Secure and Safe Medical Device Interoperability in Acute Care

Session 108, March 11, 2020

Adapted for / Presented To:

IHE Devices @ 2020.03.25

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HIMSS20

Meet Our Speakers

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Agenda

- Problem Statement: The Interoperability Challenge
- What is SDC?
- IHE Devices and SDC
- How SDC can help in solving todays alarm management mess

Learning Objectives

@ 25.03.20 IHE Update:
With COVID-19 consuming the world's full attention, the acute need to prioritize the advancement of interoperable health and medical technology has never been greater!

- Describe Medical Device Interoperability use case including Silent ICU and interoperable surgical interventions
- Describe IHE Devices & IEEE 11073 SDC standards family
- Explain how IHE Devices & IEEE 11073 SDC standards family is used to develop vendor-independent Medical Apps that solve the challenges for the Medical Device Interoperability use cases
- Identify the regulatory challenges for Medical Device Interoperability
- Identify the benefits for the Hospital and why they should buy interoperable Medical Devices that conform with international standards

THE INTEROPERABILITY CHALLENGE


Cumbersome Integration


Limited Remote Control

"Interoperability is an almost non-existent feature of medical devices"

-- Lesh et al 2007


Minimal Digitization

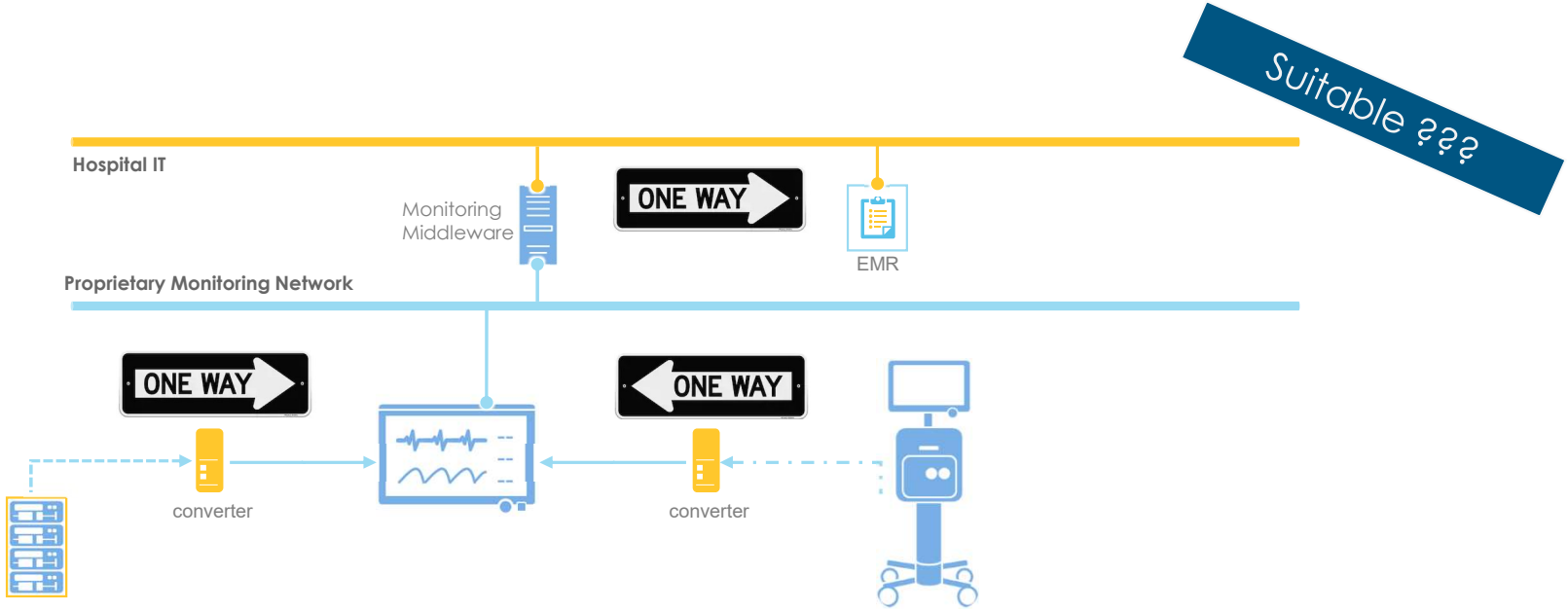

Excessive Alarming

Device point-of-care interoperability (DPI)

- **Patient Safety is Job #1**
  - External Device Control, Closed-loop, Autonomous Systems – How hard can that be?
- **Connectivity: Device-to-Device with Constraints**
- **"Hard" Real-time at Clinician Speed!**
- **Technology Evolution & Innovation & Safety: Maintaining Balance**
- **Device "Modalities" vs. Use Contexts: Semantics & Pragmatics**
- **Regulatory Science Challenges**

