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
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 several German 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

### Core Concept
Develop an interoperability architecture & protocol stack
- based on **standardized technologies for syntactic interoperability**
- and proprietary or **standardized protocols** for semantic interoperability.

*e.g. Standardized payload based on hRTM*
Introduction

OR.NET

SICHERE DYNAMISCHE VERNETZUNG IN OPERATIONSAAL UND KLINIK

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 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:
- SurgiTAIK 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:
- MEDINOVO Medical Software Solutions GmbH
- how to organize
- Conion Technology GmbH
- VISUS Technology Transfer GmbH R & D

Research institutes:
- Fraunhofer-Institut MEVIS
- Fraunhofer-Institut FOKUS
- Technische Universität München, Lehrstuhl für Mikrotechnik und Medizingerätelektronik
- ITM – Institut für Telematik, Universität zu Lübeck
- ISP - institut für Softwartechnik und Programmiersprachen, Universität zu Lübeck
- ICAS – Innovation Center Computer Assisted Surgery, Universität Leipzig
- MedIT – Lehrstuhl für Medizinische Informationsystemtechnik, 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 Teleanesthesiologie
- Technische Universität München, Lehrstuhl für Automatisierung und Informationssysteme
- Technische Universität München, Institut für Informatik, Robotics and Embedded Systems
- Technische Universität München, MTT, Minim-invasive interdisziplinäre therapeutische Intervention
- Universitätsklinikum Aachen, FIMPR, Forschungsstelle für Medizinproduktrecht

Specialist Clinics:
- Uniklinik Tübingen, Universitätsklinik für Urologie
- Uniklinik Tübingen, Universitätsklinik für Radiologie
- Uniklinik Tübingen, Universitätsklinik für 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, Fachklinik 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

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

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

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

What is it?

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

Conceptual view of a SOMDA for a clinical workplace

Concept of a clinical workplace SOMDA does not make any assumptions of the underlying network topology.
Clinical Workplace SOMDA
Proposed Protocol Stack

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

- Vital signs monitor
- Device-specific extensions
- Streaming Dual Channel Transmission
- Application-specific protocol
- Smart App Protocol
- ICE Prot X
- ICE Prot Y
- BICEPS
- MDPWS
- DPWS
- BICEPS = Basic Integrated Clinical Environment Protocol Specification
- Service discovery, Interface description, Messaging, Event propagation, and Secure information transmission

Dräger
A Proposal For Standards Adoption

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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

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

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

- **Access Control**
  - Access control for critical operations
  - Secure transmission

- **Compression**
  - XML Manifestation doesn't need to be UTF-8
  - Optional binary XML (EXI) for reduced message sizes

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

11073

BICEPS Domain Model

An architecture for distributed systems of medical devices in high acuity environments
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
An architecture for distributed systems of medical devices in high acuity environments
Remote invocation via Set Service
Exemplary Discovery sequence

- Vital signs monitor
- Smart App
- Probe
- Match
- GetMDIB
- GetMDIBResponse
- <interaction>
  - Get
  - Events
  - Waveforms
- Retrieve MDIB = Capability Description
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Results
Developed Middleware

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

Surgical microscope
Neuro Navigation
Vital Signs Monitor
US Dissector
OR Management

Demonstrator, 2009

Demonstrator, 2011
Results
Demonstrators

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

### Summary

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DDS

What is DDS?

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
Benefits 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

Weaknesses

- 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
- Original DDS standard is just an API specification
### RTPS & XTypes

#### Summary of Evaluation

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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

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_BICEPS + MDPWS meets the requirements of the project …_
Discussion on openSDC

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

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

https://sourceforge.net/projects/opensdc
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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.

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