Extending the IEEE 11073-1010X Nomenclature for the Modelling of Surgical Devices*

Björn Andersen[1], Martin Kasparick[2], Frank Golatowski[2], and Josef Ingenerf[1]

Abstract— **The current lack of medical device interoperability can only be overcome by the usage of structural and semantic standards. Therefore, a modern service-oriented architecture for systems of networked medical devices has been developed within the IEEE 11073 series. Its application to new domains such as surgery also demands an extension of the IEEE 11073-1010X Nomenclature, which was initially designed for only a limited set of device types. We thus propose new terms for surgical devices and component interactions, options for the (limited) post-coordination of terms, and term mapping to SNOMED CT and LOINC. In addition, we discuss the development of device specialisation standards.**

I. Introduction

The number of medical devices within the operating room (OR) and intensive-care unit (ICU) increases continuously while medical procedures become increasingly complex. The interoperability of medical devices is hence becoming a key enabler to keep the complexity manageable. Within this scope, there are currently three new standards being developed as part of the IEEE 11073 family of standards on point-of-care (PoC) medical device communication.

In contrast to the existing standards, the focus of these new proposals is on systems of networked medical devices rather than point-to-point connections. The device communication follows the paradigm of a *Service-Oriented Architecture (SOA)*, therein refined to a *Service-Oriented Medical Device Architecture (SOMDA)*. It is specified in three new standard drafts, of which the IEEE P11073-20701 defines the overall architecture and protocol binding between the IEEE P11073-10207 Domain Information and Service Model for Service-Oriented Point-of-Care Medical Device Communication and the IEEE P11073-20702 Medical Devices Profile for Web Services (MDPWS) that specifies communication specific parts. The latter two are developed independently from each other and are only connected through the binding in order to achieve separation of the model components and the potentially exchangeable underlying communication technology.

Whereas these proposals succeed in solving the issue of technical interoperability (the ability of software systems to automatically exchange data), they remain dependent on coding systems to achieve semantic interoperability (the ability to automatically interpret the exchanged information) [1]. The power of an exchange architecture and protocol is thus always limited by the power of the nomenclatures and coding systems that are used to convey the meaning of every data element.

This paper briefly outlines the current state of the IEEE 11073-1010X Nomenclature in Sect. II ('X' denotes a placeholder for different last digits). The standard proposals for a service-oriented architecture of medical devices are presented in Sect. III. Our argument for further extension of the nomenclature is given in Sect. IV, followed by a discussion of alternative approaches in Sect. V.

II. IEEE 11073-1010X Nomenclature

Most modern communication standards in healthcare separate the data structure from the controlled vocabularies. To annotate a data element with a machine-interpretable description, *coded values* are commonly used. These usually consist of (at least) the following identifiers:

- the *code ID*, a term code that has a well-defined meaning,
- the *coding system ID* to uniquely identify the controlled vocabulary the code is defined in,
- and the *coding system version* to handle multiple versions of the same coding system.

The preferred vocabulary of the medical device communication described in the IEEE 11073 family of standards is the nomenclature defined in the IEEE 11073-1010X series.

The core nomenclature standard IEEE 11073-10101 was released in 2004 with an initial focus on terms for patient vital signs information such as electrocardiograph (ECG), haemodynamics, respiration, blood gas, urine, fluid-related metrics, and neurology; but also including units of measurement, device events and alarms, and body sites [2]. Since its first publication it has been extended by part 10102 on annotated ECG and part 10103 on implantable cardiac devices.

Another extension, part 10101a on respiratory-, ventilator-, and anaesthesia-related terms, has only recently been submitted to the IEEE Standards Association's Review Committee for final approval. Further extensions 10101b on terms related to infusion pumps, ventilation, neuro-muscular transmission, ECG waveforms, device management control, real-time location services, and a generalised signal quality index; as well as part 10101c on device events, alarms, and alerts are currently under development by the IEEE Healthcare Devices Working Group.

*This work was supported by the German Federal Ministry of Education and Research (grant numbers 16KT1239 and 16KT1238).

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978-1-5090-2455-1/16/$31.00 ©2016 IEEE

Furthermore the standardisation of approved mappings of IEEE 11073-1010X terms to *Logical Observation Identifiers Names and Codes (LOINC)* and the *Systematised Nomenclature of Medicine: Clinical Terms (SNOMED CT)* is being pursued.