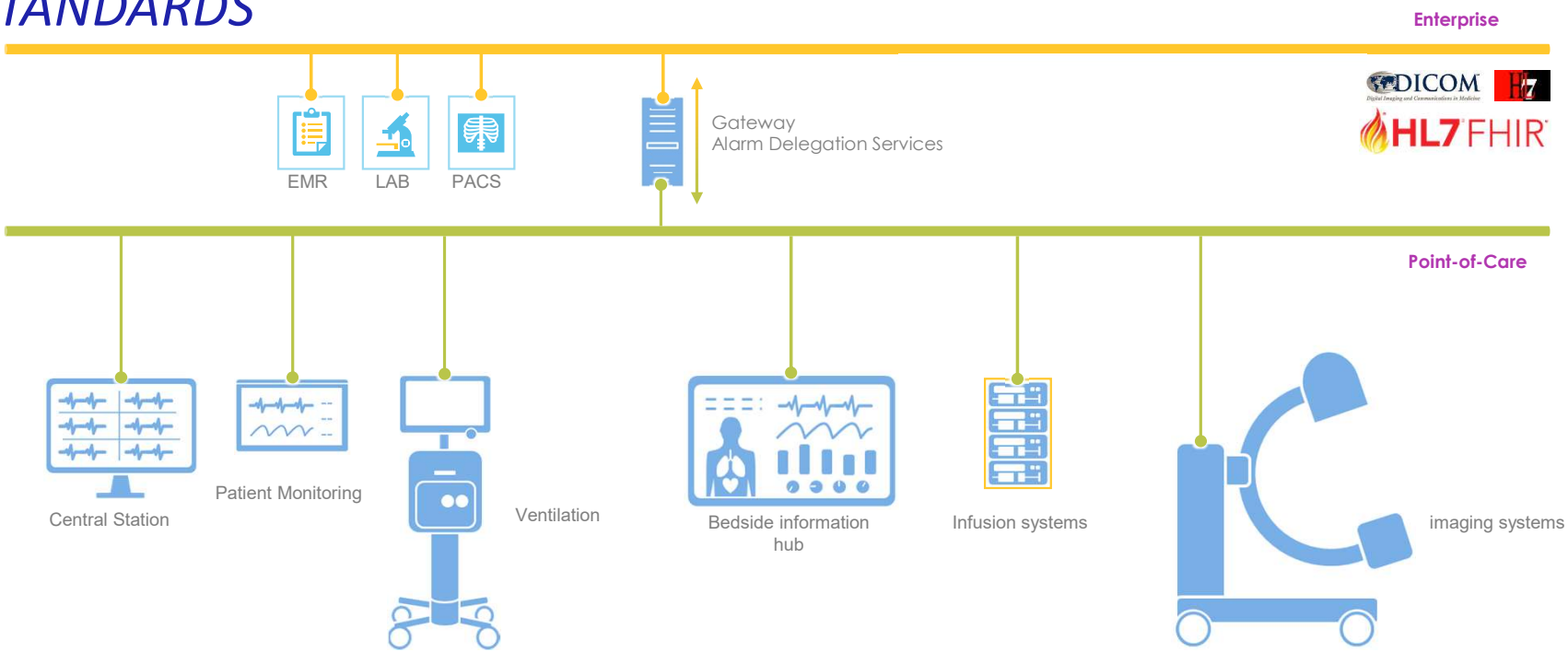
DPI remains a Business Problem, not a Technical Problem

Hospital Connectivity Today?



- Proprietary Protocols
- Incomplete Data Transfer
- Unidirectional communication
- Limited Security

HOSPITAL INTEROPERABILITY STANDARDS

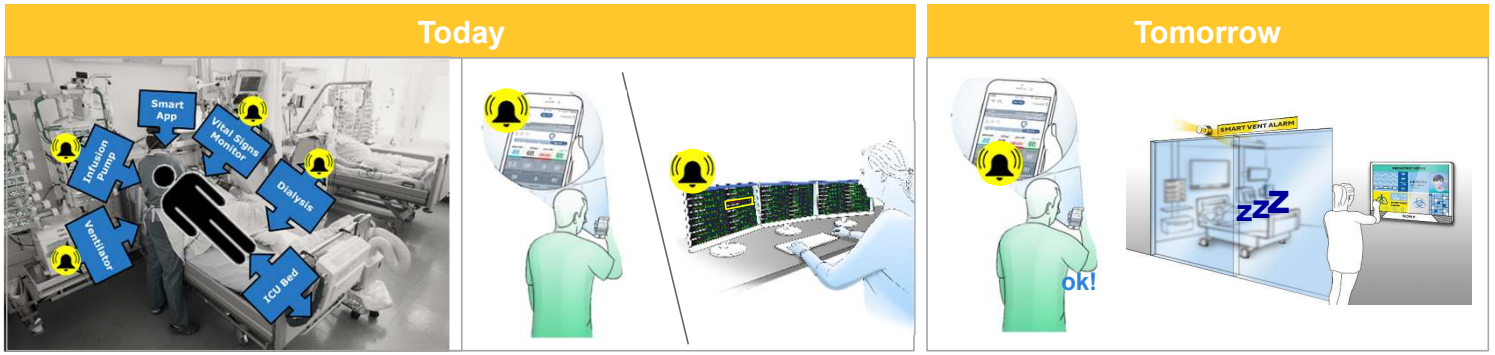


No Standard available ?

