EVS-EN ISO 11073-10101:2005

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

Nomenclature

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 11073-10101:2005 sisaldab Euroopa standardi EN ISO 11073-10101:2005 ingliskeelset teksti.

Käesolev dokument on jõustatud 29.09.2005 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.

Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN ISO 11073-10101:2005 consists of the English text of the European standard EN ISO 11073-10101:2005.

This document is endorsed on 29.09.2005 with the notification being published in the official publication of the Estonian national standardisation organisation.

The standard is available from Estonian standardisation organisation.

Käsitlusala:

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.

Scope:

The scope of this standard is nomenclature architecture for point-ofcare (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 Anomenclature components; normative Annex A and Annex B, which provide specifications of semantics and syntaxes. respectively; and informative Annex C, the bibliography.

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EUROPEAN STANDARD

EN ISO 11073-10101

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English Version

Health informatics - Point-of-care medical device communication - Part 10101: Nomenclature (ISO/IEEE 11073-10101:2004)

Informatique de santé - Communication entre dispositifs médicaux sur le site des soins - Partie 10101: Nomenclature (ISO/IEEE 11073-10101:2004)

Medizinische Informatik - Kommunikation patientennaher medizinischer Geräte - Teil 10101: Nomenklatur

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oreword

The text of ISO/IEEE 11073-10101:2004 has been prepared by Technical Committee ISO/TC 215 "Health informatics" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 11073-10101:2005 by Technical Committee CEN/TC 251 "Health informatics", the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2006, and conflicting national standards shall be withdrawn at the latest by February 2006.

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Endorsement notice

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Part 10101;

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- Communication entre dispositifs médicaux sur le Informatique de santé -site des soins -

Partie 10101: Nomenclature

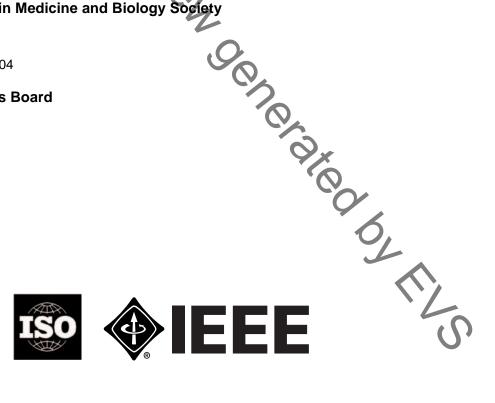


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Approved 24 June 2004

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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.

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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.

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Interpretations

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

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

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Health informatics — Point-of-care medical device communication —

Part 101015 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

¹Information 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-)

CMIP* Common Management Information Protocol using ISO/IEEE 11073 MDDL/

MDER

CNS central nervous system

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

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

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