Medical device inter-operability in Acute Care

APIBQ 2019

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Dräger
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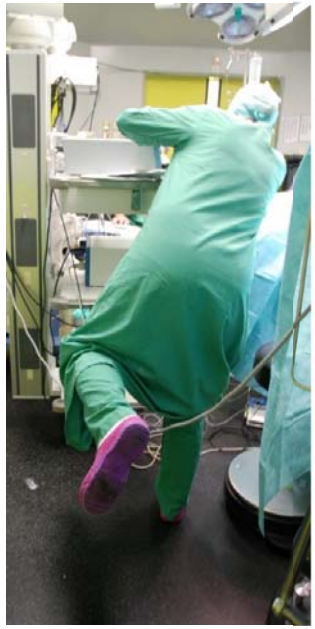
sli.do
Quelle est l'origine ou l'inspiration du mot "Bluetooth"?
Pure creation du département Marketing d'Ericsson
33%
la radiation des ondes à 2.4 Ghz rendait la dent bleue à son inventeur Jim Kardach en 1996
22%
Fait référence au roi danois Harald qui a unifié les tribus du royaume et qui portrait le surmon de la dent bleue.
45%

Objectifs

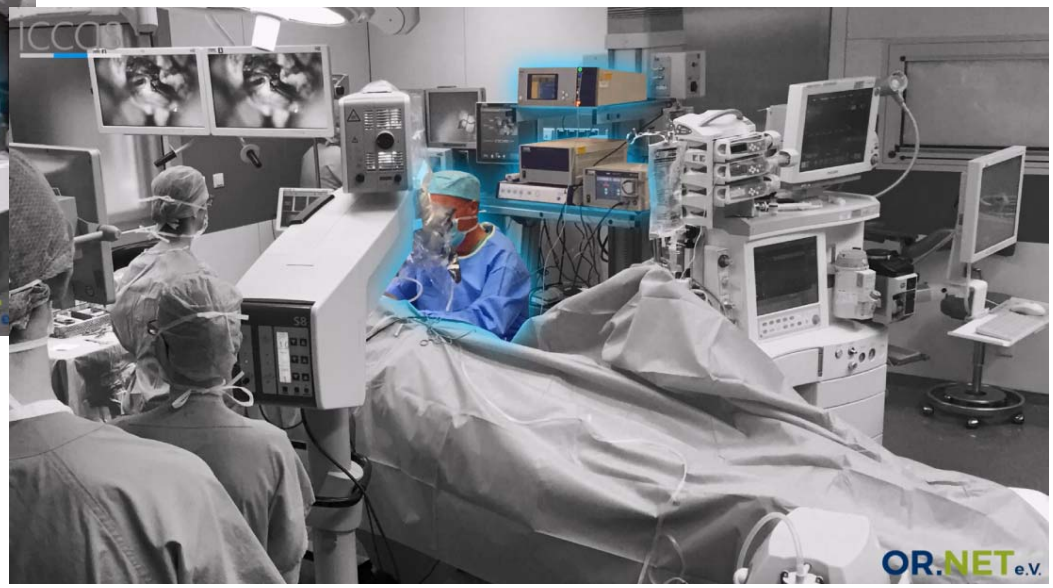
- Brève historique de la norme IEEE 11073 – SDC
- Explication du fonctionnement du standard sur l'interoperabilité.
- Présentation de concepts

Operating room today ?

Operating room today ?



Networked Medical Technology – Motivation?



OR.NET e.V.

Networked Medical Technology – Motivation?

OR.NET e.V.


The amount of medical devices in acute care is continuously increasing
The equipment is primarily selected based on features, brand preference and costs.
Workplace settings are often designed around the equipment

82%

of all critical incidents are related to loss of situation awareness due to missing perception/ comprehension.

Schulz et al., BMC Anesth[illegible]

70%

of adverse events can be related to user errors and to inadequate utilization of medical devices.

ECRI TOP 10 Health Technology [illegible]

In **50%**

of all surgeries, medication errors or adverse drug events occur.

Nanji et.al., Anesthesiology 2016

45 - 87%

of ICU patient suffer from delirium which accounts for 16 b$ healthcare costs per year in the US.[8]

Jackson et al. Crit Care Clin. 2015

up to 350

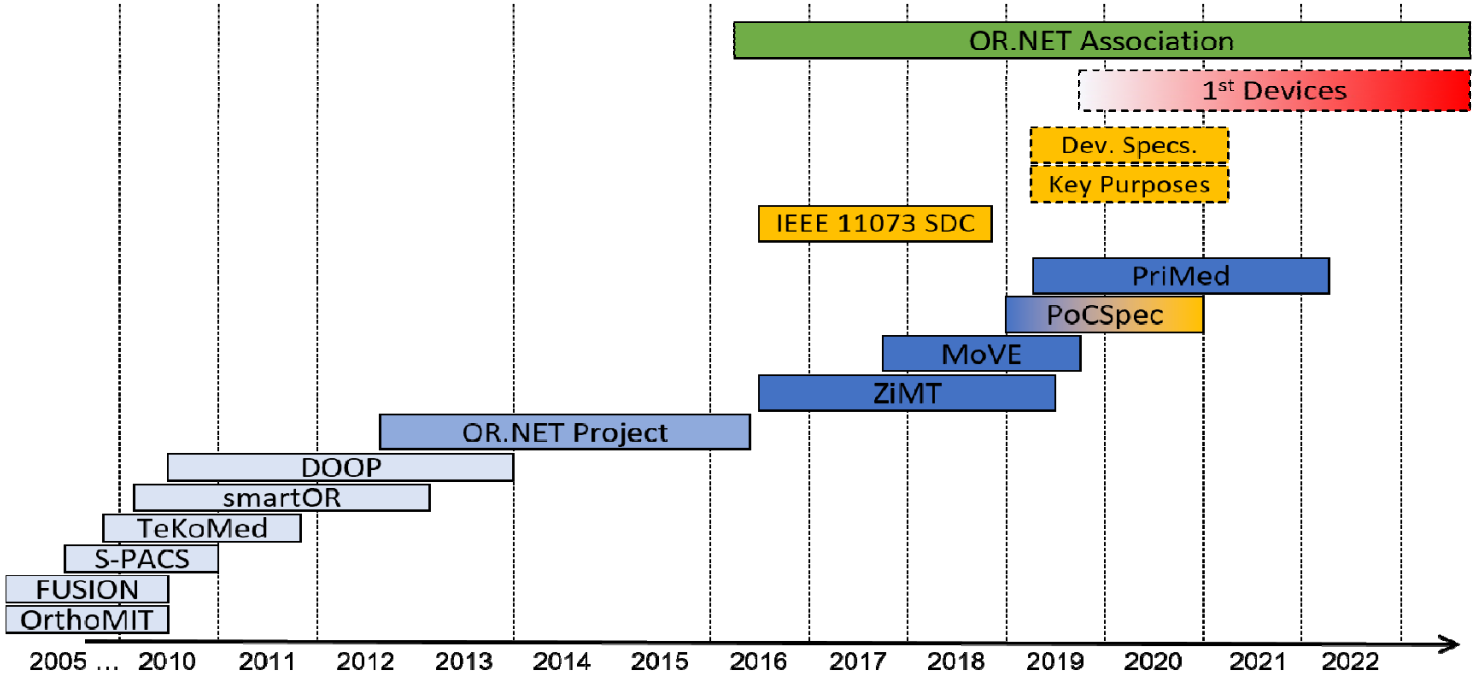
daily alarms per ICU bed, of which 90% are clinically irrelevant and 50% are not even noticed.