SDC

SERVICE-ORIENTED DEVICE CONNECTIVITY

ALARM MANAGEMENT
SILENT ICU BY ALARM SIGNAL DELEGATION



~ 80 - 95 % clinically irrelevant

up to 40 min. to alarm confirmation

50 % are not noticed

~ 40 different sounds in one ICU

Reduction of alarms

Alarm Distribution

road to **1** alarming device per patient

Alert Signal Delegation
Requirements

"**Delegation**" – *Safely enabling one system to annunciate alerts on the behalf of another system*

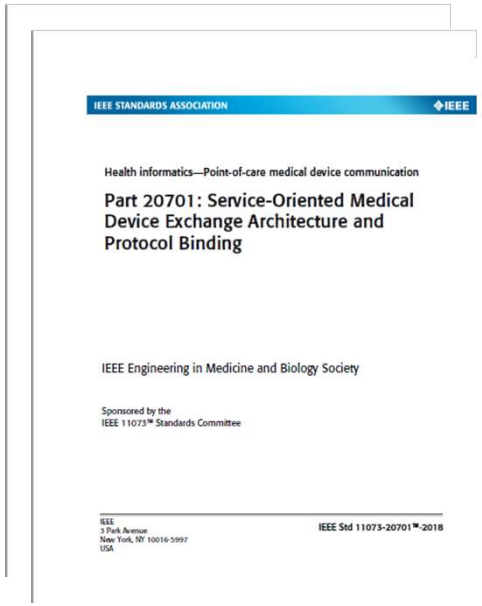
1. The alarm producer has to make **all information available** that are necessary for the remote alarm notifiers, like alert condition presence, alert manifestation, etc. **Interoperability** and semantical interpretability have to be ensured.
2. The system has to be suitable for **multiple alarm producers** and **several remote alarm notifying devices**.
3. The alarm producer has to be able to determine whether other devices are **ready to generate the alarm notification**.
4. The alarm producer has to be able to observe that the **alert is generated correctly**.

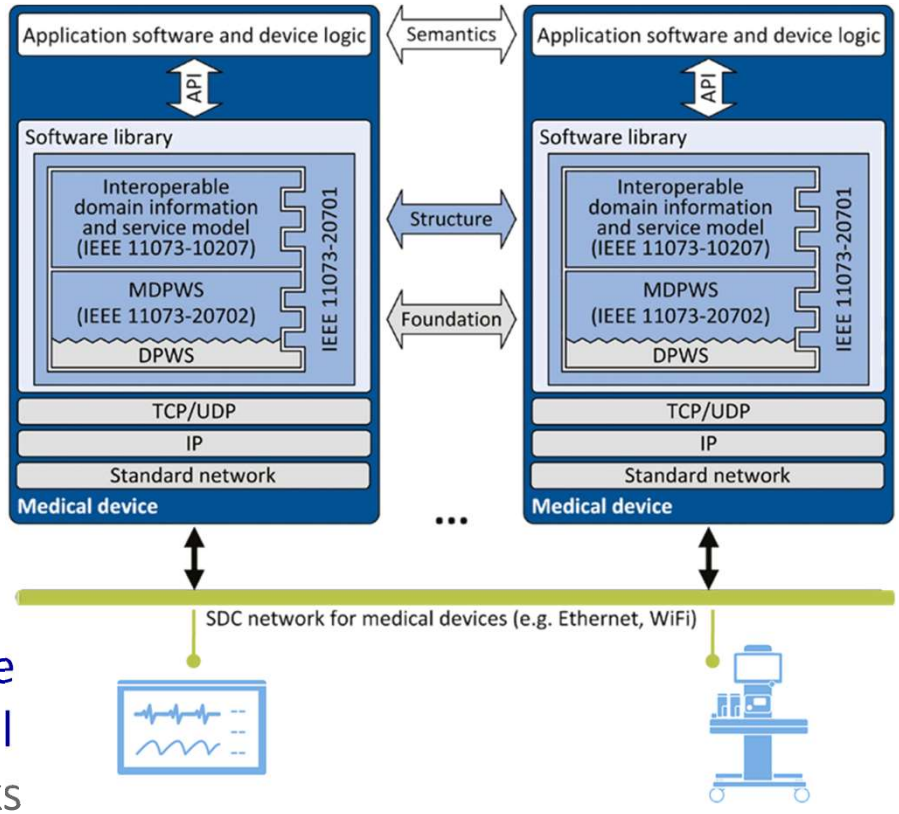
Some more information: „A Safe and Interoperable Distributed Alarm Notification System for PoC Medical Devices using IEEE 11073 SDC", Kasparick et al.

What is SDC?

What is SDC?

Service-oriented Device Connectivity





A family of international standards for interoperable exchange of real-time information between medical devices and external systems in dynamic IP networks

IEEE 11073 STANDARDS FAMILY

OR.NET e.V.

Standardization driven by OR.NET e.V. with approximately 50 partners, ranging over medical device manufacturers, clinic operators, standardization organizations and universities.

ISO

IEEE

&

SDC Project History
From an idea to an international standard

2004

2004 | 2010 | 2011 | 2013 | 2015 | 2016 | 2017 | 2018

BMBF Vision SOMIT FUSION / OrthoMIT
Foundation for the idea of interoperability

TekoMed
Feasibility study to prove the SOA approach for medical devices

Dienst-Orientierte OP Integration (DOOP)
Networking project with various medical vendors to implement DPWS and demonstrate interoperability

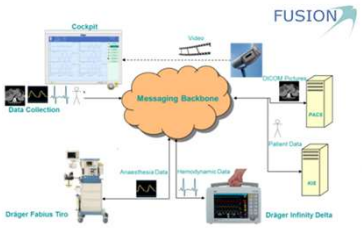
BMBF-OR.NET
A project funded by the German Ministry of Education and Research to consolidate all medical device interoperability research activities in Germany

OR.NET Consortium
An association of different stakeholders in medical device interoperability

IEEE 11073-20702
Standard approved Medical Devices Communication Profile for Web Services

IEEE 11073-10207
Standard approved Domain Information and Service Model for Service-Oriented Point-of-Care Medical Device Communication

IEEE 11073-20701
Standard approved Service Oriented Medical Device Exchange Architecture & Protocol Binding



