EESTI STANDARD

EVS-EN ISO 11073-10201:2005

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

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EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 11073-10201:2005 sisaldab Euroopa standardi EN ISO 11073-10201:2005 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 11073-10201:2005 consists of the English text of the European standard EN ISO 11073-10201:2005. 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: Within the context of the ISO/IEEE 11073 family of standards, this standard addresses the definition and structuring of information that is communicated or referred to in communication between application entities.	**Scope:** Within the context of the ISO/IEEE 11073 family of standards, this standard addresses the definition and structuring of information that is communicated or referred to in communication between application entities.

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Võtmesõnad:

EUROPEAN STANDARD

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EUROPÄISCHE NORM

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English Version

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

Informatique de santé - Communication entre dispositifs médicaux sur le site des soins - Partie 10201: Modèle d'information du domaine (ISO/IEEE 11073-10201:2004)

Medizinische Informatik - Kommunikation patientennaher medizinischer Geräte - Teil 10201: Bereichs-Informationsmodell

This European Standard was approved by CEN on 16 August 2005.

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Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN ISO 11073-10201:2005: E

Foreword

The text of ISO/IEEE 11073-10201:2004 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 11073-10201:2005 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

The text of ISO/IEEE 11073-10201:2004 has been approved by CEN as EN ISO 11073-10201:2005 without any modifications.

INTERNATIONAL STANDARD

ISO/IEEE 11073-10201

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

Part 10201:

Domain information model

Informatique de santé — Communication entre dispositifs médicaux sur le site des soins —
Partie 10201: Modèle d'information du domaine

Reference number
ISO/IEEE 11073-10201:2004(E)

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

Sponsor

IEEE 1073™ Standard Committee

of the

IEEE Engineering in Medicine and Biology Society

Approved 24 June 2004

IEEE-SA Standards Board

IEEE

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Abstract: Within the context of the ISO/IEEE 11073 family of standards for point-of-care (POC) medical device communication (MDC), this standard provides 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 object. All 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, information model, medical device communications, medical information bus, MIB, point-of-care, POC, object-oriented, patient, remote control

ISO copyright office
Case postale 56 · CH-1211 Geneva 20
Tel. + 41 22 749 01 11
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E-mail copyright@iso.org
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Institute of Electrical and Electronics Engineers
Standards Association
Manager, Standards Intellectual Property
445 Hoes Lane
Piscataway, NJ 08854
E-mail: stds.ipr@ieee.org
Web: www.ieee.org

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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.

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

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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Interpretations

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Participants

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

Todd H. Cooper, *Chair*

Wolfgang Bleicher
Francis Cantraine
Thomas Canup
Mats Cardell
Michael Chilbert
Michael Flötotto
Ken Fuchs
Kai Hassing
Gunther Hellmann
Jörg Kampmann
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Michael Krämer
Alberto Macerata
Simon Meij
Angelo Rossi Mori
Thomas Norgall
Daniel Nowicki
Thomas Penzel
Francesco Pinciroli
Melvin Reynolds
Paul Rubel
Lief Rystrom
Paul Schluter
Michael Spicer
Alpo Värri
Jan Wittenber
Paul Woolman
Christoph Zywietz

The following members of the individual balloting committee voted on this standard. Balloters may have voted for approval, disapproval, or abstention.

Thomas Canup
Michael Chilbert
Keith Chow
Todd H. Cooper
Grace Esche
Kenneth Fuchs
John Grider
Kai Hassing
Tom Kannally
Robert Kennelly
Randall Krohn
Yeou-Song Lee
Daniel Nowicki
Melvin Reynolds
Michael Spicer
Richard Schrenker
M. Michael Shabot
Lars Steubesand
Gin-shu Young

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Chuck Adams
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Daleep C. Mohla
Paul Nikolich
T. W. Olsen
Ronald C. Petersen
Gary S. Robinson
Frank Stone
Malcolm V. Thaden
Doug Topping
Joe D. Watson

*Member Emeritus

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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 10201:
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1. Scope

Within the context of the ISO/IEEE 11073 family of standards, this standard addresses the definition and structuring of information that is communicated or referred to in communication between application entities.

This standard provides a common representation of all application entities present in the application processes within the various devices independent of the syntax.

The definition of association control and lower layer communication is outside the scope of this standard.

2. Normative references

The following referenced documents are indispensable for the application of this standard. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

CEN EN 1064, Medical informatics — Standard communication protocol — computer-assisted electrocardiography.[1]

CEN ENV 12052, Medical informatics — Medical imaging communication (MEDICOM).

IEEE Std 1073™, IEEE Standard for Medical Device Communications—Overview and Framework.[2]

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

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

IETF RFC 1155, Structure and Identification of Management Information for TCP/IP-Based Internets.[3]

ISO 639-1, Code for the representation of names of languages — Part 1: Alpha-2 code.[4]

ISO 639-2, Codes for the representation of names of languages — Part 2: Alpha-3 code.

