Health informatics - Device interoperability - Part 10404: Personal health device communication - Device specialization - Pulse oximeter (ISO/IEEE 11073- 10404:2022)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO/IEEE 11073-10404:2022 sisaldab Euroopa standardi EN ISO/IEEE 11073-10404:2022 ingliskeelset teksti.	This Estonian standard EVS-EN ISO/IEEE 11073-10404:2022 consists of the English text of the European standard EN ISO/IEEE 11073-10404:2022.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 21.12.2022.	Date of Availability of the European standard is 21.12.2022.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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English Version

Health informatics - Device interoperability - Part 10404: Personal health device communication - Device specialization - Pulse oximeter (ISO/IEEE 11073-10404:2022)

Informatique de santé - Interopérabilité des dispositifs - Partie 10404: Communication entre dispositifs de santé personnels - Spécialisation des dispositifs - Oxymètre de pouls (ISO/IEEE 11073-10404:2022)

Medizinische Informatik - Kommunikation von Geräten für die persönliche Gesundheit - Teil 10404: Gerätespezifikation - Pulsoximeter (ISO/IEEE 11073-10404:2022)

This European Standard was approved by CEN on 4 December 2022.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Ref. No. EN ISO/IEEE 11073-10404:2022 E

European foreword

This document (EN ISO/IEEE 11073-10404:2022) 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 June 2023, and conflicting national standards shall be withdrawn at the latest by June 2023.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 11073-10404:2011.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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Endorsement notice

The text of ISO/IEEE 11073-10404:2022 has been approved by CEN as EN ISO/IEEE 11073-10404:2022 without any modification.

Introduction

This introduction is not part of IEEE Std 11073-10404-2020, Health informatics—Personal health device communication—Part 10404: Device specialization—Pulse oximeter.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. This document uses the optimized framework created in IEEE Std 11073-20601-2019™ and describes a specific, interoperable communication approach for the pulse oximeter.[1] These standards align with, and draw on, the existing clinically focused standards to provide support for communication of data from clinical or personal health devices.

[1] Information on references can be found in Clause 2.

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Health informatics—Personal health device communication

Part 10404: Device specialization—Pulse oximeter

1. Overview

1.1 Scope

Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of communication between personal telehealth pulse oximeter devices and compute engines (e.g., cell phones, personal computers, personal health appliances, set top boxes) in a manner that enables plug-and-play (PnP) interoperability. It leverages appropriate portions of existing standards including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for personal telehealth pulse oximeters.

1.2 Purpose

This standard addresses a need for an openly defined, independent standard for controlling information exchange to and from personal health devices (PHDs) and compute engines (e.g., cell phones, personal computers, personal health appliances, set top boxes). Interoperability is key to growing the potential market for these devices and enabling people to be better informed participants in the management of their health.

1.3 Context

See IEEE Std 11073-20601-2019™[2] for an overview of the environment within which this standard is written.

This standard, IEEE Std 11073-10404, defines the device specialization for the pulse oximeter, being a specific agent type, and provides a description of the device concepts, its capabilities, and its implementation according to this standard.

This standard is based on IEEE Std 11073-20601-2019, which in turn draws information from both ISO/IEEE 11073-10201:2004 [B6][3] and ISO/IEEE 11073-20101:2004 [B7]. The medical device encoding rules (MDER) used within this standard are fully described in IEEE Std 11073-20601-2019.

[2] Information on references can be found in Clause 2.

[3] The numbers in brackets correspond to the numbers in the bibliography in Annex A.

This standard defines specialized nomenclature codes that will be collected in IEEE Std 11073-10101-2019™. Between this standard, IEEE Std 11073-10101-2019, IEEE Std 11073-20601-2019 and other IEEE Std 11073-104xx, all required nomenclature codes for implementation are documented. New codes may be defined in newer versions / revisions of each of these documents. In the case of a conflict, where one term code has been assigned to two separate semantic concepts with different RefIDs, in general the oldest definition that is in actual use should take precedence. The same policy applies when one RefID has two different code values assigned in different specifications. The resolution of such conflicts will be determined through joint action by the responsible work groups and other stakeholders and any corrective action published as corrigenda.

NOTE—In this standard, ISO/IEEE P11073-104zz is used to refer to the collection of device specialization standards that utilize IEEE Std 11073-20601-2019, where zz can be any number from 01 to 99, inclusive.[4]

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used, so that each referenced document is cited in text and its relationship to this document is explained). For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments or corrigenda) applies.

IEEE Std 11073-20601-2019, Health informatics—Personal health device communication—Part 20601: Application profile—Optimized Exchange Protocol.[5, 6]

IEEE Std 11073-10101-2019, Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.

See Annex A for all informative material referenced by this standard.

3. Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this standard, the following terms and definitions apply. The *IEEE Standards Dictionary Online* [B1] should be referenced for terms not defined in this clause.[7]

agent: A node that collects and transmits personal health data to an associated manager.

class: In object-oriented modeling, a class describes the attributes, methods, and events that objects instantiated from the class utilize.

compute engine: *See:* **manager**.

device: A physical apparatus implementing either an agent or manager role.

handle: An unsigned 16-bit number that is locally unique and identifies one of the object instances within an agent.

[4] Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement the standard.
[5] IEEE publications are available from The Institute of Electrical and Electronics Engineers (https://standards.ieee.org/).
[6] The IEEE standards or products referred to in Clause 2 are trademarks owned by The Institute of Electrical and Electronics Engineers, Incorporated.
[7] *IEEE Standards Dictionary Online* is available at: http://dictionary.ieee.org. An IEEE Account is required for access to the dictionary, and one can be created at no charge on the dictionary sign-in page.