INCOSE Healthcare Working Group

5th Annual Systems Engineering in Healthcare Conference

May 1-2, 2019
Minneapolis, MN

Saving Cost and Schedule through Early-Phase Systems Engineering

Mark Fiebig

Philips Healthcare

Emergency Care and Resuscitation

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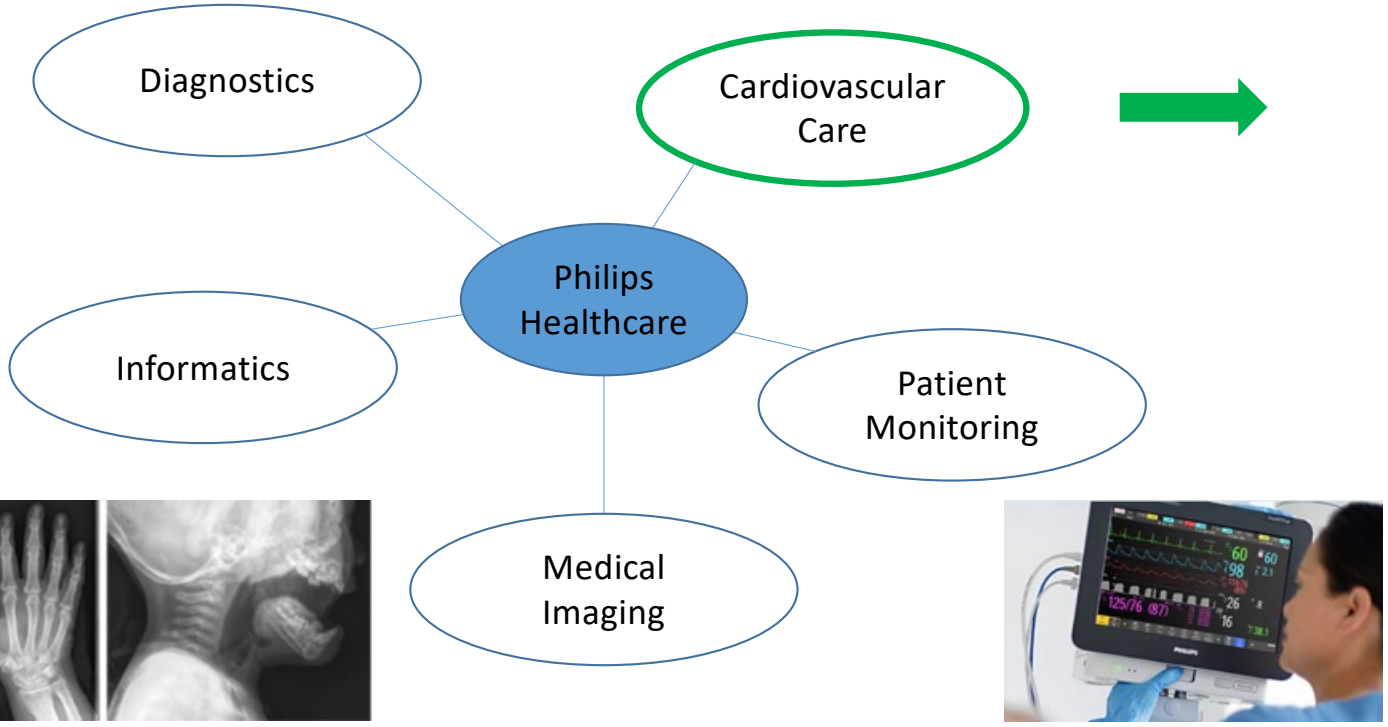
Agenda

- Philips AED Background
- Carry Case Example
- Systems Engineering Best Practices

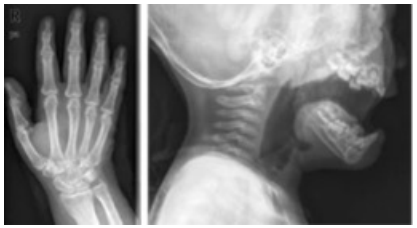
Presentation Themes

- Clearly Defined User Scenarios to Drive Requirements
- Systems Engineering Ownership
- Full Assessment of Post-Market Design Changes

Philips Healthcare



- Image-Guided Therapy
- Early Warning Scoring
- Hospital/ICU Telehealth
- **Emergency Care and Resuscitation**



Emergency Care and Resuscitation

Advanced Life Support Solutions

- EMS and Hospital Environments
- Monitor/Defibrillators and Accessories
  - 12-Lead ECG
  - AED
  - Pacing
  - CPR Assistance, NIBP, SpO2, EtCO2

