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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

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English Version

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

Informatique de santé - Interopérabilité des dispositifs - Partie 10101: Communication entre dispositifs médicaux sur le site des soins - Nomenclature (ISO/IEEE 11073-10101:2020)

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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of an identical text or by endorsement, at the latest by March 2021, and conflicting national standards shall be withdrawn at the latest by March 2021.

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Second edition
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Part 10101: Point-of-care medical device communication — Nomenclature

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ISO/IEEE 11073-10101 was prepared by the IEEE 11073 Standards Committee of the IEEE Engineering in Medicine and Biology Society (as IEEE Std 11073-10101-2019) and drafted in accordance with its editorial rules. It was adopted, under the “fast-track procedure” defined in the Partner Standards Development Organization cooperation agreement between ISO and IEEE, by Technical Committee ISO/TC 215, *Health informatics*.

This second edition cancels and replaces the first edition (ISO/IEEE 11073-10101:2004), which has been technically revised. It also incorporates the Amendment ISO/IEEE 11073-10101:2004/Amd 1:2017.

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IEEE Std 11073-10101™-2019
(Revision of
ISO/IEEE 11073-10101:2004)

Health informatics—Point-of-care medical device communication

Part 10101: Nomenclature

Developed by the

IEEE 11073™ Standards Committee
of the
IEEE Engineering in Medicine and Biology Society

Approved 13 June 2019

IEEE SA Standards Board

Abstract: Within the context of the ISO/IEEE 11073 family of standards for point-of-care (POC) and personal health devices (PHD) medical device communication (MDC), 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 nomenclature, along with extensive definitions for each conceptual area.

Keywords: codes, IEEE 11073-10101™, IHE PCD-01, independent living, information model, medical device communication, nomenclature, ontology, patient, personal health devices, PHD, POC, point-of-care, semantics, service model, terminology

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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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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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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)

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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)

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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