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Part 10207: Domain information and service model for service-oriented point-of-care medical device communication

Informatique de santé — Communication entre dispositifs de santé personnels —

Partie 10207: Informations de domaine et modèle de services pour la communication orientée services entre dispositifs médicaux sur le site des soins

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Abstract: Within the context of the ISO/IEEE 11073™ family of standards for point-of-care medical device communication, a Participant Model derived from the ISO/IEEE11073-10201 Domain Information Model is provided in this standard. The Participant Model specifies the structure of medical information objects. This standard also defines an abstract Communication Model to support the exchange of medical information objects. All elements of the Participant Model and Communication Model are specified using XML Schema. Core subjects of the Participant Model comprise modelling of medical device-related data, e.g., measurements and settings, alert systems, contextual information (e.g., patient demographics and location information), remote control, and archival information. Model extensibility is provided inherently through the use of XML Schema.

Keywords: alert systems, IEEE 11073-10207™, medical device communication, patient, point-of-care, remote control, service-oriented architecture, XML Schema

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Introduction

This introduction is not part of IEEE Std 11073-10207-2017, Health informatics—Point-of-care medical device communication—Part 10207: Domain Information and Service Model for Service-Oriented Point-of-Care Medical Device Communication.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. They provide automatic and detailed electronic data capture of patient vital signs information and device operational data. The primary goals of these standards are to

— Provide real-time, plug-and-play interoperability for patient-connected medical devices.
— Facilitate the efficient exchange of vital signs and medical device data, acquired at the point of care, in all health care environments.

“Real-time” means that data from multiple devices can be retrieved, time correlated, and displayed or processed in fractions of a second. “Plug-and-play” means that all the clinician has to do is make the connection—the systems automatically detect, configure, and communicate without any other human interaction.

“Efficient exchange of medical device data” means that information that is captured at the point of care (e.g., patient vital signs data) can be archived, retrieved, and processed by many different types of applications without extensive software and equipment support and without needless loss of information. The standards are especially targeted at acute and continuing care devices, such as patient monitors, ventilators, infusion pumps, and electrocardiogram (EKG) devices. This family of standards can be layered together to provide connectivity optimized for the specific devices being interfaced.

Note that normative statements of requirements are presented in this standard in the following manner:

Rnnnn: Statement text here.

where "nnnn" is replaced by a number that is unique among the requirements in this standard and thereby forms a unique requirement identifier, for example,

R0007: All HANDLEs SHALL be unique within one MDIB sequence of a SERVICE PROVIDER.

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Health informatics—Point-of-care medical device communication

Part 10207: Domain Information and Service Model for Service-Oriented Point-of-Care Medical Device Communication

1. Overview

1.1 Scope

The scope of this standard is the definition and structuring of information that is communicated in a distributed system of point-of-care medical devices and medical information technology (IT) systems in which medical data needs to be exchanged or networked point-of-care medical devices need to be controlled. The standard provides a Participant Model and Communication Model derived from the IEEE 11073™ Domain Information Model (IEEE 11073-10201™ DIM). Furthermore, it utilizes the IEEE 11073 Nomenclature (IEEE 11073-10101™) and supports other coding systems to convey the semantics of any information elements.[1]

The definition of network transport mechanisms is outside the scope of this standard.

1.2 Purpose

The purpose of this standard is to enable vendors of point-of-care medical devices and medical IT systems to constitute networked medical device applications from the perspective of domain experts. Therefore, this standard provides tools to virtually model point-of-care medical devices. Moreover, it defines a service-oriented architecture to access those networked-based point-of-care medical devices.

[1] Information on normative references can be found in Clause 2.

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2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used; therefore, each referenced document is cited in text, and its relationship to this document is explained). For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments or corrigenda) applies.

IEC 60050-482:2004, International Electrotechnical Vocabulary – Part 482: Primary and secondary cells and batteries.[2]

IEEE Std 11073-10101a™-2015, Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature, Amendment 1: Additional Definitions.[3,4]

ISO/IEEE 11073-10101:2004, Health informatics — Point-of-care medical device communication — Part 10101: Nomenclature.[5]

ISO/IEEE 11073-10201:2004, Health informatics — Point-of-care medical device communication — Part 10201: Domain information model.

