

# 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

Dräger. Technology for Life®

### A Proposal For Standards Adoption Agenda

# Dräger

#### 1. Introduction

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



#### 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

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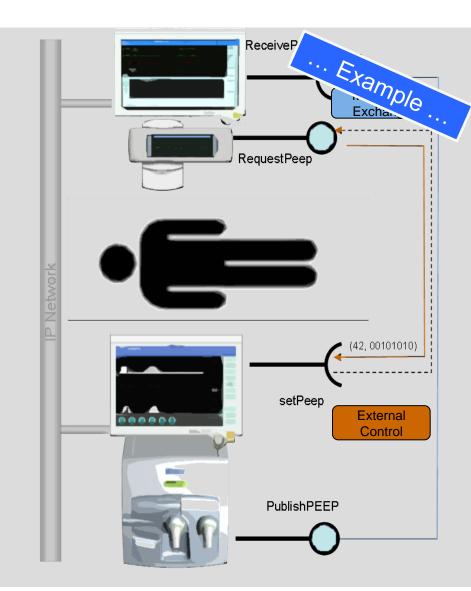
Medical Device Interoperability in high acuity clinical workplace environments,

#### that is

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

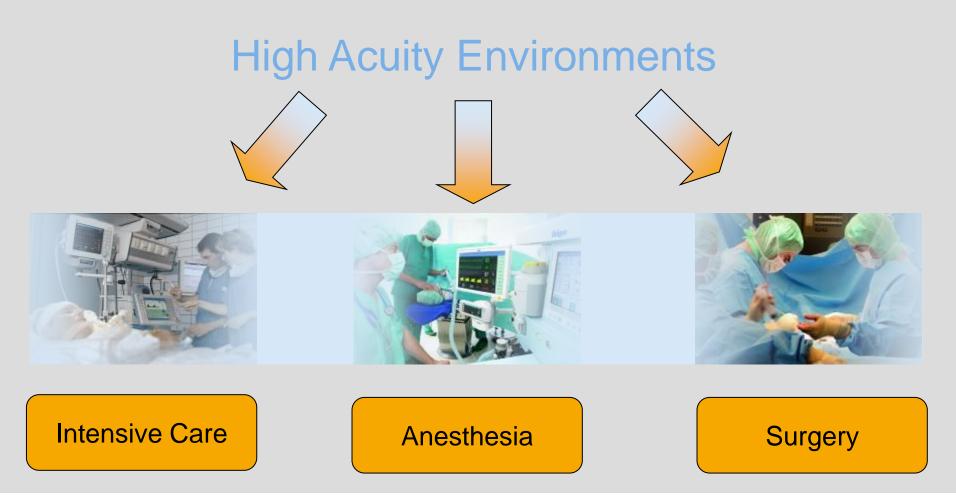
without tight system integration, yielding a flexible technical infrastructure

for smart clinical applications.



#### Introduction Examples for High Acuity Environments





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### 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

