INTERNATIONAL STANDARD

ISO/IEEE 11073-10101

First edition 2004-12-15

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

Part 10101:

Nomenclature

Informatique de santé — Communication entre dispositifs médicaux sur le site des soins — Partie 10101: Nomenclature



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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 non-enclature, 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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Print: ISBN 0-7381-4087-2 SH95255 PDF: ISBN 0-7381-4088-0 SS95255

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ISO Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 betweer 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 her 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, if any, for this and all other standards can be accessed at the following URL: http://standards.ieee.org/reading/ieee/updates/errata/index.html. Users are encouraged to check this URL for errata periodically.

Interpretations

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

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Health informatics — Point-of-care medical device communication — Part 101010 Part 101010 Nomenclature

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 commonents; 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 and 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 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 95961, Information technology — Open systems interconnection — Common Management Information Protecol — Part 1: Specification.

ISO/IEEE 1107310201, 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 as two relational components.
- **4.3 unique:** nonredundant.

5. Symbols (and abbreviated terms)

API application program interface
ASN.1 Abstract Syntax Notation One (ISO/IEC S

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 11/73-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/).

⁴ISO/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/).

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