A proposal for Standards Adoption: An architecture for distributed systems of medical devices in high acuity environments

Joint meeting of IEEE EMBS 11073 & HL7 Health Care Devices (DEV) WG, 2014/01/21, Stefan Schlichting, Stephan Poehlsen, Stan Wiley

A Proposal For Standards Adoption
Agenda

1. **Introduction**
2. Clinical Workplace SOMDA
3. MDPWS
4. BICEPS
5. Results
6. DDS
7. Discussion
8. Formal Request to IEEE 11073 Committee

Introduction

Purpose of this presentation

We seek this proposal for

an architecture of distributed medical devices

to

be adopted by the IEEE 11073 Standards Committee for inclusion

into IEEE 11073-20401.

Background

Work was initiated as a research project in 2004, and has culminated into an open framework which is supported by severalGerman consortia consisting of medical device manufacturers, research institutes, and clinical partners.

Introduction
Scope of research project

Medical Device Interoperability in high acuity clinical workplace environments ,

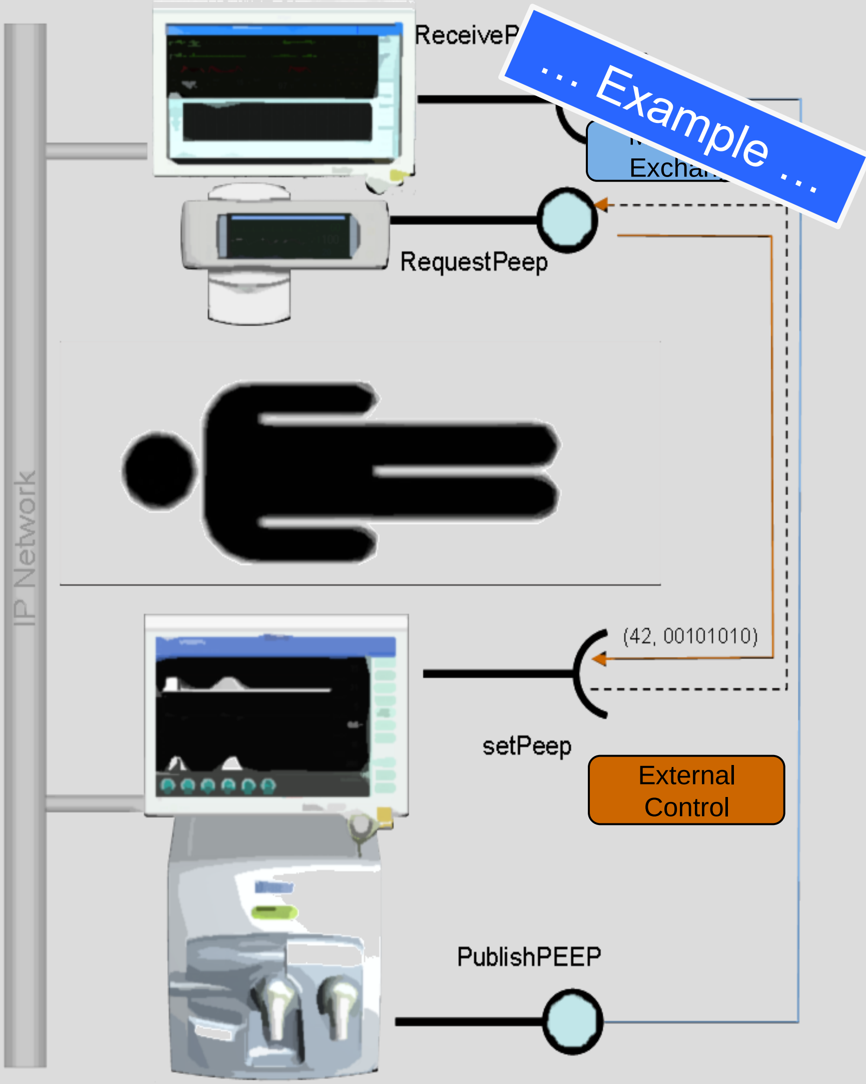
that is

… reliable cross-device data exchange between medical devices
… external control with focus on patient safety

without tight system integration,

yielding a flexible technical infrastructure

for smart clinical applications.



Introduction
Examples for High Acuity Environments

High Acuity Environments

Intensive Care

Anesthesia

Surgery

Introduction

Medical device interoperability requirements in an ICE

Functional

Plug'n Play

- Discovery and Binding
- Device capability description at runtime
- Extensibility & Openness

Communication (1-1, 1-n, n-n)

- Event Notification
- Data reporting
- External control

Non-Functional

- Risk Management
  - Safe communication
  - Access control
  - Trust establishment between participants
- Privacy of patient-related data
- Latency in milliseconds range

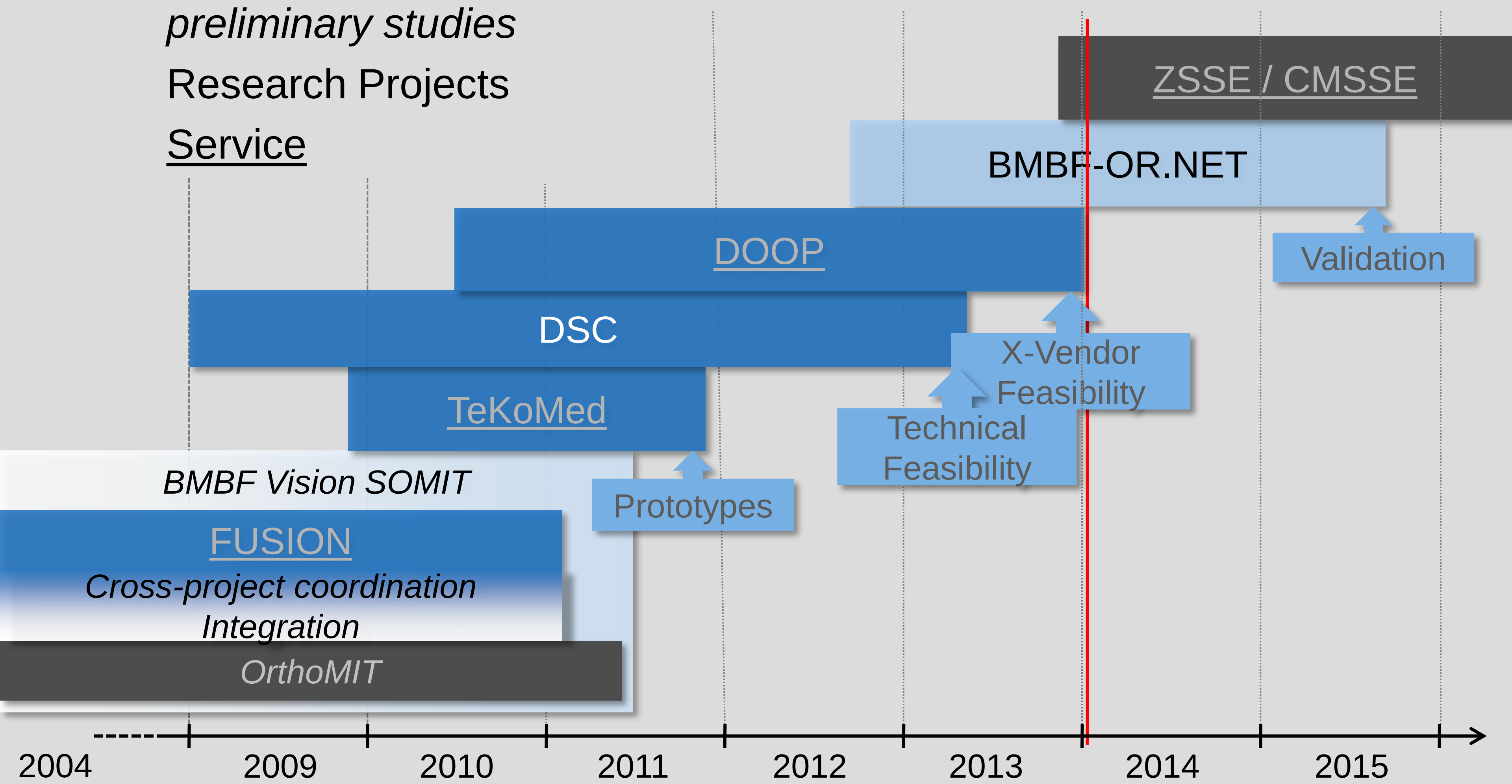
e.g. Standardized payload based on hRTM

Core Concept

Develop an interoperability architecture & protocol stack

- based on **standardized technologies for syntactic interoperability**
- and proprietary or **standardized protocols** for semantic interoperability.