[2] IEC publications are available from the International Electrotechnical Commission (http://www.iec.ch) and the American National Standards Institute (http://www.ansi.org/).
[3] The IEEE standards or products referred to in Clause 2 are trademarks owned by The Institute of Electrical and Electronics Engineers, Incorporated.
[4] IEEE publications are available from The Institute of Electrical and Electronics Engineers (http://standards.ieee.org/).
[5] ISO publications are available from the International Organization for Standardization (http://www.iso.org/) and the American National Standards Institute (http://www.ansi.org/).

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3. Definitions and notational conventions

3.1 Definitions

For the purposes of this document, the following terms and definitions apply. The *IEEE Standards Dictionary Online* should be consulted for terms not defined in this clause.[6] Any word in capital letters refers to the technical use defined in this clause. In any other case, no special spelling is given.

ALERT CONDITION: State of the ALERT SYSTEM when it has determined that a potential or actual HAZARDOUS SITUATION exists for which OPERATOR awareness or response is required.

NOTE—See also IEC 60601-1-8 (2014) [B1].[7,8]

ALERT SIGNAL DELEGATION: Capability of a POC MEDICAL DEVICE to let another PARTICIPANT generate a POC MEDICAL DEVICE's ALERT SIGNAL as primary ALERT SIGNAL in order to indicate the presence of an ALERT CONDITION on the POC MEDICAL DEVICE.

ALERT SIGNAL: Type of signal generated by the ALERT SYSTEM to indicate the presence (or occurrence) of an ALERT CONDITION.

NOTE—See also IEC 60601-1-8 (2014) [B1].

ALERT SYSTEM: Part of a POC MEDICAL DEVICE that detects ALERT CONDITIONs and, as appropriate, generates ALERT SIGNALs.

NOTE—See also IEC 60601-1-8 (2014) [B1].

ALERT: Synonym for the combination of patient-related physiological alarms, technical alarms, and equipment user advisory signals.

ATTRIBUTE: XML attribute as defined in eXtensible Markup Language .

NOTE—See XML [B5].

BASIC INTEGRATED CLINICAL ENVIRONMENT PROTOCOL SPECIFICATION (BICEPS): Non-normative name of IEEE Std 11073-10207.

BICEPS BINDING: Specification that defines how to connect BICEPS to a transport protocol layer.

CHANNEL: Abstraction for a logical or physical grouping of METRICs that allows hierarchical information organization.

CODE: Identifier used to semantically describe an entity within a CODING SYSTEM.

CODED VALUE: Value that utilizes a CODING SYSTEM and a CODE to semantically describe a certain object within the MEDICAL DATA INFORMATION BASE (MDIB). In general, CODED VALUEs are based on standardized terminologies to increase interoperability.

CODING SYSTEM: Set of CODEs.

[6] *IEEE Standards Dictionary Online* is available at http://dictionary.ieee.org.
[7] The numbers in brackets correspond to the numbers of the bibliography in Annex E.
[8] Notes in text, tables, and figures of a standard are given for information only and do not contain requirements needed to implement this standard.

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CONTAINMENT TREE ENTRY: Node of the CONTAINMENT TREE that encloses descriptive and state information.

CONTAINMENT TREE: Device configuration and capability description of an MEDICAL DEVICE SYSTEM (MDS) that represents a POC MEDICAL DEVICE and is conceivable as a four-layered tree.

CONTEXT: Abstraction of a component of a POC MEDICAL DEVICE that defines the relationship of a POC MEDICAL DEVICE with its usage environment. Technically, a CONTEXT can be understood as a token that is shared between two or more POC MEDICAL DEVICEs to let them know they are "talking about the same things."

DELEGABLE ALERT SIGNAL: ALERT SIGNAL that takes part in the ALERT SIGNAL DELEGATION process. It is controlled by a PARTICIPANT.

DEVICE COMPONENT: Term used to describe the characteristics of a medical-related component of a POC MEDICAL DEVICE. A DEVICE COMPONENT can be a physical component that is integrated inside the device, a removable physical component, or a nonphysical component that allows physiological measurement data and its derived data to be grouped in a hierarchical information organization.

NOTE—See also pm:AbstractDeviceComponentDescriptor and pm:AbstractComplexDeviceComponentDescriptor.

