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Part 10201: Point-of-care medical device communication — Domain information model

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IEEE Std 11073-10201™-2018
(Revision of
IEEE Std 11073-10201-2004)

Health informatics—Point-of-care medical device communication

Part 10201: Domain Information Model

Sponsor

IEEE 11073™ Standards Committee
of the
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Approved 5 December 2018

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Abstract: Within the context of the ISO/IEEE 11073 family of standards for point-of-care medical device communication, an abstract, object-oriented domain information model that specifies the structure of exchanged information, as well as the events and services that are supported by each type of object, is provided in this standard. All data structure elements are specified using abstract syntax (ASN.1) and may be applied to many different implementation technologies, transfer syntaxes, and application service models. Core subjects include medical, alert, system, patient, control, archival, communication, and extended services. Model extensibility is supported, and a conformance model and statement template is provided.

Keywords: abstract syntax, alarm, alert, ASN.1, DIM, domain information model, IEEE 11073-10201™, information model, medical device communications, medical information bus, MIB, object-oriented, patient, POC, point-of-care, remote control

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Introduction

This introduction is not part of IEEE Std 11073-10201-2018, Health informatics—Point-of-care medical device communication—Part 10201: Domain Information Model.

ISO/IEEE 11073 standards enable communication between different medical devices and between medical devices and other IT systems for information and for command and control. The primary goals are to:

— Provide real-time plug-and-play interoperability for patient-connected medical devices

— Facilitate the efficient exchange of patient related data and medical device related data, acquired at the point-of-care (POC), 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 when a device or system is connected to another device or system, detection, configuration, and the initiation of communication all occur automatically andwithout any other human interaction.

“Efficient exchange of medical device data” means that information that is captured at the POC (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. This standard is especially targeted at acute and continuing care devices, such as patient monitors, ventilators, infusion pumps, ECG devices, etc. It is a member of a family of standards that can be layered together to provide connectivity optimized for the specific devices being interfaced.

Contents

Health informatics—Point-of-care medical device communication

Part 10201: Domain Information Model

1. Scope

The scope of this project is to define a general object-oriented information model that may be used to structure information and identify services used in point-of-care (POC) medical device communications. The scope is primarily focused on acute care medical devices and the communication of patient vital signs information.

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used, so 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.

ISO/IEC 8824-1, Information technology — Abstract Syntax Notation One (ASN.1) — Part 1: Specification of basic notation.[1]

ISO/IEEE 11073-10101, Health informatics — Point-of-care medical device communication — Part 10101: Nomenclature.[2]

ISO/IEEE 11073-20101, Health informatics — Point-of-care medical device communication — Part 20101: Application profiles – Base standard.

OMG® Unified Modeling Language® (OMG UML®) 2.5.1.[3]

[1] ISO/IEC documents are available from the International Organization for Standardization (http://www.iso.org/), the International Electrotechnical Commission (http://www.iec.ch), and the American National Standards Institute (http://www.ansi.org/).
[2] ISO/IEEE documents are available from the International Organization for Standardization (http://www.iso.org/) and the Institute of Electrical and Electronics Engineers (http://standards.ieee.org/).
[3] The OMG UML standard can be freely downloaded at https://www.omg.org/spec/UML/

3. Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this document, the following terms and definitions apply. The *IEEE Standards Dictionary Online* should be referenced for terms not defined in this clause.[4]

agent: Device that provides data in a manager-agent communicating system.

alarm: Signal that indicates abnormal events occurring to the patient or the device system.

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

alert condition: The active (true) state of a physiologic alarm (primarily related to the patient), technical alarm (primarily related to a device), or an advisory that is typically reported to clinicians, physicians, or other healthcare staff, for responding to patient needs or related workflows.

alert monitor: Object representing the output of an alert system that considers multiple alert conditions in a scope defined by objects that are contained by a single medical device system object. An alert monitor is able to report individual, concurrent alert conditions as well as the overall system alert condition.

alert status: Object representing the output of an alert system that considers multiple alert conditions in a scope defined by objects that are contained by either a single virtual medical device object or a single medical device system object. An alert status is able to report concurrent alert conditions.

archival: Relating to the storage of data over a prolonged period.

association control service element (ACSE): Method used to establish logical connections between medical device systems.

attribute: The definition of a property of an object.

channel: An object that groups together physiological measurement data and any derived data that have a contextual relationship with each other.

class: A model which describes the properties and behaviors of a type of entity found within a problem domain.

class diagram: Diagram showing connections between classes in a system.

communication controller: Part of a medical device system responsible for communications.

communication party: Actor of the problem domain that participates in the communication in that domain.

communication role: Role of a party in a communication situation defining the party's behavior in the communication. Associated with a communication role is a set of services that the party provides to other parties.

data agent: As a medical device, a patient data acquisition system that provides the acquired data for other devices.

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[4] The *IEEE Standards Dictionary Online* is available at http://dictionary.ieee.org/. An IEEE Account is required for access to the dictionary, and one can be created at no charge on the dictionary sign-in page.

data format: Arrangement of data in a file or stream.

data logger: A device that is functioning in its capacity as a data storage and archival system.

NOTE—There may be several different types of data loggers; clinical, technical, forensic, alarm condition, user logs.[5]

data structure: A data organization format that is implemented by an application.

dictionary: Description of the contents of the medical data information base (MDIB) containing vital signs information, device information, demographics, and other elements of the MDIB.

discrete parameter: Measured, calculated, or manually entered value that can be expressed as a single numeric or textual value.

> **Example:** A non-invasive systolic blood pressure (measured), cardiac index (calculated), gender male or female.

domain information model (DIM): The model describing common concepts and relationships for a problem domain.

event: A change in device status that is communicated by a notification reporting service.

event report: Service (provided by the common medical device information service element) to report an event relating to a managed object instance.

framework: A structure of processes and specifications designed to support the accomplishment of a specific task.

graphic parameter: Parameter that requires multiple regularly sampled data points in order to be expressed properly.

> **Example:** A single ECG waveform snippet.

host system: Term used as an abstraction of a medical system to which measurement devices are attached.

information service element: Instances in the medical data information base.

instance: The realization of an abstract concept or specification, e.g., class instance, application instance, information service element instance, virtual medical device instance, operating instance.

instance method: A procedure or process that defines a behavior exhibited by the instances of a class (i.e., objects). Instance methods provide the interface by which the properties of an object may be accessed or modified.

intensive care unit (ICU): The unit within a medical facility in which patients are managed using multiple modes of monitoring and therapy.

interchange format: The representation of the data elements and the structure of the message containing those data elements while in transfer between systems. The interchange format consists of a data set of construction elements and a syntax. The representation is technology specific.

interoperability: The ability of two or more devices or systems to exchange information in a format that is usable by the receivers of the information.

[5] Notes in text, tables, and figures of a standard are given for information only and do not contain requirements needed to implement this standard.