Introduction
Project History



Introduction
OR.NET

OR.NET
SICHERE DYNAMISCHE VERNETZUNG IN OPERATIONSSAAL UND KLINIK

Gefördert vom Bundesministerium für Bildung und Forschung

CURRENT ISSUES | APPOINTMENTS | PROJECT | SUB-PROJECTS | PARTNER AREA | C

PROJECT > PARTNERS

Board

Within the project OR.NET, providers of integrated operating rooms work together with manufacturers of medical devices such as medical equipment and medical components, as well as (IT) service providers and software vendors. They are supported by numerous research institutes and clinics. Not only clinics and clinics IT departments, but also equipment operators are involved in the project. In order to make the project results internationally known, the OR.NET project is actively involved in standardization processes. This is also supported by the appropriate committees and regulatory bodies. Following partners run the project OR.NET forward and in the mean time the are receiving the support of the associate partners:

Provider of integrated operating rooms:
- Karl Storz GmbH & Co. KG
- Richard Wolf GmbH

Manufacturers of medical devices and medical equipment components:
- SurgiTAIX AG
- Inomed Medizintechnik GmbH, Research and Development
- Localite GmbH
- KLS Martin Group
- Möller-Wedel GmbH ImageNET (R&D)
- Ziehm Imaging GmbH
- Söring GmbH

(IT) service provider:
- UTK – UniTransferKlinik GmbH
- Synagon GmbH
- MedPlan Engineering GmbH
- MT2IT GmbH & Co. KG

Software and IT solutions for networking:
- MEDNOVO Medical Software Solutions GmbH
- how to organize
- Conworx Technology GmbH
- VISUS Technology Transfer GmbH/ R & D

Research institutes:
- Fraunhofer-Institut MEVIS
- Fraunhofer-Institut FOKUS
- Technische Universität München, Lehrstuhl für Mikrotechnik und Medizingerätetechnik
- ITM – Institut für Telematik, Universität zu Lübeck
- ISP -Institut für Softwaretechnik und Programmiersprachen, Universität zu Lübeck
- ICCAS – Innovation Center Comupter Assisted Surgery, Universität Leipzig
- MedIT – Lehrstuhl für Medizinische Informationstechnik, RWTH Aachen
- mediTEC – Lehrstuhl für Medizintechnik, RWTH Aachen
- OFFIS – Institut für Informatik e.V. / FuE-Bereich Gesundheit
- Institut für Angewandte Mikroelektronik und Datentechnik, Universität Rostock
- Institut für Medizinische Informatik, Universität zu Lübeck
- Universitätsklinikum RWTH Aachen, Integrierte Teleanästhesiologie
- Technische Universität München, Lehrstuhl für Automatisierung und Informationssysteme
- Technische Universität München, Institut für Informatik, Robotics and Embedded Systems
- Technische Universität München, MITI, Minimal-invasive Interdisziplinäre Therapeutische Intervention
- Universität Augsburg, FMPR, Forschungsstelle für Medizinprodukterecht

Specialist Clinics:
- Uniklinik Tübingen, Universitätsklinik für Urologie
- Uniklinik Tübingen, Universitätsklinik für Radiologie
- Uniklinik Tübingen, Universitäts-Frauenklinik
- Klinikum Rostock Anästhesie, Klinik für Anästhesiologie und Intensivmedizin
- Uniklinik Schleswig-Holstein, Klinik für Chirurgie
- Uniklinik Leipzig, Klinik für Herzchirurgie
- Uniklinik der RWTH Aachen, Klinik für Anästhesiologie
- Uniklinik der RWTH Aachen, Orthopädische Klinik
- Uniklinik der RWTH Aachen, Neurochirurgie
- Uniklinikum Heidelberg, Fachklinken für Chirurgie, Urologie und Orthopädie

Clinic-IT departments and operators:
- Uniklinikum Heidelberg, Zentrum für Informations- und Medizintechnik
- Rhön-Kliniken AG
- Uniklinik Schleswig-Holstein, IT-Planung und -Strategie

http://www.ornet.org/

A Proposal For Standards Adoption
Agenda

Clinical Workplace SOMDA
What is it?

The concept of a

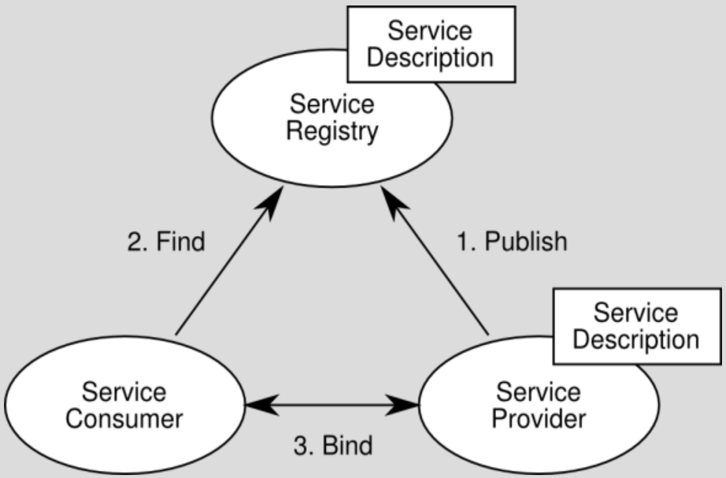
clinical workplace service-oriented medical device architecture

transfers the concept of a

service-oriented architecture

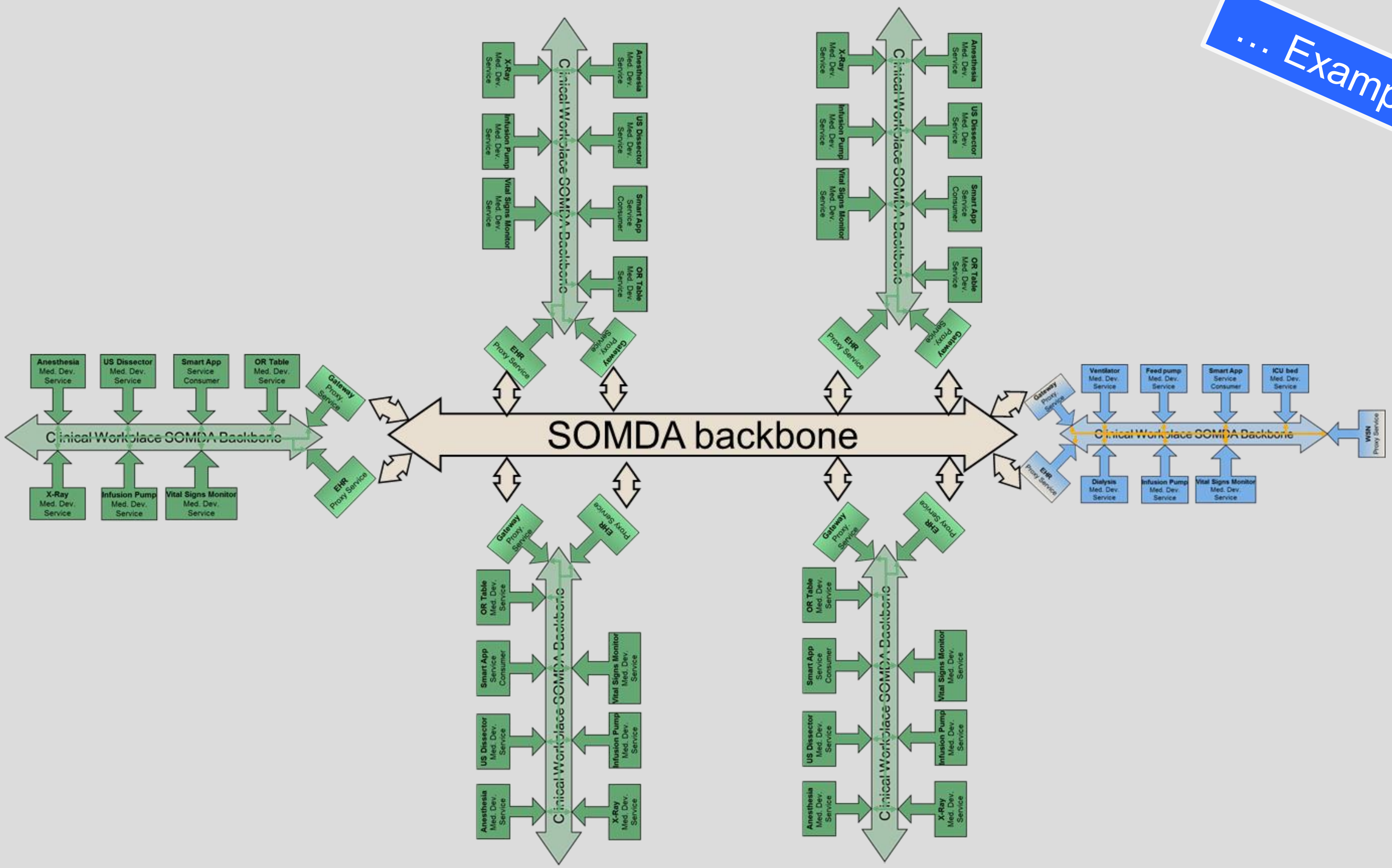
to the domain of

distributed system of medical devices for one clinical workplace.



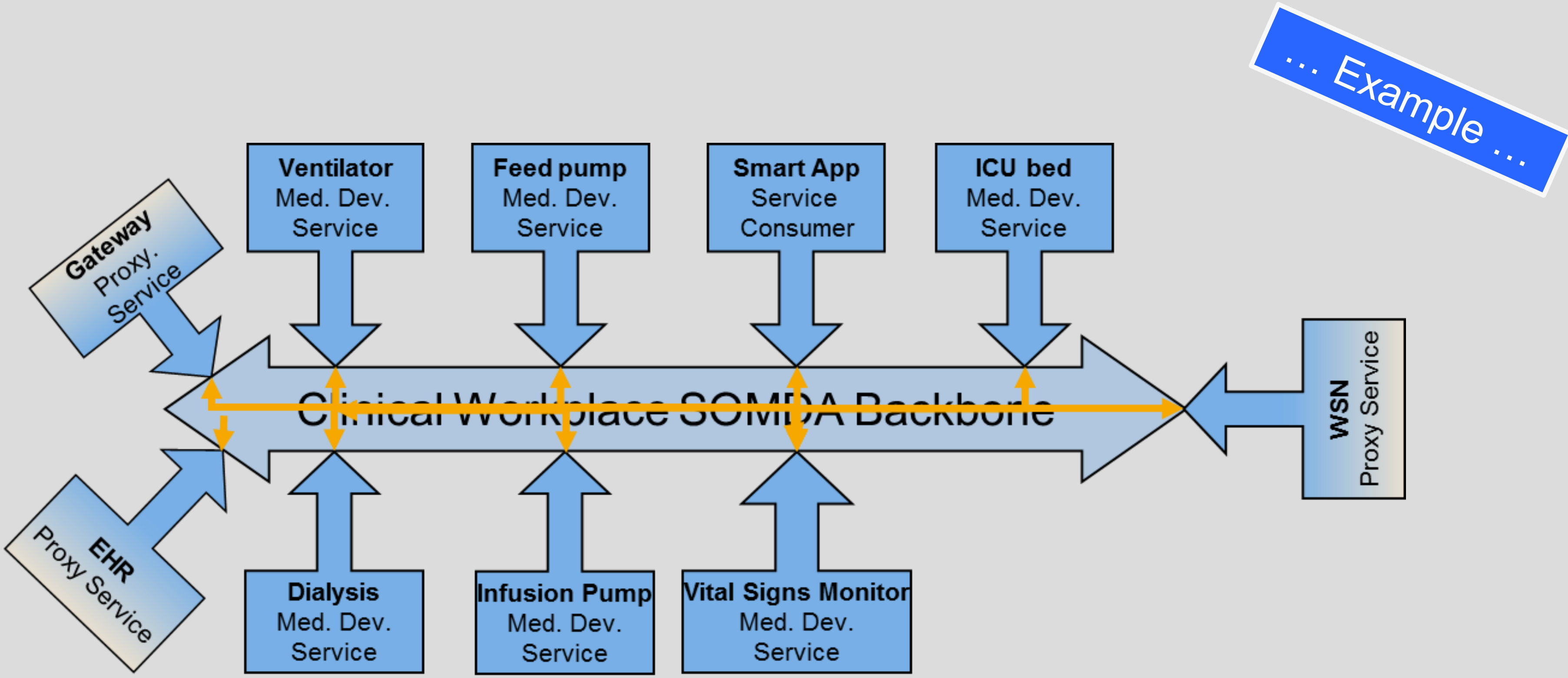
Clinical Workplace SOMDA
What is it?

