OR.NET e.V.

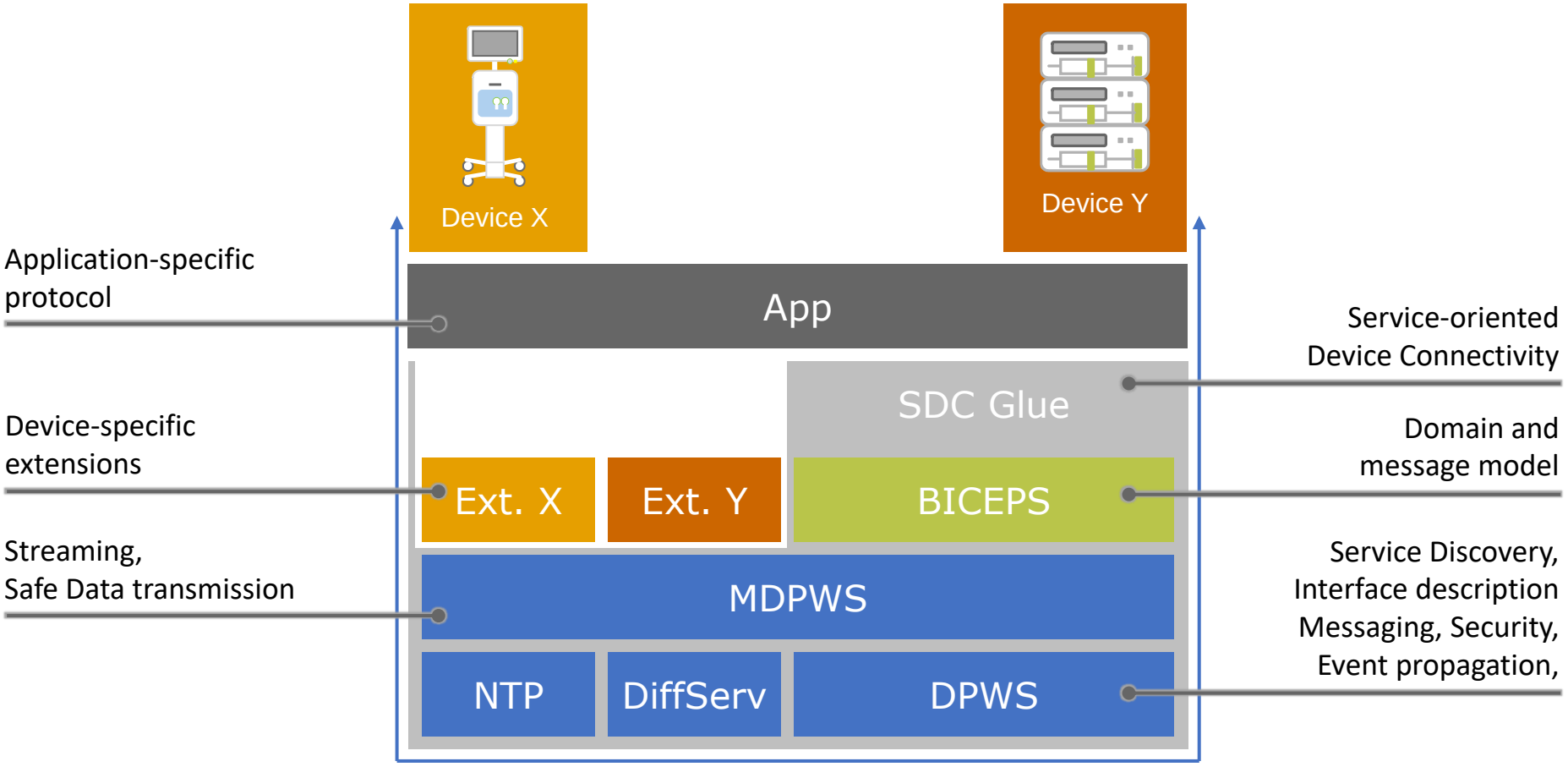
IEEE P11073-10700 Overview

Dr. David Gregorczyk
Director of Standardization @ OR.NET
System Architect @ Drägerwerk AG