AAMI Alarm Summit 2011

Today‘s interoperability: Proprietary Isolated Solutions

- Increasing complexity and number of devices
- Interoperability means to many sending data in a HL7 format
- Standalone devices without any connectivity
- Proprietary protocols and buses
  - No comprehensive user interfaces
  - Isolation of information, like patient information, vital signs, …
  - Isolation of device functionality (e.g. surgeon has to ask for changing device parameters)
- Interoperability between devices possible but:
  - With proprietary solutions (expensive and not flexible)
  - Own development (clinic responsible for risk management)

Brief History of SDC



Blue: Research; Orange: Standardization; Red: Industry; Green: OR.NET Association

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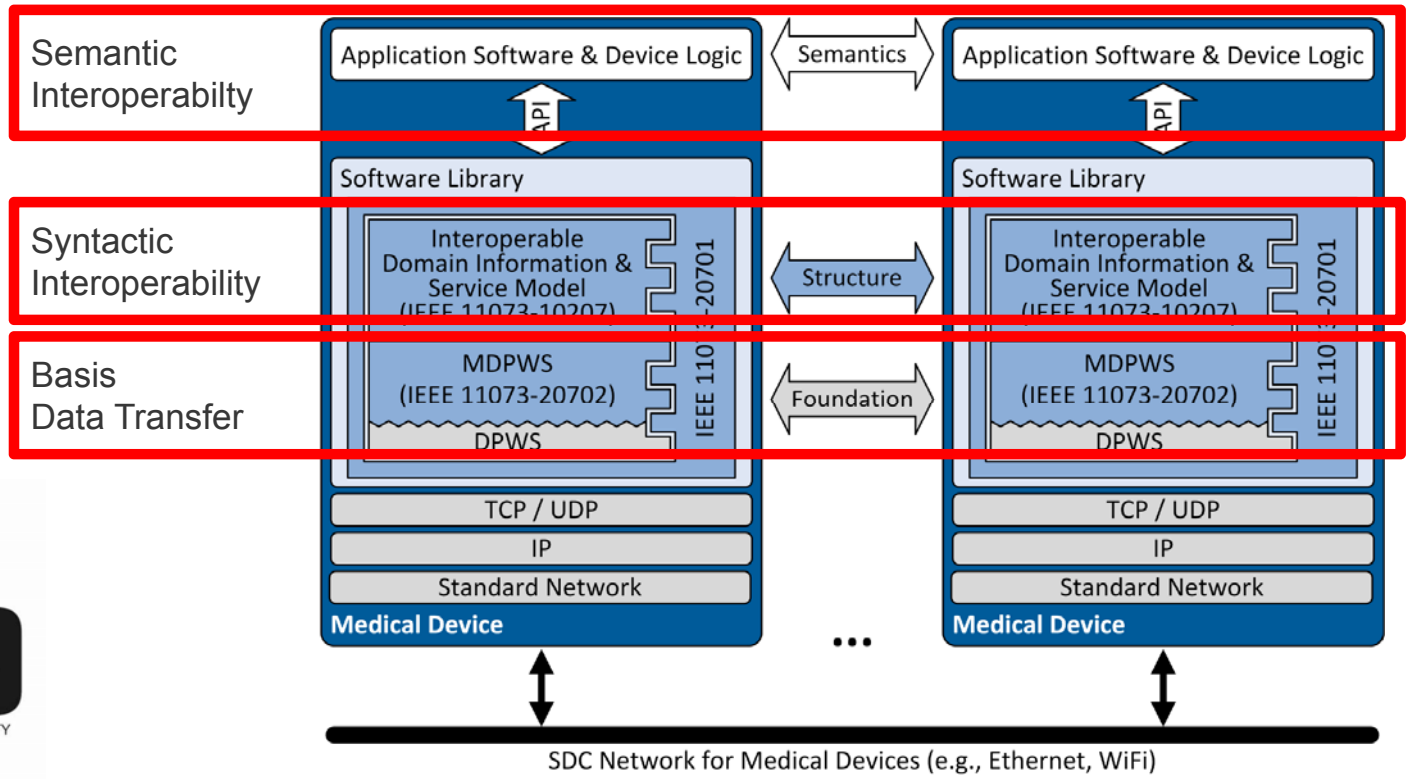
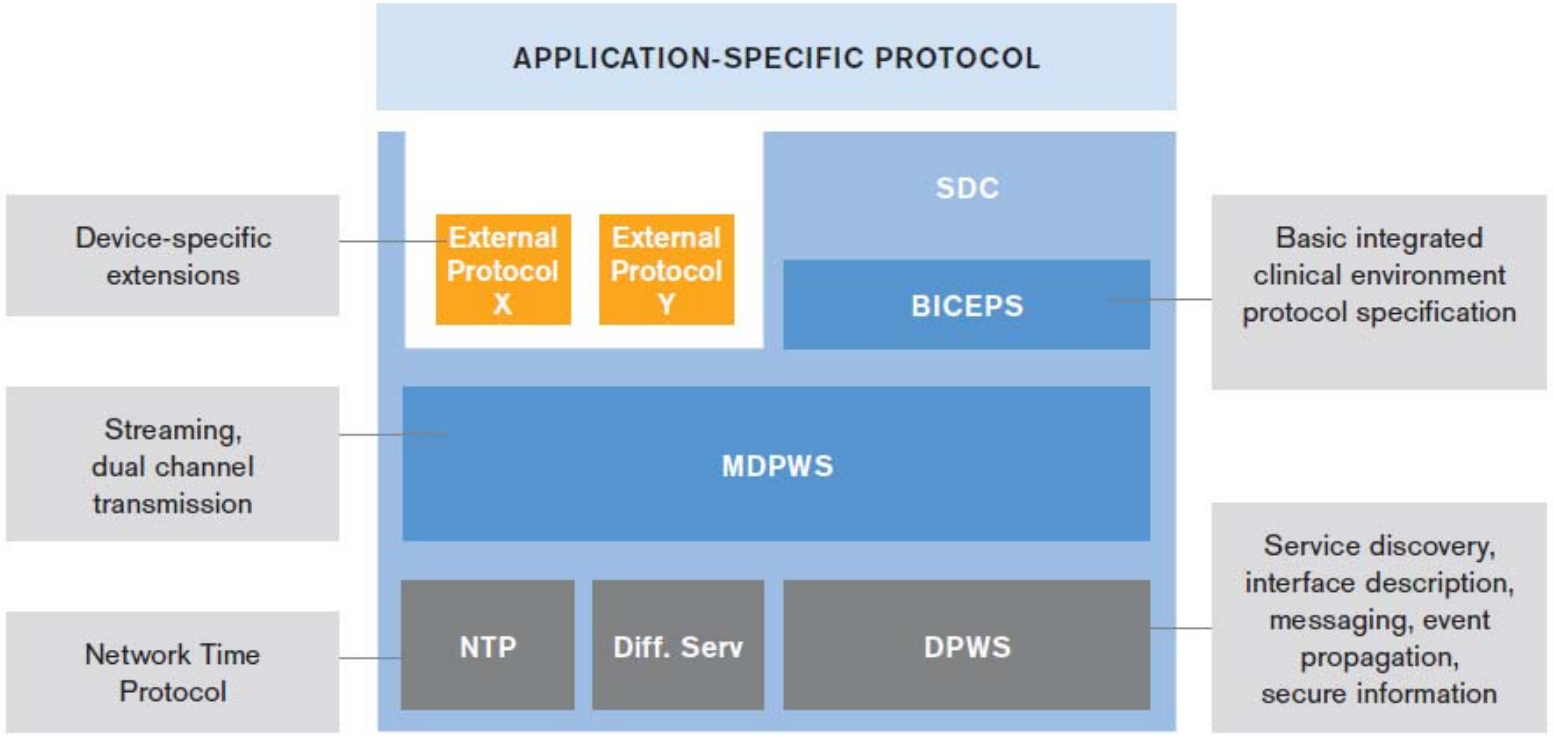
Interoperability – IEEE 11073 SDC Standard family