This work describes our current effort to extend the nomenclature with terms from the surgical domain, which had not yet been considered in the previous extensions. These new terms are a necessary prerequisite for bringing implementations of a SOMDA, as described in the next section, to the OR.

III. Standardisation of a Service-Oriented Medical Device Architecture

This section gives an introduction to the SOMDA concept for systems of networked point-of-care medical devices. It is defined in three new proposals that are currently under development to become part of the IEEE 11073 family of standards. The relationship between these new artifacts and adjacent standards is illustrated in Fig. 1.

A. IEEE P11073-20702: Medical DPWS

Device communication in a SOMDA is based on the Devices Profile for Web Services (DPWS)[3], which is an OASIS standard restricting web services to run on embedded devices. DPWS serves as one implementation of the SOA paradigm. The Medical DPWS (MDPWS) introduces extensions to meet medical safety requirements, whereas also defining additional restrictions [4], e. g. the usage of client authentication with HTTP authentication is withdrawn and X.509.v3 certificates have to be used instead.

The most important extensions are:

- a safe *dual channel transmission*, which will typically be used for remote control commands,
- the *safety context* that allows the transmission of safety-related contextual information within the message header, e. g. the assumed state of a device before triggering a remote control,
- a UDP based *data streaming* for waveform signals like an ECG,
- and, due to the fact that the XML SOAP messages of the DPWS data transmissions are not very compact, yet lot of data has to be transmitted, the possibility of a *compact data transmission using EXI* has been defined.

B. IEEE P11073-10207: Domain Information and Service Model

The proposed Domain Information and Service Model (part 10207) is one key enabler for interoperability between different medical devices as well as between devices and clinical information systems. The model is derived from the classic IEEE 11073-10201 Domain Information Model (DIM), which in its unmodified state is not well-suited for systems of networked medical devices.

All device functionalities are modelled within a tree hierarchy. A simplified example of a containment tree is visualised in Fig. 2. The root element is the *Medical Device System*

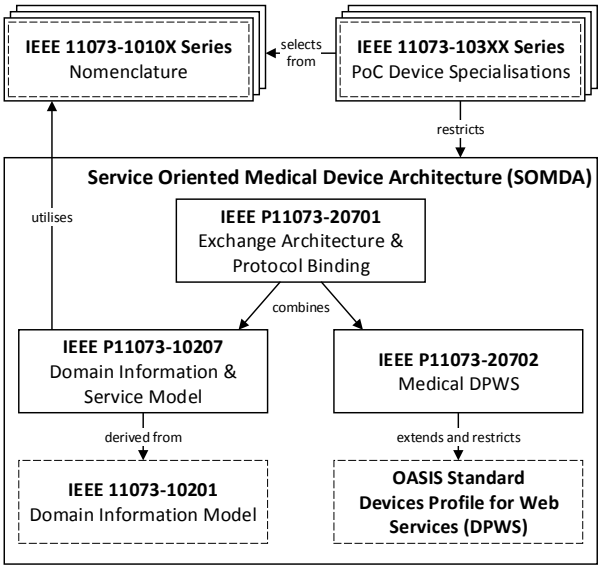

Fig. 1. Overview of considered standards and their relations. Dashed boxes indicate existing standards, solid boxes indicate new standards, and boxes with dashed and solid lines indicate existing standards that are being extended.

(MDS) that can contain several *Virtual Medical Devices (VMD)*. The measurements and settings of the devices are modelled as *Metrics*, which form the leaves of the tree. *Channels* are logical or physical groupings of Metrics on the intermediate level below a VMD.

Additionally, physiological and technical alerts can be defined as elements of the MDS, VMD, or channel respectively. An *alert system* is defined by *alert conditions* that have to be fulfilled to trigger potentially multiple *alert signals*.

Remote control capabilities are defined within the *Service Control Object (SCO)* that is an element of the MDS. There are two basic types of remote control: set and activate operations. Whereas the set operation typically changes one parameter, an activate operation can trigger a device function of arbitrary complexity. Activations range from from simple increase/decrease operations targeting a single metric to complex reconfiguration of the whole device.

The type of each element of the device description tree, down to every measurement and setting, is described by a coded value. Consequently, for the description of a higher number of more complex devices than considered in the original parts of the IEEE 11073 standard, plenty of new term codes are needed. In addition, remote control functions and device context states of networked devices need to be described that were not previously considered.