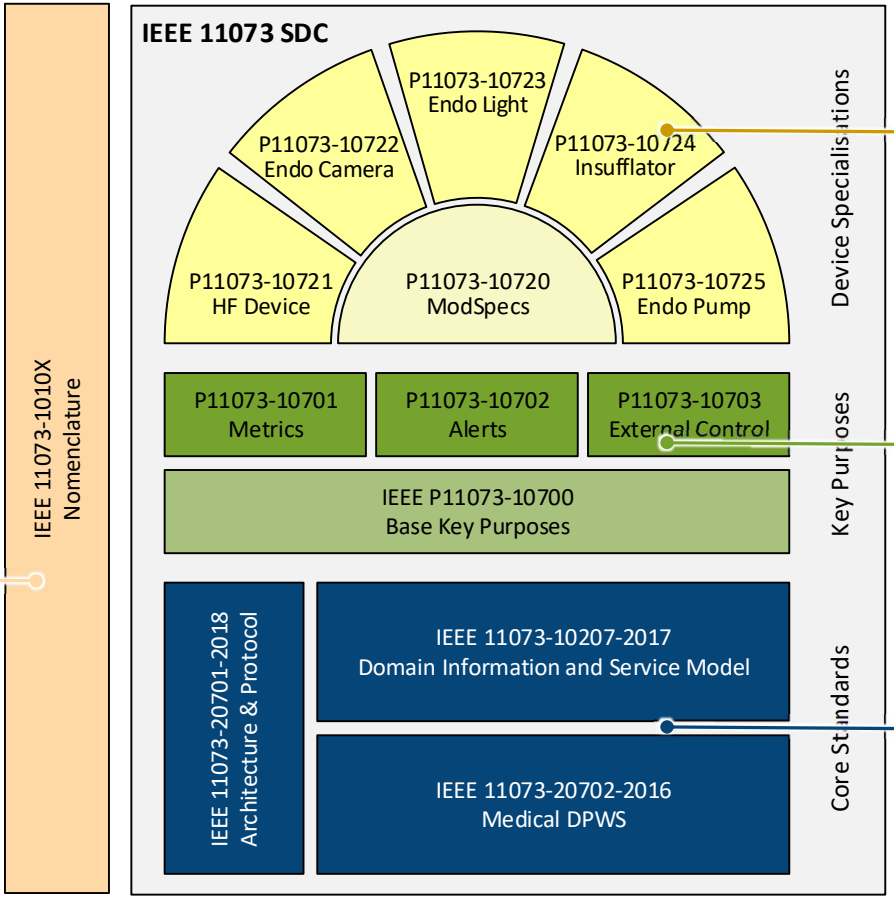
Demonstrator, 2009

Demonstrator, 2011

OR.NET, Berlin, 15/04/2015

DOOP Demonstrator, Lübeck, 11/12/2013

IEEE 11073 SDC Standards "Cathedral"



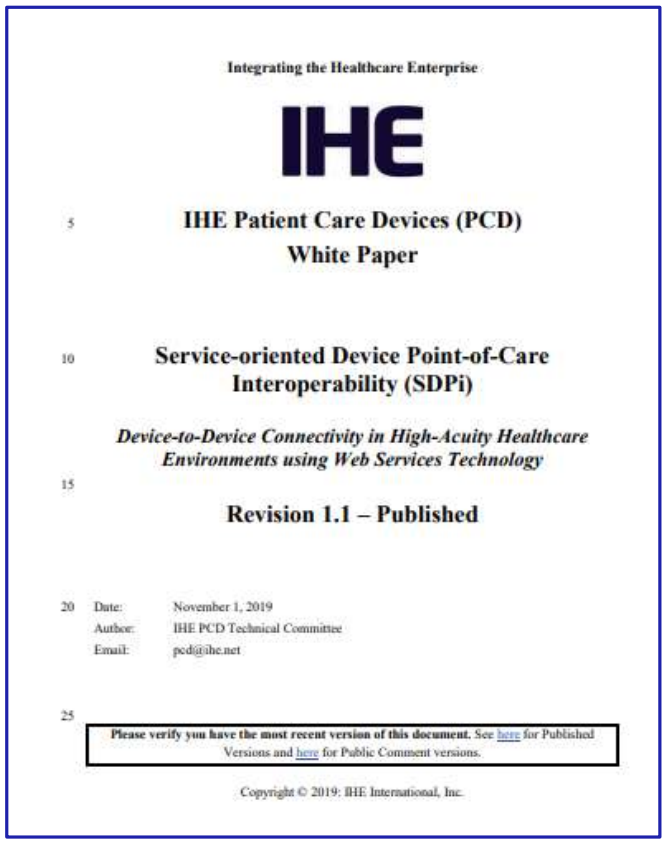
Nomenclature

Device Specializations

Participant Key Interoperability Purposes

Core Connectivity Standards

IHE DEV SDPi – Building an Acute Care Interoperable Ecosystem



Integrating the Healthcare Enterprise

IHE

IHE Patient Care Devices (PCD)
White Paper

Service-oriented Device Point-of-Care Interoperability (SDPi)

Device-to-Device Connectivity in High-Acuity Healthcare Environments using Web Services Technology

