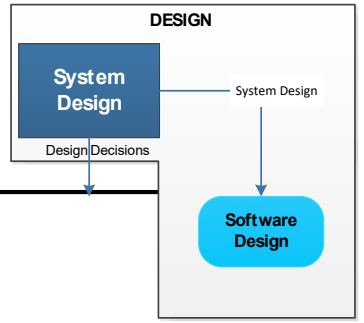
RCM Verification

- Software Output vs. RCM

Risk Result

- Evaluate Residual Risk
  * Goal: ALAP

DESIGN



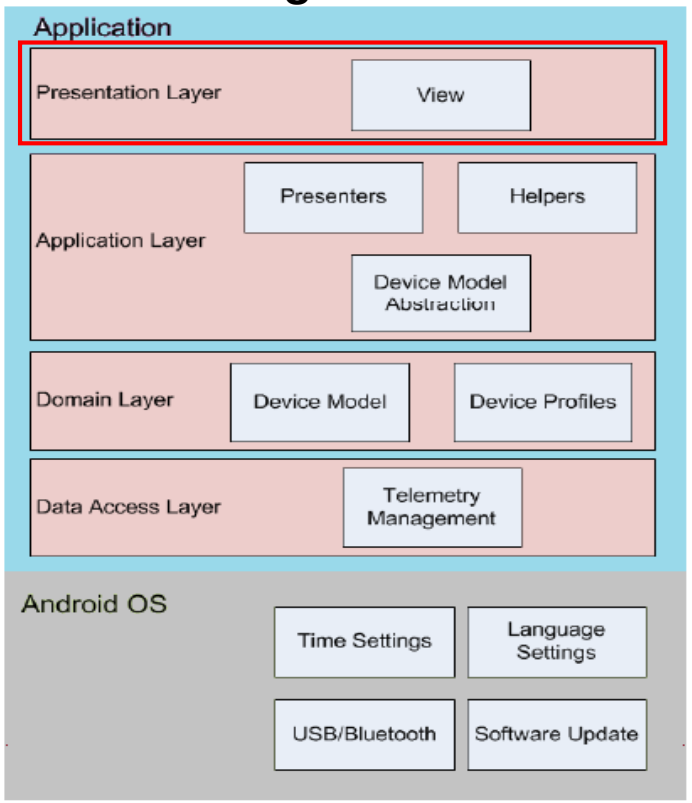
Software Design

System Functions Allocated to Software

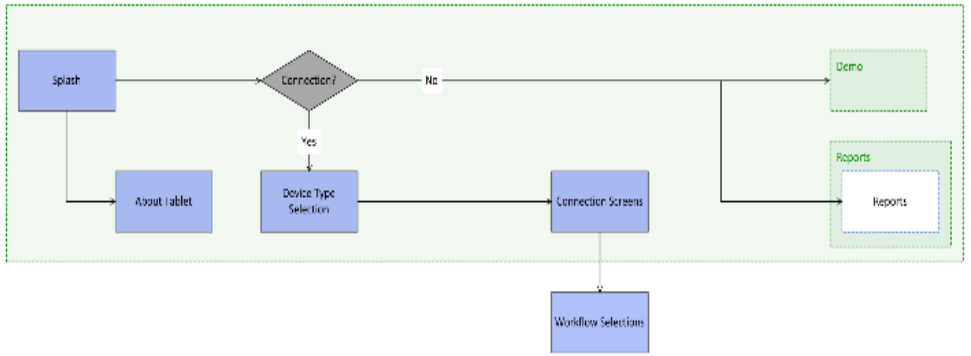
Provide therapy
- ❑ Configure/Control therapy
- ❑ Provide Information