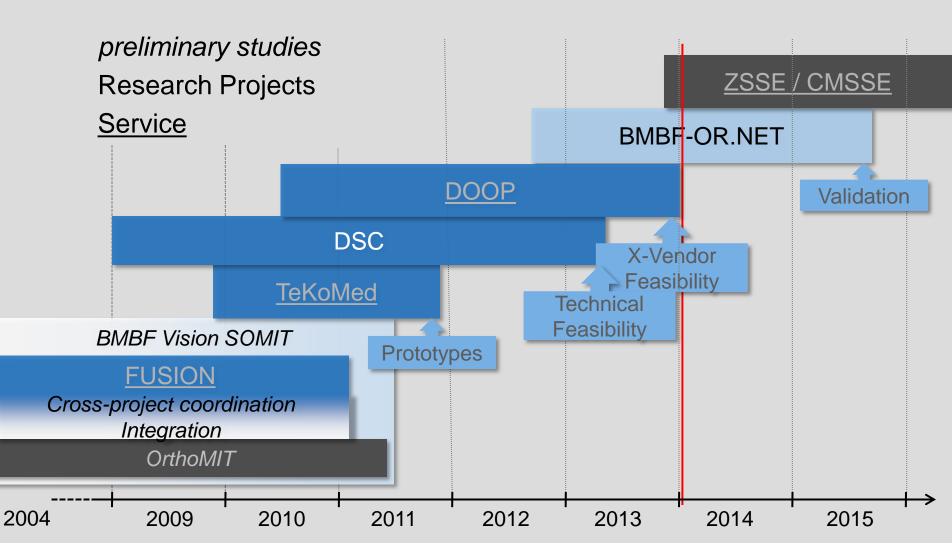
### **Core Concept**

Develop an interoperability architecture & procol stack

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







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### Introduction OR.NET





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

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:

Gefördert vom Bundesministeriur für Bildung und Enrachung

- MEDNOVO Medical Software Solutions GmbH
- how to organize
- C . 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 f
  ür Informatik e.V. / FuE-Bereich Gesundheit
- Institut f
  ür Angewandte Mikroelektronik und Datentechnik, Universit
  ät Rostock
- Institut f
  ür Medizinische Informatik, Universit
  ät zu L
  übeck
- Universitätsklinikum RWTH Aachen, Integrierte Teleanästhesiologie
- Technische Universit
  ät M
  ünchen, Lehrstuhl f
  ür 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 f
  ür Chirurgie
- Uniklinik Leipzig, Klinik f
  ür Herzchirurgie
- 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/

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#### Clinical Workplace SOMDA What is it?

The concept of a

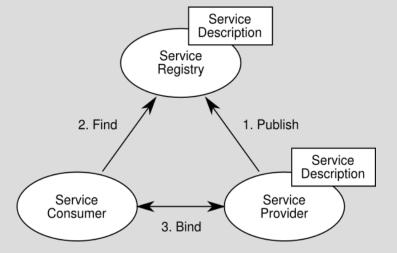
clinical workplace service-oriented medical device architecture

transfers the concept of a

service-oriented architecture

to the domain of

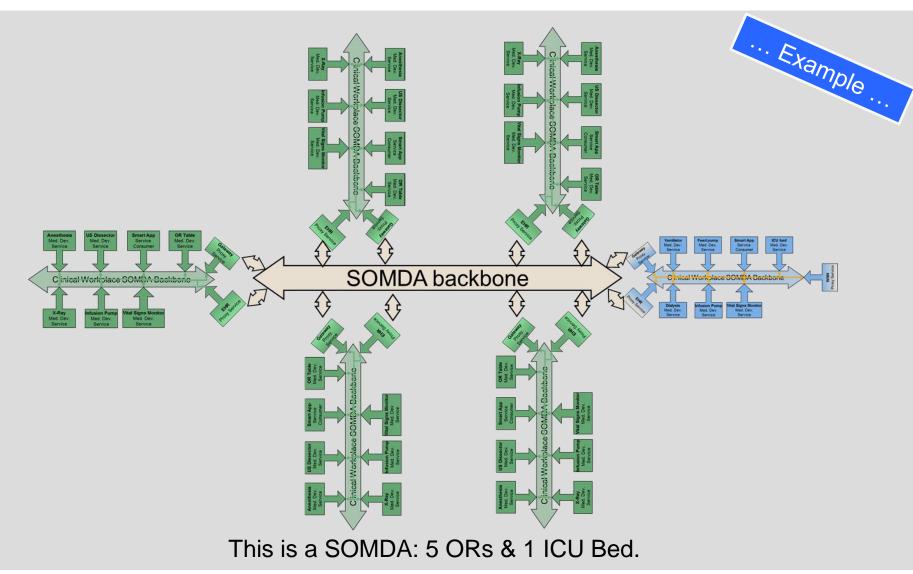
distributed system of medical devices for one clinical workplace.