Data Management Solutions

- HeartStart Configure
- Telemedicine System
- Event Review Pro

Automated External Defibrillators (AEDs)

- Rugged Environments
- Basic Life Support Personnel and Lay Users
- Easy Step-By-Step Use
- Includes Only “Over the Counter” AED

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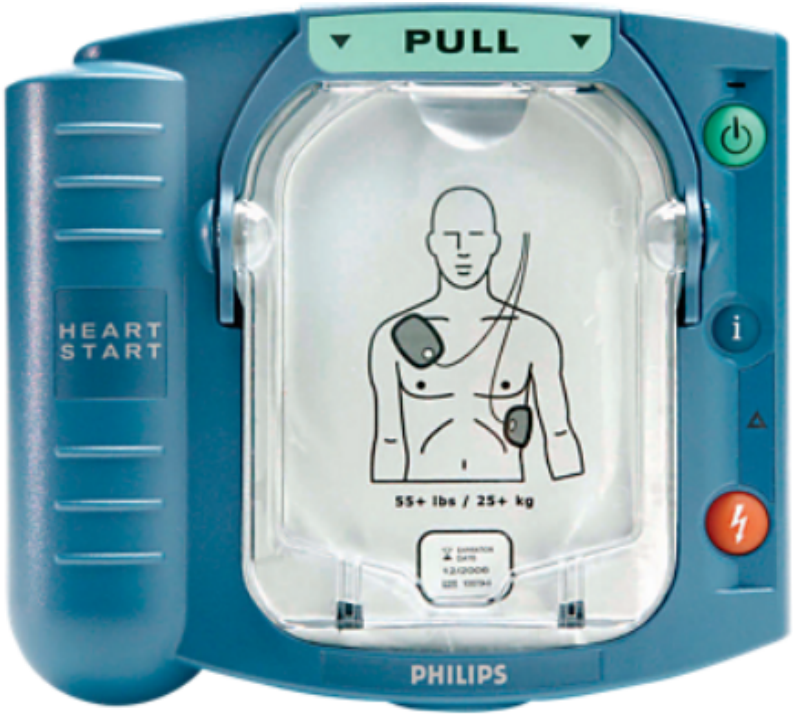
Systems Engineering Concerns for Automated External Defibrillators

- Risk Management
  - Prevent Delays in Therapy
  - Do No Harm
  - Lifecycle Risk Management
- Usability
  - Minimize Time to Therapy for Untrained Personnel
  - Simplicity in Stressful Situations
- Reliability
  - Devices May Be Rarely Used
- Compliance
  - Medical Device Regulations
  - Data Security
  - Learning Products



Systems Engineering Concerns for Automated External Defibrillators

- Accessories
  - Batteries, Pads, Cases, etc.
  - AED System Design
  - Modularity
  - Data
  - Facilitate Various Use Cases

"Case" Study

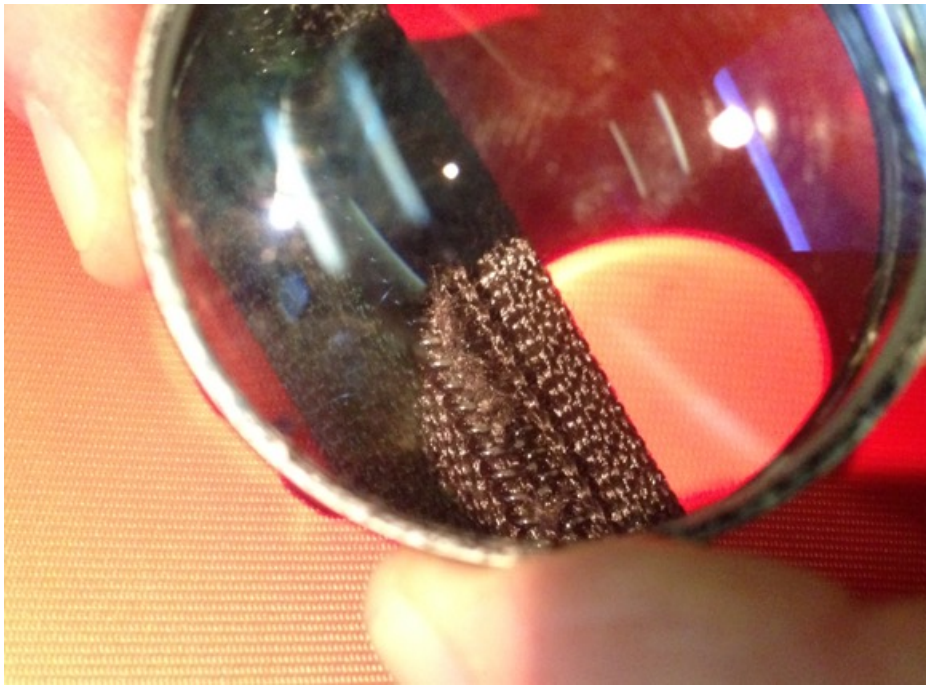
- Foam AED Carrying Case for Commercial Aircraft
- Protection from Drop/Handling Damage
- Self-Contained AED System
  - AED
  - Pre-Connected Electrode Pads
  - Fast-Response Kit
  - Quick Reference Guide
  - Spare Battery and/or Electrode Pads