Provide information
- ❑ Display information
- ❑ Display instructions

Software Logical View



1. Create Site Map



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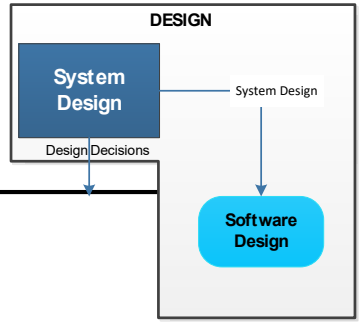
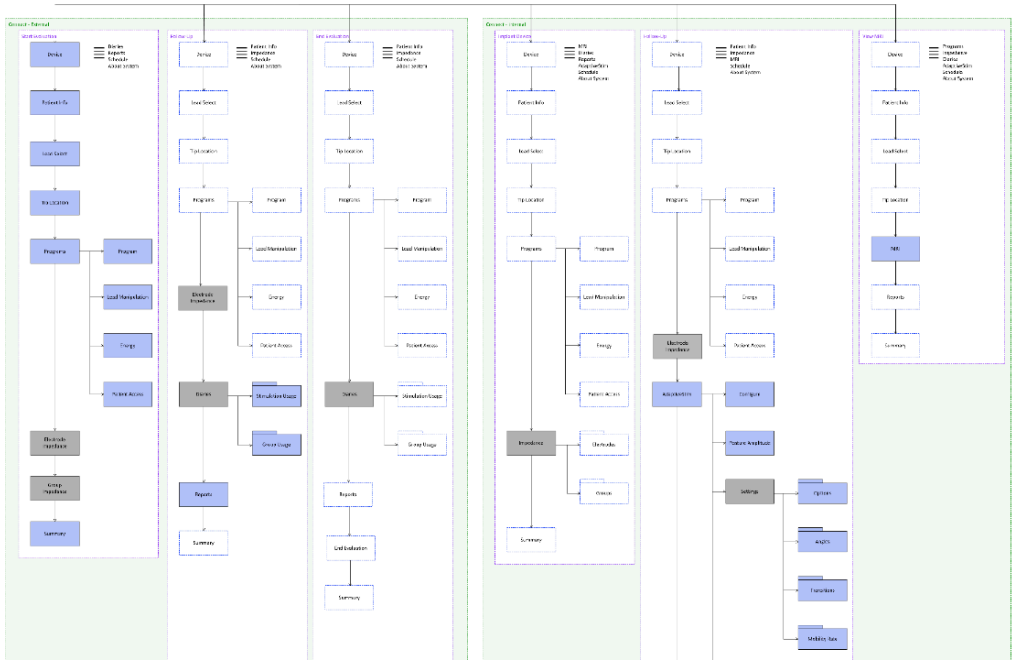
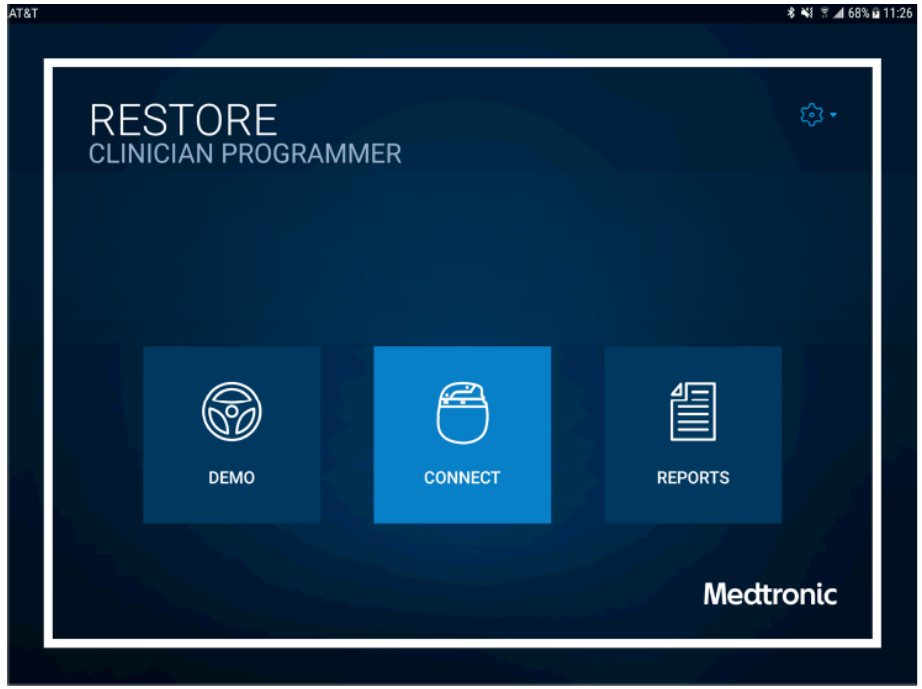