Revision 1.1 – Published

Date: November 1, 2019
Author: IHE PCD Technical Committee
Email: pcd@ihe.net

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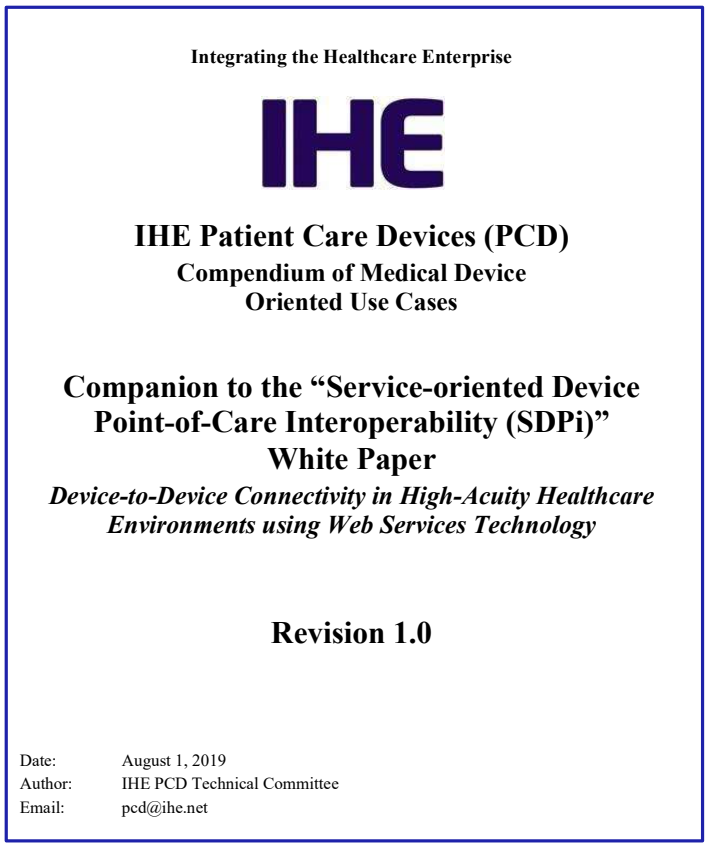
https://www.ihe.net/uploadedFiles/Documents/PCD/IHE_PCD_WP_SDPi_Rev1-1_Pub_2019-11-01.pdf

SDC@IHE 2019 Initiative laid the foundation for IHE

Service-oriented Device Point-of-Care Interoperability (SDPi)

profile family for "***PRACtical***" device-to-device interoperability



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IHE Patient Care Devices (PCD)
Compendium of Medical Device Oriented Use Cases

Companion to the "Service-oriented Device Point-of-Care Interoperability (SDPi)"
White Paper

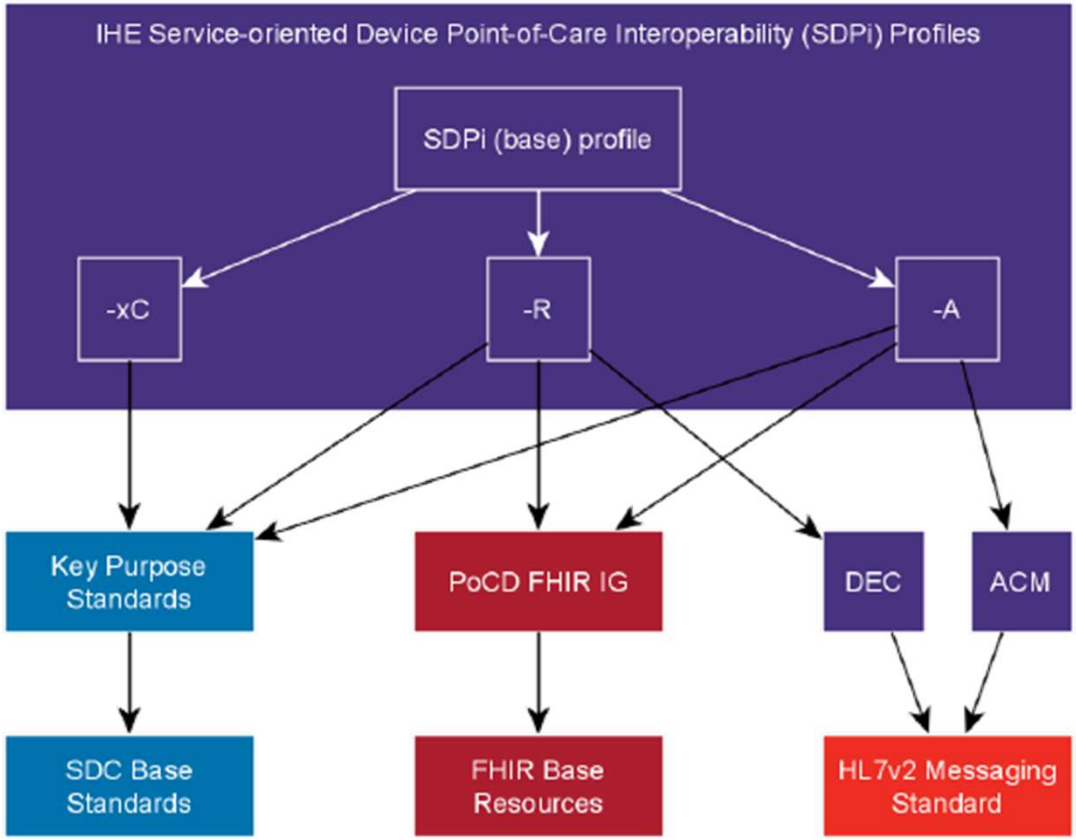
Device-to-Device Connectivity in High-Acuity Healthcare Environments using Web Services Technology

