New IEEE 11073 Standards for interoperable, networked Point-of-Care Medical Devices*

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***Abstract*— Surgical procedures become more and more complex and the number of medical devices in an operating room (OR) increases continuously. Today's vendor-dependent solutions for integrated ORs are not able to handle this complexity. They can only form isolated solutions. Furthermore, high costs are a result of vendor-dependent approaches. Thus we present a service-oriented device communication for distributed medical systems that enables the integration and interconnection between medical devices among each other and to (medical) information systems, including plug-and-play functionality. This system will improve patient's safety by making technical complexity of a comprehensive integration manageable. It will be available as open standards that are part of the IEEE 11073 family of standards. The solution consists of a service-oriented communication technology, the so called Medical Devices Profile for Web Services (MDPWS), a Domain Information & Service Model, and a binding between the first two mechanisms. A proof of this concept has been done with demonstrators of real world OR devices.**

I. INTRODUCTION

Integration and interconnection between medical devices among each other and to (medical) information systems with the aim to improve patient safety become more and more important for the actors in the operating room (OR). The increasing complexity of operations makes this indispensable. Today's solutions for integrated ORs are based on monolithic systems with vendor-dependent communication protocols. Thus these are inflexible and isolated solutions. The vendor-dependency leads to high costs and is a barrier for market access of small and medium-sized enterprises. Several publications point out that open standards and plug-and-play functionality are essential for a comprehensive integrated OR [1], [2], [3]. The service-oriented architecture (SOA) paradigm has been carved out as the enabling technology for an open and interoperable device integration.

In this paper we explain a service-oriented device communication for distributed medical systems that is currently in the process of standardization. Three standard proposals will be added to the IEEE 11073 family of standards. The first describes the Domain Information & Service Model (IEEE 11073-10207), the second defines the communication technology for data transmission (IEEE 11073-20702), and the third builds the binding between the first two artifacts (IEEE 11073-20701). The focus of this paper is on the Domain Information & Service Model. For a better and comprehensive understanding we will also introduce the other two standard proposals.

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II. STATE OF THE ART

A. Medical Device Interoperability

The challenge of interoperability between medical devices among each other and to (medical) information systems is addressed by several huge projects especially in the USA and in Germany. They are working on the definition of SOA based medical device communication architectures with the aim of standardization.

The "Medical Device 'Plug-and-Play' Interoperability Program" (MD PnP) [4] was founded in 2004 in the USA as a multi-institutional community. The MD PnP project uses Data Distribution Service (DDS) [5] standard for publish-subscribe based communication as the concrete implementation of a SOA. They provide an open-source framework for an Integrated Clinical Environment (OpenICE) [6]. The standardization process has been started with the first part of a planned series of at least five standards. Only the first part is available as ASTM standard F2761 [7].

In Germany the flagship project OR.NET [8] works on safe and dynamic networking in the OR and hospital. The Devices Profile for Web Services (DPWS) [9] is used as base technology to build up a medical device communication architecture according to the SOA paradigm. The OR.NET project concentrates and proceeds the experience and know-how of some pre-projects. E.g. the SOMIT [10] projects on gentile surgery with innovative technology called FUSION and orthoMIT, or the projects DOOP [11] and smartOR [12]. In the course of the smartOR project the specification of the Open Surgical Communication Bus (OSCB) has been developed. OSCB defines a service-oriented communication with the disadvantage of several centralized components. It has been introduced as a pre-standard, but standardization process is currently not pursued. In contrast to OSCB the OR.NET communication architecture does not need centralized components. It uses a completely distributed approach.

B. The IEEE 11073 Family of Standards

The aim of the ISO/IEEE 11073 "Health informatics - Point of Care (PoC) medical device communication / Personal health device communication" family of standards is to enable an interoperable communication between medical devices and external computer systems. Some elements of the family can be classified as "core" standards. Table I

TABLE I
OVERVIEW IEEE 11073 FAMILY OF STANDARDS (SELECTION)

IEEE Standard	Content
11073-10101	Nomenclature
11073-10201	Domain Information Model (DIM)
11073-20101	Application Profile, Communication Model
11073-30xxx	Transport Profiles
11073-10207 (new)	Domain Information & Service Model
11073-20701 (new)	Architecture & Binding
11073-20702 (new)	Medical DPWS

summarizes a selection. The IEEE 11073-10101 defines a nomenclature. For instance, codes for structural device description are included as well as codes for several measurements, parameters, and units, to enable semantic interoperability. The basic Domain Information Model (DIM) is defined in IEEE 11073-10201. It specifies an object-oriented model that represents information (including the structure) and functions that are relevant for communication between medical devices. The standard defines a tree hierarchy for modeling the device and its information of interest. This includes measurements, physiological and technical alerts, or contextual data. Furthermore a service model is clarified to provide access to medical devices.