Agenda

- Short recapture of the SDC Core standards
- The SDC cathedral window
- Main objectives of the Base PKP

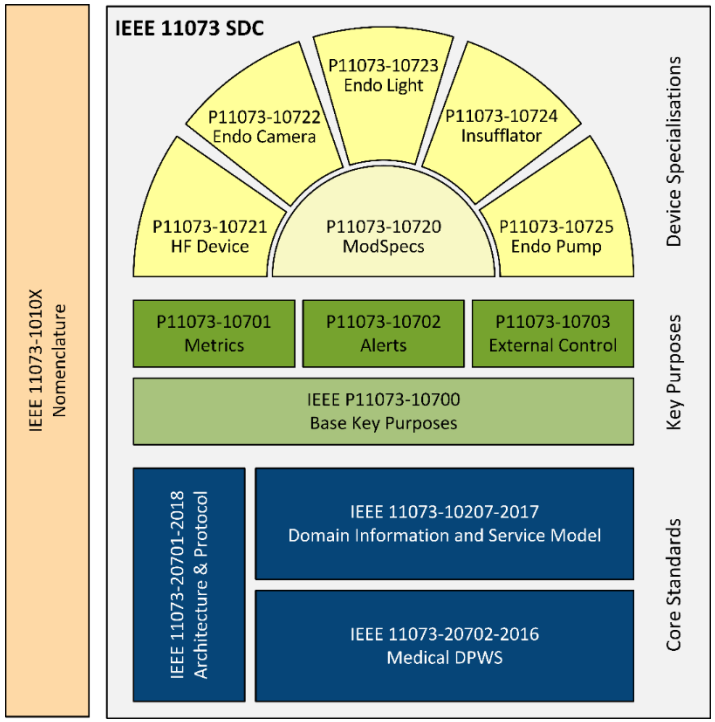
The SDC core standards



The SDC cathedral window

Nomenclature provides semantics for communicated data by introducing a mapping of concepts to unambiguous codes

Core standards provide technical basis for secure and interoperable exchange of medical data



Device Specializations provide

- Detailed specification of different types of devices including containment trees
- Modular containment tree building blocks that can be re-used across different specializations
- Optional but extremely helpful to enable vendor independent interoperability by standardized device representations