… Example …



This is a SOMDA: 5 ORs & 1 ICU Bed.

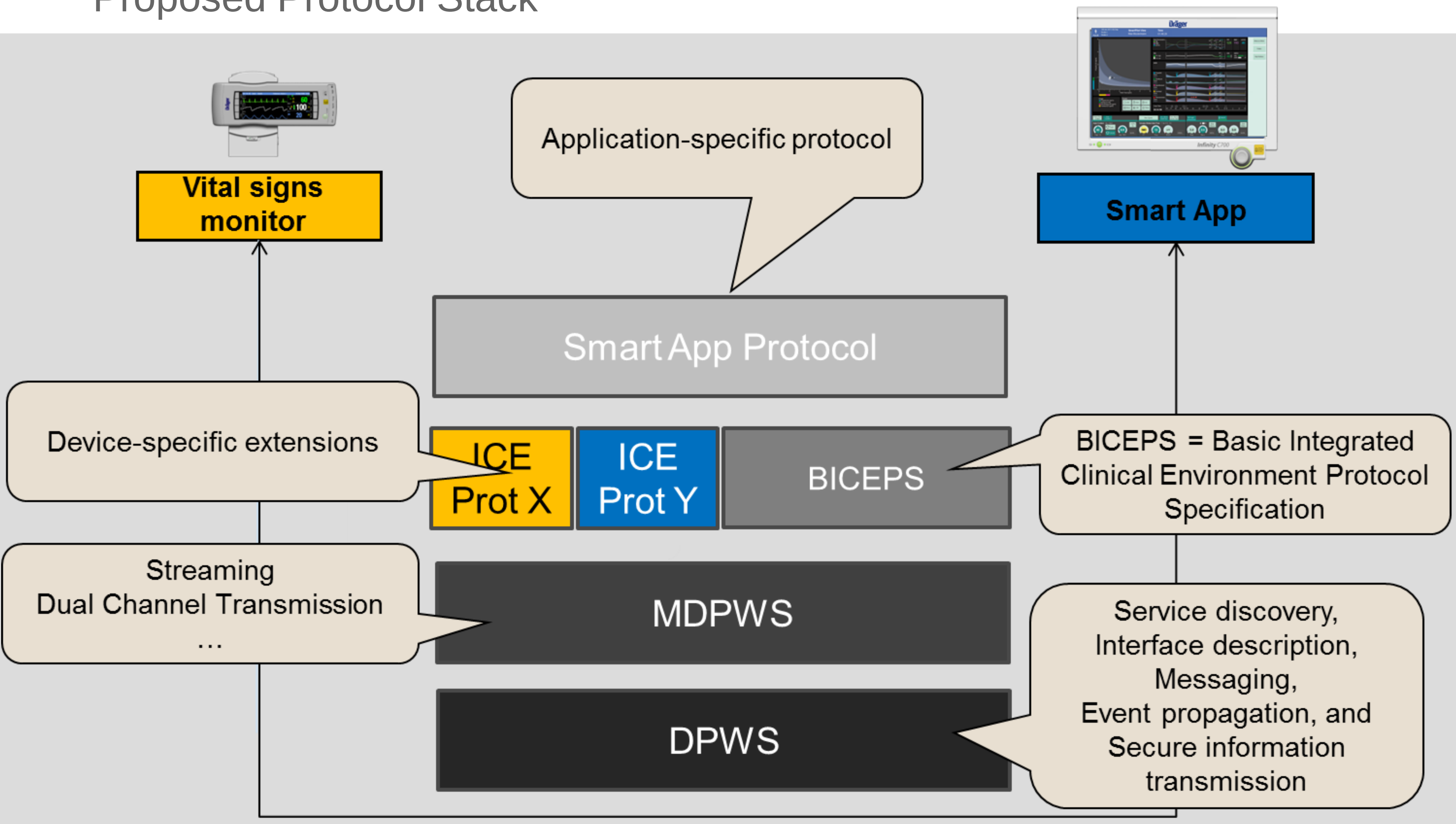
Clinical Workplace SOMDA
What is it?



Conceptual view of a SOMDA for a clinical workplace

Concept of a clinical workplace SOMDA does <u>not</u> make any assumptions of the underlying network topology.

Clinical Workplace SOMDA
Proposed Protocol Stack



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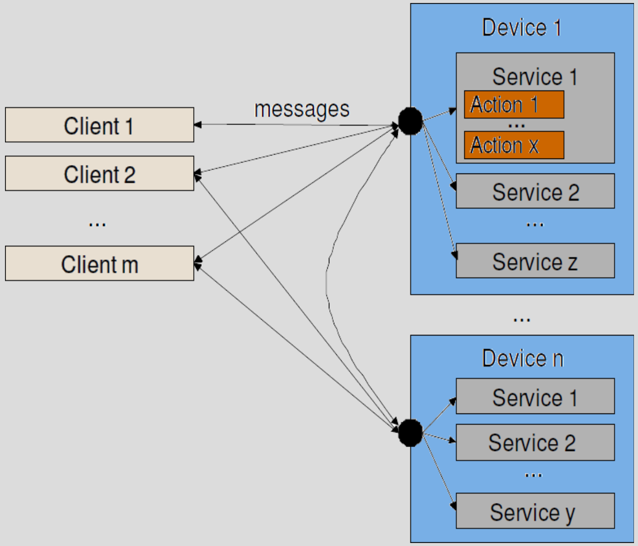
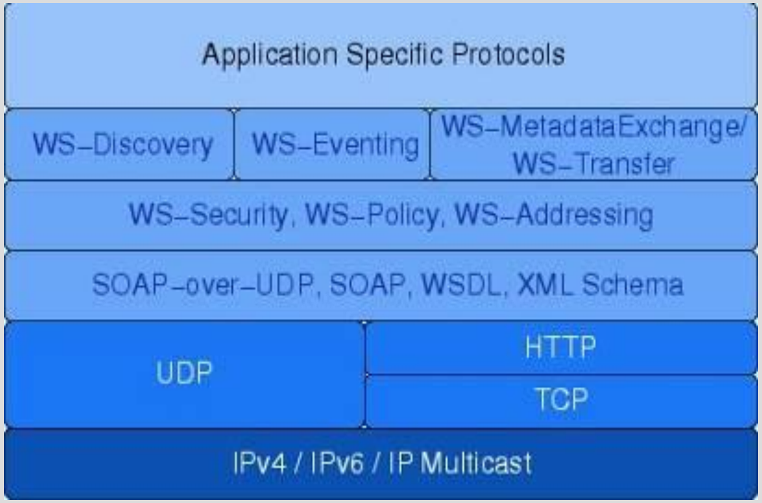
2. Clinical Workplace SOMDA
3. **MDPWS**
4. BICEPS
5. Results
6. DDS
7. Discussion
8. Formal Request to IEEE 11073 Committee

MDPWS
Medical Device Profile for Web Services

- DPWS:2009* is the core of MDPWS
  - OASIS standard (since 07/2009)
  - Utilizes a subset of the WS-* standard
  - Covers
    - Service discovery,
    - Interface description,
    - Messaging,
    - Event propagation, and
    - Secure information transmission
  - Designed for resource-constrained devices





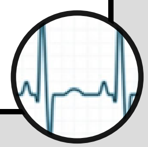
- MDPWS
  - Added some missing parts e.g. safe transmission of control requests

*See https://www.oasis-open.org/committees/ws-dd/

MDPWS
Extensions

- WS-Streaming based on SOAP-over-UDP for (numeric) data streaming
  - Maybe unreliable
  - Multiple receivers

Waveform Streaming

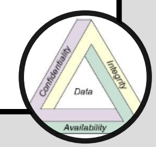


- Safe & reliable data exchange based on
  - WS-SafetyInformation
    - e.g. Dual Channel
- Liveliness assurance

Patient Safety

- Access control for critical operations
- Secure transmission

Access Control



- XML Manifestation doesn‘t need to be UTF-8
- Optional binary XML (EXI) for reduced message sizes