SDC
SERVICE-ORIENTED DEVICE CONNECTIVITY

IEEE 11073 SDC
(Service-oriented device connectivity)

Interoperability – IEEE 11073 SDC Standard family



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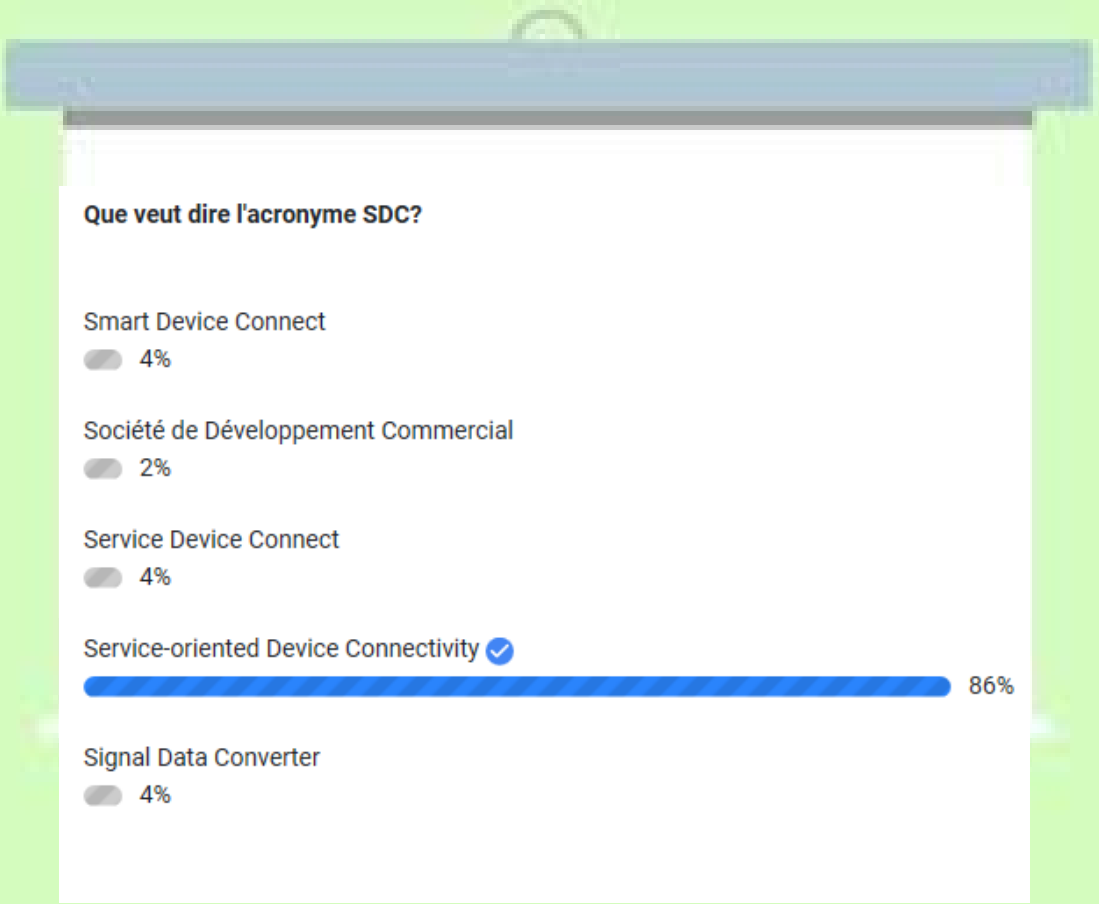
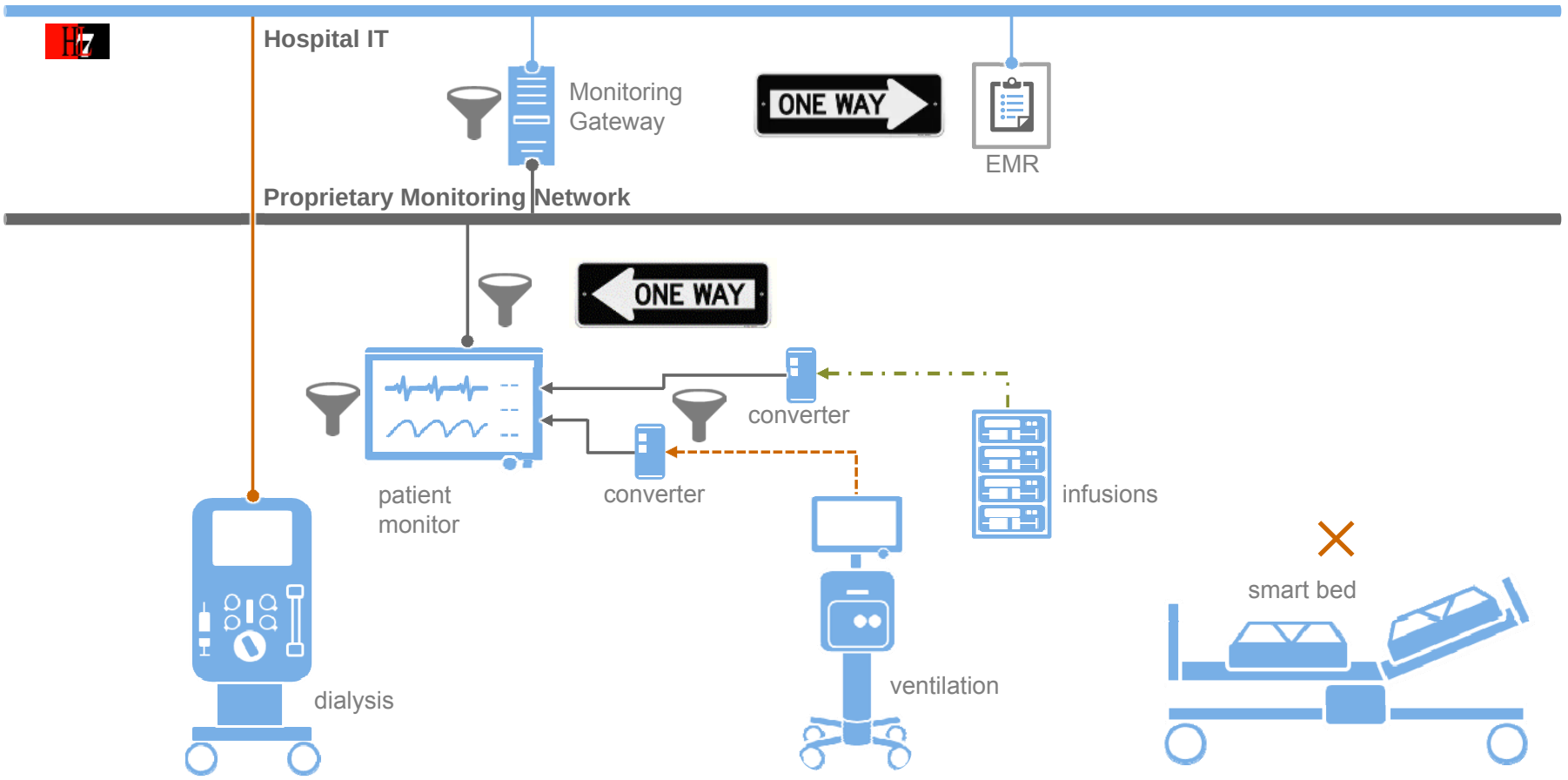
OR.NET e.V.