ELEMENT: XML element as defined in eXtensible Markup Language.

NOTE—See XML [B5].

FALLBACK ALERT SIGNAL: ALERT SIGNAL that is emitted by a POC MEDICAL DEVICE when a DELEGABLE ALERT SIGNAL is not confirmed by the generating PARTICIPANT in time, i.e., it exceeds a confirmation timeout.

HANDLE: Term used to uniquely identify a certain object within the MEDICAL DATA INFORMATION BASE (MDIB) without designating any semantics.

HAZARDOUS SITUATION: Situation when people are exposed to a hazard or when property or the environment is threatened. A HAZARDOUS SITUATION exists when a vulnerable entity is exposed to a hazard.

NOTE—See also ISO 14971:2007 [B2].

MEDICAL DATA INFORMATION BASE (MDIB): Structured collection of any data objects that are provided by a particular POC MEDICAL DEVICE. MDIB includes descriptive and state information.

MEDICAL DEVICE SYSTEM (MDS): Abstraction of a system comprising one or more medical functions. In the context of IEEE Std 11073-10207, the term is specifically used as an object-oriented abstraction of a POC MEDICAL DEVICE that provides medical information in the form of information objects that are defined in IEEE Std 11073-10207.

MESSAGE: Set of data in a specific format that is exchanged between two PARTICIPANTs.

METRIC: Abstraction of a component of a POC MEDICAL DEVICE that is able to generate or store direct and derived, quantitative and qualitative biosignal measurements, settings, and status values.

PARTICIPANT: Any network node that is part of a SERVICE-ORIENTED MEDICAL DEVICE SYSTEM (SOMDS) and exchanges information by means of a service-oriented architecture. A PARTICIPANT can be either a SERVICE PROVIDER or a SERVICE CONSUMER.

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POC ENVIRONMENT: Environment encompassing a particular diagnostic, bed, or treatment area that is specific to one patient and usually including the systems and personnel that are involved in the acute monitoring and treatment of the patient.

POC MEDICAL DEVICE: Point of care (POC) medical device that directly interacts with, monitors, provides treatment to, or is in some way associated with a single patient. For IEEE Std 11073-10207, the scope of POC MEDICAL DEVICEs is further limited to patient-connected medical devices that provide support for electronic communication.

RESPONSIBLE ORGANIZATION: Entity that is accountable for the use and maintenance of a POC MEDICAL DEVICE.

SERVICE CONSUMER: Participant that utilizes at least one SERVICE.

SERVICE INTERFACE: Set of SERVICE OPERATIONs that is provided by a SERVICE to describe its capabilities.

SERVICE OPERATION: Single operation that can be executed remotely at a SERVICE PROVIDER.

SERVICE PERSONNEL: Individuals or entity accountable to the RESPONSIBLE ORGANIZATION for installing, assembling, maintaining, or repairing a POC MEDICAL DEVICE.

SERVICE PROVIDER: Participant that provides at least one SERVICE. A SERVICE PROVIDER can be hosted on the POC MEDICAL DEVICE itself or on an external appliance (e.g., converter box) or information technology (IT) system (e.g., aggregator).

SERVICE: Part of a software system in a SERVICE-ORIENTED MEDICAL DEVICE SYSTEM (SOMDS) that exposes functional capabilities on a communication backbone.

SERVICE-ORIENTED MEDICAL DEVICE SYSTEM (SOMDS): Instance of a distributed system that implements a service-oriented architecture composed of SERVICE PROVIDERs and SERVICE CONSUMERs as defined for IEEE Std 11073-10207.

TYPE: Complex or simple type definition as defined in eXtensible Markup Language Schema.

NOTE—See XML Schema [B8].

VIRTUAL MEDICAL DEVICE (VMD): Abstraction for a medical-related subsystem (e.g., hardware or even pure software) of a POC MEDICAL DEVICE.

3.2 Notational conventions

3.2.1 General

This standard defines a Participant Model and a Communication Model that comprises a Message Model, Service Model, and Discovery Model. Both the Participant Model and Communication Model can be extended using the mechanisms defined in the Extension Model.

