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Service-Oriented Device Connectivity: Device Specialisations for Interoperability

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Abstract

There are IEEE 11073 standards for foundational, structural, and semantic point-of-care medical device interoperability, but the first devices with this interface have yet to enter the market. One of the missing pieces for implementation and approval are Device Specialisations that specify how to use information and service models to represent a specific type of device on the network. Required and optional metrics need to be standardised as well as nomenclature terms, units of measure, and extension points. Finally, device-to-device interaction at runtime has to be defined for automatic verification during testing and approval. Applications include C-arm fluoroscopes used in different clinical settings.

Keywords:

Health Information Interoperability; Reference Standards; Computer Communication Networks

Introduction

Modern, sophisticated medical devices still lack the ability to exchange data with devices from different manufacturers despite the increasing demand from clinicians and operators [1]. Until recently, the options for integration were indeed limited: Next to proprietary solutions, the only open alternative was the *ISO/IEEE 11073 Point-of-Care Medical Device (PoCD) Communication Standard* that enabled simple point-to-point interaction between an agent and a manager. The requirement for a loosely-coupled system of networked medical devices, however, was only met by the introduction of the ISO/*IEEE 11073 Service-Oriented Device Connectivity (SDC)* sub-series of standards. Driven by the research project OR.NET [2], this series now provides point-of-care medical and surgical devices with a contemporary communication protocol based on web service technology.

In SDC, the information exchange is based on the *IEEE 11073-20702-2016 Standard for Medical Devices Communication Profile for Web Services (MDPWS)* that defines safety, streaming, and compression features on top of previously existing web service standards. In addition, the *IEEE 11073-10207-2017 Standard for Domain Information & Service Model for Service-Oriented Point-of-Care Medical Device Communication* specifies a participant model, which allows for the structured network representation of a medical device's capabilities, and a message model, which defines communication endpoints for these capabilities. Both models are represented in XML Schema (XSD), whereas a device capability description must be expressed in eXtensible Markup Language (XML). This allows for the validation of a device's description against the standardised model.

The endpoints defined therein are bound to MDPWS through the *IEEE 11073-20701-2018 Standard for Service-oriented Medical Device Exchange Architecture & Protocol Binding* [3]. For semantic interoperability, every item of a device description is annotated with a code from the IEEE 11073-1010X series of nomenclature standards. Furthermore, the SDC standards provide mechanisms for authentication, authorisation, and encryption in order to maintain the confidentiality of personal and associated medical data [3].

Whereas the components of a device description are well-defined, different manufacturers may yet model their functionally equivalent devices differently. For personal health devices (PHD), the introduction of *Device Specialisations* facilitated interchangeability of devices from different manufacturers in the patient's home environment. These formal definitions of device types specify the structure of the hierarchical *containment tree* that constitutes the capability description.

Device Specialisations are also necessary for SDC devices, but the specifications must allow for a wider range of applications than their PHD counterparts. In addition to the mostly static containment tree, it is necessary to describe the dynamic interaction and the requirements towards communication partners to allow for automated testing and validation procedures, which are currently under development within the scope of the research project *Modular Validation Environment for Medical Device Networks (MoVE)* [4]. These Device Specialisations will not only be required for regulatory issues and type approval, but also for actual plug-and-play of medical devices.

Methods

Requirements Analysis

The most important difference between PHD and SDC is the device-to-device interaction and remote control that is one of the key benefits of device interoperability at the point-of-care. For patient safety, it is paramount to describe the underlying interaction patterns in a way that allows for automatic verification. This includes the definition of non-trivial safe states and fall-back mechanisms in case of a communication error or breakdown.

Furthermore, medical devices may need other network participants in order to provide their own functionality. A universal foot switch, for example, requires some device that can be controlled. Deploying a component within a medical device network can be assisted by automatic assessment of

compatibility by validating the functionality that is offered by a system of medical devices against the required capabilities.