Que veut dire l'acronyme SDC?
Smart Device Connect
4%
Société de Développement Commercial
2%
Service Device Connect
4%
Service-oriented Device Connectivity
86%
Signal Data Converter
4%

Classical peer-to-peer Interface

Unsecured unidirectional data transmission



- Proprietary Interfaces
- Restricted Data Utilization
- Incomplete Data Transfer
- Unidirectional communication
- Limited Data Security

We envision a future of Acute Care where…

Enabling Connectivity at the Point-of-Care

Service-oriented Device Connectivity (SDC)

SDC

An IEEE 11073 Standard

New international standard for secure and dynamic connectivity enabling interoperability of medical devices in high acuity environments

IEEE

Standardized and published by the Institute of Electrical and Electronics Engineers (IEEE). An ISO standardization will follow.

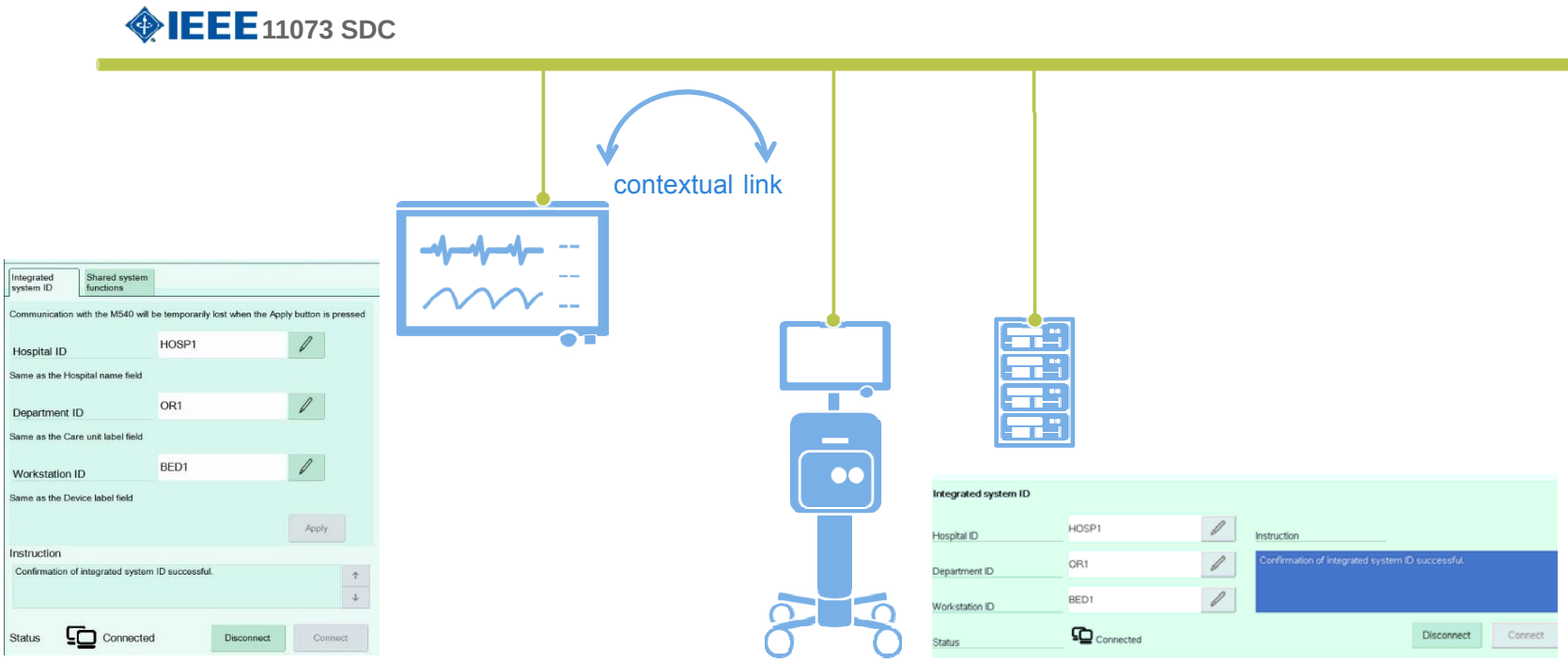
OR.NET e.V.

Concept and development of the standard driven by the non-profit organization OR.NET with more than 50 international partners.

2019

Published internationally in January 2019 as an enhancement of the IEEE 11073 standards family.

SDC: The Standardized Network Protocol
for secure bidirectional data exchange



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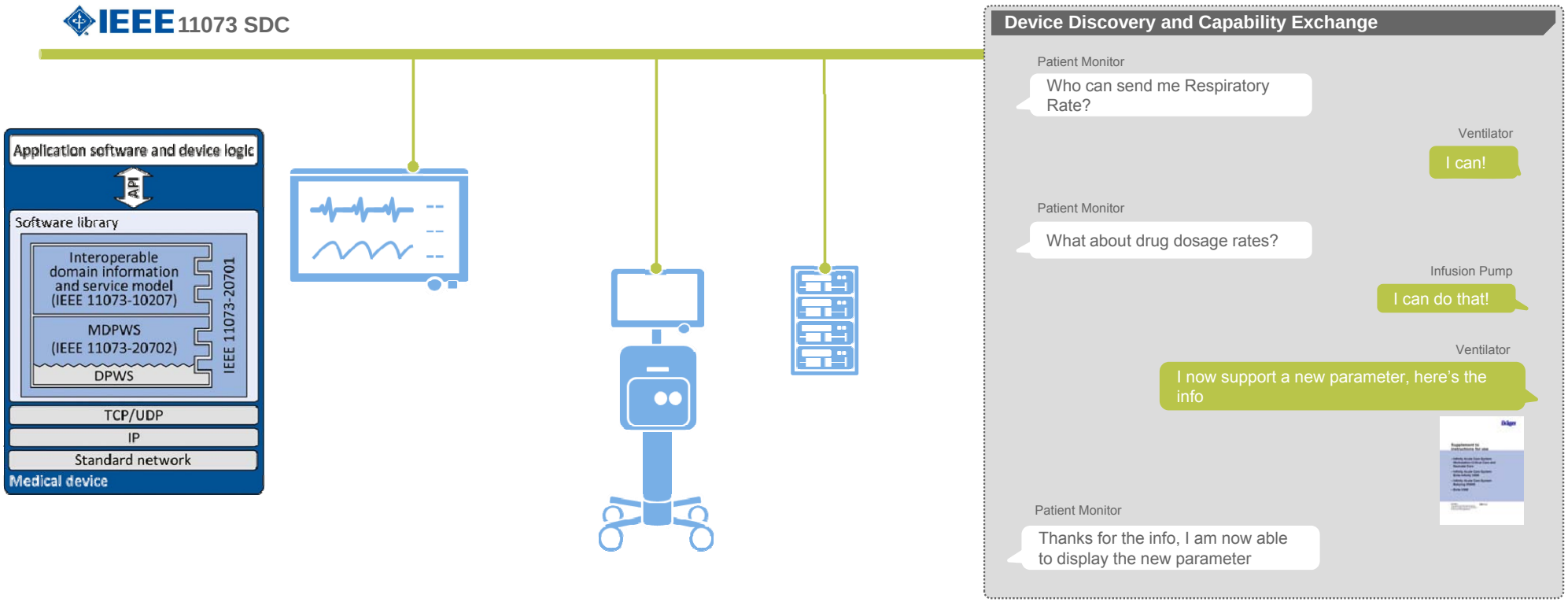


