Medical Device Interoperability

SE principles as an enabler to introduce system-of-systems for medtech devices

Christian Buser, Dr. Stefan Schlichting, 2020-09-16

Why do we need interoperable medical devices?

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The ability to view data and control devices from outside the patient´s room, as well as be informed about the alarm status

Ventilators

Infusion Pumps

Patient Monitoring

„Ingenuity.. this is one of MANY things that make me proud to be part of a great group of Respiratory Therapists! Removing the control monitor of Hamilton G5 ventilator and linking outside a closed door. RTs effectively limiting exposure and conservation of PPE!" – A. Smith BS, RRT-ACCS on LinkedIn

Source: https://bit.ly/2Robdw2

Interoperable Medical Device System that limits staff exposure

Todays most Common Integration Pattern

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A traditional integration pattern provides certain limitations

BC2

How could an interoperable System of Products look like?

SoP: A interoperable system of product consists of product from various vendors

Slide 4

BC2 Buser, Christian, 20/05/2020

Challenges for SoP

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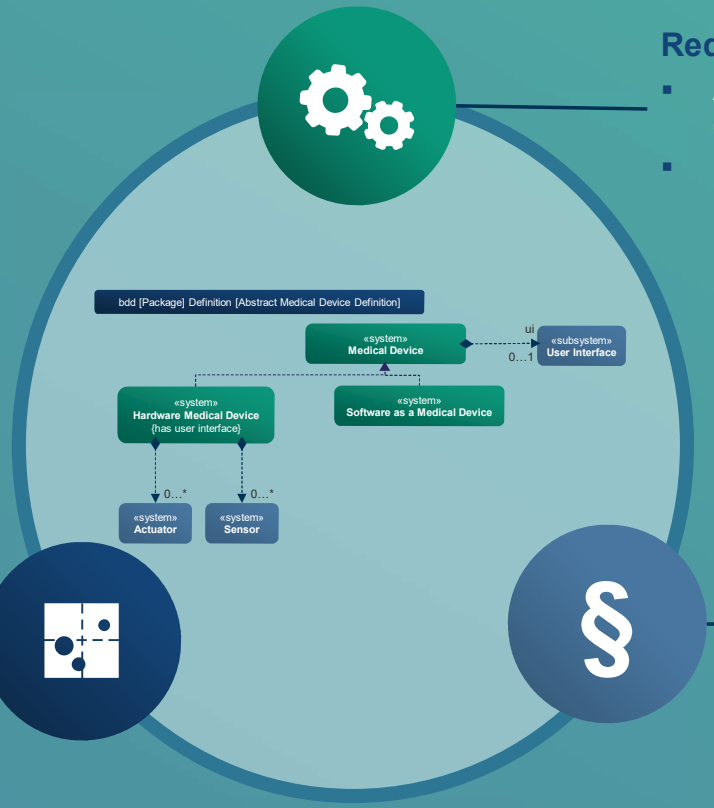
Requirements / Achitecture definition challenges

- Allocation of responsibilities of requirements and interface definition missing
- Flexibility to react on independent changes



Strategic challenges

- Lack of planning security
- New role of vendor

V & V challenges

- Feasibility of end-to-end testing
- Single “authority” responsible for the entire SoP is absent

System engineering provides a suitable toolbox to tackle the challenges. However, the lack of responsibility has to be resolved.

