

**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.

ICS 11.040.40

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardimis- ja Akrediteerimiskeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardimis- ja Akrediteerimiskeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardimis- ja Akrediteerimiskeskusega: Koduleht www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation and Accreditation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation and Accreditation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation and Accreditation:

Homepage www.evs.ee; phone +372 605 5050; e-mail info@evs.ee

December 2022

ICS 35.240.80

Supersedes EN ISO 11073-10404:2011

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.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

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 11073-20601-2019TM 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.

Contents

1. Overview	12
1.1 Scope	12
1.2 Purpose	12
1.3 Context	12
2. Normative references.....	13
3. Definitions, acronyms, and abbreviations	13
3.1 Definitions	13
3.2 Acronyms and abbreviations	14
4. Introduction to ISO/IEEE 11073 personal health devices	14
4.1 General	14
4.2 Introduction to IEEE 11073-20601 modeling constructs.....	15
4.3 Compliance with other standards.....	15
5. Pulse oximeter device concepts and modalities.....	16
5.1 General	16
5.2 Device types	16
5.3 General concepts.....	16
5.4 Collected data	17
5.5 Derived data.....	19
5.6 Stored data	19
5.7 Device configurations.....	19
6. Pulse oximeter DIM	20
6.1 Overview	20
6.2 Class extensions.....	20
6.3 Object instance diagram	20
6.4 Types of configuration.....	21
6.5 MDS object.....	22
6.6 Numeric objects.....	26
6.7 Real-time sample array (RT-SA) objects.....	36
6.8 Enumeration objects	37
6.9 PM-store objects.....	41
6.10 Scanner objects.....	45
6.11 Class extension objects.....	48
6.12 Pulse oximeter information model extensibility rules	48
7. Pulse oximeter service model.....	48
7.1 General	48
7.2 Object access services.....	48
7.3 Object access EVENT REPORT services	52
8. Pulse oximeter communication model.....	52
8.1 Overview	52
8.2 Communications characteristics	52
8.3 Association procedure	53
8.4 Configuring procedure.....	55
8.5 Operating procedure	56
8.6 Time synchronization	57

9. Test associations	57
9.1 Behavior with standard configuration.....	57
9.2 Behavior with extended configurations	58
10. Conformance	58
10.1 Applicability	58
10.2 Conformance specification	58
10.3 Levels of conformance	58
10.4 Implementation conformance statements (ICSs)	59
Annex A (informative) Bibliography	63
Annex B (normative) Additional ASN.1 definitions	64
Annex C (normative) Allocation of identifiers	65
Annex D (informative) Message sequence examples	67
Annex E (informative) PDU examples.....	69
Annex F (informative) Revision history.....	81

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^{TM2} 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.