Compression

- Policy assertions
- Limit options in DPWS spec
- New Device Type for Discovery

General

A Proposal For Standards Adoption

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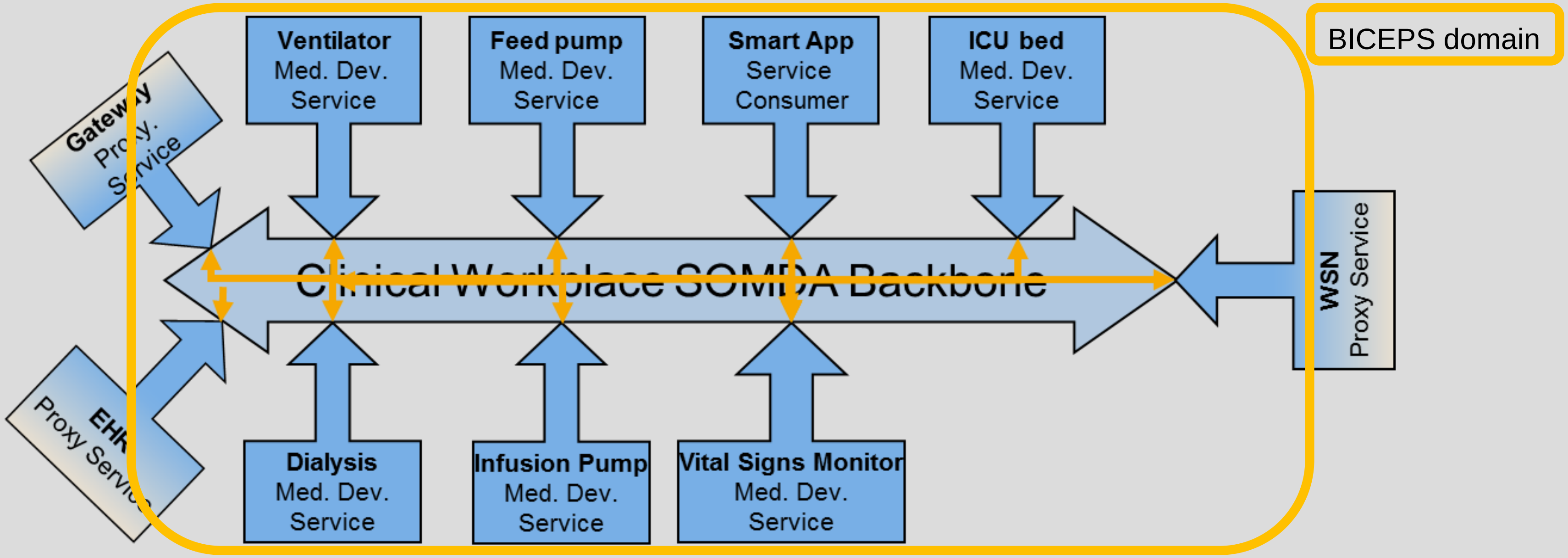
What is BICEPS?

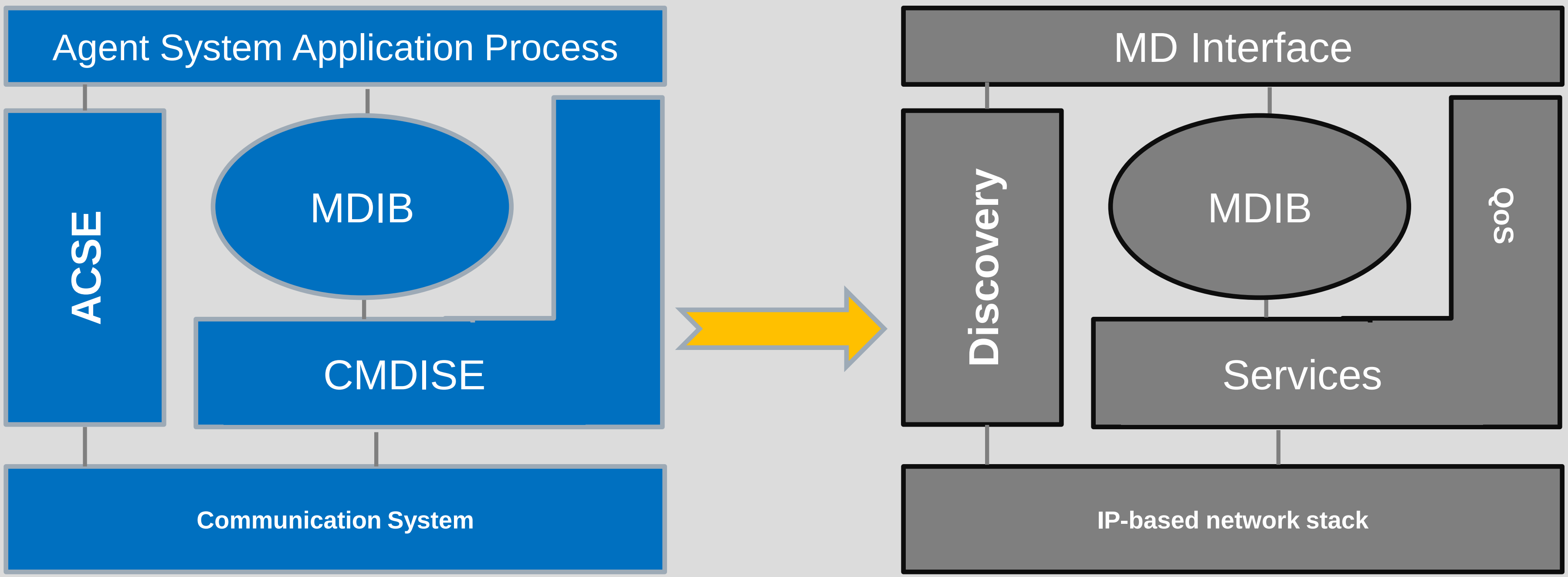
BICEPS is communication protocol specification that has the objective to allow communication between participants in a **distributed system of medical devices** in high acuity environments that directly interact with, monitor, provide treatment to, or are by some other means directly associated with a **single patient**.

➔ facilitate medical device interoperability in a distributed system of medical devices that follows the **clinical workplace SOMDA architecture paradigm**



BICEPS
… and ISO/IEEE 11073

11073 **BICEPS**



- ACSE, which provides services to establish logical connections between Agent & Manager
- Managed medical objects are accessible only through services provided by CMDISE

- **BICEPS Discovery**, which provides services to establish logical connections between Device & Client
- Managed medical objects are accessible only through **BICEPS services** hosted by the Device

BICEPS
Parts of the specification

BICEPS Services

- Control access to the managed objects
- Extensible, functional groups of operations
- No transport protocol defined

BICEPS Discovery

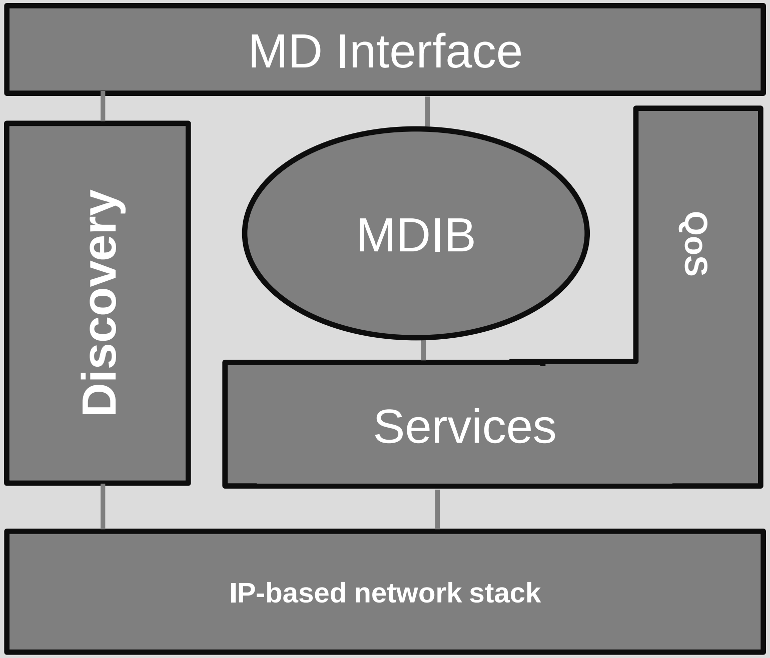
- Fosters Plug & Play by defining requirements for transport protocol
- Implicit & explicit discovery
- No mandatory central service registry
- Utilizes the BICEPS Get Service

BICEPS Message Information Model

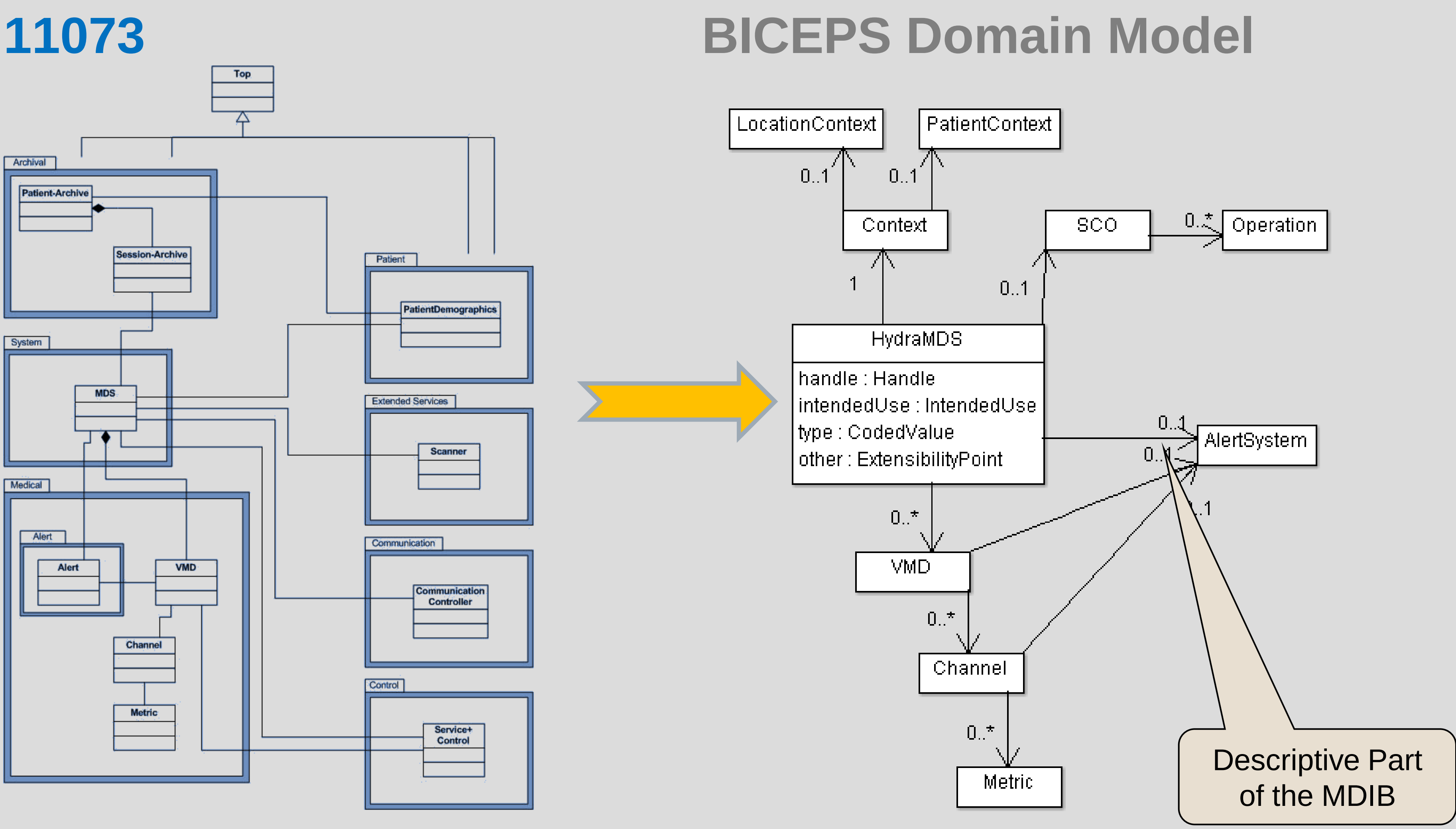
- Message for conveying state data and descriptive meta-information
- Extensibility points
- No transport protocol defined