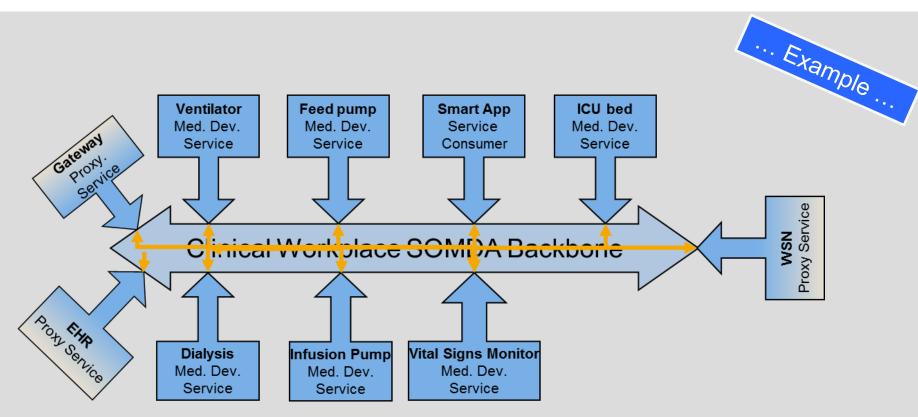


### **Clinical Workplace SOMDA** What is it?





#### **Clinical Workplace SOMDA** What is it?



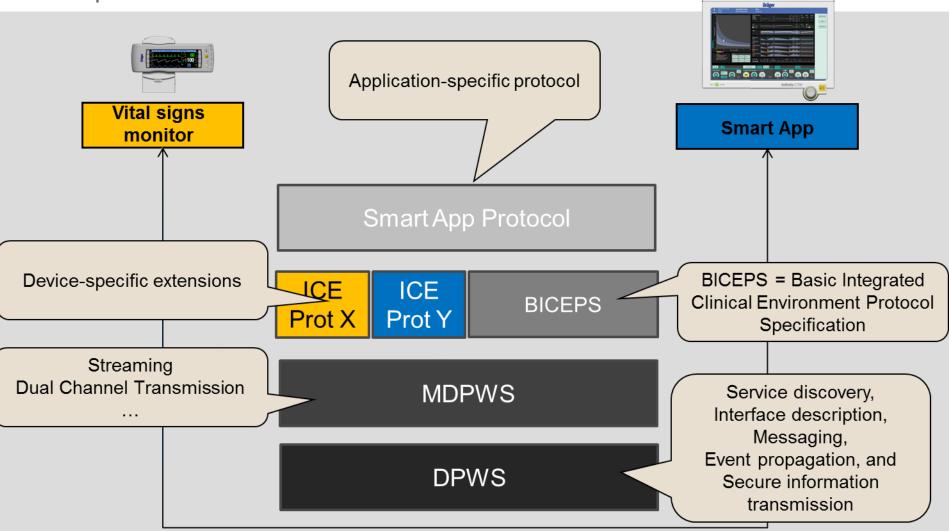
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Conceptual view of a SOMDA for a clinical workplace

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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## **MDPWS** Medical Device Profile for Web Services

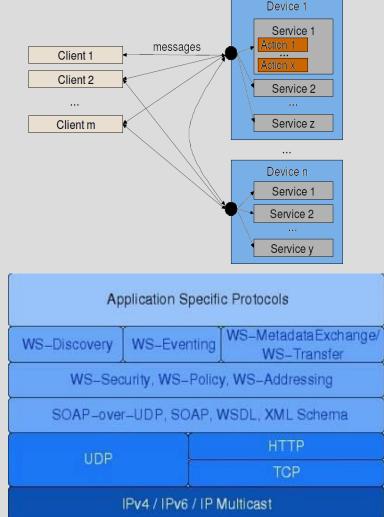


- OASIS standard (since 07/2009)
- Utilizes a subset of the WS-\* standard
- Covers
  - Service discovery,
  - Interface description,
  - Messaging,
  - Event propagation, and
  - Secure information transmission
- Designed for resource-constrained devices