Currently the IEEE 11073 family of standards is not sufficient for a safe and interoperable service-oriented networked PoC medical device communication. On the one hand the communication model (IEEE 11073-20101) and transport profiles (IEEE 11073-30xxx series) are not suitable for a communication based on a SOA. This is addressed by the new standards IEEE 11073-20701 and -20702. On the other hand the DIM has to be extended for the service-oriented device communication. Thus the new IEEE 11073-10207 defines a Domain Information & Service Model for this purpose.

III. SERVICE-ORIENTED DEVICE COMMUNICATION FOR DISTRIBUTED MEDICAL SYSTEMS

In this section we present a SOA-based medical device communication that allows an interoperable communication between medical devices among each other and to the clinic information systems. It fulfills the requirements of distributed medical device systems in high acuity environments and enables plug-and-play functionality. This architecture is going to be standardized as sub-standards at the IEEE 11073 family. Currently this activity is done in official projects: IEEE P11073-10207, P11073-20701, and P11073-20702.

The left part of Fig. 1 shows a schematic representation of a loose-coupled, non-centralized service-oriented device communication. Multiple medical devices are interconnected among each other. E.g. vital signs provided by a patient monitor system including several corresponding physiological alerts. These data can be read from other devices. A remote control of device parameters is also possible, e.g. setting new alert thresholds of the patient monitor from another device like a central OR-dashboard. The architecture

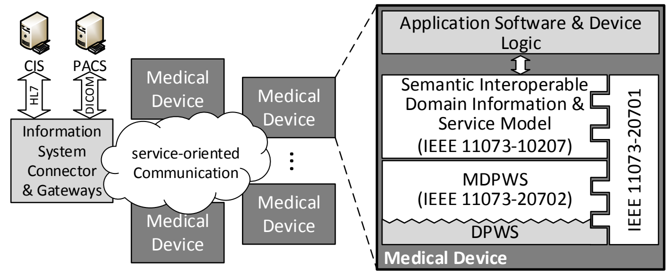

Fig. 1. Schematic overview of the device communication and the new IEEE 11073 Standards

allows the integration of the hospital's medical information system infrastructure. The clinic information system (CIS) provides e.g. patient demographics data or order information accessible via the information system connector. The Picture Archiving and Communication System (PACS) provides image data accessible via a special gateway. It is not intended to re-implement or suppress such well-established standards like DICOM. In fact the new system can be used to add plug-and-play functionality to DICOM.

The communication mechanisms to achieve the described functionality for patient's safety critical systems are specified in three new parts of the IEEE 11073 family. Their relationship and interlocking is displayed in the right part of Fig. 1. For this paper the focus is on IEEE 11073-10207. Nevertheless we will give a brief introduction into both other standards to provide a general overview.

A. Domain Information & Service Model: IEEE 11073-10207

The new Domain Information & Service Model is derived from the IEEE 11073-10201 DIM. A new one is needed to ensure semantic interoperability and accessibility in distributed systems of medical devices. The definition is done in the "Standard for Domain Information & Service Model for service-oriented Point-of-Care medical device communication" (IEEE 11073-10207). It defines the structures and necessary elements for the capability description of the device and the description of the current state information. Both parts, capability description and current state, are stored in the Medical Device Information Base (MDIB).