BICEPS QoS

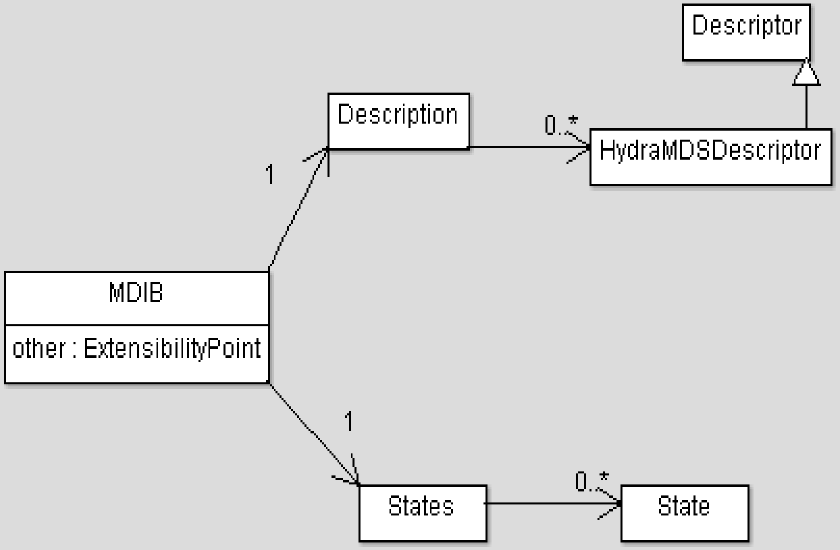
- No QoS on its own, as QoS may be transport protocol specific
- Extensibility points for transport



BICEPS
Message Information Model



BICEPS
Message Information Model



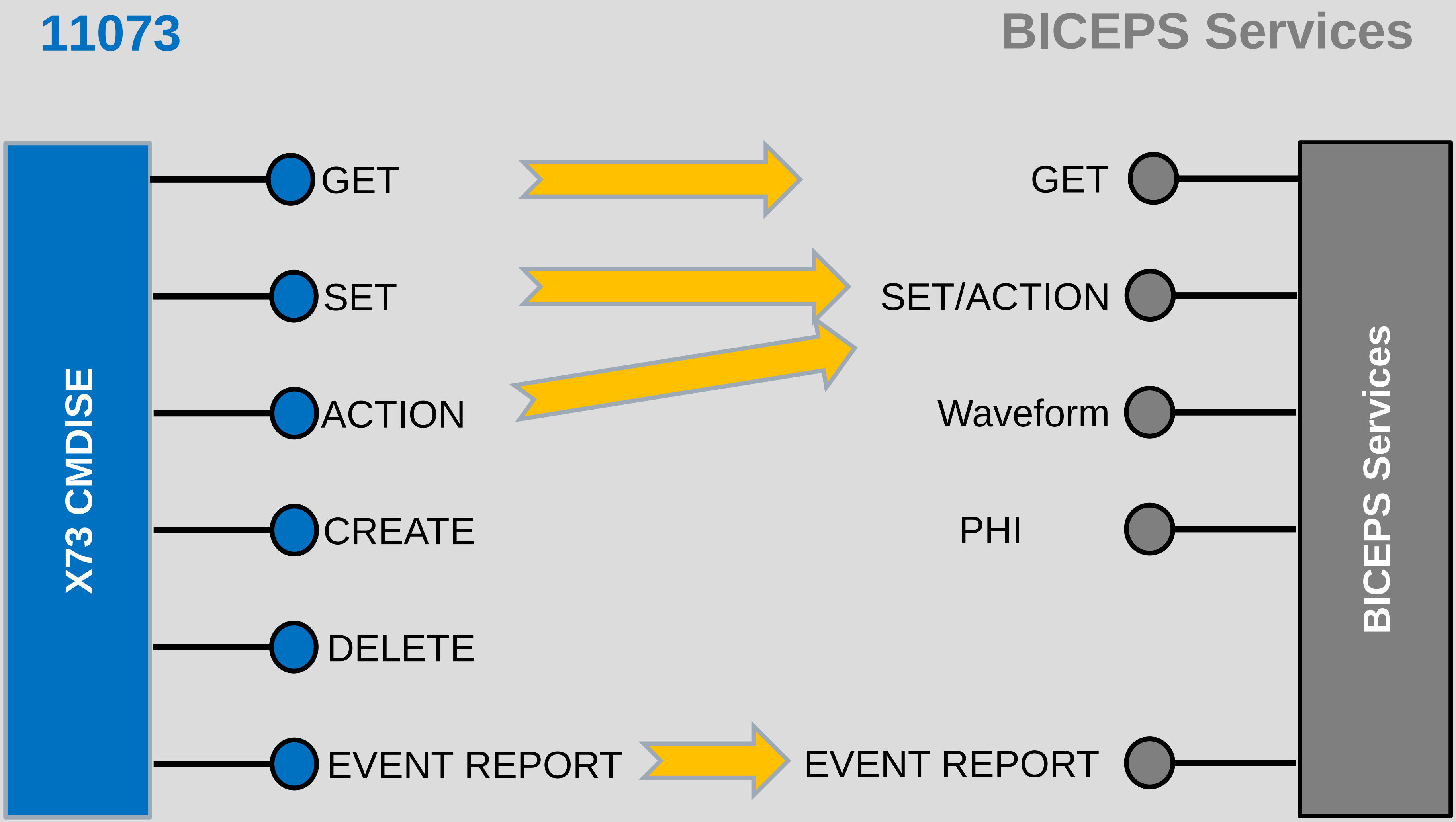
Descriptive Part

- Capabilities of the MD
- CodedValue concept
- (Rare) Update Reports

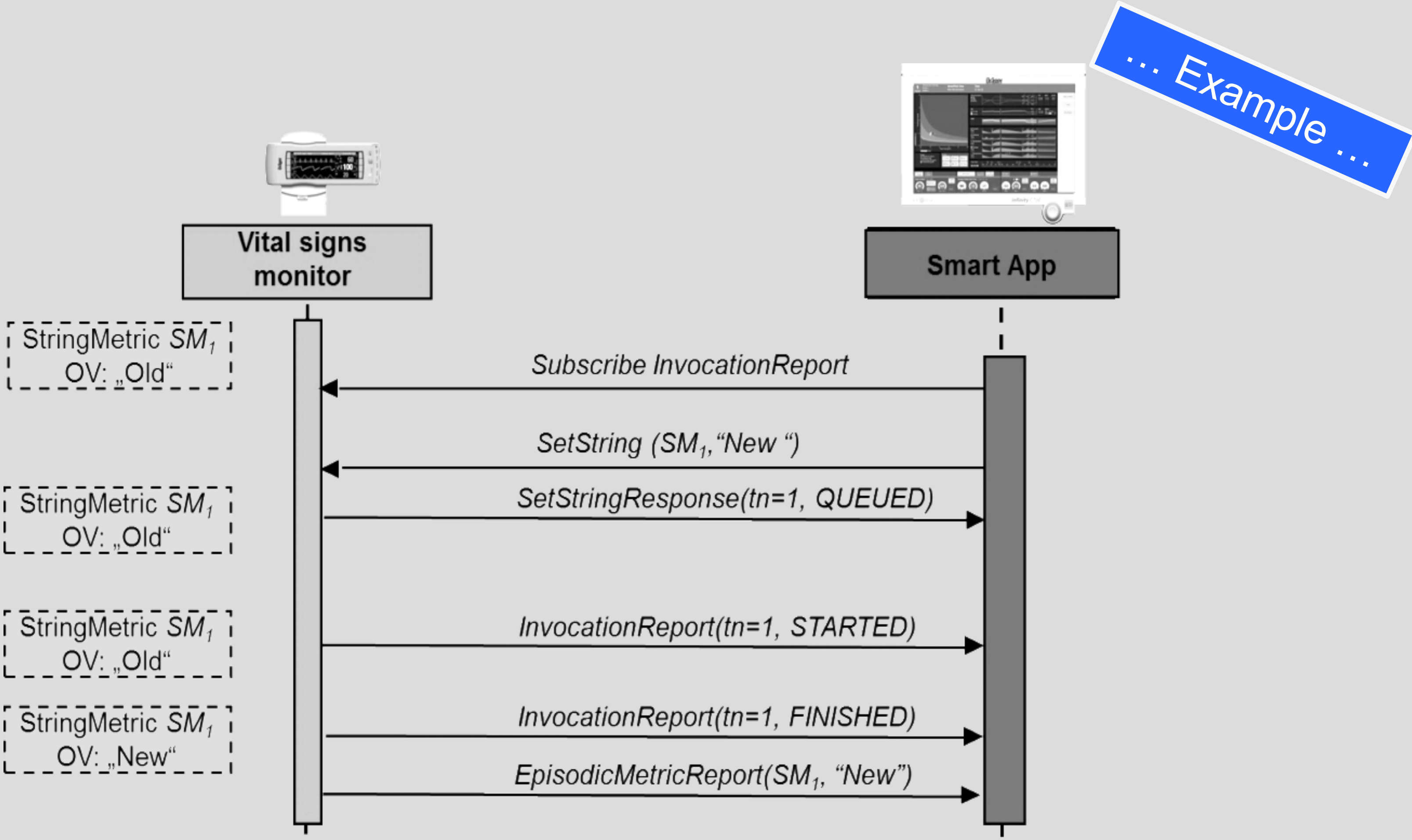
State Part

- Dynamic State of the MD
- All States reference to one Descriptor
- Episodic/Periodic Update Reports
- Streams