SDC Security Concept

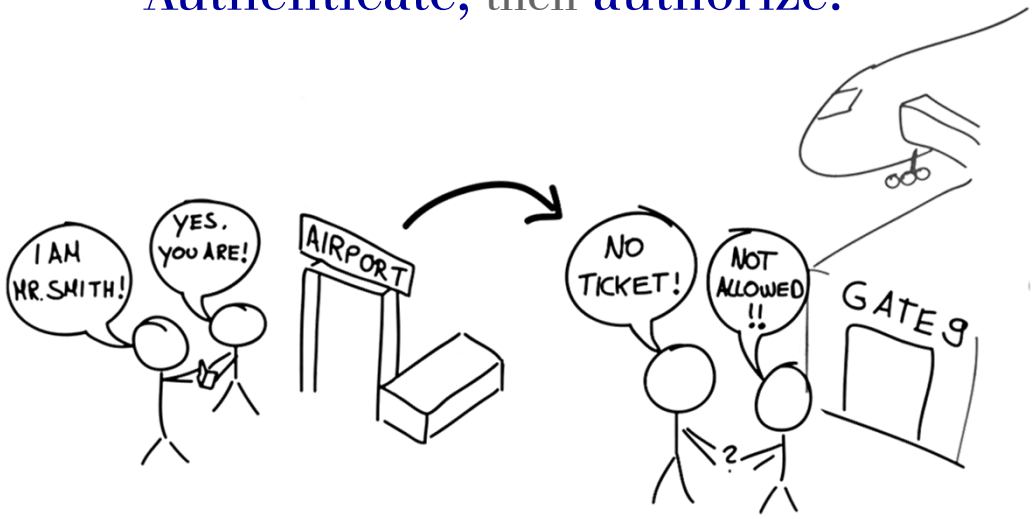
Authentication

verifies the integrity of an identify

Authorization

grants or withdraws access based on a set of rules

Authenticate, then authorize.



Certificates for Authentication

Digital Certificates enable devices to automatically verify the identity of the other connected devices.

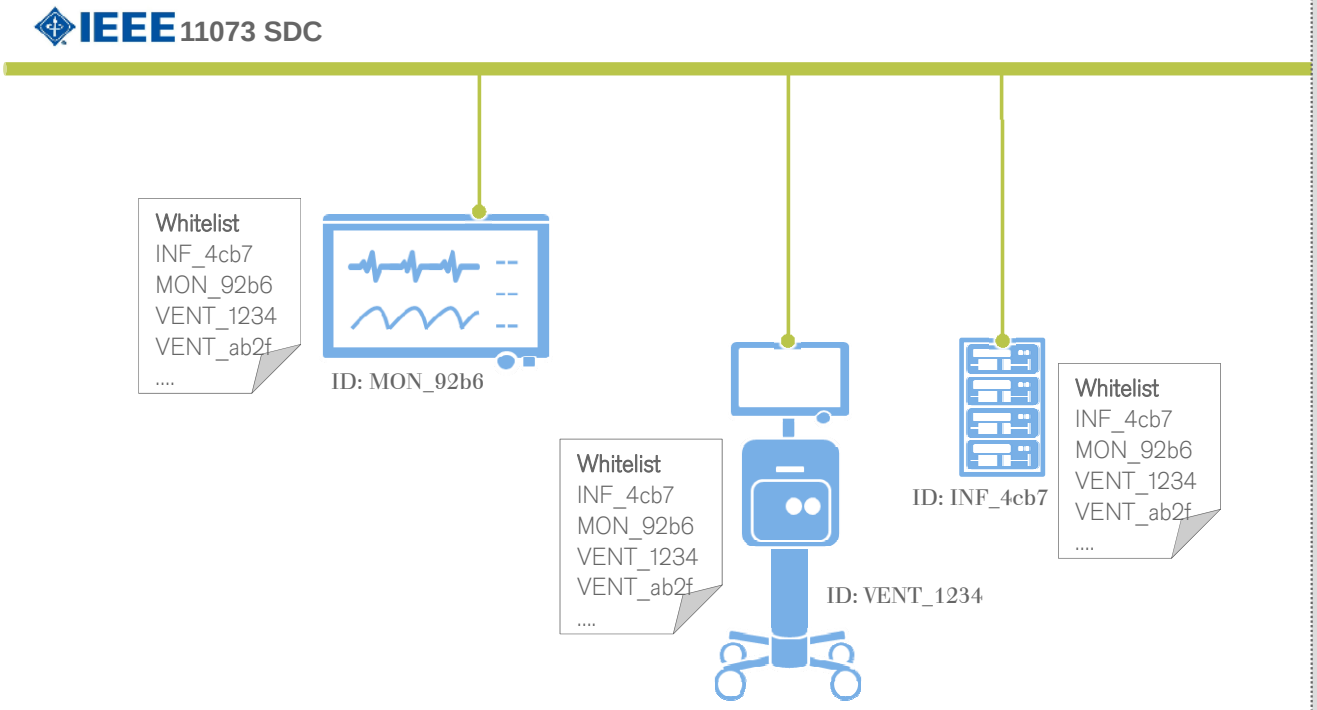
X.509 certificates from the Dräger Public Key Infrastructure (PKI) will be installed on each Dräger device

Whitelists for Authorization

A whitelist determines whether or not the identified device is allowed to connect and what level of access it will have.

Whitelists are optional but recommended and they will be maintained by the hospital.

SDC: The Standardized Network Protocol
Authentication and Authorization



1. Authentication

I'm a Patient Monitor.
My device ID is MON_92b6

I'm a Ventilator. My device ID is VENT_1234

I'm a Dräger device and I have a certificate to prove it

Me too!

2. Authorization

Your device ID is in my whitelist, let's connect!

Let me check…

•••

You're in my list too! Let's connect!