Besides the descriptive part, there is the medical device state. It is modelled as a set of states representing the current values of the measurements, adjustments of the settings, etc. of every component and metric of the device, including meta-information like value validity, and bound to a descriptor.

Finally, the service model defines the possibilities of interacting with the device, including reading access, remote control access, event subscriptions and alert notifications, and the waveform service. [5]

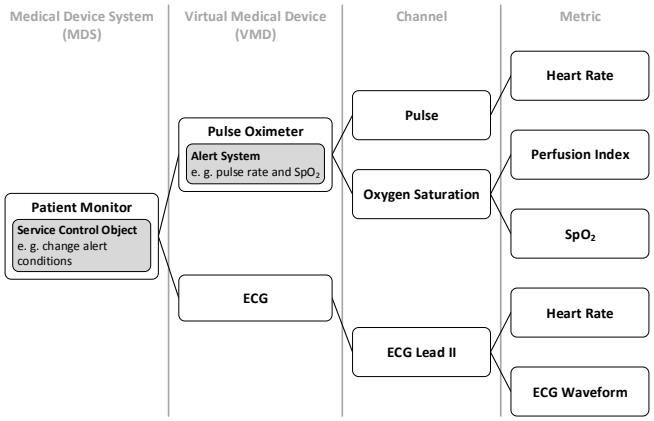

Fig. 2. Schematic overview of device capability modeling (containment tree for a simple patient monitor; note that a real patient monitor is much more complex than this example).

C. IEEE P11073-20701: Architecture and Protocol Binding

The encircling proposal part 20701 defines the overall architecture and the binding between the Domain Information and Service Model and the Medical DPWS. In addition, features like quality-of-service (QoS) requirements and time synchronisation are addressed.

IV. Nomenclature Extension

A. Interoperability

The Healthcare Information and Management Systems Society (HIMSS) refers to the definition of interoperability in healthcare as "the ability of different information technology systems and software applications to communicate, exchange data, and use the information that has been exchanged" [1]. The HIMSS further differentiates between foundational, structural and semantic interoperability. [6]

Foundational interoperability, i. e. the ability to exchange data, in the context of the proposed SOMDA is provided through the use of MDPWS (see Sect. III-A), which specifies how to employ web services and the underlying communication architecture.

Syntactic or *structural interoperability* is ensured by representing every device and component on the network modelled in accordance with the Domain Information and Service Model as described in Sect. III-B and by using the protocol binding to MDPWS (Sect. III-C).

The nomenclature is the missing piece in order to reach the highest level: *semantic interoperability*. Using coded values that are well-defined by a controlled vocabulary allows for machine-interpretability of the exchanged data. Only this level facilitates safe and dynamic information exchange and remote control between devices in various clinical settings.

B. Device Systems in Surgery

Surgery is an important domain for interconnected systems of medical devices at the point-of-care. Besides the intensive-care unit (ICU), the operating room (OR) is likely to have the highest density of devices and benefits most from manufacturer-independent connectivity of medical devices. Yet only few components – of these mostly diagnostic devices – can be modelled with the current set of terms available from the IEEE 11073-1010X Nomenclature.

C. New Terms and Concepts

It is thus necessary to extend the nomenclature by introducing new term codes for generic (Sect. IV-C.1) and specific surgical devices (Sect. IV-C.2). Furthermore, the component interaction patterns in a network of medical devices may require additional terms or even mechanisms for the coded representation of remote control operations (Sect. IV-C.3).

1) Generic Terms for Surgery: In previous nomenclature extensions, it has been common practice to model device parameters individually for every device type. As many devices share a set of properties, we propose defining these in a more generic way. Examples for these generic terms include settings such as brightness and contrast of device displays, interface languages, or operational parameters, like flow, pressure, operating hours, hard-disk capacity, etc.

For another example, consider the parameters flow and pressure that are used by several point-of-care devices like infusion pumps, ventilators, endoscopic pumps, and others. If at all existing, the term codes are currently defined only for one specific device, respectively one group of similar devices.

The SOMDA standard proposals also allow for dynamic configuration of *Digital Imaging and Communications in Medicine (DICOM)* connections. Another extension is under development for *Health Level Seven (HL7)* messages. A set of terms for interfacing with other standards is thus beneficial as well.

2) Specific Surgical Devices and Instruments: In addition to generic terms, it is necessary to define terms that relate to specific types of surgical devices. The following examples are taken from the use cases defined in the German national flagship project *OR.NET* on safe and dynamic networking of medical devices and clinical information systems. A working group of device manufacturers and researchers is currently drafting an extension proposal for these sub-domains.