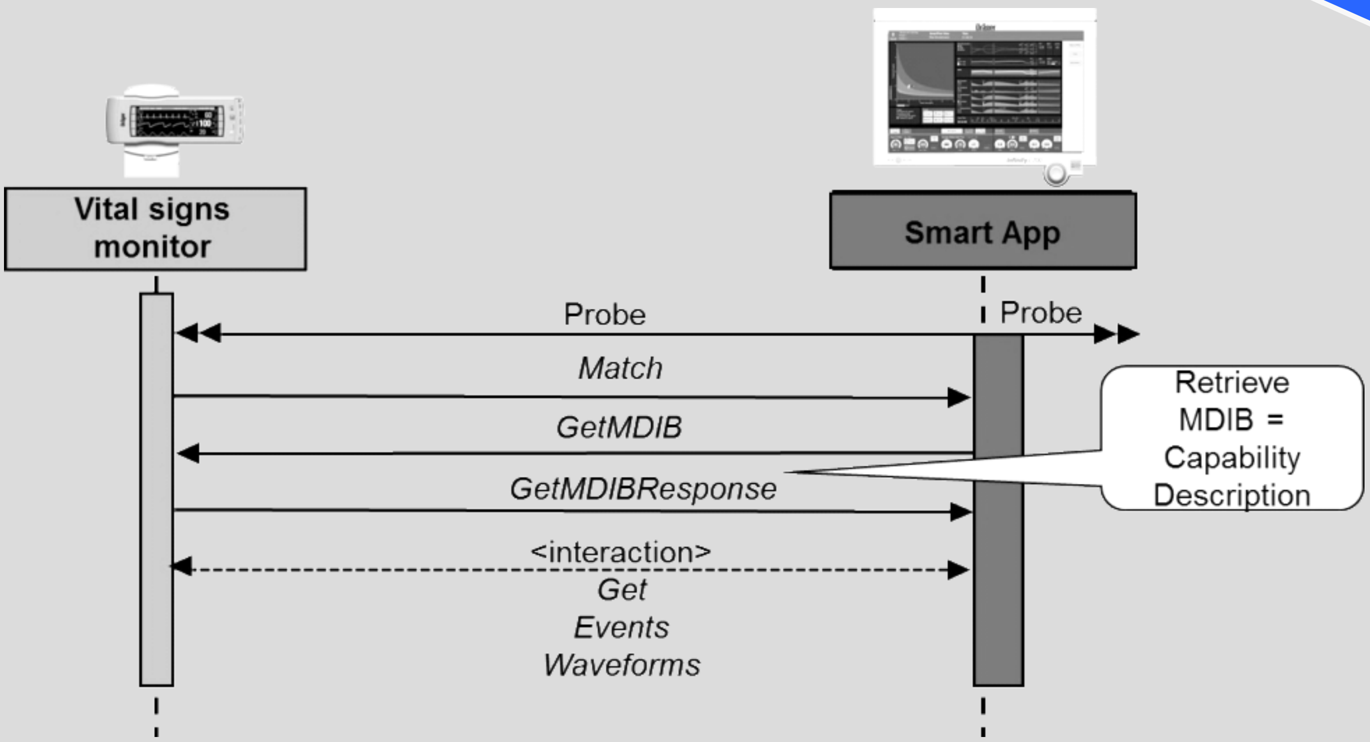
BICEPS
Services



BICEPS
Remote invocation



Remote invocation via Set Service



… Example …

Exemplary Discovery sequence

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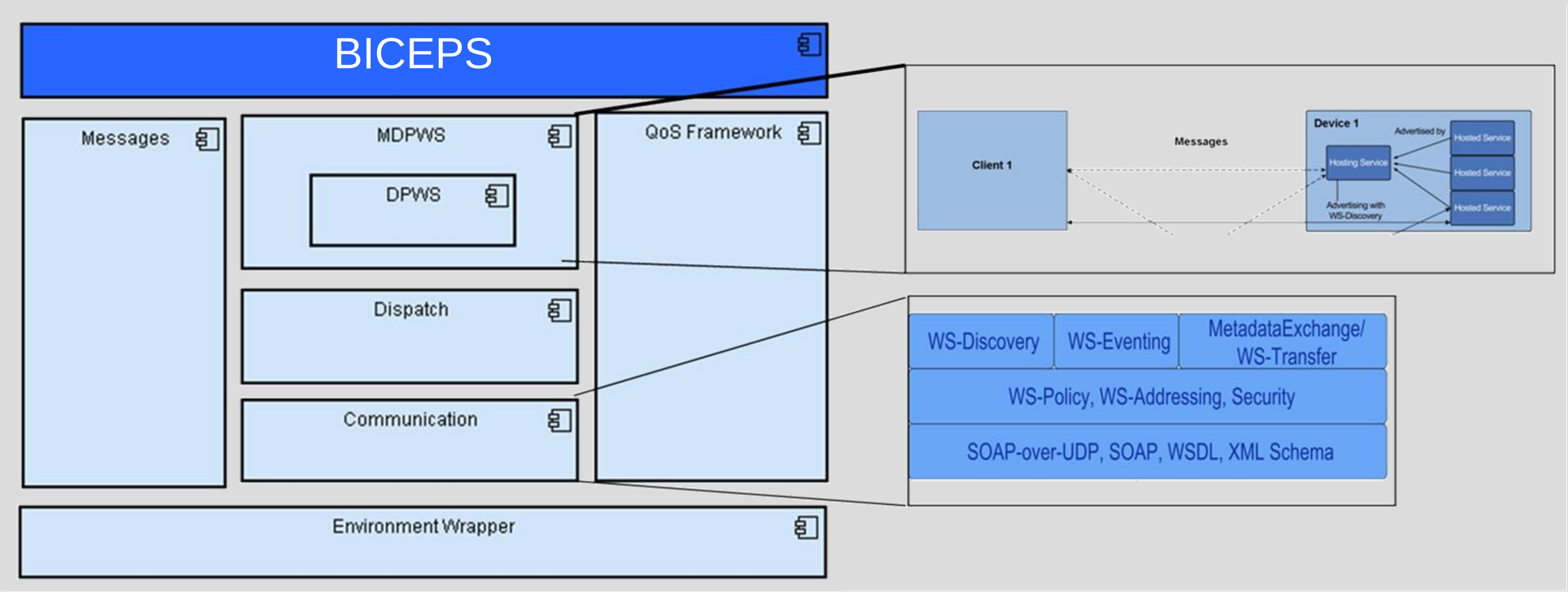
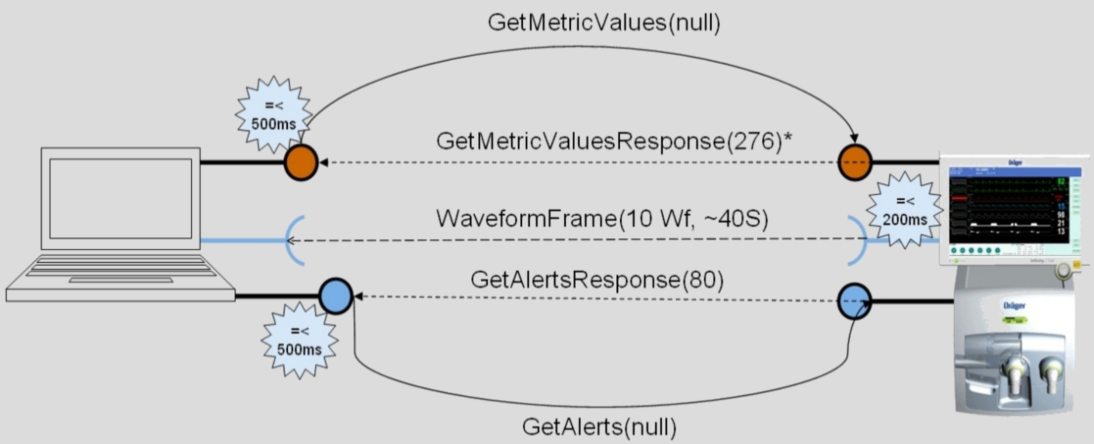
Java-based reference implementation