Device Specialisations for Service-Oriented Device Connectivity

An SDC Device Specialisation combines knowledge of the composition and usage of a medical/surgical device with expertise in device modelling. Manufacturers of a certain type of device agree on a containment tree structure that is then brought into a machine-readable representation using XSD. This enables the validation of a device's description not only against the standardised data model but also against this schema in order to determine the correctness of the device model and the compliance with the standard.

However, the underlying semantics of the device description are of equal if not greater importance. Therefore, besides the semantic information that is conveyed implicitly through the structure of the containment tree, every description and state element is annotated with a *type* using standardised nomenclature codes, the same applies for units of measure. These codes are either taken from the preferred IEEE 11073-1010X series of nomenclature standards or from other controlled vocabularies that can be referenced by the device description. Which term(s) to use is either strictly defined by the Device Specialisation or can be chosen from a limited set for a specific metric.

Whereas items that are defined in a Device Specialisation cannot be omitted in a device that is to fulfil the standard, adding specific functionality is allowed. It is thus possible to integrate manufacturer-exclusive innovations into the network representation or to fulfil more than one Device Specialisation at a time. For example, a complex patient monitor may serve as an electrocardiograph *and* a pulse oximeter *and* a blood pressure monitor.

Oftentimes, elements of the containment tree depend on one another, e.g. the dose area product (DAP) calculated by a C-arm fluoroscope depends on settings such as tube voltage, current, and exposure time. These dependent metrics are expressed in the specification as well as (safety) requirements towards devices that exercise remote control. In this example, a controlling device that modifies critical parameters of the fluoroscope may have to visualise the estimated DAP to the human operator for confirmation. In the same way, quality-of-service (QoS) parameter boundaries or technical infrastructure requirements can be expressed.

Finally, the dynamic interaction of a medical device with other devices and components needs to be defined and verified. Therefore, the runtime behaviour of the device is specified in a machine-readable way. The MoVE project currently explores the usage of *Testing and Test Control Notation version 3 (TTCN-3)* [5] for this purpose. It allows for the definition of simple and complex test cases involving an arbitrary number of participants including the device-under-test (DUT).

Regulatory Issues and Type Approval

SDC Device Specialisations simplify the development and testing process for medical device manufacturers, but they also play an important role in type approval. In addition to conformance testing against the IEEE 11073 SDC communication protocol, Notified Bodies are also expected to validate the functionality of a device against the Device Specialisation for its type. This kind of integration testing involves interoperability with other (simulated) devices as well as *intraoperability* – the correct representation of the actual (physical) device state on the network [6].

Ultimately, medical devices that perform a given task as part of an ensemble of components will need to obtain certification for the precise role they play in the ensemble. This role and the interaction capabilities thus need to be explicitly stated in the intended use description of the device and may modify the classification of the device if it is, for example, intended to control a device of a higher class [6]. Referring to roles and capabilities that have been standardised in the form of a Device Specialisation significantly simplifies this procedure for both the manufacturer and the Notified Body.

These benefits have also been identified by the U.S. Food and Drug Administration (FDA) in a guidance document on interoperable medical devices [7]. Whereas the European Union's 2017 Medical Device Regulation (MDR) [8] also offers a definition of interoperability, it remains vague with regard to its regulatory impact and the benefits of communication standards.

Results

In this section, we present how specifying the characteristics of a C-arm fluoroscope facilitates device interchangeability in two example use cases. Figure 1 shows a simplified containment tree with channels for the operational parameters of the fluoroscope, dosage information, and the motion of the C-arm.

Surgical Navigation: Collision Avoidance

For this use case, consider the task of collision avoidance, for example in the operating room: For intraoperative radiography or fluoroscopy, a C-arm is often used as it can move around the operating table to acquire image data. Obviously, this motion should not cause a collision with the table. Through the provision of positional data from the C-arm, a surgical navigation system could warn the user before a collision occurs or could even remotely stop the repositioning completely. In addition to the containment tree, the interaction pattern for this control operation is also part of a Device Specialisation.

Synchronisation of Fluoroscopy and Ventilation

Another use case that greatly benefits from standardised devices is the synchronised fluoroscopy. It would allow this procedure to be carried out with any two devices from different manufacturers. The fluoroscopy can be synchronised with the breathing cycle of a patient who is connected to a ventilator if both devices provide the respective data. For projectional radiography, it would also be possible to stop the ventilator for the duration of the X-ray image acquisition in order to minimise motion artefacts and continue the breathing cycle afterwards.