#### MDPWS

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

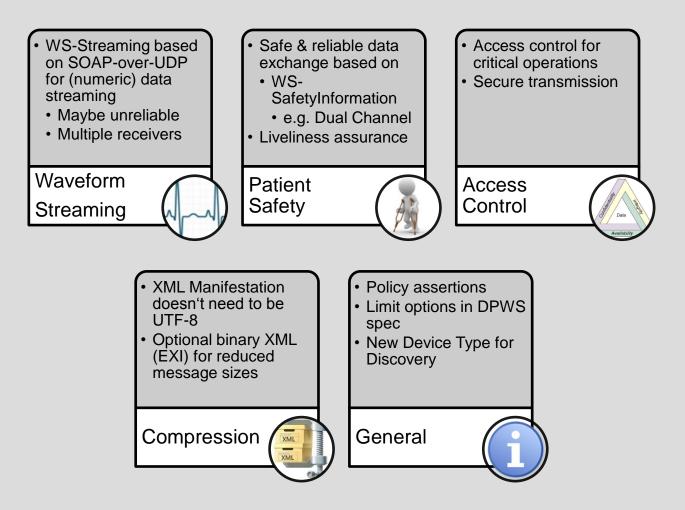
\*See https://www.oasis-open.org/committees/ws-dd/





### MDPWS Extensions





### A Proposal For Standards Adoption Agenda



#### 1. Introduction

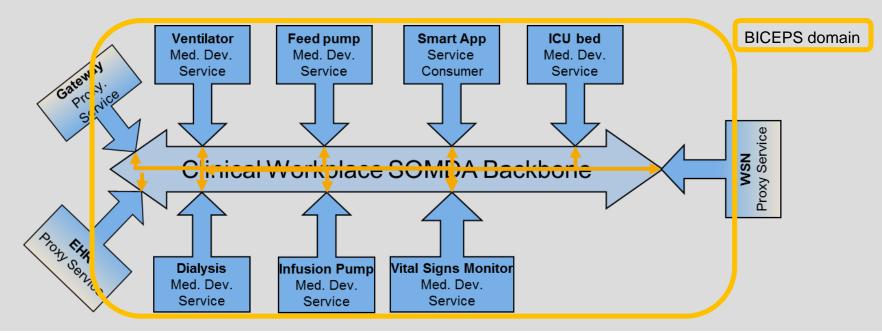
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### **BICEPS** What is BICEPS?



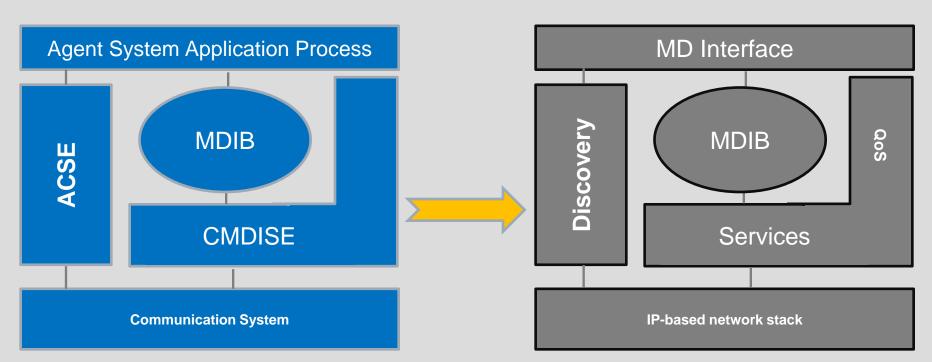
**BICEPS** is communication protocol specification that has the objective to allow communication between participants in a **distributed system of medical devices** in high acuity environments that directly interact with, monitor, provide treatment to, or are by some other means directly associated with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



- 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

# Control access to the managed objectsExtensible, functional groups of operations

Parts of the specification

No transport protocol defined

#### **BICEPS Discovery**

**BICEPS Services** 

BICEPS

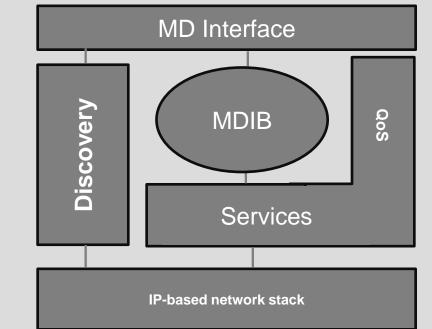
- Fosters Plug & Play by defining requirements for transport protocol
- Implicit & explicit discovery
- No mandatory central service registry
- Utilizes the BICEPS Get Service