"Case" Study

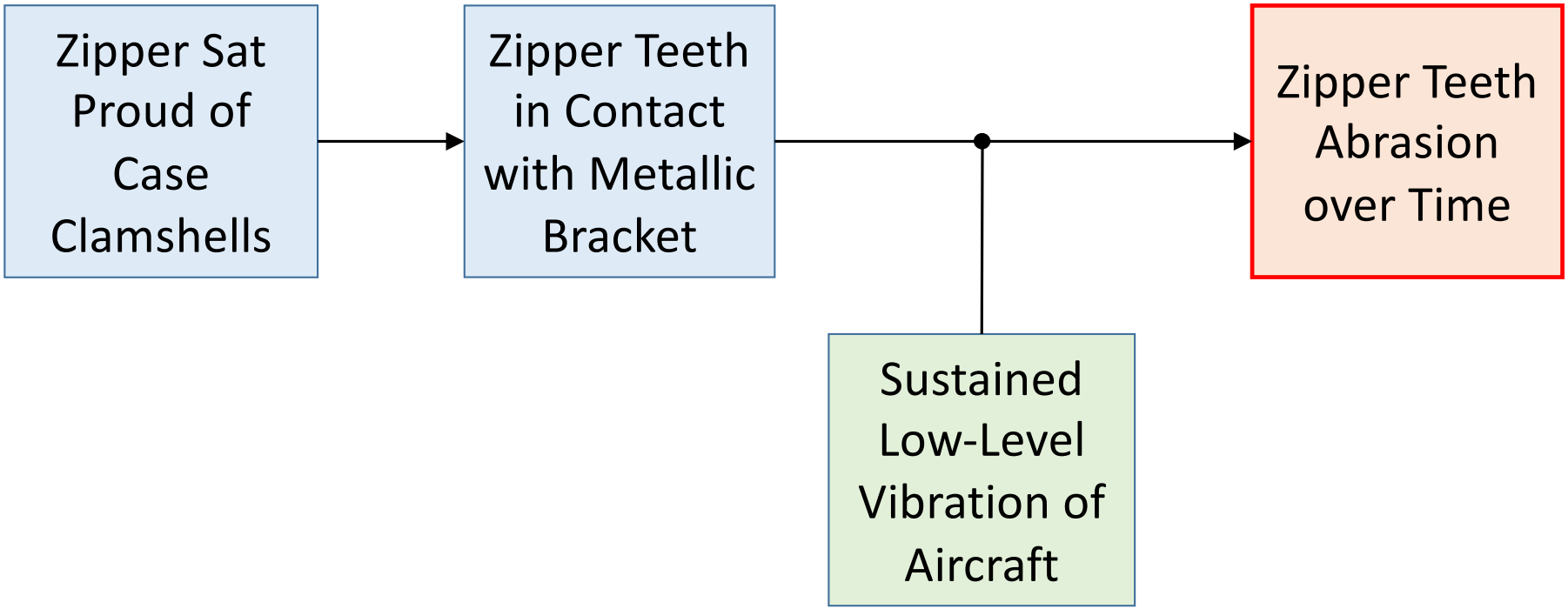
- Loaded Carrying Case Stored in Metallic Bracket in Aircraft Storage Compartment

Observed Damage

- Customer Complaints in 2013-2014
  - Observed Damage (Abrasion) to Zipper Teeth and Zipper Fabric
  - Difficulty Closing Case Due to Damage
- Loaded Carrying Case Stored in Metallic Bracket in Aircraft Storage Compartment
- NO SAFETY IMPLICATIONS CITED