Strategic Challenges

Possible Business Roles of within SoP

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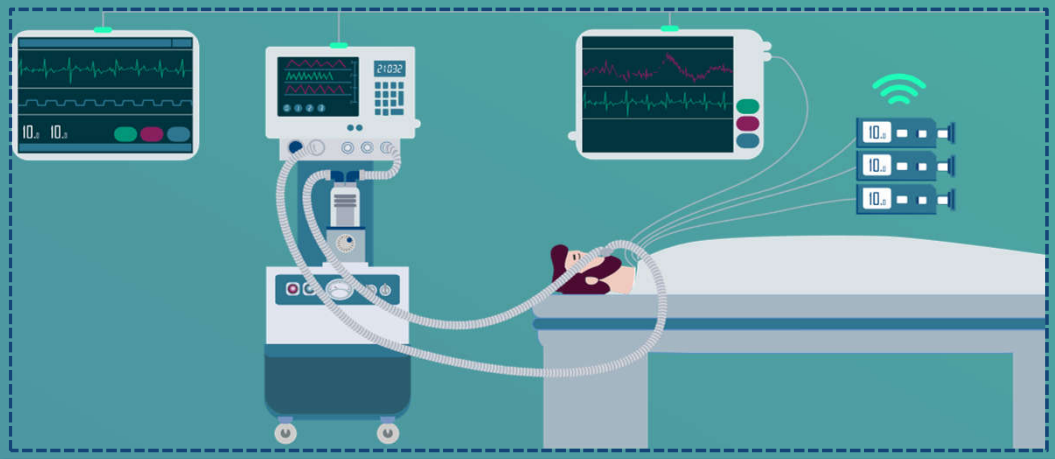


System function provider:

- SoP element which by itself is not fulfilling a medical intended purpose
- Dependent on collaboration

Constituent system provider:

- SoP element with a standalone medical intended purpose and contributing to the SoP

System integrator:

