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Health informatics — Device interoperability —

Part 10404: Personal health device communication — Device specialization — Pulse oximeter

Informatique de santé — Interopérabilité des dispositifs —

Partie 10404: Communication entre dispositifs de santé personnels — Spécialisation des dispositifs — Oxymètre de pouls

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IEEE Std 11073-10404™-2020
(Revision of IEEE Std 11073-10404-2008)

Health informatics—Personal health device communication

Part 10404: Device specialization—Pulse oximeter

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

Approved 30 January 2020
IEEE SA Standards Board

Abstract: 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 oximetry devices and compute engines (e.g., cell phones, personal computers, personal health appliances, set top boxes) in a manner that enables plug-and-play 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.

Keywords: IEEE 11073-10404™, medical device communication, personal health devices, PHD, pulse oximeter

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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.

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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.

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manager: A node receiving data from one or more associated agent systems. Examples of managers include a cellular phone, health appliance, set top box, or a computer system.

object: In object-oriented modeling, a particular instantiation of a class. The instantiation realizes attributes, methods, and events from the class.

obj-handle: *See:* **handle**.

personal health device: A device used in personal health applications.

personal telehealth device: *See:* **personal health device**.

photoplethysmographic waveform: *See:* **plethysmogram**.

plethysmogram: Sequence of samples related to the sequential time-varying light absorption due to effects of pulsatile blood flow.

plethysmographic: *See:* **plethysmogram**.

SpO_2: Percentage oxygen saturation of haemoglobin as measured by a pulse oximeter, where this measurement is an estimate of the fraction of functional haemoglobin (or hemoglobin) in arterial blood that is saturated with oxygen.

NOTE—For more information about SpO_2, see ISO 80601-2-61:2017 [B9].

3.2 Acronyms and abbreviations

APDU	application protocol data unit
ASN.1	Abstract Syntax Notation One
DIM	domain information model
EUI-64	extended unique identifier (64 bits)
ICS	implementation conformance statement
ID	identifier
MDC	medical device communication
MDER	medical device encoding rules
MDS	medical device system
MOC	managed object class
OID	object identifier
PDU	protocol data unit
PHD	personal health device
RT-SA	real-time sample array
SpO_2	percentage oxygen saturation of haemoglobin
VMO	virtual medical object

4. Introduction to ISO/IEEE 11073 personal health devices

4.1 General

This standard and the remainder of the series of ISO/IEEE 11073 personal health device (PHD) standards fit in the larger context of the ISO/IEEE 11073 series of standards. The full suite of standards enables agents to interconnect and interoperate with both managers and computerized healthcare information systems. See IEEE Std 11073-20601-2019 for a description of the guiding principles for this series of ISO/IEEE 11073 Personal Health Device standards.

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