

**Health informatics - Device interoperability - Part
10101: Point-of-care medical device communication -
Nomenclature (ISO/IEEE 11073-10101:2020)**

EESTI STANDARDI EESSÕNA**NATIONAL FOREWORD**

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- Partie 10101: Communication entre dispositifs
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COMITÉ EUROPÉEN DE NORMALISATION
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European foreword

This document (EN ISO 11073-10101:2020) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with 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of an identical text or by endorsement, at the latest by March 2021, and conflicting national standards shall be withdrawn at the latest by March 2021.

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Introduction

This introduction is not part of IEEE Std 11073-10101-2019, Health informatics—Point-of-Care Medical Device Communication—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 focus on acute care devices, such as patient monitors, ventilators, infusion pumps, ECG devices, etc, and personal health devices and systems. They comprise a family of standards that can be layered together to provide connectivity optimized for the specific devices being interfaced.

IEEE Std 11073-10101 was originally published in 2004 in conjunction with the International Organization for Standardization (ISO). In 2015, IEEE published an amendment that expanded the nomenclature and definitions covered in the standard to reflect the continued innovation in medical device and system design. This 2019 revision integrates the amendment into the original text and further updates and expands the nomenclature and definitions.

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Health informatics—Point-of-care medical device communication

Part 10101: Nomenclature

1. Scope

This standard defines a nomenclature for communication of information from point-of-care medical devices. Primary emphasis is placed on acute care medical devices and patient vital signs information. The nomenclature also supports concepts in an object-oriented information model that is for medical device communication.

2. 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.

IEEE Std 1073™, IEEE Standard for Medical Device Communications—Overview and Framework.^{1,2}

IEEE Std 11073-10102™-2012, Health informatics—Point-of-care medical device communication—Part 10102: Nomenclature—Annotated ECG.

IEEE Std 11073-10103™-2012, Health informatics—Point-of-care medical device communication—Part 10103: Nomenclature—Implantable device, cardiac.

ISO/IEC 8824 (all parts), Information technology — Abstract Syntax Notation One (ASN.1).³

ISO/IEC 8825 (all parts), Information technology —ASN.1 encoding rules.

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³ ISO/IEC documents can be obtained from the International Organization for Standardization (<http://www.iso.ch/>), International Electrotechnical Commission (<http://www.iec.ch/>), and the American National Standards Institute (<http://www.ansi.org/>).

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.

ISO/IEEE 11073-20601, Health informatics — Personal health device communication — Part 20601: Application profile—Optimized Exchange Protocol

ISO/IEEE 11073-10404, Health informatics — Personal health device communication — Part 10404: Device specialization — Pulse Oximeter

ISO/IEEE 11073-10406, Health informatics — Personal health device communication — Part 10406: Device specialization — Basic electrocardiograph (ECG) (1- to 3-lead ECG)

ISO/IEEE 11073-10407, Health informatics — Personal health device communication — Part 10407: Device specialization — Blood Pressure

ISO/IEEE 11073-10408, Health informatics — Personal health device communication — Part 10408: Device specialization — Thermometer

ISO/IEEE 11073-10415, Health informatics — Personal health device communication — Part 10415: Device specialization — Weighing Scale

ISO/IEEE 11073-10417, Health informatics — Personal health device communication — Part 10417: Device specialization — Glucose Meter

ISO/IEEE 11073-10418, Health informatics — Personal health device communication — Part 10418: Device specialization — International Normalized Ratio (INR) monitor

ISO/IEEE 11073-10419, Health informatics — Personal health device communication — Part 10419: Device specialization — Insulin Pump

ISO/IEEE 11073-10420, Health informatics — Personal health device communication — Part 10420: Device specialization — Body composition analyzer

ISO/IEEE 11073-10421, Health informatics — Personal health device communication — Part 10421: Device specialization — Peak expiratory flow monitor (peak flow)

ISO/IEEE 11073-10422, Health informatics — Personal health device communication — Part 10422: Device specialization — Urine analyzer

ISO/IEEE 11073-10424, Health informatics — Personal health device communication — Part 10424: Device specialization — Sleep Apnoea Breathing Therapy Equipment (SABTE)

ISO/IEEE 11073-10425, Health informatics — Personal health device communication — Part 10425: Device specialization — Continuous Glucose Monitor (CGM)

ISO/IEEE 11073-10427, Health informatics — Personal health device communication — Part 10427: Device specialization — Power Status Monitor of Personal Health Devices

ISO/IEEE 11073-10441, Health informatics — Personal health device communication — Part 10441: Device specialization — Cardiovascular fitness and activity monitor

ISO/IEEE 11073-10442, Health informatics — Personal health device communication — Part 10442: Device specialization — Strength fitness equipment

ISO/IEEE 11073-10471, Health informatics — Personal health device communication — Part 10471: Device specialization — Independent living activity hub

ISO/IEEE 11073-10472, Health informatics — Personal health device communication — Part 10472: Device specialization — Medication monitor

3. Terms, definitions, symbols, and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply. The *IEEE Standards Dictionary Online* should be consulted for terms not defined in this clause.⁴

base term: A fundamental semantic concept.

co-constraint: A rule describing a constraint whose scope is inclusive of more than one term.

corollary: A semantic and a syntactical representation that are correlated by a unique code.

discriminators: A mechanism to provide additional semantic refinement to multiple base terms.

domain information model (DIM): The model describing common concepts and relationships for a problem domain.

reference identifier (RefId): A unique, symbolic, and programmatic form for the term. The form is correlated to the context-free code (i.e., terms are by definition context-free with respect to all other terms); in this standard, terms are prefixed with “MDC_” for consistency.

systematic name: An organization of differentiating, relational descriptors that are unique for each term.

terminology: A synonym for nomenclature.

tuple: A component of a relation; e.g., a 2-tuple has two relational components.

unique: Nonredundant.

3.2 Symbols and abbreviated terms

AI	aging independently
aka	also known as
API	application program interface

⁴ *IEEE Standards Dictionary Online* is available at <http://dictionary.ieee.org>.