- ensures the integration of all devices
- responsible for operation of SoP

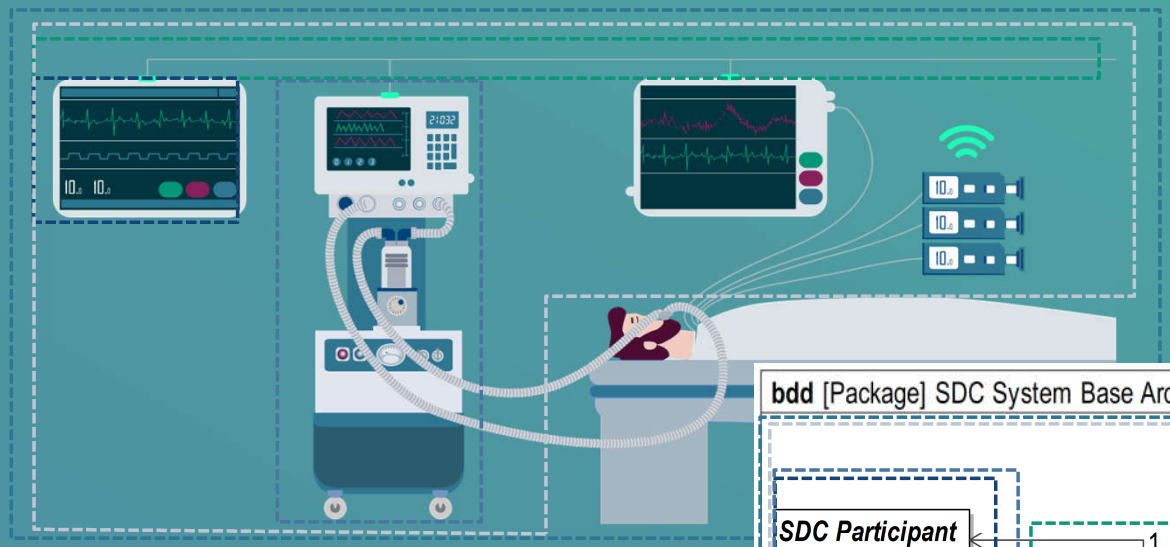
System-of-systems Manufacturer

- Provides a full SoP

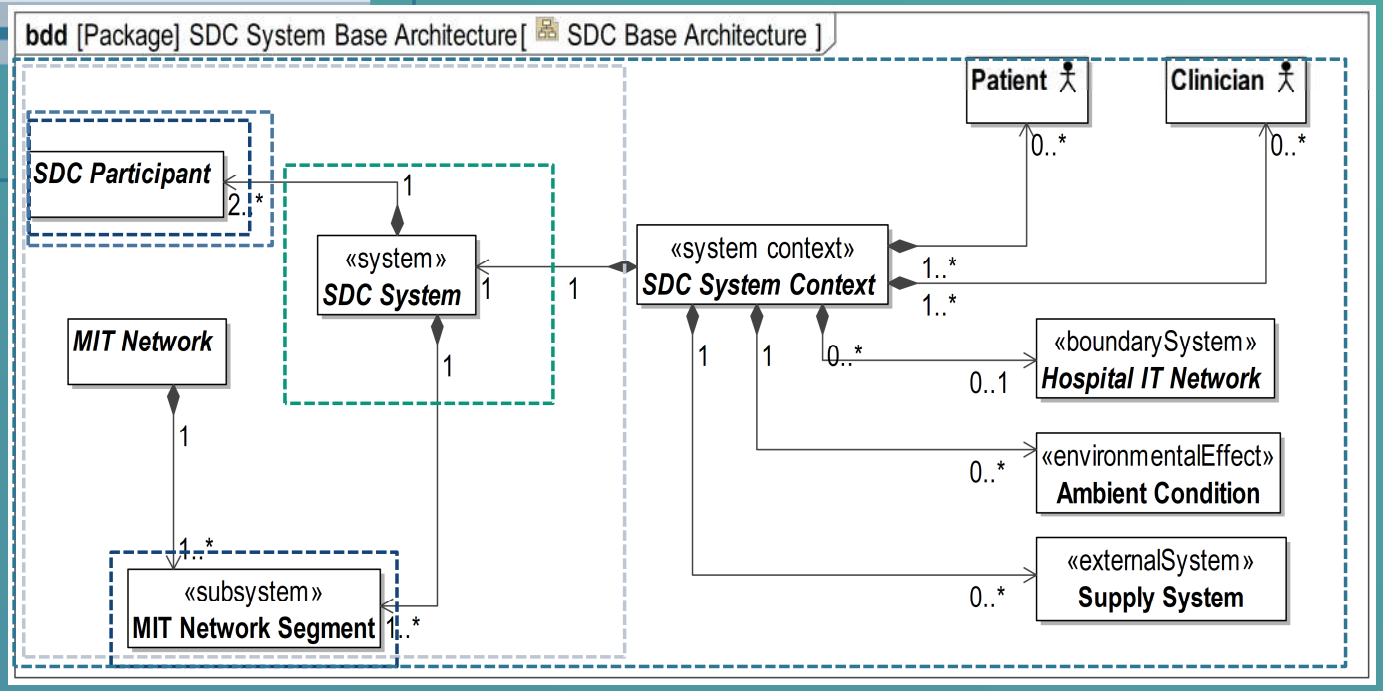
SoP Operator

- Operates the SoP on daily basis (maintenance, monitoring)

Medical device SoP & its context



- System Function Provider
- Constituent System Provider
- System Integrator
- SoP manufacturer
- SoP Operator



