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Health informatics — Personal health device communication —

Part 10404:

Device specialization — Pulse oximeter

Informatique de santé — Communication entre dispositifs médicaux sur le site des soins —

Partie 10404: Spécialisation des dispositifs — Oxymètre de pouls



Reference number
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Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Institute of Electrical and Electronics Engineers, Inc.
3 Park Avenue, New York • NY 10016-5997, USA
E-mail stds.ipr@ieee.org
Web www.ieee.org

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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ISO/IEEE 11073-10404 was prepared by the 11073 Committee of the Engineering in Medicine and Biology Society of the IEEE (as IEEE Std 11073-10404-2008). It was adopted by Technical Committee ISO/TC 215, *Health informatics*, in parallel with its approval by the ISO member bodies, under the “fast-track procedure” defined in the Partner Standards Development Organization cooperation agreement between ISO and IEEE. Both parties are responsible for the maintenance of this document.

ISO/IEEE 11073 consists of the following parts, under the general title *Health informatics — Personal health device communication* (text in parentheses gives a variant of subtitle):

- *Part 10101: (Point-of-care medical device communication) Nomenclature*
- *Part 10201: Domain information model*
- *Part 10404: Device specialization — Pulse oximeter*
- *Part 10407: Device specialization — Blood pressure monitor*

- *Part 10408: (Point-of-care medical device communication) Device specialization — Thermometer*
- *Part 10415: (Point-of-care medical device communication) Device specialization — Weighing scale*
- *Part 10417: Device specialization — Glucose meter*
- *Part 10471: (Point-of-care medical device communication) Device specialization — Independant living activity hub*
- *Part 20104: (Point-of-care medical device communication) Application profiles — Base standard*
- *Part 20601: (Point-of-care medical device communication) Application profile — Optimized exchange protocol*
- *Part 30200: (Point-of-care medical device communication) Transport profile — Cable connected*
- *Part 30300: (Point-of-care medical device communication) Transport profile — Infrared wireless*

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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^a 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.

^a For information on references, see Clause 2.

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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 11073-20601-2008¹ 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]² 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.³

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.⁴

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.

¹ Information on references can be found in Clause 2.

² The numbers in brackets correspond to the numbers in the bibliography in Annex A.

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

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