#### **BICEPS Message Information Model**

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

#### **BICEPS QoS**

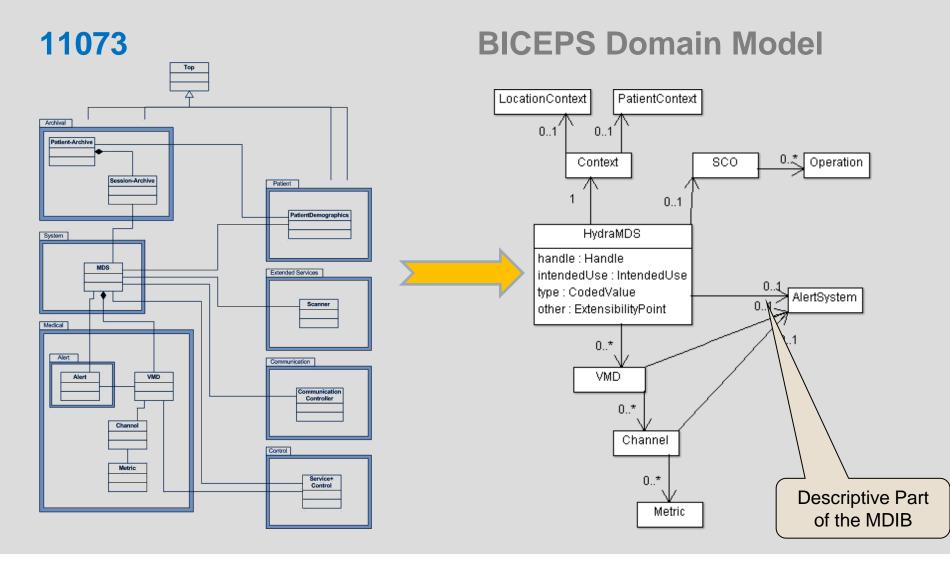
- No QoS on its own, as QoS may be transport protocol specific
- Extensibility points for transport





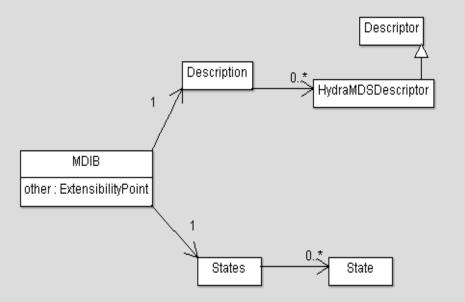
## **BICEPS** Message Information Model





### **BICEPS** Message Information Model





#### **Descriptive Part**

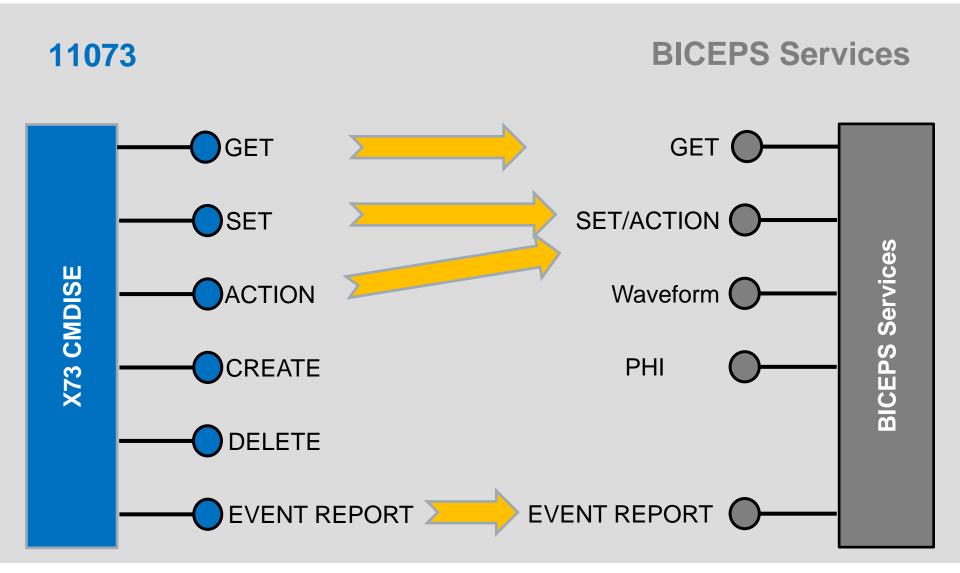
- · Capabilities of the MD
- CodedValue concept
- (Rare) Update Reports