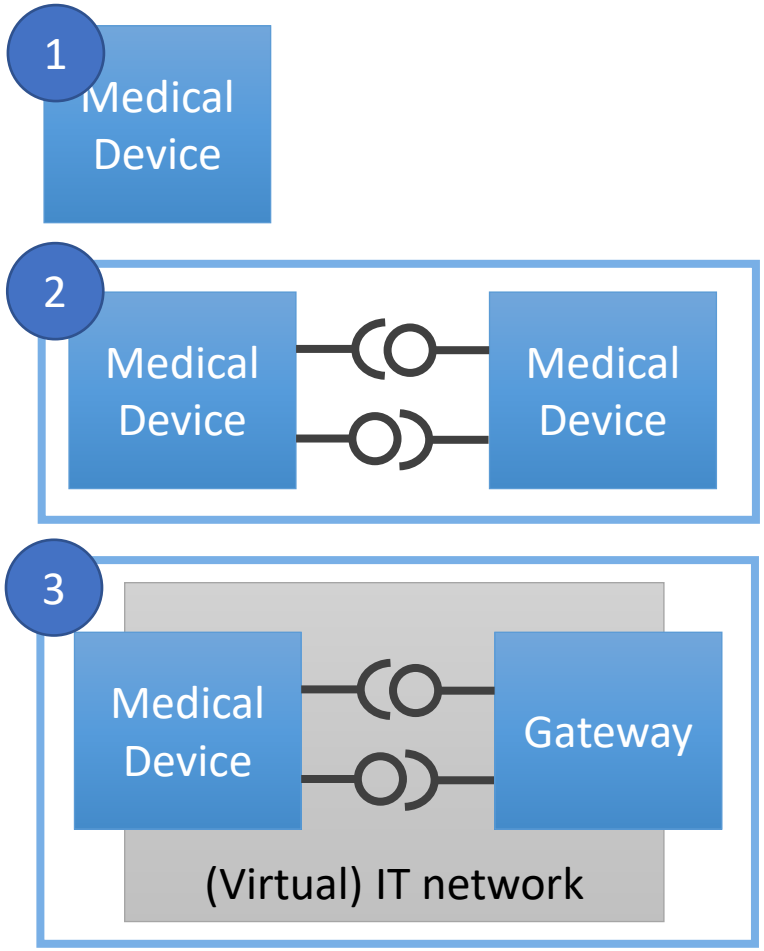
PKP standards provide

- Technical design and process requirements to ensure safe execution of clinical functions in an SDC system
- Assignment of responsibilities to allow for safe operation of devices in an SDC system
- Support market approvals for individual devices as components participating in an SDC system

Definition

- **SDC participant**
  A software system that runs SDC
- **SDC system**
  System of SDC participants that is operated in a medical IT network
- **SDC service provider**
  An SDC participant that provides a network interface to access MDIB data and external control
- **SDC service consumer**
  An SDC participant that consumes MDIB data and external control at an SDC service provider‘s network interface
- **Manufacturer**
  Legal person with responsibility for the design, manufacture, packaging, labelling of medical equipment, systems etc.
- **Responsible organization**
  Entity accountable for the use and maintenance of a medical equipment and IT networks in which medical equipment is operated

Conventional medical devices



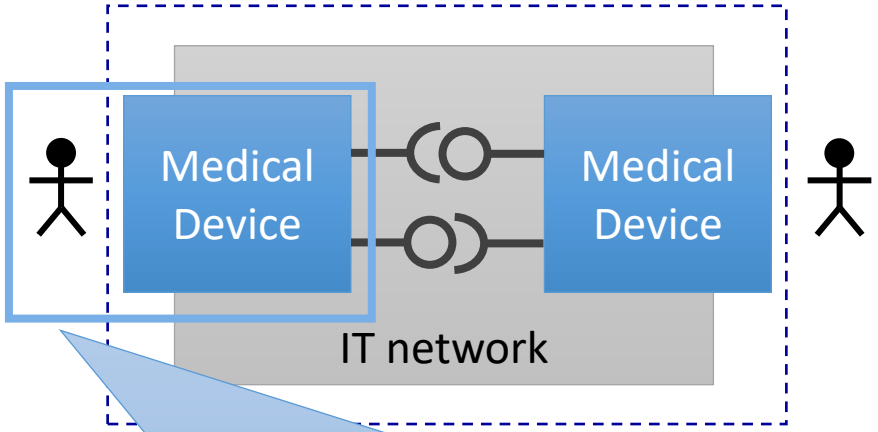
- Safety, security, and efficiency is primarily in responsibility of one manufacturer
  1. Standalone devices, e.g. anesthesia machines, infusion pumps, …
  2. Device combinations running on proprietary solutions, e.g. ventilator + infusion pump
  3. Device combinations communicating via a (virtual) IT network, e.g. patient monitor + HL7 gateway
- Safety & effectiveness of devices and combinations is ensured by one manufacturer
- Combinations are known a-priori and are considered throughout the development and deployment processes

Challenge: unknown device combinations I

- An SDC System is instantiated by a responsible organization using SDC participants from potentially different manufacturers. This does not make the hospital a medical device manufacturer.
- By leveraging SDC, manufacturers are no longer developing devices for a known system that is under sole control by them
- Manufacturers now need to develop devices that can be used safely and effectively
  - in a dynamic system of unknown devices operated in a medical IT network
  - in combination with other “SDC conformant” products from the same or a different vendor