Implication of interoperable SoP on Requirement / Architecture

Traditional SE approach cannot fulfill the requriements

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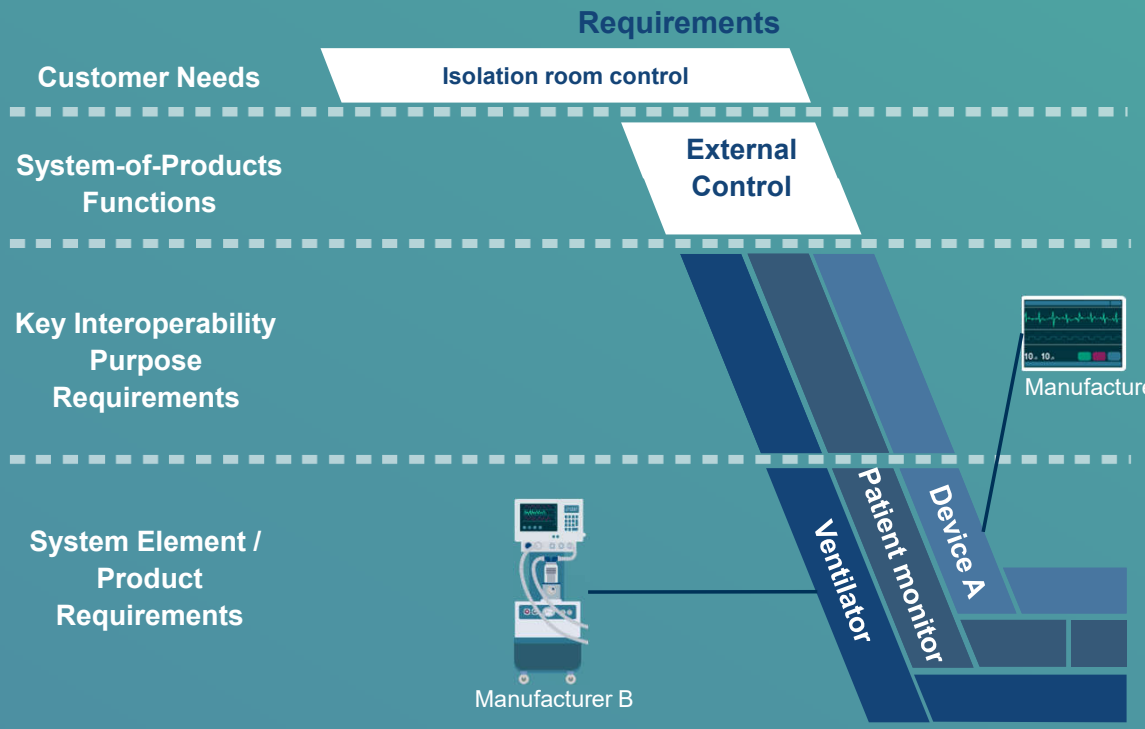
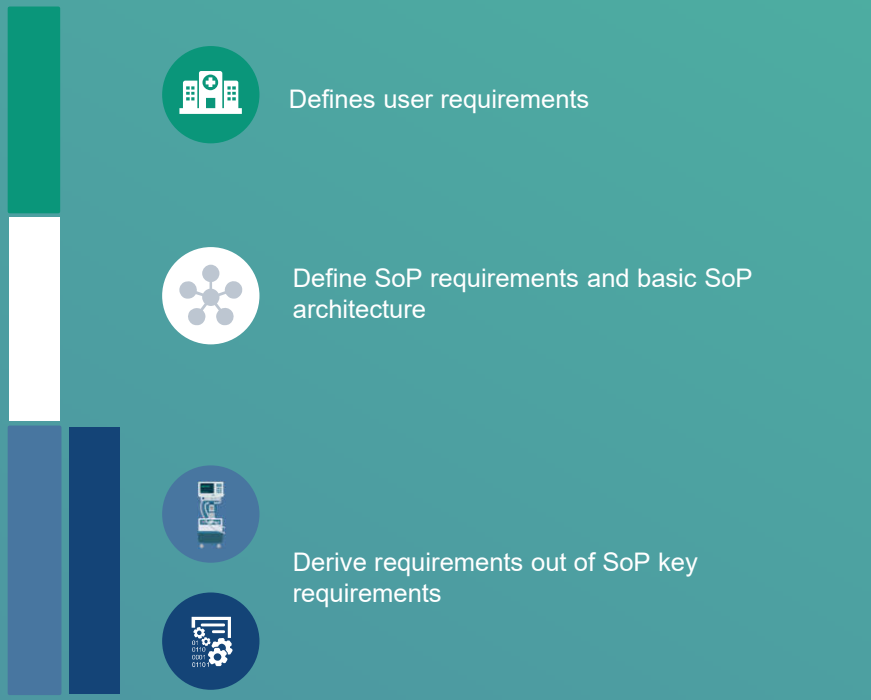


Role within requirement / architecture definition



Using the traditional SE approach leads to a lack of responsibility between the User requirements of the system-of-system and the system requirements / architecture of the constituent systems and functions

Possible solution to lack of requirement / architecture ownership

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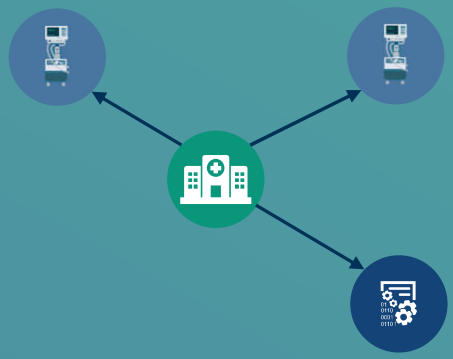
Centralized