#### State Part

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

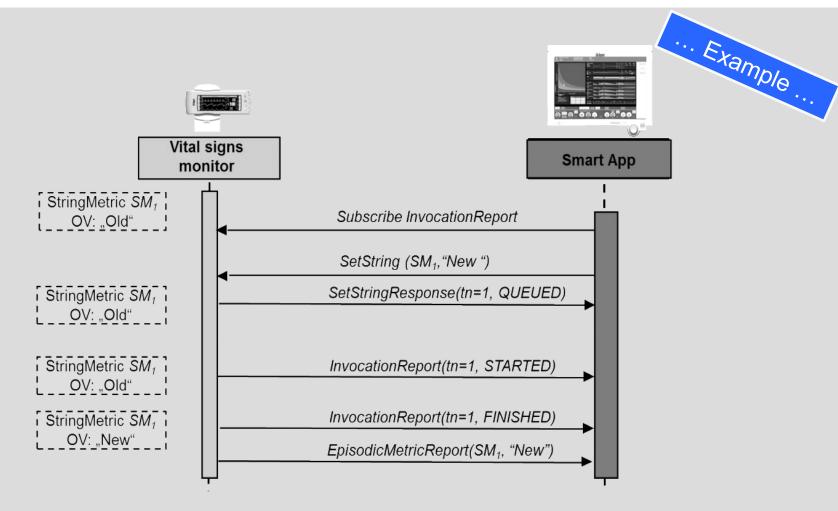
BICEPS Services





### **BICEPS** Remote invocation

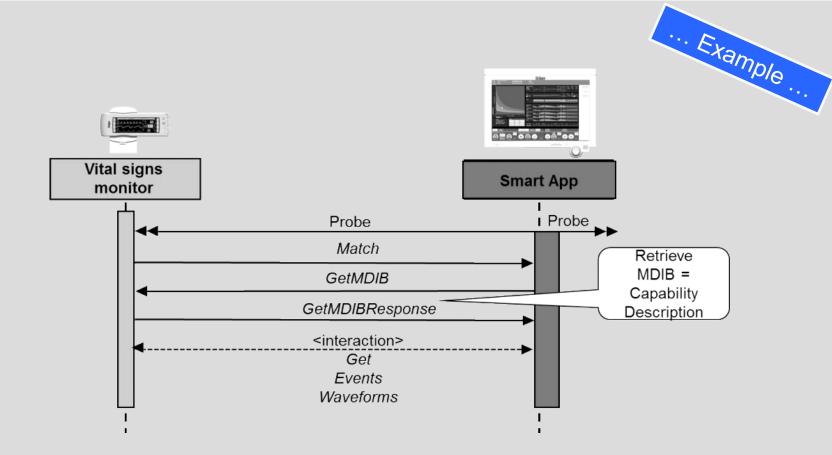




#### Remote invocation via Set Service

### **BICEPS** Discovery





#### **Exemplary Discovery sequence**

### A Proposal For Standards Adoption Agenda

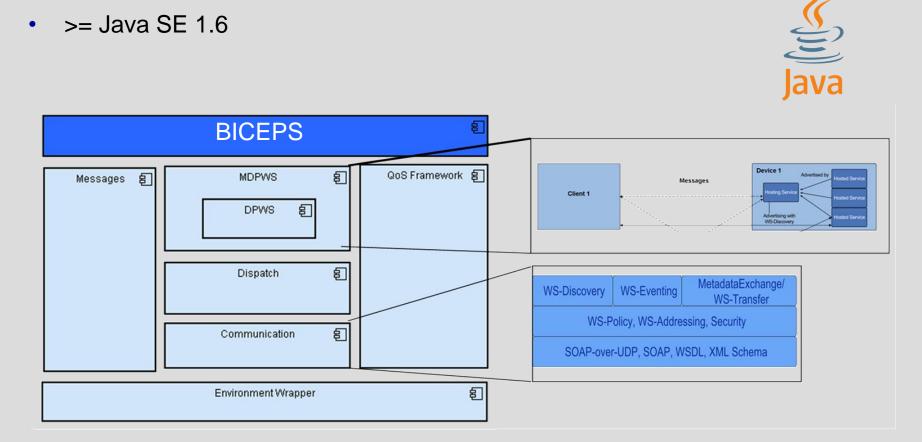


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### **Results Developed Middleware**

