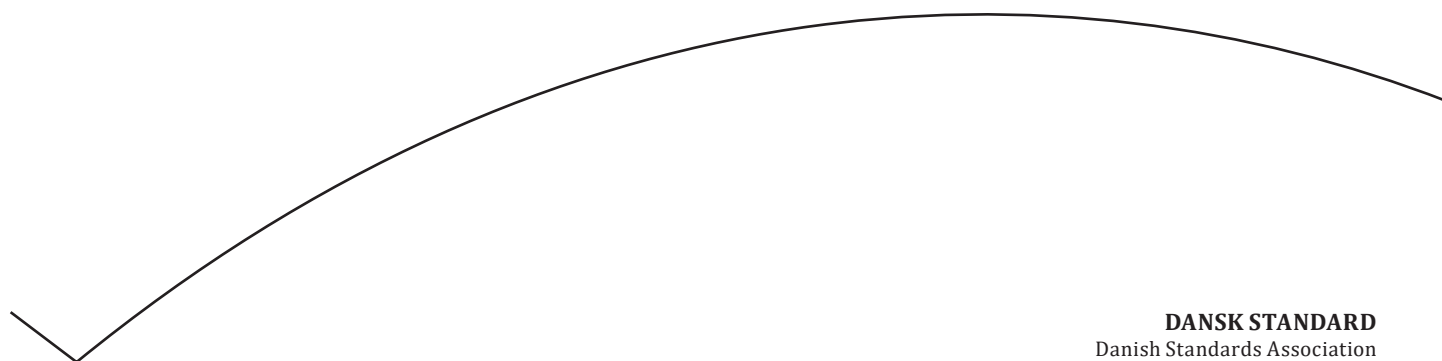


Sundhedsinformatik – Interoperabilitet mellem enheder – Del 10404: Kommunikation med personligt sundhedsudstyr – Udstyrsspecifikation – Pulsoximeter

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



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Danish Standards Association

Göteborg Plads 1
DK-2150 Nordhavn

Tel: +45 39 96 61 01
dansk.standard@ds.dk
www.ds.dk

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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
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Second edition
2022-12

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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This second edition cancels and replaces the first edition (ISO/IEEE 11073-10404:2010), which has been technically revised.

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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

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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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Participants

At the time this standard was completed, the Personal Health Devices Working Group had the following membership:

Daidi Zhong, Co-Chair
Michael J. Kirwan, Co-Chair

Karsten Aalders
Charles R. Abbruscato
Nabil Abujbara
Maher Abuzaid
James Agnew
Manfred Aigner
Jorge Alberola
David Aparisi
Lawrence Arne
Diego B. Arquillo
Serafin Arroyo
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Kit August
Doug Baird
David Baker
Anindya Bakshi
Abira Balanadarasan
Ananth Balasubramanian
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Gilberto Barrón
David Bean
John Bell
Olivia Bellamou-Huet
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Kathryn M. Bennett
Daniel Bernstein
George A. Bertos
Chris Biernacki
Ola Björnsne
Thomas Blackadar
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Thomas Bluethner
Douglas P. Bogia
Xavier Boniface
Shannon Boucousis
Julius Broma
Lyle G. Bullock, Jr.
Bernard Burg
Chris Burns
Jeremy Byford-Rew
Satya Calloji
Xiaoying Cao
Carole C. Carey
Craig Carlson
Santiago Carot-Nemesio
Randy W. Carroll
Simon Carter
Seungchul Chae
Rahul Chauhan
Peggy Chien
David Chiu
Jinyong Choi

Chia-Chin Chong
Saeed A. Choudhary
Jinhan Chung
John A. