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Health informatics — Point-of-care medical device communication — Part 10101: Nomenclature

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Partie 10101: Nomenclature

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Health informatics — Point-of-care medical device communication — Part 10101: Nomenclature

Sponsor

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IEEE Engineering in Medicine and Biology Society

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IEEE-SA Standards Board

Abstract: Within the context of the ISO/IEEE 11073 family of standards for point-of-care (POC) medical device communication (MCD), this standard provides the nomenclature that supports both the domain information model and service model components of the standards family, as well as the semantic content exchanged with medical devices. The nomenclature is specialized for patient vital signs information representation and medical device informatics, with major areas including concepts for electrocardiograph (ECG), haemodynamics, respiration, blood gas, urine, fluid-related metrics, and neurology, as well as specialized units of measurement, general device events, alarms, and body sites. The standard defines both the architecture and major components of the nomenclature, along with extensive definitions for each conceptual area.

Keywords: codes, information model, medical device communication, nomenclature, ontology, patient, point-of-care, POC, semantics, service model, terminology

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Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75% of the member bodies casting a vote.

A pilot project between ISO and the IEEE has been formed to develop and maintain a group of ISO/IEEE standards in the field of medical devices as approved by Council resolution 43/2000. Under this pilot project, IEEE is responsible for the development and maintenance of these standards with participation and input from ISO member bodies.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. Neither ISO nor the IEEE shall be held responsible for identifying any or all such patent rights.

ISO/IEEE 11073-10101:2004(E) was prepared by IEEE 1073 Committee of the IEEE Engineering in Medicine and Biology Society.

IEEE Introduction

This introduction is not part of ISO/IEEE 11073-10101:2004(E), Health informatics — Point-of-care medical device communication — Part 10101: Nomenclature.

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 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, ECG devices, etc. They comprise a family of standards that can be layered together to provide connectivity optimized for the specific devices being interfaced.

Notice to users

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Errata

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Interpretations

Current interpretations can be accessed at the following URL: http://standards.ieee.org/reading/ieee/interp/index.html.

Participants

At the time this standard was completed, the working group of the IEEE 1073 Standard Committee had the following membership:

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Mats Cardell	Simon Meij	Paul Schluter
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The following members of the individual balloting committee voted on this standard. Balloters may have voted for approval, disapproval, or abstention.

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Keith Chow	Tom Kannally	Richard Schrenker
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When the IEEE-SA Standards Board approved this standard on 24 June 2004, it had the following membership:

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Also included are the following nonvoting IEEE-SA Standards Board liaisons:

Satish K. Aggarwal, *NRC Representative*
Richard DeBlasio, *DOE Representative*
Alan Cookson, *NIST Representative*

Don Messina
IEEE Standards Project Editor

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Health informatics — Point-of-care medical device communication — Part 10101: Nomenclature

1. Scope

The scope of this standard is nomenclature architecture for point-of-care (POC) medical device communication (MDC). It consists of three parts: the body of the standard, which defines the overall architecture of the organization and relationships among nomenclature components; normative Annex A and Annex B, which provide specifications of semantics and syntaxes, respectively; and informative Annex C, the bibliography.

This standard is intended for use within the context of IEEE Std 1073,[1] which sets out the relationship between this and other documents in the POC MDC series.

2. Conformance

There are no particular implementation conformance requirements defined in this standard, but some requirements for nomenclature representation are established in this standard to guide specification of semantics and syntax in other parts of the overall standard.

3. Normative references

The following normative documents contain provisions that, through reference in this text, constitute provisions of ISO/IEEE 11073-10101. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on ISO/IEEE 11073-10101 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid international standards.

[1]Information on references can be found in Clause 3.

CEN ENV 12611, Medical Informatics — Categorical structure of systems of concepts — Medical Devices.[2]

IEEE Std 1073™, IEEE Standard for Medical Device Communications—Overview and Framework.[3]

ISO/IEC 8824 (all parts), Information technology — Abstract Syntax Notation One (ASN.1).[4]

ISO/IEC 8825 (all parts), Information technology —ASN.1 encoding rules.

ISO/IEC 9596-1, Information technology — Open systems interconnection — Common Management Information Protocol — Part 1: Specification.