Note that ventilators at the point-of-care (e.g. in the ICU or for anaesthesia) require a different Device Specialisation than a Home Healthcare Environment Ventilator from the PHD domain. The latter, which is under development as IEEE P11073-10426, targets a different device category and is not expected to include device-to-device interaction or remote control capabilities.

Discussion

The benefit of a standardised medical device communication protocol in general and an SDC Device Specialisation in particular lies in facilitating real-world applications. The manufacturer-independent interchangeability reflects the clinical reality of heterogeneous devices that need to interoperate.

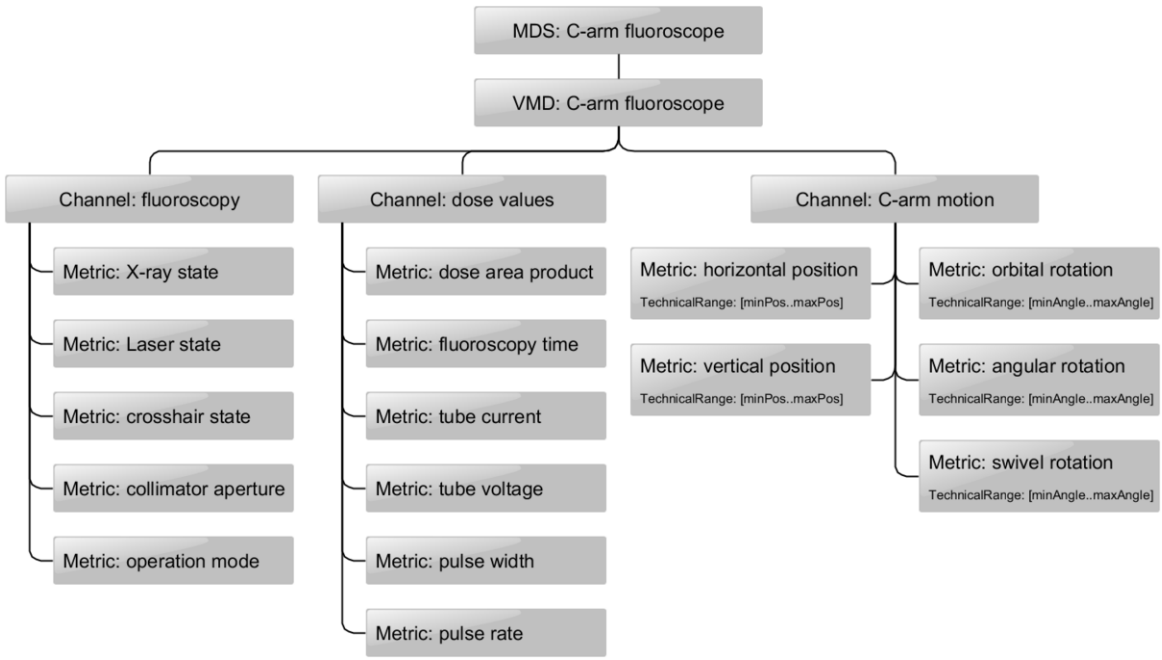

Figure 1 - Simplified model of a C-arm fluoroscope as a hierarchical containment tree; operations, contextual information, and alerts are omitted for brevity.

Whereas the PoC Device Specialisations currently under development refer to the SDC series and are going to be standardised within the new IEEE 11073-107XX sub-series, the payload of all IEEE 11073 communications is semantically described using the same vocabulary. Therefore, physiological measurements and other data can be combined from multiple sources, e.g. the home environment and the clinical workplace.

Conclusions

The standardisation of SDC Device Specialisations will further the implementation of open communication interfaces into actual medical devices, support the approval process, and facilitate plug-and-play. Devices that are interconnected using SDC will provide their operators with better assistance, perform more complex tasks in an ensemble, and ultimately increase patient safety.

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