Java-based reference implementation

>= Java SE 1.6 •

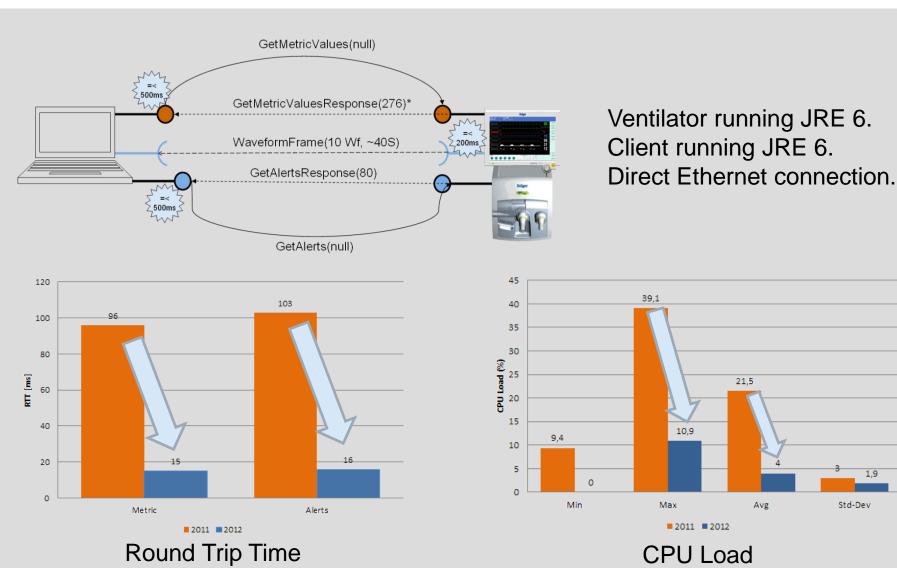




#### **Results Test Scenario**



1,9



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### Results Test Scenario

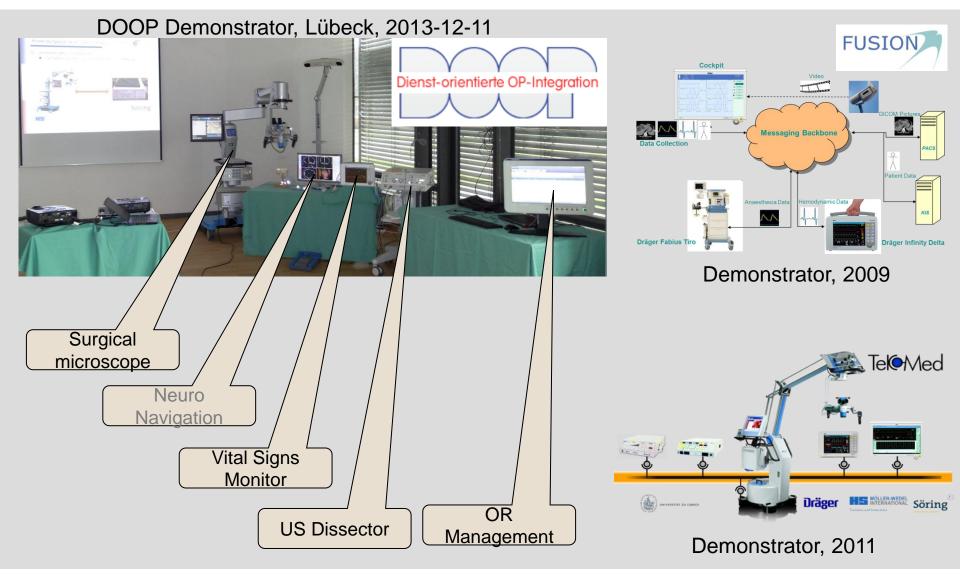


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#### Raspberry PI runs as a device in the test scenario. No optimization performed.



#### Results Demonstrators



#### **Results** Demonstrators





#### DOOP Demonstrator, Lübeck, 2013-12-11

31 | An architecture for distributed systems of medical devices in high acuity environments

### **Proposed Architecture** Summary



Functional		Non-Functional	
Plug'n Play		-Risk Management	1)
<ul> <li>Discovery and Binding</li> </ul>	S	<ul> <li>– Safe communication</li> </ul>	6
<ul> <li>Device capability description</li> </ul>	6	<ul> <li>Access control</li> </ul>	5
at runtime		-Trust establishment between	() J
– Openness	S	participants	
Communication (1-1, 1-n, n-n)		<ul> <li>Privacy of patient-related data</li> </ul>	Ð
- Event Notification	S	-Latency in milliseconds range	1
<ul> <li>Data reporting</li> </ul>	E)		
<ul> <li>External control</li> </ul>	S		

### 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

## **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



#### Benefits

# Weaknesses of RTPS & XTypes

#### as perceived by Dräger

- 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

- 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		Non-Functional	
Plug'n Play		-Risk Management	(B)
<ul> <li>Discovery and Binding</li> </ul>	6	<ul> <li>– Safe communication</li> </ul>	(P
<ul> <li>Device capability description</li> </ul>	()	<ul> <li>Access control</li> </ul>	(F
