

**Health informatics - Point-of-care medical  
device communication - Part 20101:  
Application profiles - Base standard**

Health informatics - Point-of-care medical device  
communication - Part 20101: Application profiles -  
Base standard

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 11073-20101:2005 sisaldab Euroopa standardi EN ISO 11073-20101:2005 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 29.09.2005 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 11073-20101:2005 consists of the English text of the European standard EN ISO 11073-20101:2005.</p> <p>This document is endorsed on 29.09.2005 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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<p><b>Käsitlusala:</b></p> <p>The scope of this standard is upper layer [i.e., the International Organization for Standardization's (ISO's) open systems interconnection (OSI) application, presentation layer, and session layer] services and protocols for information exchange under the ISO/IEEE 11073 standards for medical device communications (MDC).</p>	<p><b>Scope:</b></p> <p>The scope of this standard is upper layer [i.e., the International Organization for Standardization's (ISO's) open systems interconnection (OSI) application, presentation layer, and session layer] services and protocols for information exchange under the ISO/IEEE 11073 standards for medical device communications (MDC).</p>
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English Version

**Health informatics - Point-of-care medical device communication  
- Part 20101: Application profiles - Base standard (ISO/IEEE  
11073-20101:2004)**

Informatique de santé - Communication entre dispositifs  
médicaux sur le site des soins - Partie 20101: Profils  
d'applications - Norme de base (ISO/IEEE 11073-  
20101:2004)

Medizinische Informatik - Kommunikation patientennaher  
medizinischer Geräte - Teil 20101: Anwendungsprofil -  
Basisnorm

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## Foreword

The text of ISO/IEEE 11073-20101:2004 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 11073-20101:2005 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 11073-20101:2004 has been approved by CEN as EN ISO 11073-20101:2005 without any modifications.

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**Health informatics — Point-of-care  
medical device communication —  
Part 20101:  
Application profiles — Base standard**

*Informatique de santé — Communication entre dispositifs médicaux sur le  
site des soins —  
Partie 20101: Profils d'applications — Norme de base*



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

**Part 20101:**

**Application profiles — Base standard**

Sponsor

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Approved 24 June 2004

**IEEE-SA Standards Board**



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**Abstract:** The scope of this standard is upper layer [i.e., the International Organization for Standardization (ISO's) open systems interconnection (OSI) application, presentation layer, and session layer] services and protocols for information exchange under the ISO/IEEE 11073 standards for medical device communications (MDC). This standard is the base standard of the ISO/IEEE 11073-20000 medical device application profiles (MDAP), as harmonized through the Committee for European Normalization (CEN) and the ISO.

**Keywords:** abstract syntax, alarm, alert, communication, control, information model, medical device, object-oriented, point-of-care, POC, services

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ISO/IEEE 11073-20101:2004(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 11073-20101:2004(E), Health informatics — Point-of-care medical device communication — Part 20101: Application profiles — Base standard.

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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## Contents

1.	Overview.....	1
1.1	Scope.....	2
1.2	Purpose.....	2
1.3	Goals .....	2
1.4	Audience .....	2
2.	References.....	2
3.	Definitions and abbreviations .....	4
3.1	Definitions .....	4
3.2	Acronyms and abbreviations .....	4
4.	Conventions .....	6
5.	Rationale .....	6
5.1	Communication model.....	6
5.2	Information model .....	7
6.	Communication model.....	8
6.1	General.....	8
6.2	ACSE protocol .....	10
6.2.1	General.....	10
6.2.2	ACSE services .....	10
6.2.3	ACSE ASN.1 message definition.....	12
6.2.4	ACSE user information fields.....	12
6.3	Session-layer protocol.....	12
6.3.1	General.....	12
6.3.2	Session-layer services .....	12
6.3.3	Session-layer message definitions .....	13
6.4	Presentation-layer protocol .....	13
6.4.1	General.....	13
6.4.2	Presentation-layer services .....	14
6.4.3	Presentation-layer messages .....	14
6.5	ROSE protocol.....	14
6.5.1	General.....	14
6.5.2	ROSE services .....	14
6.5.3	ROSE message definitions.....	14
6.6	CMDISE protocol (CMDIP).....	15
6.6.1	General.....	15
6.6.2	CMDISE services .....	15
6.6.3	CMDIP message definitions .....	15
6.6.4	SNTP.....	15
7.	Information model .....	16
7.1	Object model.....	16
7.2	Format model.....	16

7.2.1	Syntax .....	16
7.2.2	Compatibility .....	16
8.	Conformance .....	17
8.1	Scope .....	17
8.2	Object identifier administration .....	17
8.3	MDAP subset conformance .....	17
8.4	Implementation conformance .....	17
Annex A	(normative) Medical device encoding rules (MDER) .....	18
Annex B	(normative) Allocation of identifiers .....	29
Annex C	(informative) Time synchronization .....	32
Annex D	(informative) Dynamic model .....	33
Annex E	(normative) Abstract syntax .....	38
Annex F	(informative) PDU examples .....	59
Annex G	(informative) Specialization of ASN.1 .....	72
Annex H	(informative) Compatibility cases .....	75
Annex I	(informative) Bibliography .....	77

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

Part 20101.