1) Medical Device Description: The device capabilities are described in a tree structure with the height of four. A schematic illustration with some examples is given in Fig. 2. The root element is the Medical Device System (MDS) that can contain multiple subsystems, called Virtual Medical Devices (VMDs). A VMD consists of Channels (Cha.) that are groupings (physical or logical) of metrics (Met.). A metric is an "Abstraction for components of a medical device that is able to generate or store direct and derived, quantitative and qualitative biosignal measurement, settings, status, and context data." To give a short and partial example: The MDS patient monitor includes the VMDs pulse oximeter and ECG (among others). The pulse oximeter contains a Channel for oxygen saturation that groups the Metrics SpO2

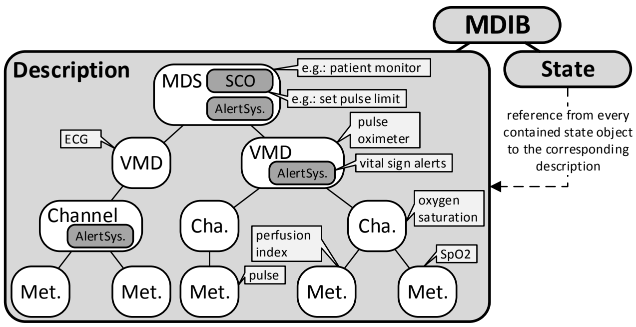

Fig. 2. Schematic overview of device capability modeling (example containment tree; speech bubbles contain example content)

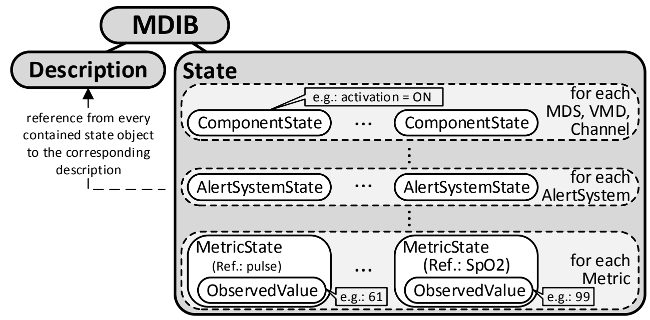

Fig. 3. Schematic illustration of selected (partial) states of the device state (speech bubble contain example values)

and the perfusion index. The semantic (including units) is described via codes and corresponding coding systems like the IEEE 11073-10101 nomenclature. E.g. the pulse rate metric has the code 18442 (or MDC_PULS_RATE) with the unit code 2720 (or MDC_DIM_BEAT_PER_MIN) that indicates beats per minute. Both type codes are part of the IEEE 11073-10101. Additional parameters of the metric can be defined, like its category (measurement, setting), availability (intermittent or continuous), or the way how the metric state can be retrieved via the services (active reading or periodic / episodic notification to subscribed clients).

Central aspects of medical systems are (physiological and technical) alerts. The described systems fulfils the IEC 60601-1-8 [13]. The definition of alerts consists of an alert condition that has to be fulfilled and an alert signal that describes the way the alert is calling for attention. Such alert systems can be defined on the hierarchy of MDS, VMD, or Channel. The definition of the alert condition takes place under specification of a condition code (description of the condition via the code and coding system mechanism), a kind (e.g. physiological, technical), a priority, sources that cause the alert condition (like a metric that exceeds a threshold), limits that are monitored, and information about the possible causes and the way they can be remedied. An alert condition can have multiple assigned alert signals that inform the users that condition has been triggered. An alert signal is essentially described by a reference to the condition that is communicated by the signal, its manifestation (audible, visible, or tangible), and the definition whether the signal will turn off automatically when the condition is not fulfilled anymore (not latching) or whether it has to be turned off by an user interaction when the condition has been triggered anytime (latching).

The remote invocation capabilities of the whole MDS can be defined in the Service and Control Object (SCO). Among others there are operations to set the (absolute) value of a metric, to set an alert state or to change ranges e.g. of alert conditions. Additionally there is the activate operation. Activations enable the possibility to trigger the processing of functions with arbitrary complexity on the remote device. Common quite simple use cases are relative changes of metrics or the switch-on / -off of device components.