Revision 1.0

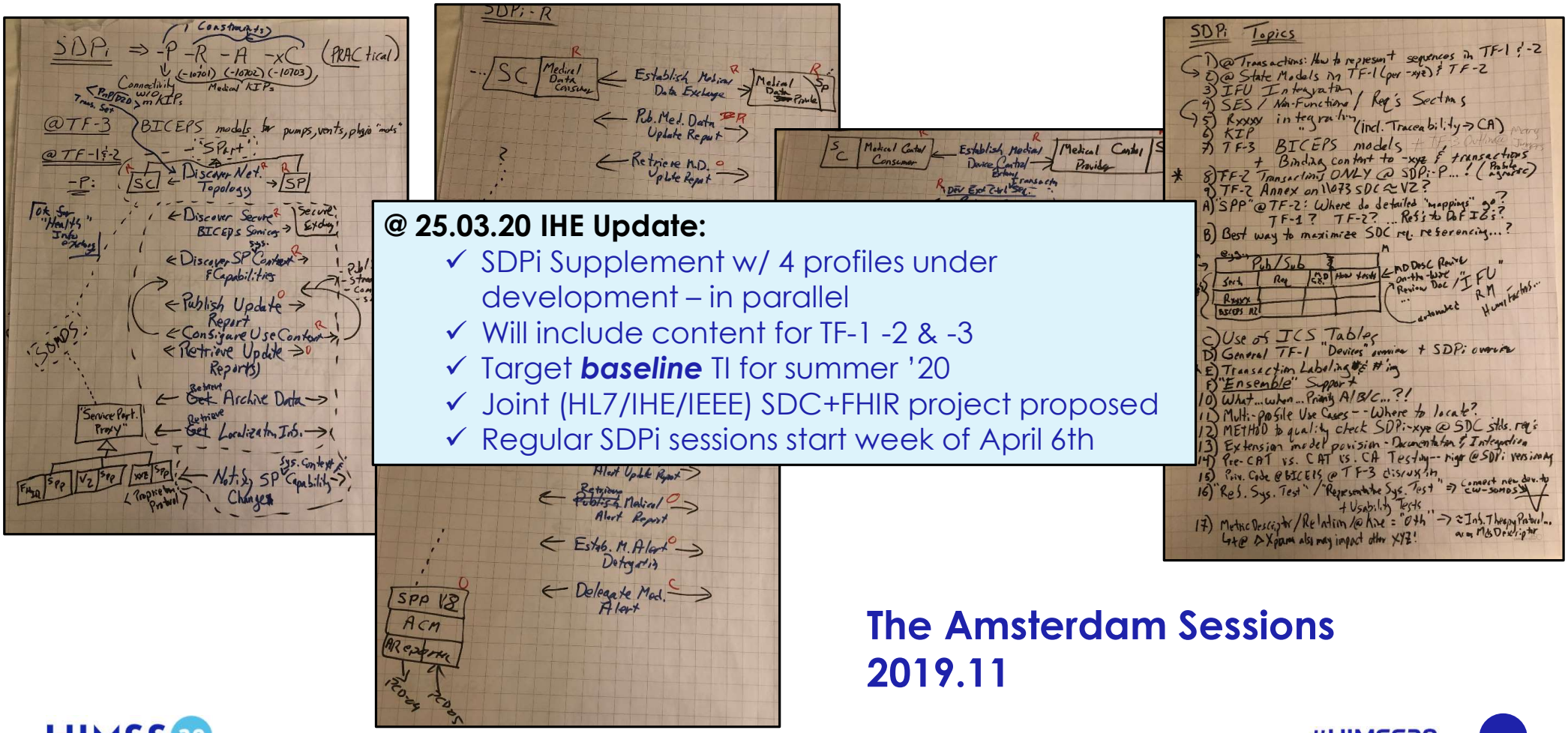
Date: August 1, 2019
Author: IHE PCD Technical Committee
Email: pcd@ihe.net

https://wiki.ihe.net/index.php/SDC@IHE_White_Paper

IHE DEV SDPi
Relation to other Standards



IHE SDPi Supplement – From Concept to Specifications

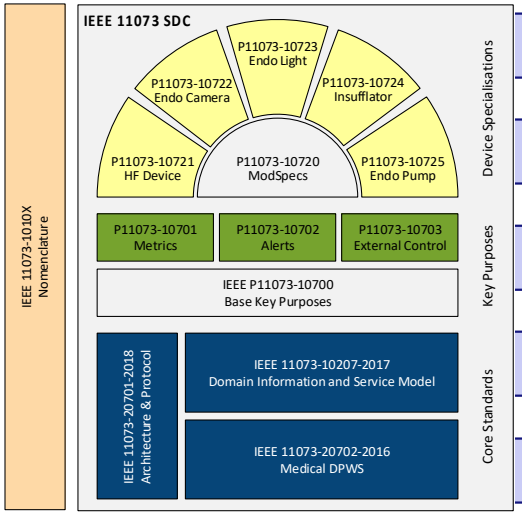


@ 25.03.20 IHE Update:

- ✓ SDPi Supplement w/ 4 profiles under development – in parallel
- ✓ Will include content for TF-1 -2 & -3
- ✓ Target ***baseline*** TI for summer '20
- ✓ Joint (HL7/IHE/IEEE) SDC+FHIR project proposed
- ✓ Regular SDPi sessions start week of April 6th