Class diagrams, sequence diagrams, component diagrams, and state machine diagrams follow the Unified Modeling Language (UML) notation. Beyond UML diagrams, the following subclauses describe notational conventions used to describe and reference XML Schema types.

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3.2.2 XML Schema namespaces

Annex A, Annex B, and Annex C include an XML Schema [B8] to describe an Extension Model, the object hierarchy, and ATTRIBUTEs of an MDIB instance as well as a set of MESSAGE structures that is used to request MDIB objects. The MDIB object hierarchy and ATTRIBUTEs are also known as the Participant Model. The set of MESSAGE structures is also known as the Message Model. All models possess dedicated XML namespaces (see XML Namespaces [B6]). These are defined in Table 1.

Table 1—Namespace mapping of Extension, Participant, and Message Models

Namespace prefix	URI	Model part
ext	http://standards.ieee.org/downloads/11073/11073-10207-2017/extension	Extension Model
pm	http://standards.ieee.org/downloads/11073/11073-10207-2017/participant	Participant Model
msg	http://standards.ieee.org/downloads/11073/11073-10207-2017/message	Message Model

This standard also uses the XML namespace prefix “xsd” to point to the XML Schema namespace specified in XML Schema [B8]:

```
http://www.w3.org/2001/XMLSchema
```

3.2.3 XML Schema referencing

References to TYPE or ELEMENT definitions of the XML Schema are made by using the corresponding QName (see XML Namespaces [B6]). To reference a nested TYPE definition, the QName is enhanced with a chain of QNames and unqualified ATTRIBUTE names, each separated by XPath delimiters (see XPath [B7]). Examples:

- pm:Handle points to the *Handle* TYPE defined in the Participant Model.
- msg:OperationInvokedReport/msg:ReportPart/@OperationTarget points to the ATTRIBUTE *OperationTarget* that is defined as part of the *ReportPart*, which is included in the *OperationInvokedReport*. Since the QName prefix is msg, the referenced TYPE refers to the Message Model.
- ./@ActivationDuration refers to an ATTRIBUTE within an arbitrary TYPE definition.

Throughout the XML Schema, a camel case notation is used:

- Every artifact begins with a capital letter (e.g., “Handle”)
- Names are separated by a capital letter (e.g., “ActivationState”)
- Abbreviations are denoted in camel case (e.g., “VmdDescriptor”)

3.2.4 XML Schema type description

Any XML Schema type that is defined in Annex A, Annex B, and Annex C, follows a certain layout. The subclause title corresponds to the type name. Beneath the title the XML Schema type is defined, which is in accordance to XML Schema either “element,” “attribute,” “simpleType,” or “complexType.” Every type is explained in more detail by a properties table (see Table 2).

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Table 2—Description of XML Schema type properties

Property name	Description
Type	Type name, including inheritance information if applicable.
Children	List of child elements of the XML Schema type.
Used by	A list of elements and complex types in which the XML Schema type is used.
Attributes	List of attributes defined by the XML Schema type.
Documentation	General description of the data type.
Constraints	Special restrictions to contents, e.g., valid values for enumerations.
Properties	If given, the minimum and maximum occurrence of the XML Schema type.
Use	Usage: “opt” for optional, “req” for required.

Beyond those properties, element and complex type definitions include a picture that describes the structure of the data type graphically. An example is given in Figure 1. The box on the left side describes the data type name and its cardinality. Connected by a solid line are the super types in a yellow box, followed by the attributes and child elements. There are two kinds of boxes. Solid lined boxes are required data fields and dotted lined boxes are optional data fields. If a child element count has a particular range, this range is noted as a cardinality at the bottom right of the box. A plus sign at the right of a solid-lined or dotted box signalizes the existence of child element or attribute definitions that are not shown for sake of brevity.

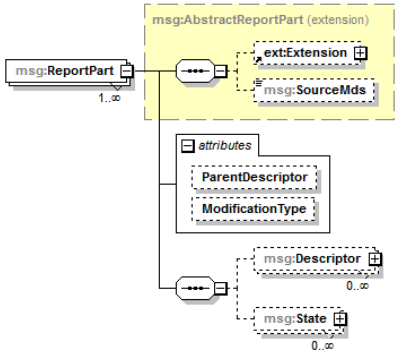


Figure 1—Example XML Schema element type structure

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