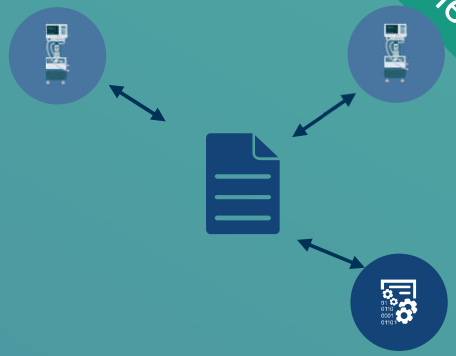
The **system integrator** defines the overall SoP

- Overall responsibility
- Degraded to executor
- Degraded to executer
- Endangered
- Technology push prevented

Not Feasible

Harmonized

Medtec

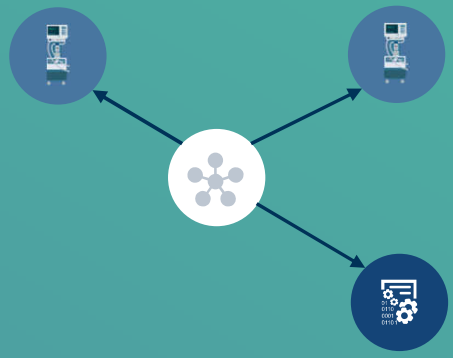


Participants of a SoP agree to common rules which are jointly set

- Can configure SoP based on available products. Does not have overall responsibility
- Use of harmonized approach eases internal coordination
- System development independent of other systems.
- Reduction of development cycles
- Function development independent of other products
- Reduction of development cycles

Feasible

Hierarchical



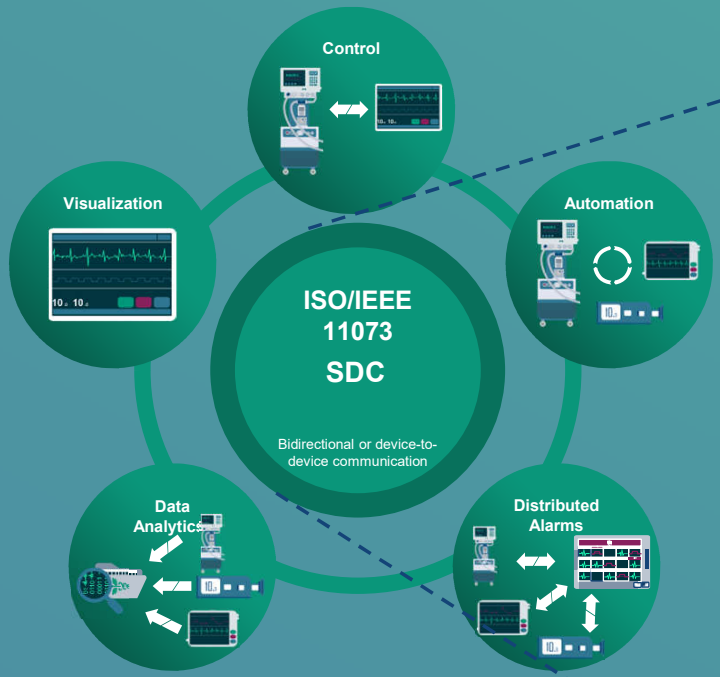
Participants use their **own rules**, but show them transparent to others

- Can configure SoP based on available products. Does not have overall responsibility
- Defines his rules and force smaller vendors to adapt
- Need to adapt to large manufacturer rules
- Will become provider to manufacturer
- Need to adapt to large manufacturer rules
- Will become provider to manufacturer