The Amsterdam Sessions
2019.11

"SDC+FHIR" Specification Layers



Clinical / Therapeutic Applications & Protocols

JOHNS HOPKINS APPLIED PHYSICS LABORATORY **MDIRA/ICE Framework**

IHE **"Device" Specializations**

IHE **Participant Key Interoperability Purposes (PKIP)**

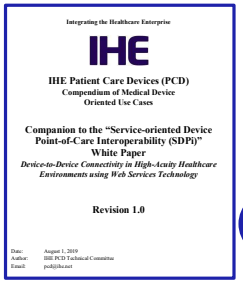
IHE **SDPi "PRACtical" Interoperability**

SDC (BICEPS & SOMDA)

MDPWS / WS-* | **HL7 V2 / FHIR**

REQUIREMENTS

Functional & Non-Functional + Testable Assertions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Revision 1.0

"Devices" = *bundles of sensor / actuator / intelligence capability with an intended medical / healthcare purpose*

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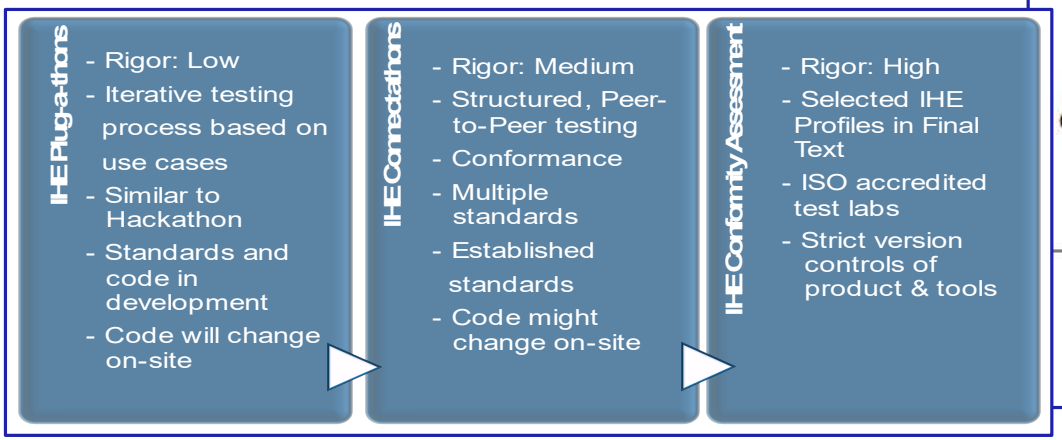
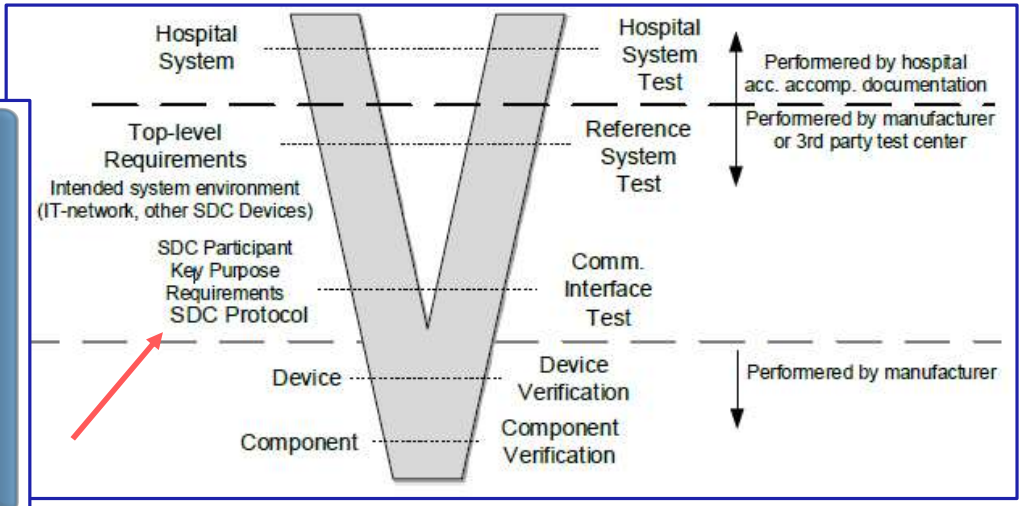
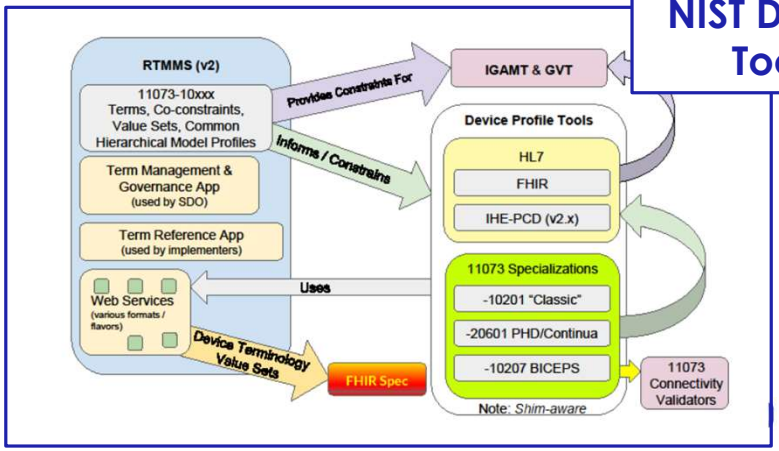
Conformity Assessment & Product Certification
IHE PAT, CAT and CA





Objective: ***Leverage IHE Test & Tooling*** *to establish an SDC-enabled interoperable medical technology ecosystem where certified test reports can be directly included in regulatory submissions*