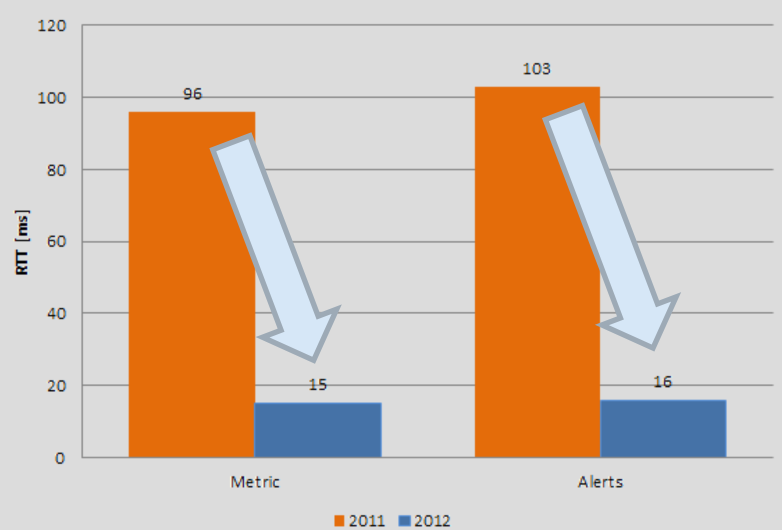
- >= Java SE 1.6



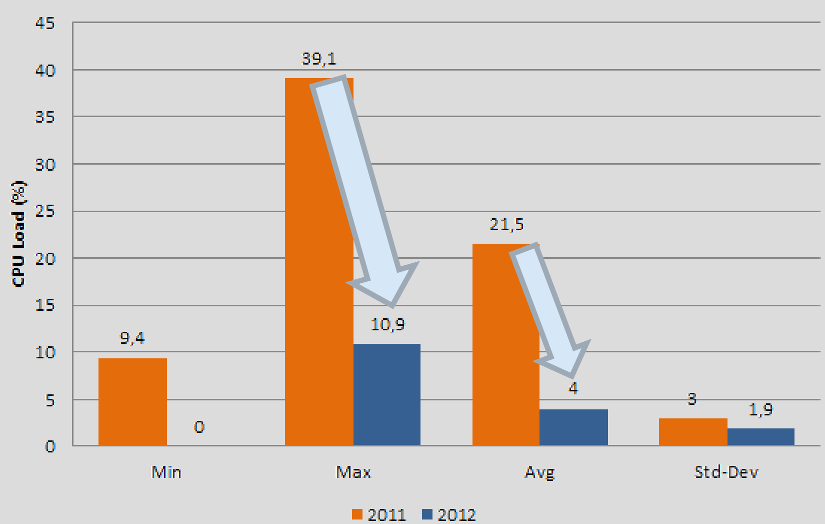
Results
Test Scenario



Ventilator running JRE 6.
Client running JRE 6.
Direct Ethernet connection.

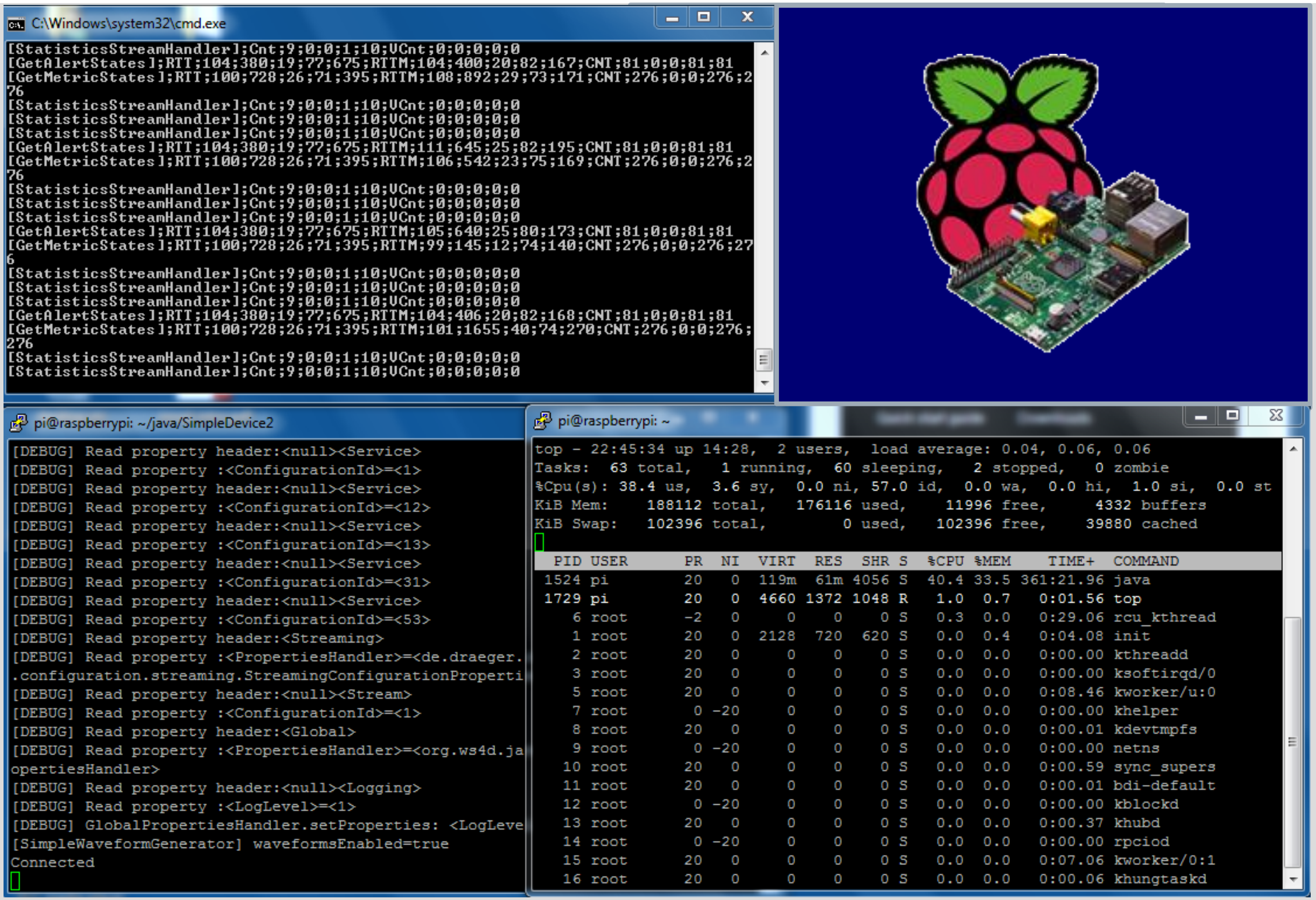


Round Trip Time



CPU Load

Results
Test Scenario

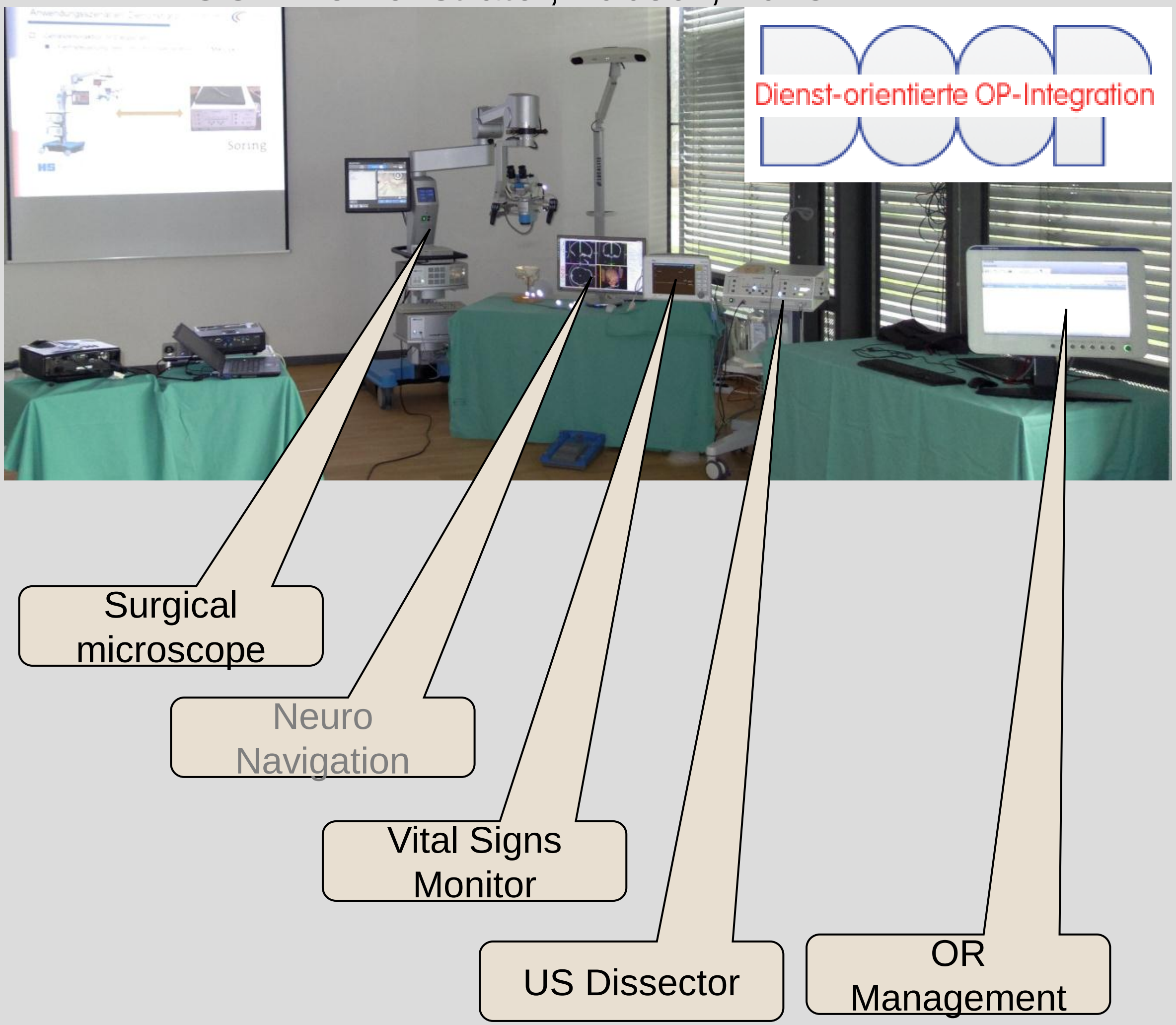


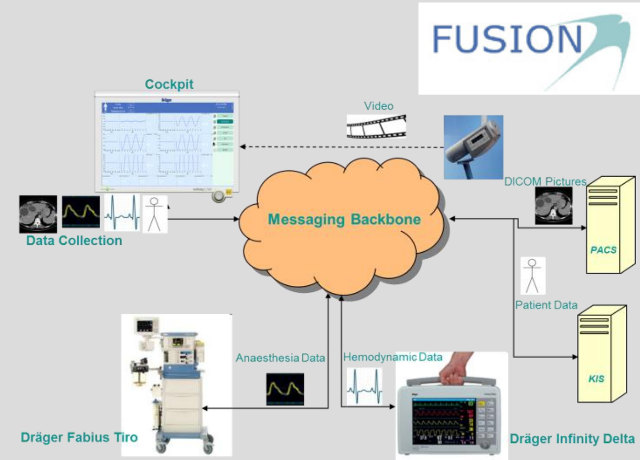
Raspberry PI runs as a device in the test scenario. No optimization performed.