3. Interoperability

MON_92b6, I would like to use your PAW and CO2 data

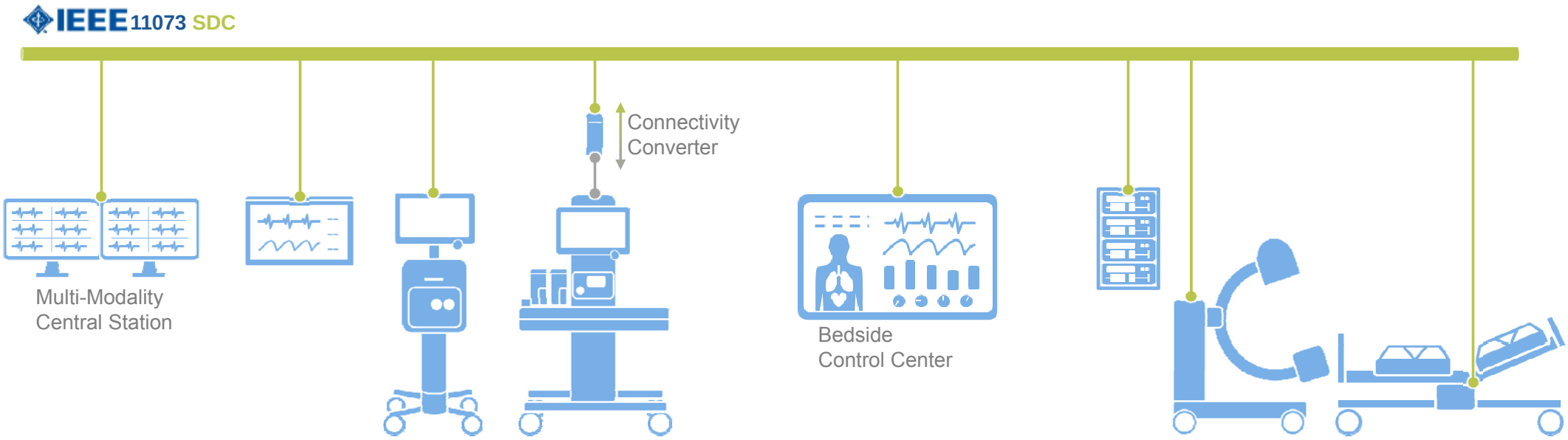
I'll provide you with that information!

My alarm has been paused. Please pause your alarm, too.

Good to know. Done!

A System of Systems

Enabling the Internet of Medical Things in Acute Care



A System of Systems

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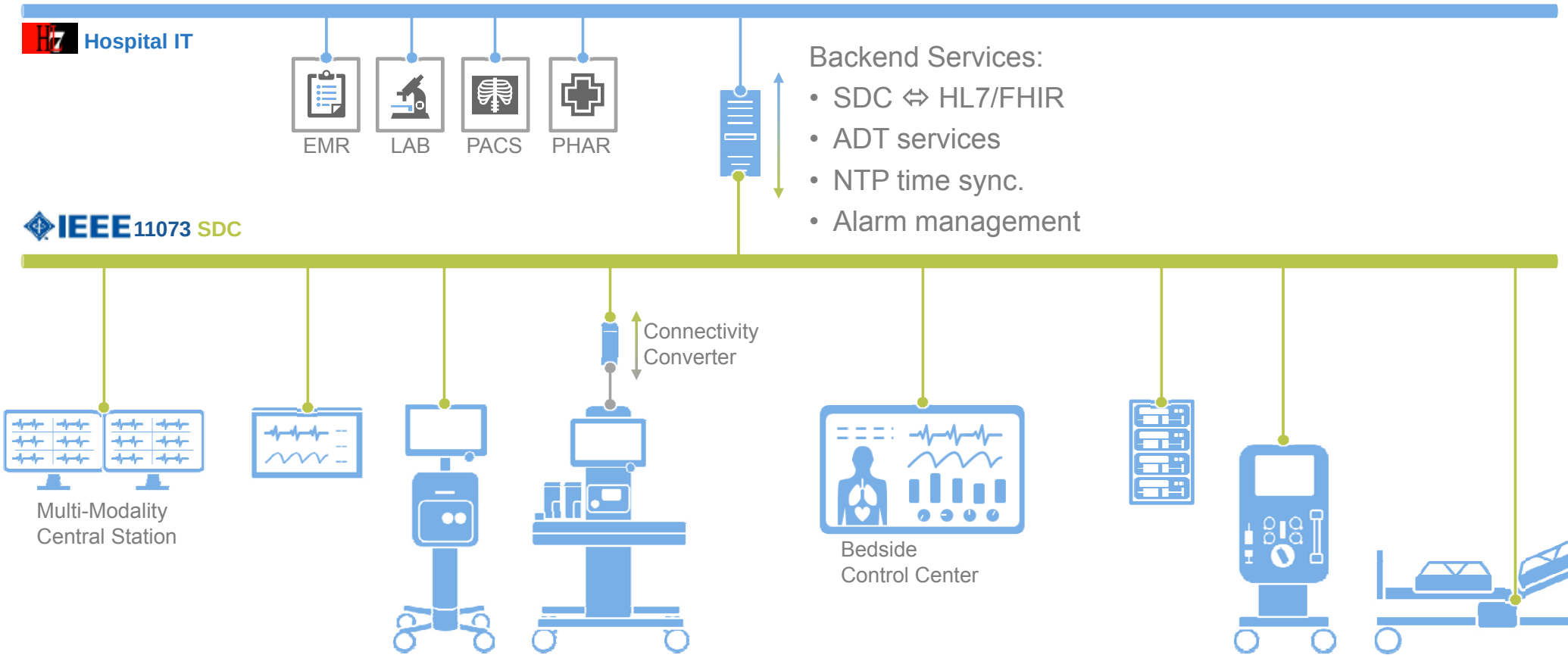
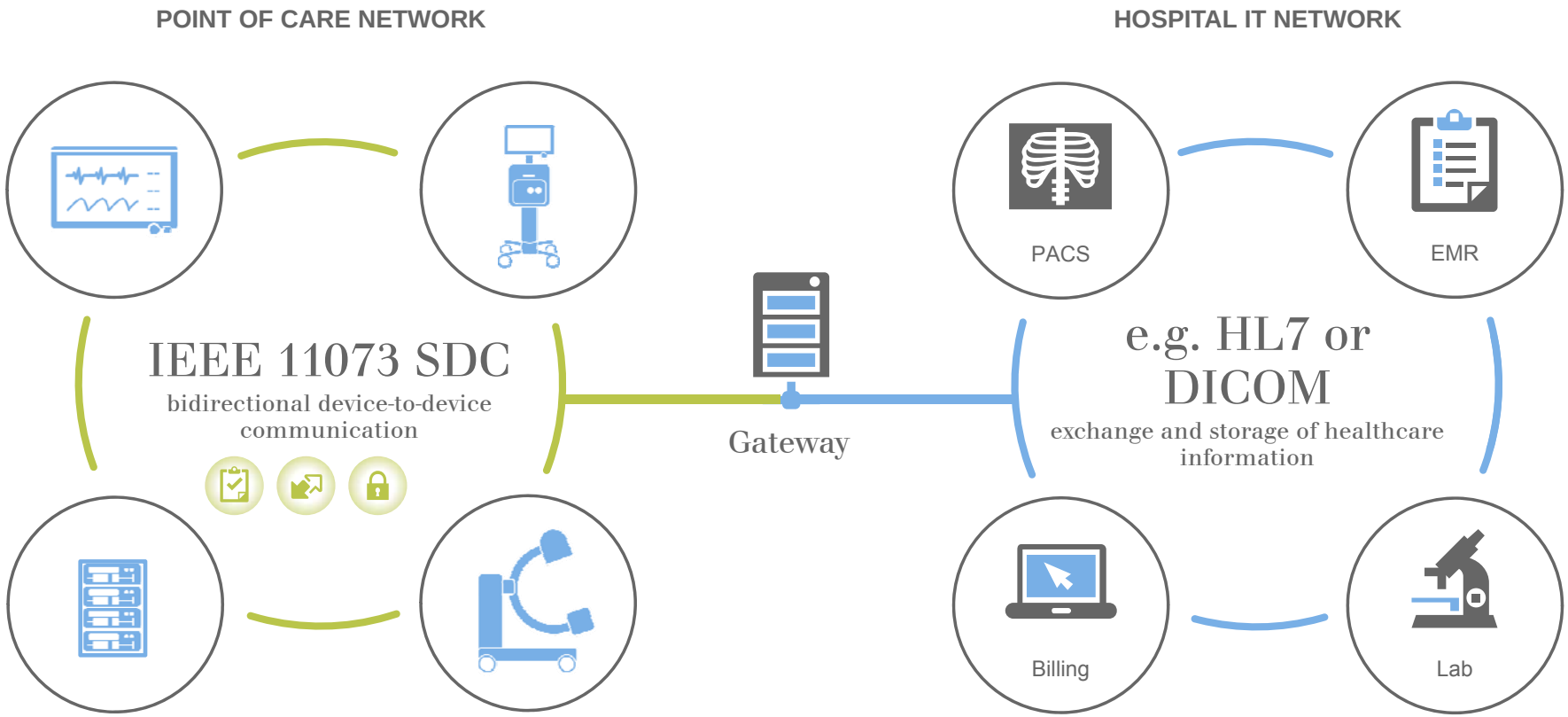