NIST Device Tools



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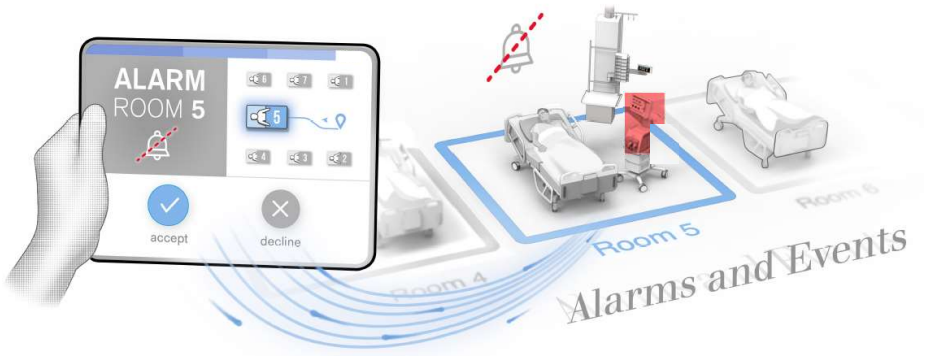
SDC
Superior Security, Safety and Effectiveness

- Standard based encryption of communication: TLS 1.2+
- Each endpoint has a certificate.
- Authentication at both endpoints
- No communication if no trust chain can be established

- Certificates are used to secure communication
- Authorization and Authentication
- *Certificates carry roles of participants*
- Each device can decide if remote control is OK based on certificate roles and certifying organization

SDC = Enables Trusted Decoupling

ALERT SIGNAL DELEGATION
USE CASE



From IEEE 11073-10207 (BICEPS)

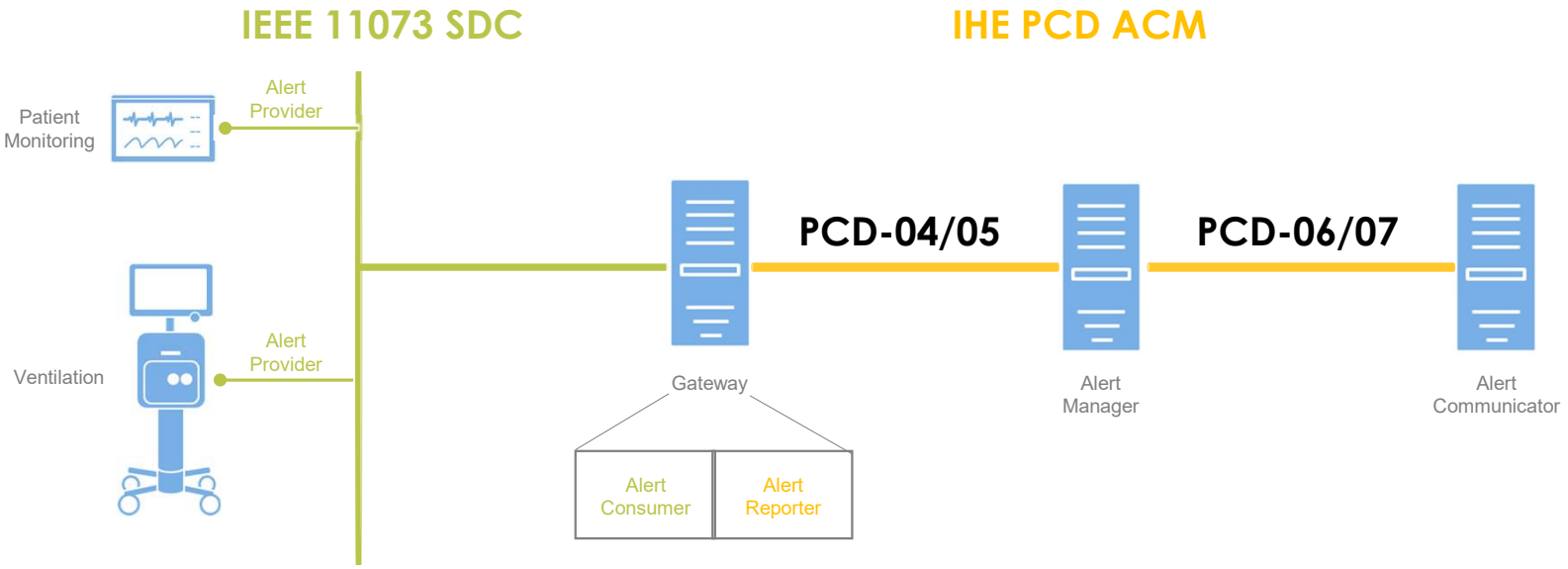
ALERT SIGNAL DELEGATION is the capability of a POC MEDICAL DEVICE to let another PARTICIPANT generate a POC MEDICAL DEVICE's ALERT SIGNAL as primary ALERT SIGNAL in order to remotely indicate the presence of an ALERT CONDITION on the POC MEDICAL DEVICE.

➔ a POC MEDICAL DEVICE delegates its ALERT SIGNAL generation to another PARTICPANT, e.g., to facilitate a silent workplace

➔ **Delegable & Fallback Alert Signals**

Alert Signal Distribution

Combining IEEE 11073 SDC & IHE PCD ACM



Summary

- IEEE 11073 SDC can fix todays interoperability challenge
- SDC integrates into the IHE world as IHE-DEV-SDPI
- Conformance testing will allow vendor-independent solutions
- Conformance testing can help in solving the regulatory challenges of healthcare organizations

Questions

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