2) Medical Device State: Every node of the description tree has its correspondent state. The state is a set of information about this element at a given point of time. Every state has a reference to its corresponding description of the element it represents, like a metric, channel, alert system, operation, and so on. Due to traceability and safety aspects a state version counter is included. The state version is incremented every time the state changes. The specific information that is included in the state differs from one type of the element to the other. Following we will give some examples for common states: A metric state includes the current value that is observed by the metric, its validity and the observation time. A component state delivers the current operating mode (activation state) that indicates whether the component is on, off, in standby mode, and so on. The state of an alert condition includes the information whether the condition has been detected and is still present or not. For the alert signal this presence information additionally includes whether it is latched (condition not present anymore, but signal still present) or acknowledged (condition still present, but signal turned off by user interaction). Fig. 3 gives a schematic illustration of some parts of the state information. E.g. pulse value is 61 (information like the unit are part of the description that is referenced by its handle).

3) Service Model: There are several possibilities for a remote interaction with the MDIB of the medical device. The five basic services are defined in the service-oriented communication model (or short: service model):

- **get service**: reading access to fetch information about capability description and device state (explicit access to MDIB objects possible)
- **event report service**: reading access according to the publish-subscribe pattern (episodic: triggered by a change; periodic: time triggered), incl. alert notifications
- **waveform stream service**: transmission of waveforms, e.g. ECG or EEG
- **set service**: writing access to manipulate parameters and invocation of function processing (has to be declared in the SCO)
- **context service**: access (r/w) to context information

The described services are available for objects if corresponding capability are defined, e.g. the retrievability get, episodic, or periodic of metric states. Contexts are used to group devices into logical units that are related to a patient, an order, or a location for instance. Patient demographics and order data can be part of the corresponding context.

B. Medical DPWS: IEEE 11073-20702

The Devices Profile for Web Services (DPWS) [9] is used as basic communication technology. DPWS provides messaging, dynamic device discovery, basic mechanisms for device description, and eventing. Medical Devices Profile for Web Services (MDPWS) (IEEE 11073-20702) defines constraints and extensions on the DPWS. There are some modifications in discovery, messaging and event propagation to allow utilization for Point-of-Care medical devices. There are some major extensions: dual channel transmission, safety context, and data-stream transmission.

The first two aspects enable a safe remote control for medical devices using one physical medium for an IP-based transmission. The dual channel transmission can be done within one SOAP message and provides a single-fault safe remote control. A checksum is used for this functional safety. The transformation and the algorithm that has to be applied on the data can be negotiated via MDPWS. The second aspect is the so called SafetyContext. A device that has the ability to be remote controlled can define the requirement for transmitting safety-relevant contextual information for a message in the message header. A concrete example is the requirement to send the last power value of an ultrasonic dissector within the header of the command to change the power output. The data-streaming enables the transmission of waveforms.

C. Architecture & Binding: IEEE 11073-20701

The "Standard for Service-oriented Medical Device Exchange Architecture & Protocol Binding" completes the presented package of standards. It defines a structure based on the SOA paradigm for medical devices and specifies the binding between MDPWS and the Domain Information & Service Model.

IV. REFERENCE IMPLEMENTATION AND DEMONSTRATORS

Currently there are two reference implementations available for the described service-oriented device communication for distributed medical systems: The Open System & Device Connectivity libraries (openSDC) [14] and the Open Surgical Communication Library (OSCLib) [15].

Based on both reference implementations we developed demonstrators that are shown in Fig. 4. The left one includes parts of an endoscopic working place, like camera, light source, saver, and irrigation pump (the latter two devices not shown in figure), and a pulse oximeter as medical devices. As control units a dynamically assignable switch and a generic dashboard can be used. The dashboard displays all desired parameters and allows a remote control. It can be used on standard PC hardware as well as on mobile devices. The right picture shows a more comprehensive demonstrator with much more devices, presented in cause of the OR.NET project at the conhIT exhibition in April 2015 at Berlin.

Fig. 4. Demonstrators (left: Rostock; right: conhIT exhibition 2015, Berlin)

V. CONCLUSION

The described service-oriented device communication for distributed medical systems is currently in the process of standardization as part of the IEEE 11073 family of standards. It includes all necessary requirements for safety critical PoC devices. We presented a comprehensive Domain Information & Service Model (IEEE 11073-10207) that allows modeling all aspects of PoC devices. This is divided into the capability description, including alert systems and the declaration of remote control capabilities, and the state of the medical device at the given point of time. Currently there are two reference implementations available for the new standards. A proof of concept has been done in partial demonstrators as well as in demonstrators that represent complex real world scenarios.

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