at runtime		-Trust establishment between	(F
– Openness	Ē	participants	
Communication (1-1, 1-n, n-n)		<ul> <li>Privacy of patient-related data</li> </ul>	(F
- Event Notification	S	-Latency in milliseconds range	5
<ul> <li>Data reporting</li> </ul>			
<ul> <li>External control</li> </ul>	(P		

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

### A Proposal For Standards Adoption Agenda



- 1. Introduction
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## **Discussion** Summary



Functional		Non-Functional	
Plug'n Play		-Risk Management	5
<ul> <li>Discovery and Binding</li> </ul>	Solution	<ul> <li>– Safe communication</li> </ul>	5
<ul> <li>Device capability description</li> </ul>	S	<ul> <li>Access control</li> </ul>	ß
at runtime		-Trust establishment between	(J)
– Openness	5	participants	
Communication (1-1, 1-n, n-n)		<ul> <li>Privacy of patient-related data</li> </ul>	1)
<ul> <li>Event Notification</li> </ul>	S	<ul> <li>–Latency in milliseconds range</li> </ul>	
<ul> <li>Data reporting</li> </ul>	<pre>S</pre>		
<ul> <li>External control</li> </ul>	4		

### **BICEPS + MDPWS** meets the requirements of the project ...

## Discussion openSDC



··· Feedback requested ...

Dräger

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

https://sourceforge.net/projects/opensdc

### A Proposal For Standards Adoption Agenda



- 1. Introduction
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#### 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.



# Thank you for your attention.

Contact Dr. Stefan Schlichting Research Unit, Drägerwerk AG stefan.schlichting@draeger.com

Dräger. Technology for Life<sup>®</sup>