SDC and HL7 / FHIR
Complementing standards for Medical Systems



Service-oriented Device Connectivity (SDC)

Breaking Today‘s Boundaries

Dräger

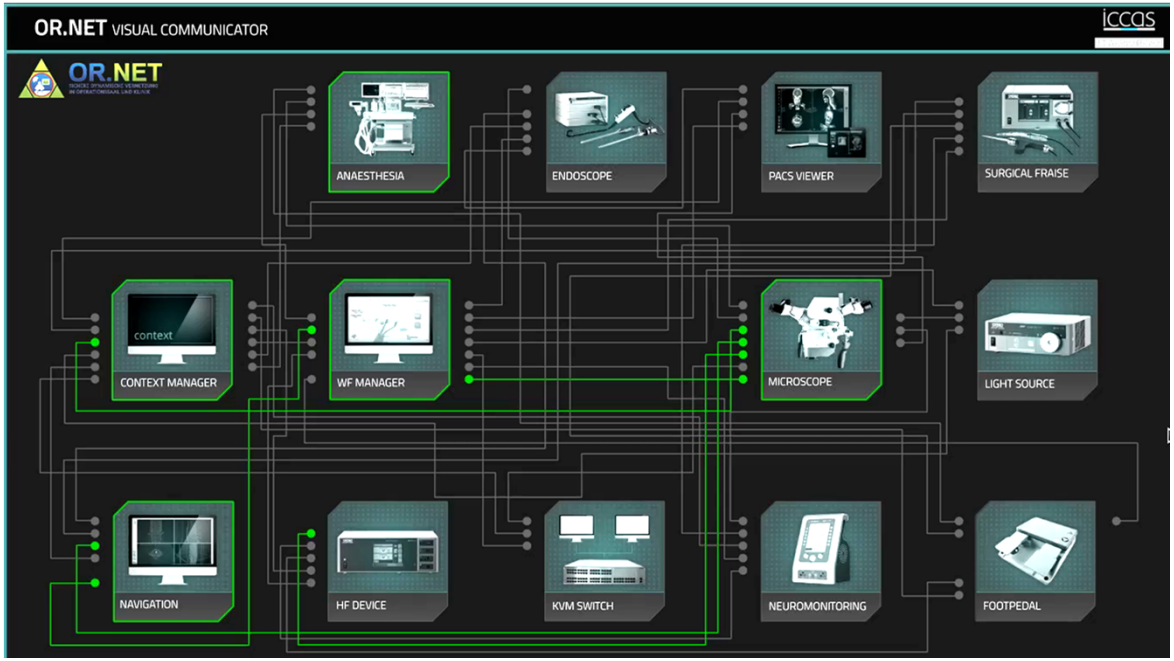

sli.do
Qu'est ce que le X.509?
un certificate d'authentification qui ne s'expire jamais
4%
un certificat d'authentification qui a besoin d'etre renouvelé tous les ans
11%
un certificat d'authentification qui a besoin d'etre renouvelé tous les deux ans
85%

First Implementation and possible Concepts

IEEE 11073 SDC – Practical Realization

Demo OR @ ICCAS, Leipzig

Real-time network visualization

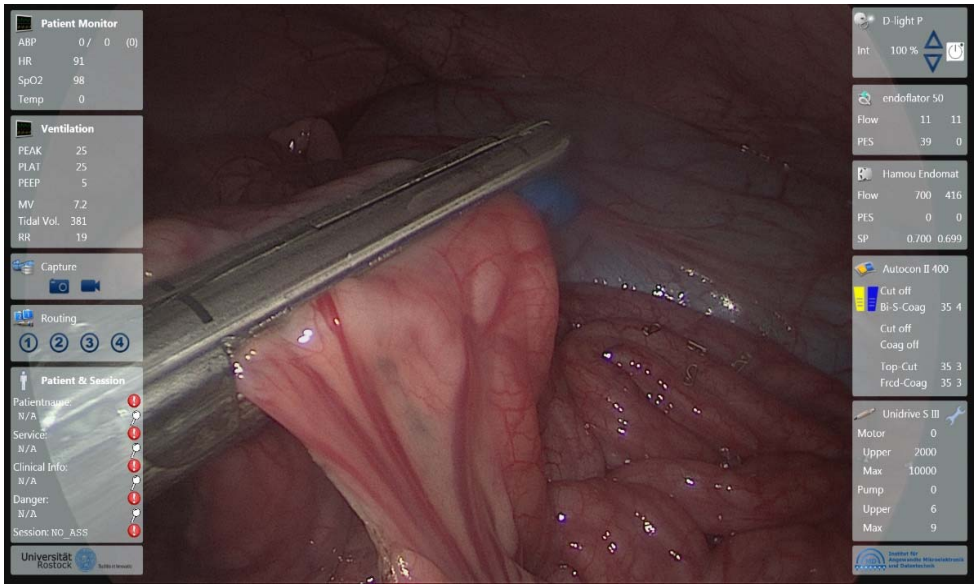


Source: University of Leipzig, ICCAS

IEEE 11073 SDC – Practical Realization

Stage 1 – Vendor independent presentation of information

- Overlay of medical device parameters, measurements and alarms



Source: University of Leipzig, ICCAS

IEEE 11073 SDC – Practical Realization

Stage 3 – Intelligent surgical working environment

- Combination of a context aware Workflow Information System and SDC connected devices