Application profiles — Base standard

## 1. Overview

This standard is divided into eight clauses, as follows:

- Clause 1 provides the scope of this standard.
- Clause 2 lists references to other standards that are useful in applying this standard.
- Clause 3 provides definitions and abbreviations.
- Clause 4 provides conventions.
- Clause 5 provides the rationale for this standard.
- Clause 6 provides a communication, i.e., protocol and service, model.
- Clause 7 provides an information, i.e., object, model.
- Clause 8 provides conformance requirements.

This standard also contains nine annexes, as follows:

- Annex A defines the specialized medical device encoding rules (MDER). (normative)
- Annex B describes the allocation of object identifiers. (normative)
- Annex C provides references to time synchronization protocols applied by this standard.
- Annex D includes state transition diagrams as part of the dynamic model.
- Annex E provides abstract syntax, which offers extensions to leveraged standards, such as minimal open systems interconnection (mOSI), that are specific to this standard. (normative)
- Annex F includes examples of a number of protocol data unit (PDU) examples.
- Annex G describes a specialization of Abstract Syntax Notation One (ASN.1).
- Annex H deals with compatibility of ASN.1 between the 1988/90 and 1994 versions.
- Annex I provides a bibliography of useful references.

## 1.1 Scope

The scope of this standard is upper layer [i.e., the International Organization for Standardization's (ISO's) open systems interconnection (OSI) application, presentation layer, and session layer] services and protocols for information exchange under the ISO/IEEE 11073 standards for medical device communications (MDC).

This standard is the base standard of the ISO/IEEE 11073-20000 medical device application profiles (MDAP), as harmonized through the Committee for European Normalization (CEN) and the ISO.

## 1.2 Purpose

The purpose of this standard is to define MDC upper layer application, i.e., ISO A-type profiles for interchange of data, which are defined by the medical device data language (MDDL) format, or ISO F-type profiles (ISO/IEEE 11073-10000 series).

## 1.3 Goals

The primary goal of MDAP standards is to support MDC upper layer data interchange, based on MDDL, among a wide range, by type and scale, of future and current devices for use in point-of-care (POC) settings in the acute care sections of hospitals.

## 1.4 Audience

The primary user of the MDAP standards is a software engineer who is creating a MDC system or attempting to establish an interface to one.

Because this family of standards is based largely upon international standardization profiles, familiarity with a range of related standards and technologies is useful if not necessary. The following are recommended as a minimum background:

- a) ISO/IEEE 11073 architecture, especially IEEE Std 1073<sup>TM1</sup>, ISO/IEEE 11073-10201, and lower layer standards (e.g., ISO/IEEE 11073-30200)
- b) ISO's OSI layered architecture, primarily the upper layers, i.e., application, presentation, and session
- c) Systems management
- d) Object-oriented analysis and design
- e) Machine language theory

## 2. References

This standard shall be used in conjunction with the following publications. When the following standards are superseded by an approved revision, the revision shall apply.

IEEE Std 1073, IEEE Standard for Medical Device Communications—Overview and Framework.<sup>2</sup>

<sup>1</sup>Information on references can be found in Clause 2.

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

ISO/IEC 8327-1, Information technology — Open systems interconnection — Connection-oriented session protocol — Part 1: Protocol specification.<sup>3</sup> (same as ITU-T Recommendation X.225)

ISO/IEC 8650-1, Information technology — Open systems interconnection — Connection-oriented protocol for the association control service element — Part 1: Protocol. (same as ITU-T Recommendation X.227)

ISO/IEC 8824-1, Information technology — Abstract Syntax Notation One (ASN.1) — Part 1: Specification of basic notation. (same as ITU-T Recommendation X.680)

ISO/IEC 8824-2, Information technology — Abstract Syntax Notation One (ASN.1) — Part 2: Information object specification. (same as ITU-T Recommendation X.681)

ISO/IEC 8825-1, Information technology — ASN.1 encoding rules — Part 1: Specification of Basic Encoding Rules (BER), Canonical Encoding Rules (CER) and Distinguished Encoding Rules (DER). (same as ITU-T Recommendation X.690)

ISO/IEC 9072-2, Information processing systems — Text communication — Remote operations — Part 2: Protocol specification.

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 9899, Programming languages — C.

ISO/IEC ISP 11188-3, Information technology — International standardization profile — Common upper layer requirements — Part 3: Minimal OSI upper layer facilities.

ISO/IEEE 11073-10101, Health informatics — Point-of-care medical device communication — Part 10101: Nomenclature.<sup>4</sup>

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 11073-30200, Health informatics — Point-of-care medical device communication — Part 30200: Transport profile — Cable connected.

ISO/IEEE 11073-30300, Health informatics — Point-of-care medical device communication — Part 30300: Transport profile — Infrared Wireless.

ITU-T Recommendation X.681, Information Technology—Abstract Syntax Notation One (ASN.1)—Information Object Specification. (same as ISO/IEC 8824-2)<sup>5</sup>

<sup>3</sup>ISO/IEC publications are available from the ISO Central Secretariat, Case Postale 56, 1 rue de Varembe, CH-1211, Genève 20, Switzerland/Suisse (<http://www.iso.ch/>). ISO/IEC publications are also available in the United States from Global Engineering Documents, 15 Inverness Way East, Englewood, CO 80112, USA (<http://global.ihs.com/>). Electronic copies are available in the United States from the American National Standards Institute, 25 West 43rd Street, 4th Floor, New York, NY 10036, USA (<http://www.ansi.org/>).

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