Results

Demonstrators

DOOP Demonstrator, Lübeck, 2013-12-11



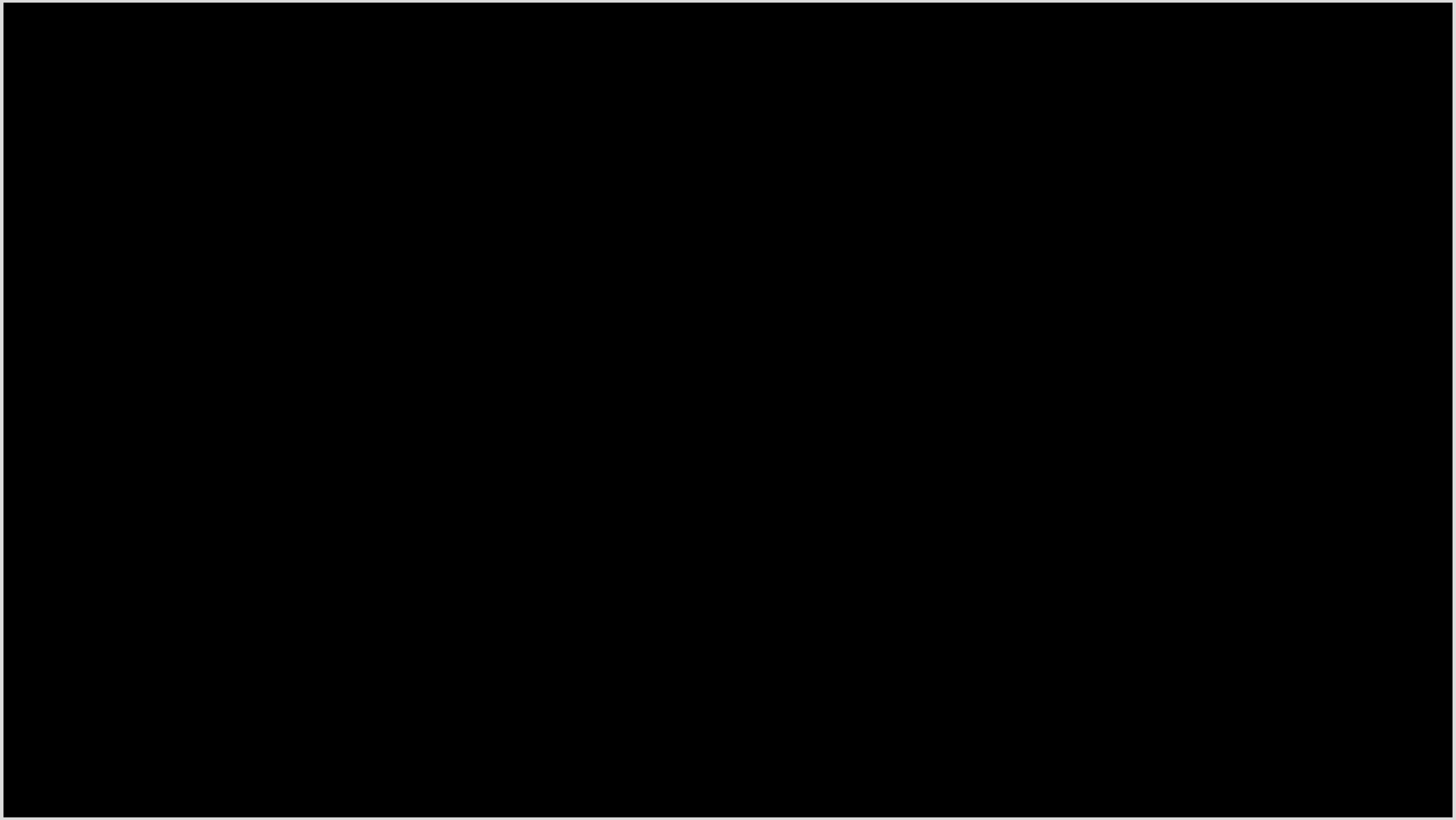


Demonstrator, 2009

Demonstrator, 2011

Results

Demonstrators



DOOP Demonstrator, Lübeck, 2013-12-11

Proposed Architecture

Summary

Functional

Plug'n Play

- Discovery and Binding 👍
- Device capability description at runtime 👍
- Openness 👍

Communication (1-1, 1-n, n-n)

- Event Notification 👍
- Data reporting 👍
- External control 👍

Non-Functional

- Risk Management 👍
  - Safe communication 👍
  - Access control 👍
  - Trust establishment between participants ☞
- Privacy of patient-related data 👍
- Latency in milliseconds range 👍

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DDS
What is DDS?

Date: January 2007

Data Distribution Service for Real-time Systems
Version 1.2

OMG Available Specification
formal/07-01-01

Date: January 2009

The Real-time Publish-Subscribe Wire Protocol
DDS Interoperability Wire Protocol
Specification

Version 2.1

Date: November 2012

Extensible and Dynamic Topic Types for DDS

Version 1.0

DDS

- OMG standard for distributed systems
- utilize an architecture that relies on the indirect communication paradigm that is based on a data-centric publish-subscribe (DCPS) model
- several QoS features
  - HISTORY, LIFESPAN, RELIABILITY, PARTITION, DEADLINE, OWNERSHIP, PRESENTATION, TIME_BASED_FILTER, RESOURCE_ LIMITS,…
- Conformance profiles: minimal, Content-subscription, Persistence, …
- API standard
  - Different DDS implementations may be incompatible on the wire

RTPS

- RTPS extension to DDS or stand alone specification
- Messages & Behavior of participants
- Simple Discovery mechanisms
- One transport module based on UDP

XTypes

- DDS has a static, non extensible type model
- Limited support for extensions
- Data types must be known at compile time
- Xtypes extension for DDS & RTPS

DDS

Evaluation Results of DDS standards family

Dräger

… Evaluation in 2009 & 2013…

Benefits

- DDS is a non-proprietary specification for a data distribution API for distributed systems
- Proven to allow implementation of scalable DS
- Rich set of QoS parameters
- RTPS to ensure interoperability on the wire
- XTypes to ensure model extensibility

- RTPS & XTypes are the relevant specifications for an open distributed system
  - Original DDS standard is just an API specification

Weaknesses of RTPS & XTypes as perceived by Dräger

- Transport security not standardized
  - Only vendor specific options available at the moment
- RTPS doesn’t support all DDS QoS features on its own as most are not wire-protocol related
- RTPS is designed for data distribution, not remote invocation
- Indirect communication may complicate implementation of risk measures
- Topic-based model may lead to intermingling of message model & transport channel related safety implementations

RTPS & XTypes
Summary of Evaluation

Functional

Plug’n Play
- Discovery and Binding 👍
- Device capability description at runtime ☞
- Openness ☞

Communication (1-1, 1-n, n-n)
- Event Notification 👍
- Data reporting 👍
- External control ☞

Non-Functional

- Risk Management ☞
  - Safe communication ☞
  - Access control ☞
  - Trust establishment between participants ☞
- Privacy of patient-related data ☞
- Latency in milliseconds range 👍

RTPS & XTypes is great for distributed systems of one vendor where data distribution is the focus

Examples: Airplane, Car, Inside of a CT

It is not our first choice for implementation of an open distributed system of medical devices from multiple vendors

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Discussion

Summary

Functional

Plug'n Play

– Discovery and Binding 👍

– Device capability description 👍

at runtime

– Openness 👍

Communication (1-1, 1-n, n-n)

– Event Notification 👍

– Data reporting 👍

– External control 👍

Non-Functional

–Risk Management 👍

– Safe communication 👍

– Access control 👍

–Trust establishment between participants ☞

– Privacy of patient-related data 👍

–Latency in milliseconds range 👍

BICEPS + MDPWS meets the requirements of the project …

Discussion
openSDC

… Feedback requested …

… and you can evaluate it yourself by downloading the **open-source reference implementation** from sourceforge

https://sourceforge.net/projects/opensdc

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Formal Request to IEEE 11073 Committee

We seek adoption of the DPWS architecture as the basis for IEEE 11073-20401.

- We have demonstrated the strong functional and non-functional attributes of the proposed architecture to meet both near-term and longer-term requirements for the point of care integration of medical devices.
- We have disclosed a list of collaborating partners who have evaluated and are utilizing the proposed architecture as strong references for its ease of use and its adaptability.
- We are prepared to work with the Committee in the development of IEEE 11073-20401 to support its completion.
- In order to accelerate acceptance and allow evaluation, Dräger is announcing to the IEEE 11073 Standards Committee that a reference implementation of this architecture is now available as open source.
- We respectfully ask for your favorable and timely consideration to our proposal.

Dräger

Thank you for your attention.

Contact
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