Feasible

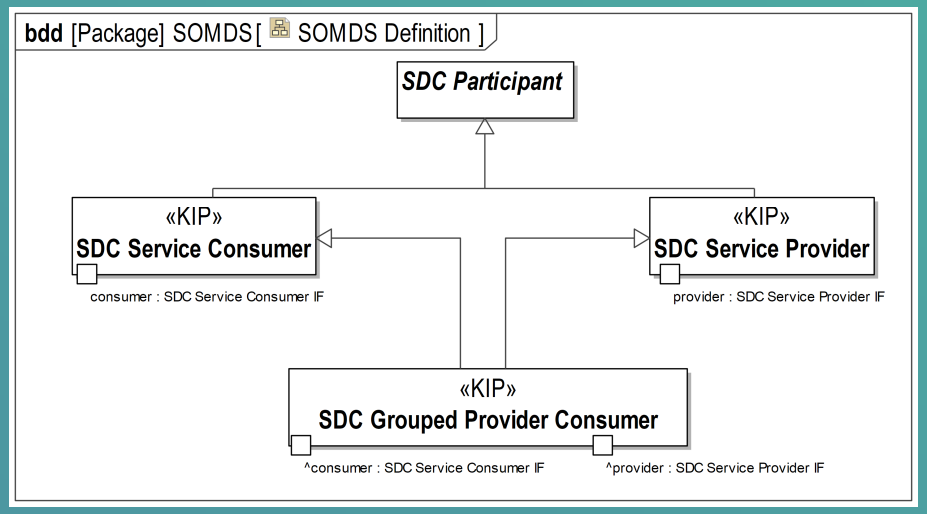
Medical Device Approach to overcome interface challenges

Interoperable Medical Device System Functions



- Defined functional architecture of SoP
- Defined interface of SoP
- Defined SoP requirements to device

Logic of the different roles and their interactions



Responsibility and Validation Challenges

Verification and validation responsibilities

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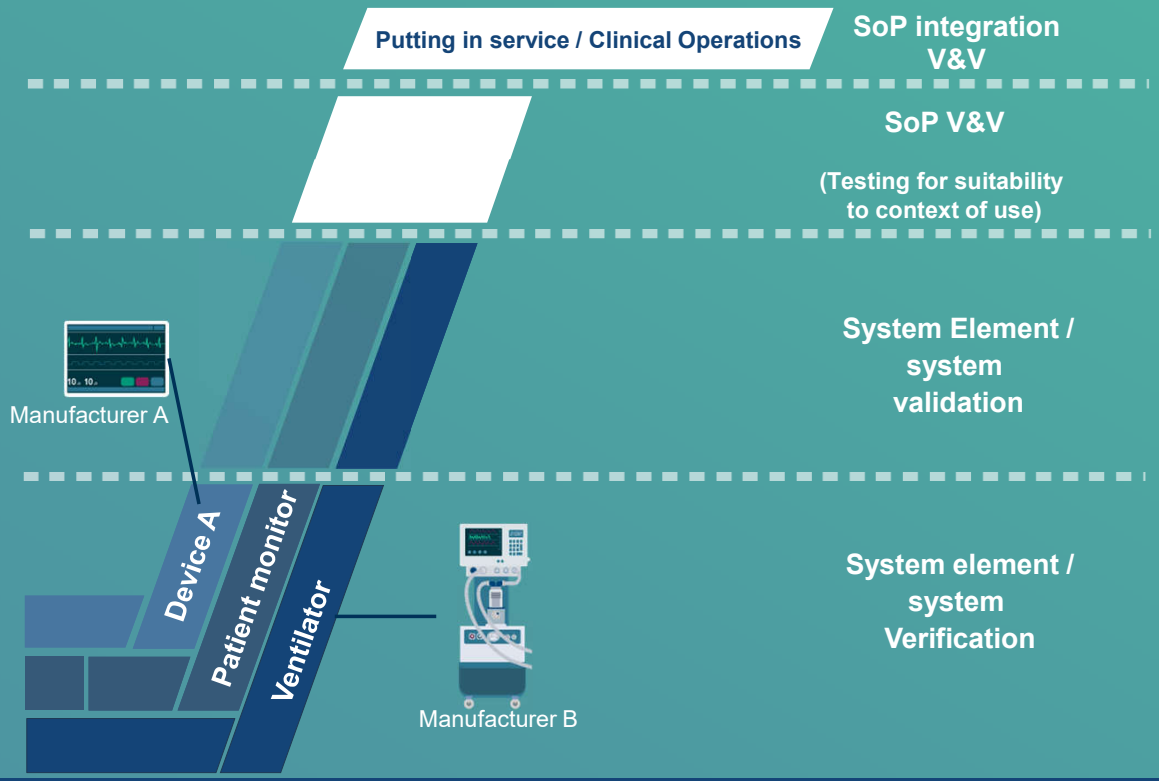
V & V for integration into surrounding SoP (e.g. hospital network)