Software Design

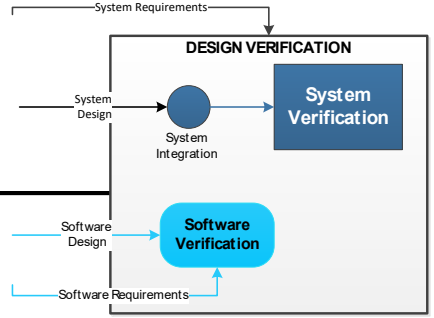
2. Create Workflows



3. Develop Screen Designs



DESIGN VERIFICATION



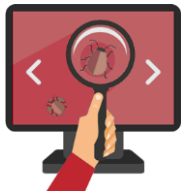
System Integration and Testing

System Integration

- Connect system components to assess functionality

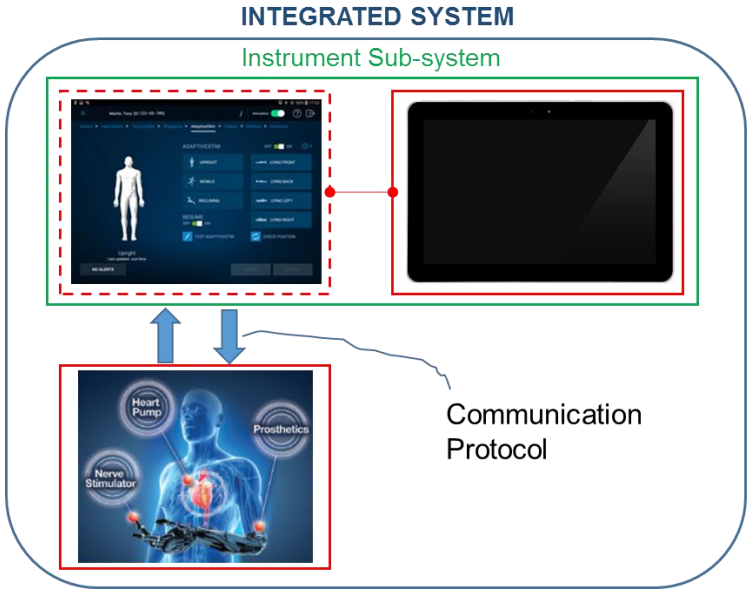
System Integration Testing

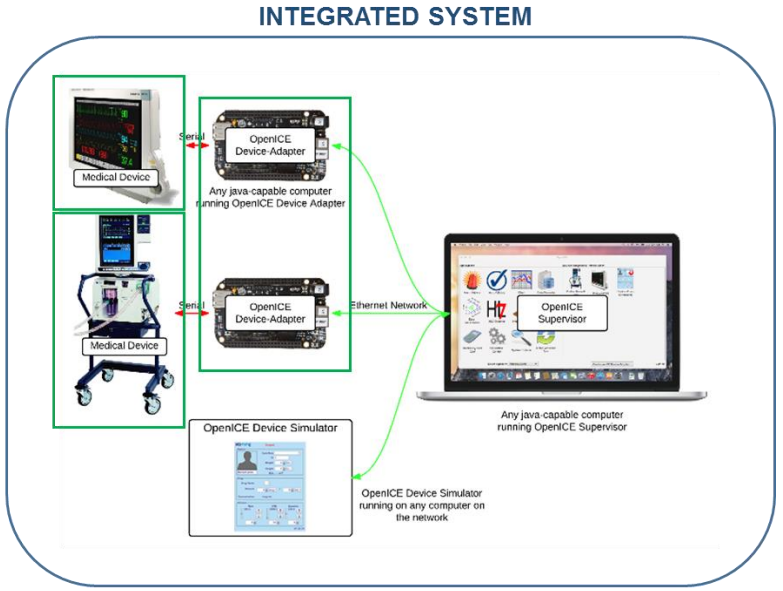
- Test of the integrated system
- Identify issues
- Fix the issues



