

**Health informatics - Personal health device  
communication - Part 10404: Device specialization -  
Pulse oximeter (ISO/IEEE 11073-10404:2010)**

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 11073-10404:2011 sisaldab Euroopa standardi EN ISO 11073-10404:2011 ingliskeelset teksti.

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ICS 35.240.80

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English Version

Health informatics - Personal health device communication -  
Part 10404: Device specialization - Pulse oximeter (ISO/IEEE  
11073-10404:2010)

Informatique de santé - Communication entre dispositifs de  
santé personnels - Partie 10404: Spécialisation des  
dispositifs - Oxymètre de pouls (ISO/IEEE 11073-  
10404:2010)

Medizinische Informatik - Kommunikation von Geräten für  
die persönliche Gesundheit - Teil 10404:  
Gerätespezifikation - Pulsoximeter (ISO/IEEE 11073-  
10404:2010)

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## Foreword

The text of ISO/IEEE 11073-10404:2010 has been prepared by Technical Committee ISO/TC 215 "Health informatics" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 11073-10404:2011 by 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of an identical text or by endorsement, at the latest by September 2011, and conflicting national standards shall be withdrawn at the latest by September 2011.

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The text of ISO/IEEE 11073-10404:2010 has been approved by CEN as a EN ISO 11073-10404:2011 without any modification.

<b>Contents</b>	<b>Page</b>
Foreword.....	v
Introduction.....	vii
1. Overview.....	1
1.1 Scope.....	1
1.2 Purpose.....	1
1.3 Context.....	2
2. Normative references.....	2
3. Definitions, acronyms, and abbreviations.....	2
3.1 Definitions.....	2
3.2 Acronyms and abbreviations.....	3
4. Introduction to ISO/IEEE 11073 personal health devices.....	3
4.1 General.....	3
4.2 Introduction to IEEE 11073-20601 modeling constructs.....	4
5. Pulse oximeter device concepts and modalities.....	4
5.1 General.....	4
5.2 Device types.....	5
5.3 General concepts.....	5
5.4 Collected data.....	6
5.5 Derived data.....	8
5.6 Stored data.....	8
5.7 Device configurations.....	8
6. Pulse oximeter DIM.....	9
6.1 Overview.....	9
6.2 Class extensions.....	9
6.3 Object instance diagram.....	9
6.4 Types of configuration.....	10
6.5 MDS object.....	11
6.6 Numeric objects.....	14
6.7 Real-time sample array (RT-SA) objects.....	24
6.8 Enumeration objects.....	25
6.9 PM-store objects.....	29
6.10 Scanner objects.....	33
6.11 Class extension objects.....	37
6.12 Pulse oximeter information model extensibility rules.....	37

7. Pulse oximeter service model .....	37
7.1 General.....	37
7.2 Object access services.....	37
7.3 Object access EVENT REPORT services.....	40
8. Pulse oximeter communication model.....	41
8.1 Overview.....	41
8.2 Communications characteristics.....	41
8.3 Association procedure.....	42
8.4 Configuring procedure.....	43
8.5 Operating procedure.....	45
8.6 Time synchronization.....	46
9. Test associations.....	46
9.1 Behavior with standard configuration.....	46
9.2 Behavior with extended configurations.....	46
10. Conformance.....	46
10.1 Applicability.....	46
10.2 Conformance specification.....	47
10.3 Levels of conformance.....	47
10.4 Implementation conformance statements (ICSs).....	48
Annex A (informative) Bibliography.....	52
Annex B (normative) Additional ASN.1 definitions.....	53
Annex C (normative) Allocation of identifiers.....	55
Annex D (informative) Message sequence examples.....	57
Annex E (informative) PDU examples.....	59

## Introduction

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. This standard uses the optimized framework created in IEEE Std 11073-20601™-2008<sup>a</sup> and describes a specific, interoperable communication approach for pulse oximeters. These standards align with, and draw upon, the existing clinically focused standards to provide support for communication of data from clinical or personal health devices.

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<sup>a</sup> For information on references, see Clause 2.

# Health informatics—Personal health device communication—

## Part 10404: Device specialization—Pulse oximeter

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### 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 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 11073-20601-2008<sup>1</sup> for an overview of the environment within which this standard is written.

This standard, IEEE Std 11073-10404-2008, 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 11073-20601-2008, which in turn draws information from both ISO/IEEE 11073-10201:2004 [B3]<sup>2</sup> and ISO/IEEE 11073-20101:2004 [B4]. The medical device encoding rules (MDER) used within this standard are fully described in IEEE Std 11073-20601-2008.

This standard reproduces relevant portions of the nomenclature found in ISO/IEEE 11073-10101:2004 [B2] and adds new nomenclature codes for the purposes of this standard. Between this standard and IEEE Std 11073-20601-2008, all required nomenclature codes for implementation are documented.

NOTE—In this standard, ISO/IEEE P11073-104zz is used to refer to the collection of device specialization standards that utilize IEEE Std 11073-20601-2008, where zz can be any number from 01 to 99, inclusive.<sup>3</sup>

## 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 11073-20601-2008, Health informatics—Personal health device communication—Part 20601: Application profile—Optimized Exchange Profile.<sup>4</sup>

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 Authoritative Dictionary of IEEE Standards* [B1] should be referenced for terms not defined in this clause.

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

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

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

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

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

<sup>1</sup> Information on references can be found in Clause 2.

<sup>2</sup> The numbers in brackets correspond to the numbers in the bibliography in Annex A.

<sup>3</sup> Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement the standard.

<sup>4</sup> IEEE publications are available from the Institute of Electrical and Electronics Engineers, 445 Hoes Lane, Piscataway, NJ 08854, USA (<http://standards.ieee.org/>).