End-to-end testing of system-of-system functionality

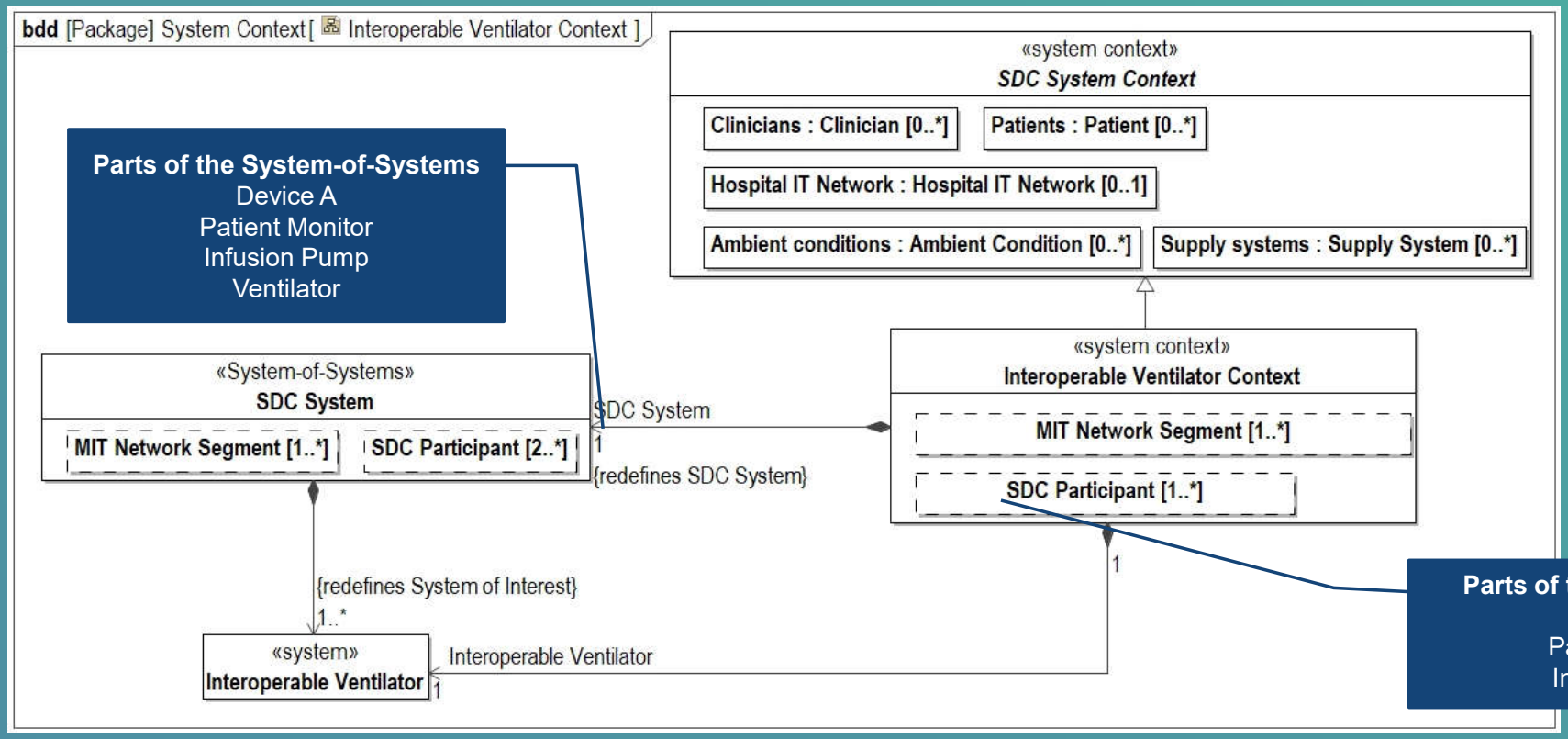
V&V for constituent system

Verifies and validates single functions but not integration in SoP



A lack of end-to-end testing responsibility is observed in traditional SE approach

