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

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site des soins — Partie 20101: Profils d'applications — Norme de base*



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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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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 11073-20101:2004(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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Health informatics — Point-of-care medical device communication — Part 20101: Application profiles — Base standard

1. Overview

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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

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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.

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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™,¹ 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.²

¹Information on references can be found in Clause 2.

²IEEE 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.³ (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.⁴

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)⁵

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