Source: University of Leipzig, ICCAS

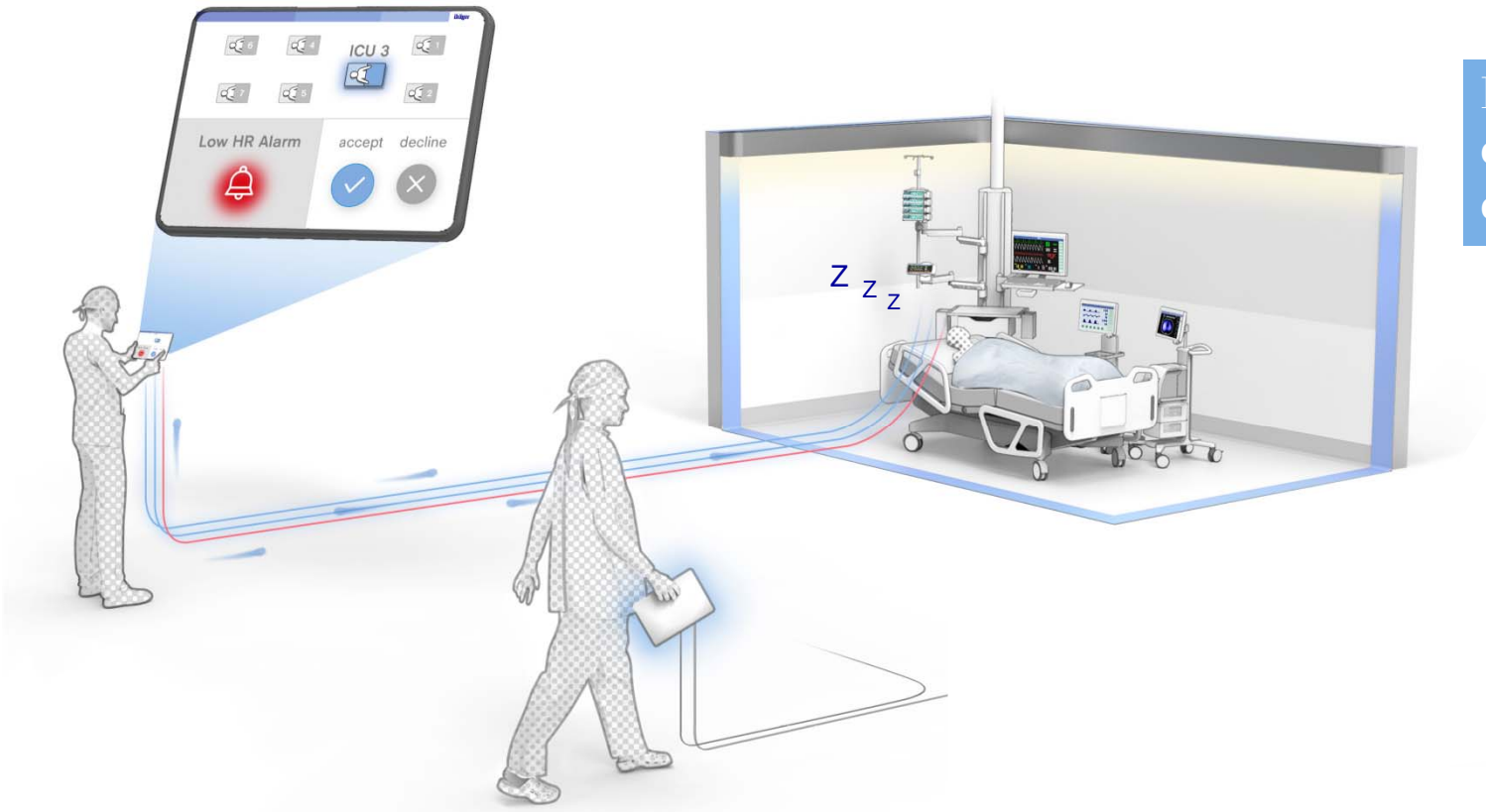
What if...

Examples:

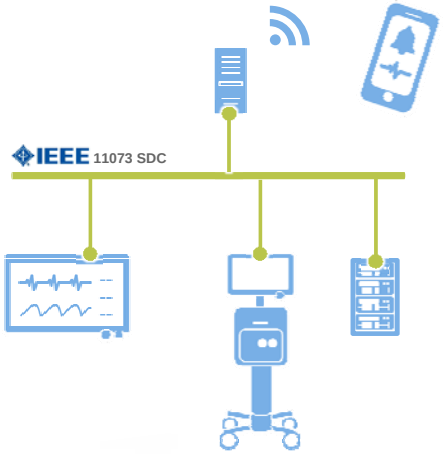
- Closed-loop controls
- Automated maneuvers
- Remote alarm silence
- Synchronized adjustments
- Smart alarms

...data from different sources could be used to optimize therapy algorithms and maneuvers?

What if...



Integration of all medical devices into one secure alarm distribution system.



... alarms could be distributed to the responsible caregiver while devices at the bedside remain silent?

What if…

Examples:

- Alarm analytics
- Utilization Data
- Results of automatic self tests
- Centralized SW distribution and upload

…data from connected devices could be remotely accessed and analyzed?

IEEE 11073 SDC
Benefits

Open Information Exchange

SDC
IEEE 11073 Series

Medical Grade Data Output

High Level of Data Security

Reduced Integration Complexity

Quelles sont pour vous les deux plus grands bénéfices que la norme SDC peut apporter a votre établissement de santé?

Échange ouvert d'informations / sécurité accrue des données

Ergonomie d'espace

Faciliter l'implantation Améliorer intégration

Réduire la manipulation des donnés

- intégration des données patients. - simplifier l'interface entre les équipements

Simplification d'intégration

Sécurité et interopérabilité

Améliorer l'efficacité Sécurité

1 interface multi-modalité multi-marque

Economies $ et efficacité accrue

Réduire la complexité Augmenter la sécurité

Contrôle et affichage unifié Simplification pour utilisateur

Bidirectionnalité Contrôle à distance

sécurité, facilité, réduction du temps

Transmission des données

Normalisation et sécurité

Interopérabilité au bloc opératoire Contrôle des équipements des chambres à distance

Information widely available in system Data grade information

Interopérabilité au bloc opératoire Contrôle des équipements des chambres à distance

Moins de risque d'erreur

Facilite d'intégration par rapport à aujourd'hui Meilleure intégration des paramètres pour les cliniciens

Interopérabilité et protection des données

Pas de perte de temps à développer des interfaces, diminution des manipulations et donc baissé erreurs

Réseau TI médical uniquement

Économie du temps

Questions ouvertes

Quel processus faut-il mettre en place à moyen et long terme pour s'assurer d'une bonne implémentation du standard et d'en tirer bénéfices (réduction des couts d'interfaces et développement d'applications cliniques?

- Formation spécialisée pour les techniciens biomédicaux ?
- Faut-il créer un consortium/groupe d'experts au Québec entre établissement de sante et manufacturiers pour préparer au mieux la transition?
- …

Merci de votre attention

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Questions non répondues Durant la présentation et posées avec slido

1) Les risques d'erreurs de l'utilisateur en modifiant les paramètres de fonctionnement du mauvais appareil (par exemple modification du débit de perfusion de la mauvaise pompe) ont-ils été adressés…
   - De façon conceptuel et comme montré dans l'exemple de l'université de Leipzig, ce type d'erreurs peut être inclus dans workflow automatisé ou ce type de contexte clinique est reconnue.

2) Quel est le niveau de formation pour les utilisateurs pour être capable de l'utiliser ? Dans la cours des techniciens GBM ou dans la cours des infirmières?

   - le niveau de formation des techniciens biomédicaux devra être évaluée et une formation spécifique offerte pour les techniciens qui seront plus focalisés sur les systèmes et l'inter-operabillité .
   - Pour les infirmières, la formation sera identique a celle donnée aujourd'hui. l'association des équipements sera fera de façon simple pour l'utilisateurs.