Examples:

- ❑ Functionality testing
- ❑ Use case testing
- ❑ Compatibility testing
- ❑ Free-form testing





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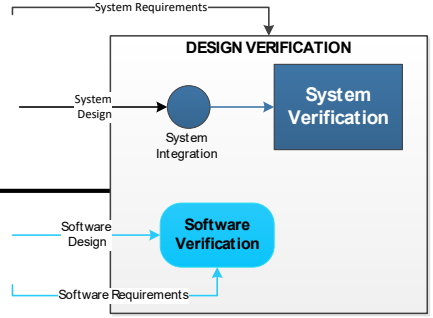
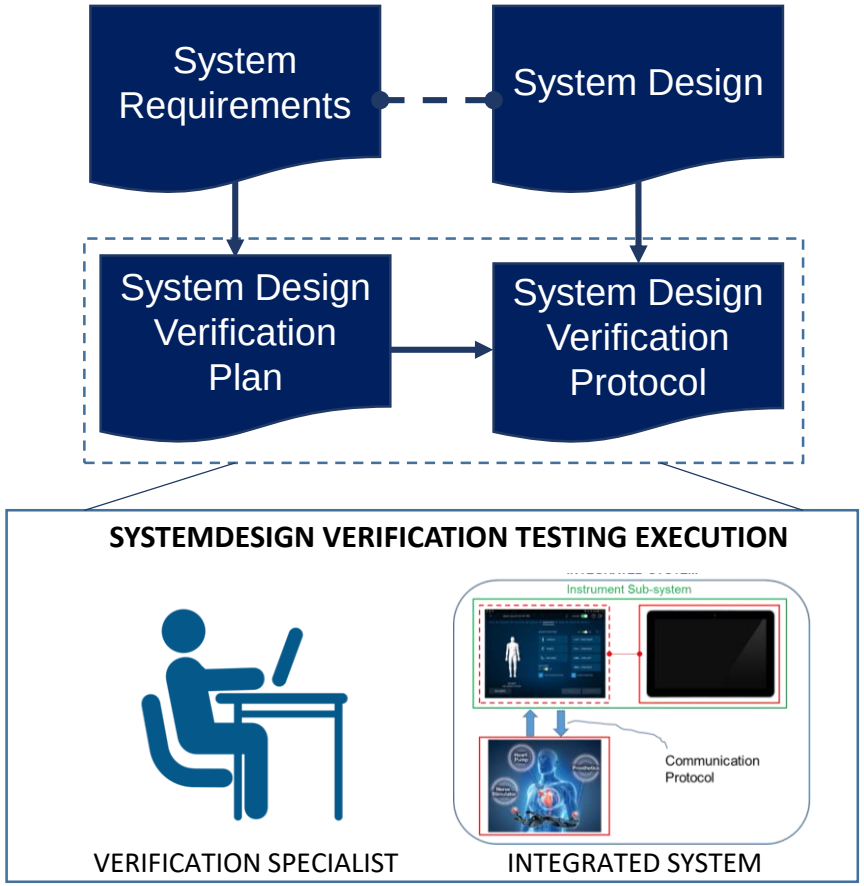