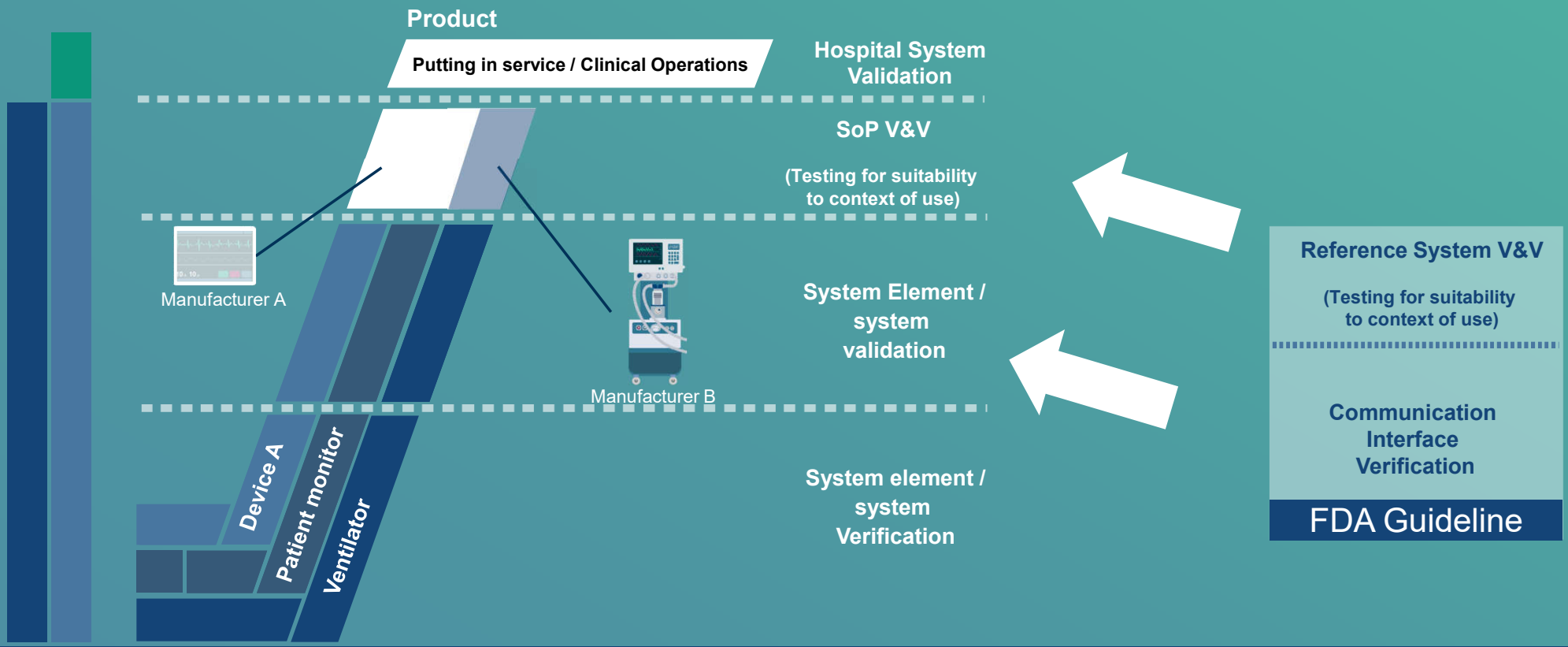
Solution to lack of responsibility in verification / validation



Verification/validation of products can be performed by means of interface verification and reference system testing

Verification and validation responsibilities

Example Medical Device



Introducing system reference testing and system interface verification enables to empower the constituent system providers to take full responsibility of their system within a SoP

Summary

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Challenges:

- Lack of planning security
- New role of organization

Solution:

- Using appropriate roles and defined rules within a SoP will help to enable organizations to plan their devices

- Lack of requirements and interface definition
- Flexibility to react on independent changes

- Base architecture with core functions and interfaces
- Harmonized way fosters innovation

- Feasibility of end-to-end
- Single authority responsible for the entire SoP is absent

- Interface testing and reference system testing
- MBSE can support this procedure

To ensure success in a SoP, the vendors role and its interfaces to other products must be clear. Using approaches of harmonized rules ensures the efficient closing of responsibility gaps within the development.

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