- In the context of endoscopic surgery light sources and insufflators must be described with their metrics as well as commands and events.
- High-frequency surgery cutting devices need to be modelled in order to be remote-controlled from other user interfaces.
- For navigated procedures, position data can be shared in the medical device network. Example use cases include automatic collision detection of intraoperative X-ray imaging.

3) Component Interaction: In its current version, the structure and nomenclature standards do not support the post-coordination of concepts, i. e. the combination through the use of well-defined relations between terms. Such a mechanism would, however, considerably reduce the number of new terms required. Consider an operation to increase the brightness of an endoscopic light source: An appropriate term could be post-coordinated using terms for brightness and for

an increase by n per cent, bound by a relation that describes a relative change to a parameter.

Introducing post-coordination on an ontology level comparable to SNOMED CT is inherently difficult in the IEEE 11073 standards, given the general structure of the nomenclature. Limited support within the coding system could be accomplished using a root identifier and a distinguishing offset, similar to how part 10101a realises statistical discriminators (minimum, maximum, mean) for existing terms through the extension of identifiers with additional bits.

The usage of structural standardisation is another approach. An activation command, for example, could be comprehensively described by including the reference to the operation target: The term of an increase command targeting a metric, which represents the flow of an endoscopic pump, does not have to be specific for a pump flow. If it can be ensured that the target information is available and well-defined, a generic increase term would be sufficient.

In addition, it is conceivable to replace hard-coded value sets within structural standards with coded values from the nomenclature. For example, component activation states of device components and the retrievability of metrics are currently modelled as enumerations in part 10207. The substitution with coded values would separate structural and semantic description even more strictly.

V. Discussion

Whereas the interaction and communication of medical point-of-care devices can well be modelled using the proposed extensions to the IEEE 11073-1010X Nomenclature, the communication across domain borders remains an issue. It has been shown that foundational and structural interoperability of medical devices and clinical information systems can be achieved by mediating between communication standards. Transforming patient demographic and order information contained in HL7 messages from a clinical IT system to an equivalent representation in a SOMDA [7] as well as aggregating device observations into HL7 messages [8] has been presented in previous work. This semantic interoperability, however, relies on either the clinical IT systems being able to interpret nomenclature codes from the IEEE 11073-1010X or the tedious translation from one coding system to another.

Making device data such as measurements and settings available in the domains of clinical IT and clinical research on a large scale requires a mapping of IEEE 11073-1010X term codes to *Meaningful Use* approved terminologies. Such a mapping would not only facilitate cross-domain usage of device data, it would also connect the nomenclature to more powerful coding schemes such as linking concepts through relations and post-coordinating terms as possible in SNOMED CT. This powerful ontology-based terminology system, together with the widely used laboratory observation nomenclature LOINC, can considerably leverage the semantic interoperability of devices and adjoining domains.

Furthermore, backward compatibility with systems already using LOINC and forward compatibility with standards like HL7 Fast Healthcare Interoperability Resources (FHIR) that allow for usage of SNOMED CT could be greatly improved.

For these reasons, there are current efforts within the IEEE Healthcare Devices Working Group and an *Integrating the Healthcare Enterprise (IHE)* initiative *Device Clinical Bridge (DCB)* to map existing IEEE 11073-1010X terms to SNOMED CT and LOINC. In addition, we are providing mappings to these other controlled vocabularies wherever possible for any new term we propose for submission to the nomenclature.

Although the SOMDA standard proposals already allow for the usage of other coding systems than the IEEE 11073-1010X for coded values, it is not expected that this nomenclature will be obsolete or replaced in the near future.

VI. Conclusions

We proposed extending the IEEE 11073-10101 Nomenclature with terms for the modelling of surgical devices. Collaboration from any interested party, especially from device manufacturers, is highly appreciated. Please refer to the IEEE Healthcare Devices Working Group.

VII. Prospective Endeavours

Besides our effort to extend the nomenclature, we also aim to define surgical *device specialisations*. These constrain the Domain Information and Service Model for the representation of a specific device type and specify the nomenclature terms to be used for the model components (see Fig. 1). Previously authorised IEEE 11073 standardisation projects include part 10301 on infusion pumps, part 10302 on physiologic monitors, and part 10303 on ventilator devices.

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