Challenge: unknown device combinations II

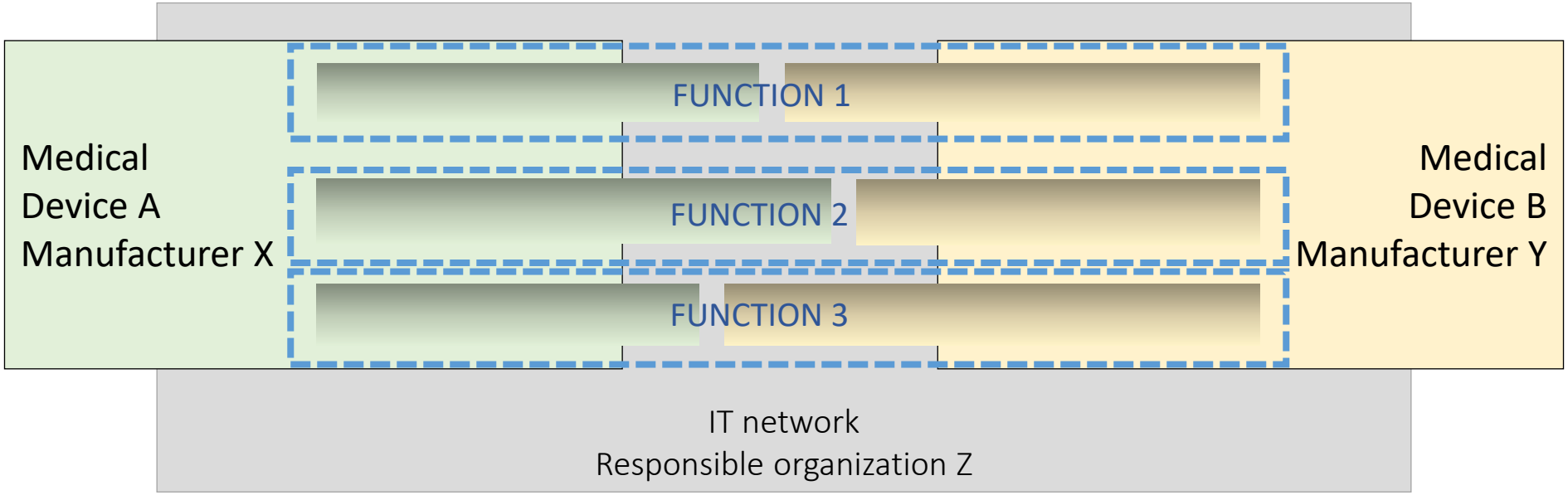
Dashed line: SDC system boundaries;
encompass all devices including the IT network w/o users



Blue line: process scope of the manufacturer;
responsibility for the IT network nearly impossible;
manufacturer is not responsible for user interactions at medical devices from other vendors/device types

PKP approach: consistently split responsibilities

- Guidance is given w.r.t. technical design, quality, risk management, verification, usability, post-production
- Manufacturers follow PKP requirements which makes them trustworthy for other manufacturers



Main topics of the Base PKP (10700)