ISO 3166-1, Codes for the representation of names of countries and their subdivisions — Part 1: Country codes.

ISO 3166-2, Codes for the representation of names of countries and their subdivisions — Part 2: Country subdivision code.

ISO 3166-3, Codes for the representation of names of countries and their subdivisions — Part 3: Code for formerly used names of countries.

ISO 8601, Data elements and interchange formats — Information interchange — Representation of dates and times.

ISO 15225, Nomenclature — Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange.

ISO/IEC 646, Information technology — ISO 7-bit coded character set for information interchange.[5]

ISO/IEC 2022, Information technology — Character code structure and extension techniques.

ISO/IEC 5218, Information technology — Codes for the representation of human sexes.

ISO/IEC 7498-1, Information technology — Open systems interconnection — Basic reference model — Part 1: The basic model.

ISO/IEC 7498-2, Information processing systems — Open systems interconnection — Basic reference model — Part 2: Security architecture.

ISO/IEC 7498-3, Information processing systems — Open systems interconnection — Basic reference model — Part 3: Naming and addressing.

ISO/IEC 7498-4, Information processing systems — Open systems interconnection — Basic reference model — Part 4: Management framework.

ISO/IEC 8649, Information processing systems — Open systems interconnection — Service definition for the Association Control Service Element.

ISO/IEC 8650-1, Information technology — Open systems interconnection — Connection-Oriented Protocol for the Association Control Service Element — Part 1: Protocol.

[3]Internet requests for comment (RFCs) are available from the Internet Engineering Task Force at http://www.ietf.org/.

[4]ISO publications are available from the ISO Central Secretariat, Case Postale 56, 1 rue de Varembé, CH-1211, Genève 20, Switzerland/Suisse (http://www.iso.ch/). ISO 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]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/).

ISO/IEC 8650-2, Information technology — Open systems interconnection — Protocol Specification for Association Control Service Element — Part 2: Protocol Implementation Conformance Statements (PICS) proforma.

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

ISO/IEC 8824-2, Information technology — Abstract Syntax Notation One (ASN.1) — Part 2: Information object specification.

ISO/IEC 8859-*n*, Information processing — 8-bit single-byte coded graphic character sets — Part 1 to Part 15: Various alphabets.

ISO/IEC 9545, Information technology — Open systems interconnection — Application layer structure.

ISO/IEC 9595, Information technology — Open systems interconnection — Common management information service definition.

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

ISO/IEC 10040, Information technology — Open systems interconnection — Systems management overview.

ISO/IEC 10164-1, Information technology — Open systems interconnection — Systems management — Part 1: Object management function.

ISO/IEC 10164-2, Information technology — Open systems interconnection — Systems management — Part 2: State management function.

ISO/IEC 10164-3, Information technology — Open systems interconnection — System management — Part 3: Attributes for representing relationships.

ISO/IEC 10164-4, Information technology — Open systems interconnection — Systems management — Part 4: Alarm reporting function.

ISO/IEC 10164-5, Information technology — Open systems interconnection — Systems management — Part 5: Event management function.

ISO/IEC 10164-6, Information technology — Open systems interconnection — Systems management — Part 6: Log control function.

ISO/IEC 10164-7, Information technology — Open systems interconnection — Systems management — Part 7: Security alarm reporting function.

ISO/IEC 10164-8, Information technology — Open systems interconnection — Systems management — Part 8: Security audit trail function.

ISO/IEC 10164-9, Information technology — Open systems interconnection — Systems management — Part 9: Objects and attributes for access control.

ISO/IEC 10164-10, Information technology — Open systems interconnection — Systems management — Part 10: Usage metering function for accounting purposes.

ISO/IEC 10164-11, Information technology — Open systems interconnection — Systems management — Part 11: Metric objects and attributes.

ISO/IEC 10164-12, Information technology — Open systems interconnection — Systems management — Part 12: Test management function.

ISO/IEC 10164-13, Information technology — Open systems interconnection — Systems management — Part 13: Summarization function.

ISO/IEC 10164-14, Information technology — Open systems interconnection — Systems management — Part 14: Confidence and diagnostic test categories.

ISO/IEC 10165-1, Information technology — Open systems interconnection — Structure of management information — Part 1: Management information model.

ISO/IEC 10165-2, Information technology — Open systems interconnection — Structure of management information — Part 2: Definition of management information.

ISO/IEC 10646-1, Information technology — Universal multiple-octet coded character set (UCS) — Part 1: Architecture and basic multilingual plane.

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

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

NEMA PS 3, Digital imaging and communications in medicine (DICOM).[6]

3. Definitions

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

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

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

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

3.4 alert monitor: Object representing the output of a device or system alarm processor and as such the overall device or system alarm condition.

3.5 alert status: Object representing the output of an alarm process that considers all alarm conditions in a scope that spans one or more objects.

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

[6]NEMA publications are available from Global Engineering Documents, 15 Inverness Way East, Englewood, Colorado 80112, USA (http://global.ihs.com/).

