An architecture for medical cyber physical systems in high acuity environments

KoSSE-Tag 2015, Lübeck
2015/06/03, Stefan Schlichting
1. Introduction
2. Clinical Workplace SOMDA
3. Protocol Stack
4. Results
5. Discussion
Introduction
The Interoperability Problem

“Interoperability is an almost non-existent feature of medical devices.”

Lesh et al. 2007
Introduction
Interoperability Standards in the Hospital

Hospital

AAMI/UL JC 2800, Cybersecurity, IEC 80001-1

HIS
PACS
CIS
LAB

Bedside Device Aggregator

HL7, DICOM,…

Point-of-Care

ISO/IEEE 11073, ASTM F2761

Dialysis Machine
Ventilator
Infusion Pump
Patient Monitoring
Anesthesia Workstation
Surgical Devices

Enterprise
Introduction
ASTM F2761 - Integrated Clinical Environment

Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE)
— Part 1: General requirements and conceptual model

- Requirements for **safe and effective integration** of devices in high-acuity environments
- Functional conceptual model for the setup of an Integrated Clinical Environment
- Components are described on an abstract level

No technical specification!
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 medical cyber physical system apps.
## 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.

**Standardized payload based on hRTM**
Agenda

1. Introduction
2. **Clinical Workplace SOMDA**
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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 medical cyber physical systems for one clinical workplace.
Clinical Workplace SOMDA

What is it?

An architecture for medical cyber physical systems in high acuity environments

Conceptual view of a clinical workplace SOMDA does not make any assumptions of the underlying network topology.
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Protocol Stack
Proposed Protocol Stack

An architecture for medical cyber physical systems in high acuity environments
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/
A communication middleware for remote control should ensure **single fault safety**.

Definitions from IEC 60601-1

- **Single Fault Safety**
  
  “characteristic of ME equipment or its parts whereby it remains free of unacceptable risk during its expected service life under single fault condition”

- **Single Fault Condition**
  
  “condition in which a single means for reducing a risk is defective or a single abnormal condition is present”

- utilization of a dual channel architecture

Implement a protocol that allows a dual channel transmission on top of the DPWS protocol stack
The service provider detects a failure, e.g., by means of an invalid checksum.
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Results
Demonstrators

OR.NET, Berlin, 2015-04-15

DOOP Demonstrator, Lübeck, 2013-12-11

Demonstrator, 2009

Demonstrator, 2011
Results

Demonstrators

DOOP Demonstrator, Lübeck, 2013-12-11, watch on youtube: http://goo.gl/OJ3GlA
Agenda

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### Discussion Summary

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**Protocol stack meets the requirements …**
### IEEE 11073 Standard

#### P11073-10702
- **Submitter Email**: stefan.schlichting@draeger.com
- **Type of Project**: New IEEE Standard
- **PAR Request Date**: 19-Oct-2014
- **PAR Approval Date**: 10-Dec-2014
- **PAR Expiration Date**: 31-Dec-2018
- **Status**: PAR for a New IEEE Standard

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   - **1.2 Type of Document**: Standard
   - **1.3 Life Cycle**: Full Use

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- **Status**: PAR for a New IEEE Standard

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   - **1.2 Type of Document**: Standard
   - **1.3 Life Cycle**: Full Use

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11073 standard projects
Discussion
openSDC

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

https://sourceforge.net/projects/opensdc
Thank you for your attention.

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