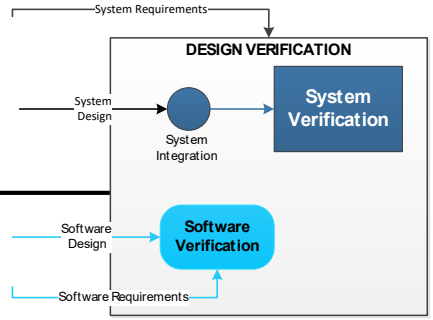
System Design Verification



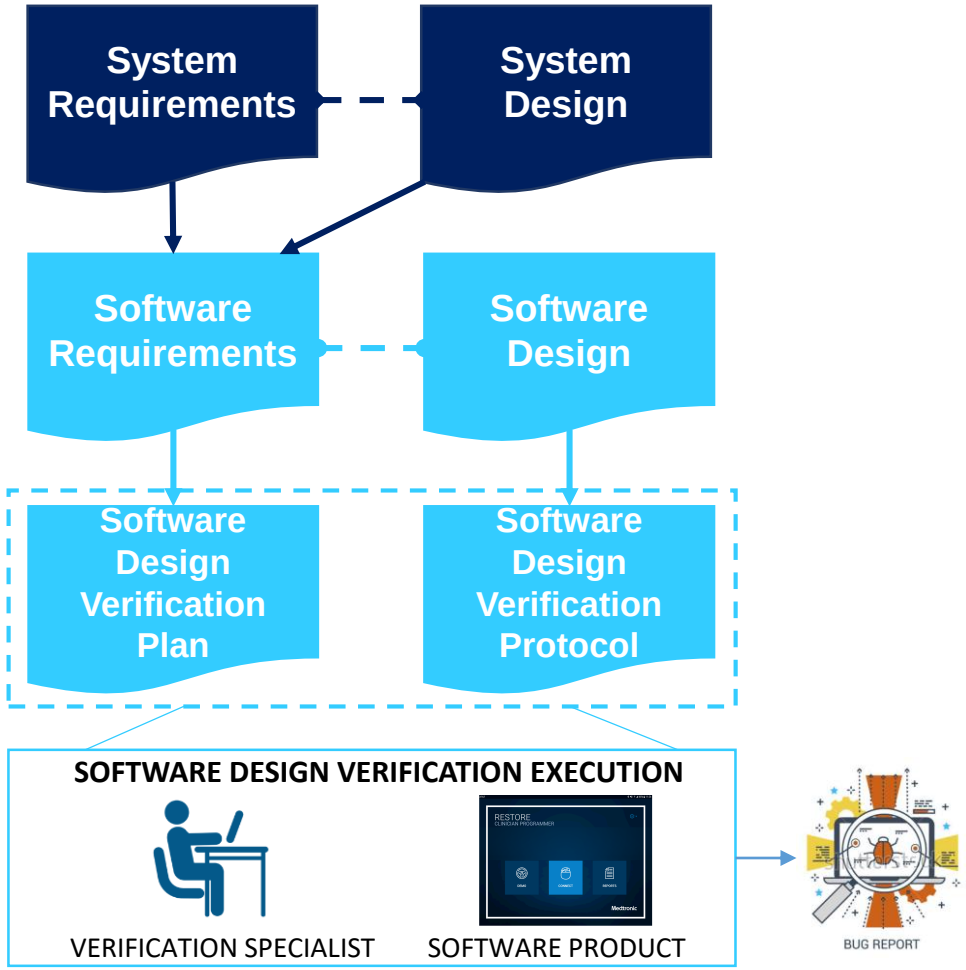
- System Design Verification
  - Verifies system requirements
  - Did we build the system right?

- System Design Verification Techniques
  - Test
  - Inspection
  - Demonstration
  - Leverage Child Verification
  - Analysis – Similarity/ Rationale

DESIGN VERIFICATION



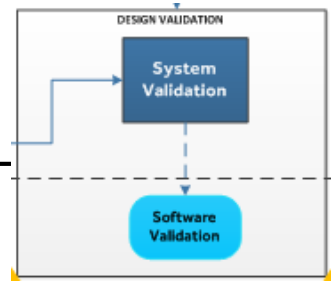
Software Design Verification



- Software Design Verification
  - Verifies software requirements
  - Did we build the product right?
- Software Design Verification Techniques
  - Feature Acceptance Tests
  - User Story Acceptance Tests
  - Software System Tests
  - Integration Tests

DESIGN VALIDATION

Did we build the right product?



Use Spec

System Design

Software Design

Validation Methods

Human Factors Summative Tests

System Validation Test

Analysis Rationale/ Similarity

Leverage Verification

- Validate the final design against the intended use /user needs in actual or simulated use environments
- Focus on features with high risk (harm severity) as identified through risk analyses
- Focus on evaluating usability of software

Thank you