System functions and system function contributions

Safety & essential performance standards indication

SDC participant ensembles

Definition

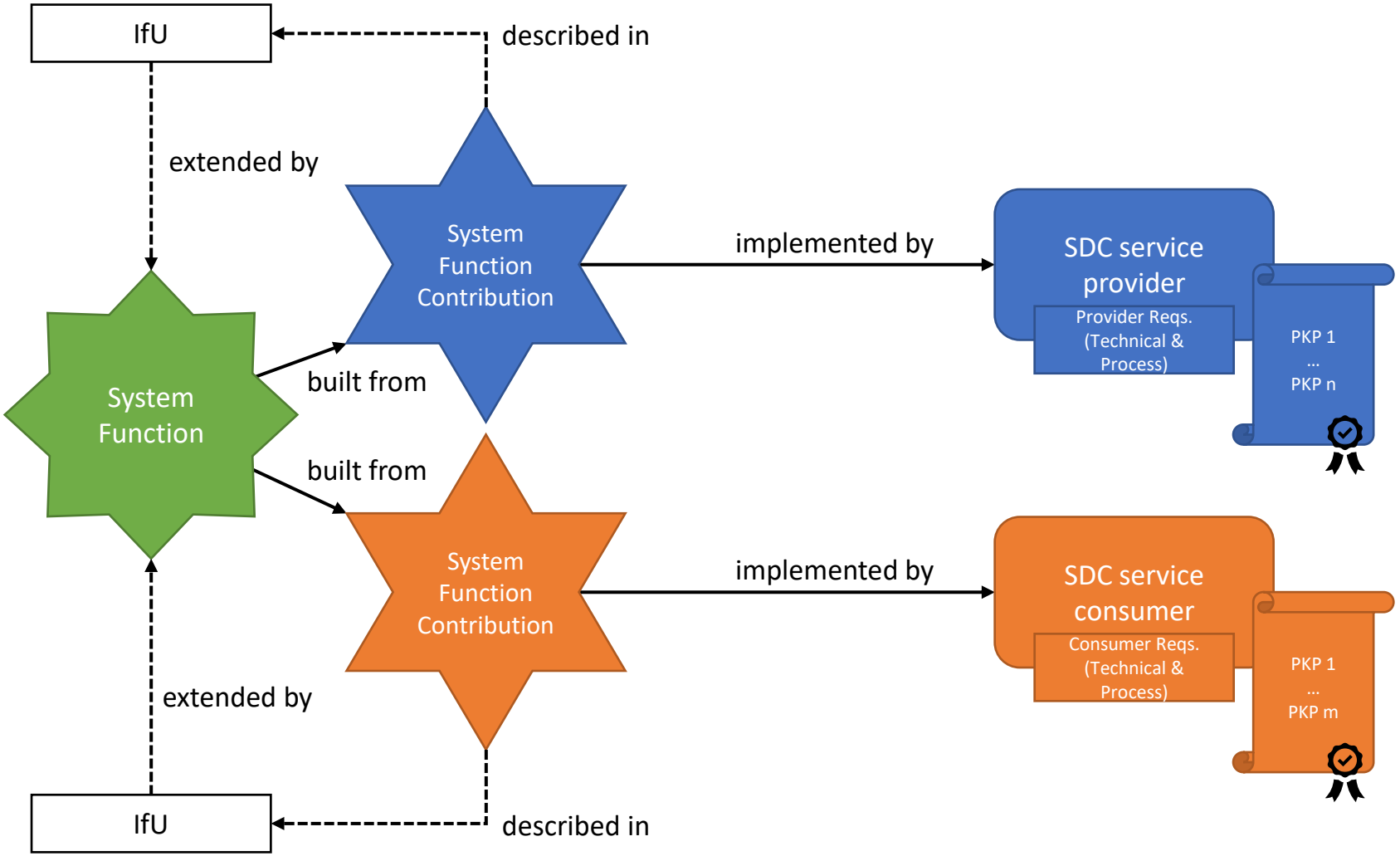
- **System function**

  Clinical function provided by a system of SDC participants that are connected by a medical IT network