Technical Root Cause



Costs

- Customer Satisfaction & Confidence
  - Product Damage
  - Availability
- Company Reputation
- CAPA Manpower and Duration
- Case Redesign Effort

Could Have Been Avoided Through Early-Phase Systems Engineering

Risk-Benefit Analysis

- No Safety Risk Associated with Zipper Damage
  - No Risk to AED Functionality or Performance
  - Cases Open without Issue

- Customer Satisfaction Risk-Benefit Analysis
  - No Recall, But Communication Was Distributed to Customers
  - Case Availability Vs. Damage Occurrence

Best Practice: Design Change Process

- Initial Product Development Vs. Post-Market Design Changes
- "Minor" Vs. "Large" Design Changes

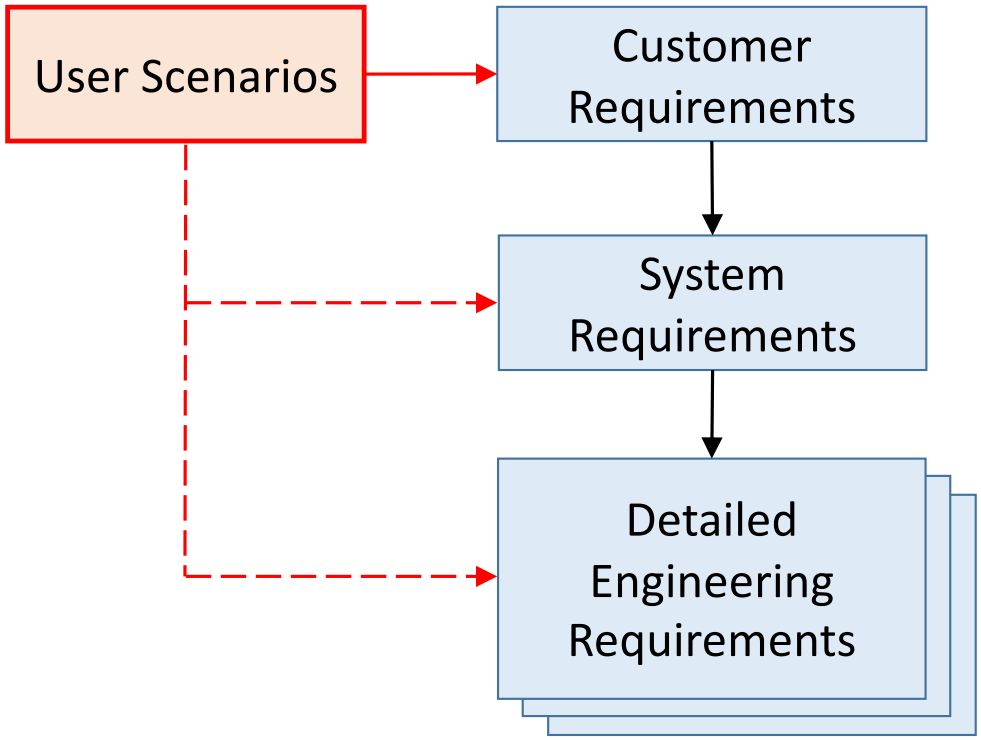
- Best Practices for Design Change Processes:
  - Thorough Design Change Impact Assessment
  - DFMEA and Risk Management Analysis
  - Verification/Validation Regression Analysis
  - Full Design Review

Best Practice: Ownership

- Systems Engineering Responsible End-to-End
- Inputs Should Be Incorporated into Design, Not Necessarily Taken AS Design
  - Marketing Requirements
  - Customer Requests
  - Off-The-Shelf Designs

Best Practice: User Scenarios

- Requirements Should Be Rooted in Clearly Defined User Scenarios
  - May Need To Go Beyond Established Standards
  - May Dictate How Requirements are Resolved at Lower Levels
  - May Determine Validation Methods
- Customer Requirements Need a Story Associated With Them



Summary

- AED Carrying Case Experienced Damage Due to Long-Duration Vibration
- Customer Dissatisfaction and Costs Could Have Been Avoided Through Early-Phase Systems Engineering (Specifically Good User Scenarios)
- Case Study Highlights Systems Engineering Tenets of End-to-End Ownership, Thorough Design Change Processes, and Clear Definition of User Scenarios

QUESTIONS?

https://www.usa.philips.com/healthcare/solutions/emergency-care-resuscitation

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Thank you for attending!

Share your experiences at #HWGSEC