ISO/IEEE 11073-10201, Health informatics — Point-of-care medical device communication — Part 10201: Domain information model (referred to hereinafter as the “DIM”).

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

4. Terms and definitions

For the purposes of this standard, the following terms and definitions apply. *The Authoritative Dictionary of IEEE Standards Terms*, Seventh Edition, [B10][5] should be referenced for terms not defined in this clause.

4.1 corollary: a semantic and a syntactical representation that are correlated by a unique code.

4.2 -tuple: a component of a relation; e.g., a 2-tuple has two relational components.

4.3 unique: nonredundant.

5. Symbols (and abbreviated terms)

API	application program interface
ASN.1	Abstract Syntax Notation One (ISO/IEC 8824)
BAEP	brainstem acoustic evoked potential
BCC	bedside communication controller
BER	basic encoding rules (ISO/IEC 8825-1).
CMDISE	communication medical device information service element (CEN ENV 13735 [B5])
CMIP	Common Management Information Protocol (ISO/IEC 9596-1)
CMIP*	Common Management Information Protocol using ISO/IEEE 11073 MDDL/ MDER
CNS	central nervous system

[2]CEN publications are available from the European Committee for Standardization (CEN), 36, rue de Stassart, B-1050 Brussels, Belgium (http://www.cenorm.be).

[3]IEEE publications are available from the Institute of Electrical and Electronics Engineers, Inc., 445 Hoes Lane, Piscataway, NJ 08854, USA (http://www.standards.ieee.org/).

[4]ISO/IEC documents can be obtained from the ISO office, 1 rue de Varembé, Case Postale 56, CH-1211, Genève 20, Switzerland/ Suisse (http://www.iso.ch/) and from the IEC office, 3 rue de Varembé, Case Postale 131, CH-1211, Genève 20, Switzerland/Suisse (http://www.iec.ch/). ISO/IEC publications are also available in the United States from the Sales Department, American National Standards Institute, 25 West 43rd Street, 4th Floor, New York, NY 10036, USA (http://www.ansi.org/).

[5]The numbers in brackets correspond to the numbers of the bibliography in Annex C.

CSF	cerebrospinal fluid
CVS	cardiovascular system
DCC	device communication controller
DIM	domain information model, as defined in vital signs information representation (VITAL), interoperability of patient-connected medical devices (INTERMED), and medical device data language (MDDL) (ISO/IEEE 11073-10201[6])
ECG	electrocardiogram or electrocardiograph
ECoG	electrocochleograph
EEG	electroencephalogram or electroencephalograph
EMG	electromyogram or electromyograph
EOG	electrooculogram
ERG	electroretinogram or electroretinograph
FEF	file exchange format (CEN/TC251/PT-40 [B7])
FFT	fast Fourier transform
FSM	finite state machine
HL7®[7]	Health Level Seven
ICU	intensive care unit
ID	identifier
INTERMED	interoperability of patient-connected medical devices (CEN ENV 13735 [B5])
LLAEP	long latency acoustic evoked potential
MDAP	medical device application profile (The acronym *MDAP* may be substituted for the phrase *ISO/IEEE 11073-20000 family of standards*.")
MDC	medical device communication
MDDL	medical device data language (The acronym *MDDL* may be substituted for the phrase *ISO/IEEE 11073-10000 family of standards*.")
MDER	medical device encoding rules, as defined in medical device application profile (MDAP)
MDIB	medical data information base, as defined in ISO/IEEE 11073-10201
MDS	medical device system, an abstraction for a medical device (ISO/IEEE 11073-10201)
MIB	management information base
MLAEP	middle latency acoustic evoked potential
NCS	nerve conductens study
NOS	not otherwise specified
OO	object-oriented
OID	object identifier
PCA	patient-controlled analgesia
PDU	protocol data unit (also referred to as a *message*; by convention, the term *PDUs* is used in text to indicate multiplicity)
PFC	physiological function code, which represents a physiological concept such as heart rate, blood pressure, etc.
POC	point of care or point-of-care
SCADA	supervisory control and data acquisition
SCO	service and control object

[6]The DIM was originally defined in CEN ENV 13734 [B4] and CEN ENV 13735 [B5], which are now superseded by ISO/IEEE 11073-10201.

[7]HL7 is a registered trademark of Health Level Seven, Inc. (www.hl7.org).