- **System function contribution**

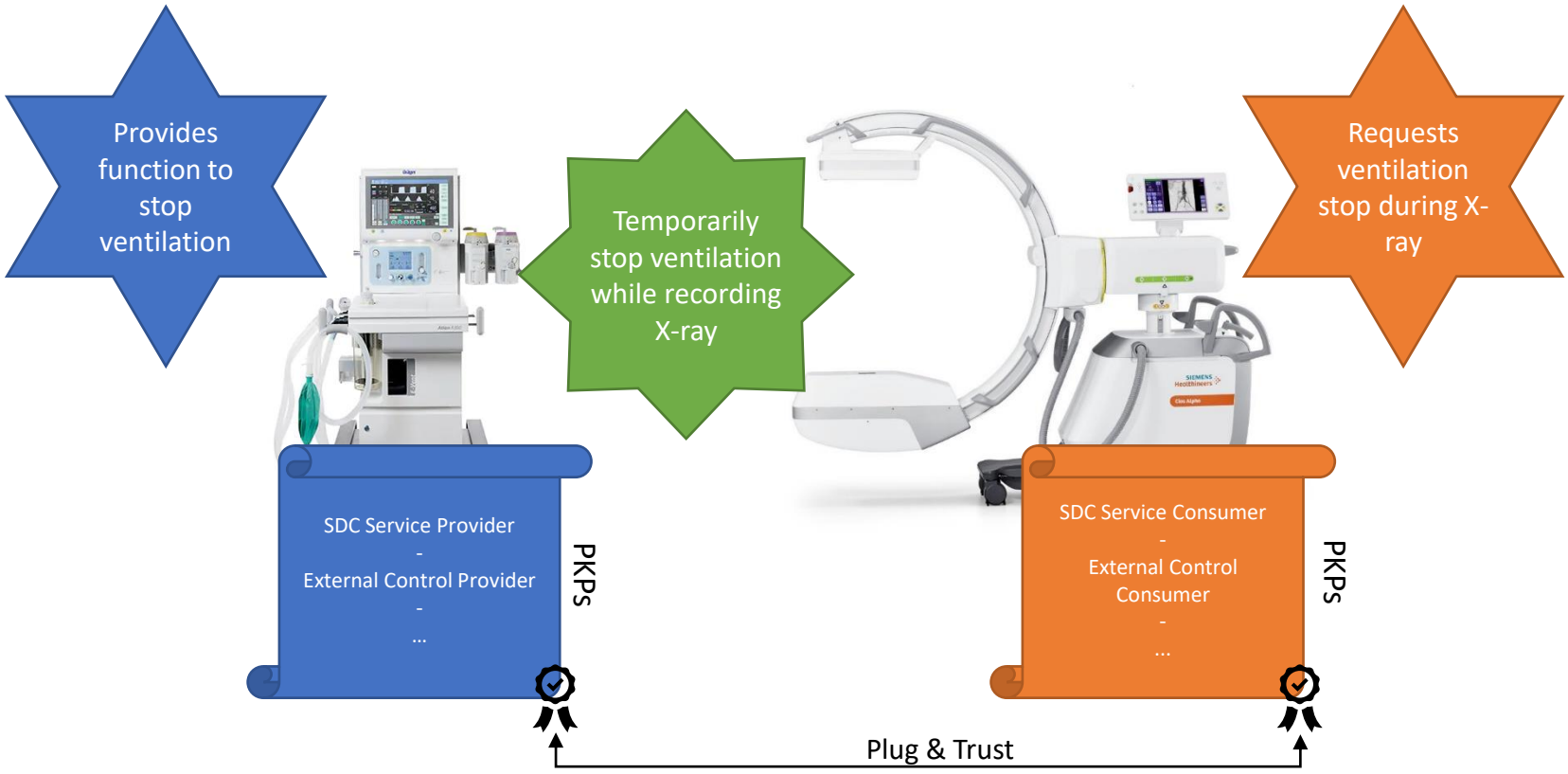
  Function of an SDC participant that contributes to a system function

System functions and SF contributions



OR.NET e.V.

Example: Ventilator + C-arm



Example setup brought to you by MD PnP [http://www.mdpnp.org/uploads/MDPnP_Booklet_February_2007_p1-21.pdf]

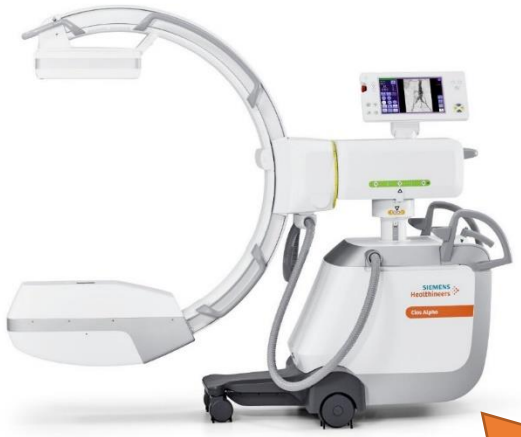
Safety & Essential Performance Indication I

- There are system functions that may come with specific safety and essential performance requirements
- A manufacturer of an SDC service provider is aware of the requirements the provider fulfills
- The SDC service consumer may not be aware of such requirements, e.g. particular standards that apply to the SDC service provider

Necessary information is added to an SDC service provider‘s MDIB. This allows SDC service consumers to identify if there are additional safety and essential performance requirements applied to the SDC service provider.

Safety & Essential Performance Indication II

Provider: I am in compliance with particular standard X



Consumer: I am in compliance with applicable requirements from particular standard X for any provider that is complying to that standard as well.

SDC participant ensembles

- Condition under which an SDC participant is permitted to execute a system function with another SDC participant
  - Prerequisite: both participants have at least one ensemble context identification in common
- Base PKP provides the technical framework
  - No assumption on how the ensemble context state information is retrieved
  - Inference of location and patient context states are available

Thank you!

David Gregorczyk
OR.NET e.V. Director of Standardization
System Architect @ Drägerwerk AG, Germany

david.gregorczyk@draeger.com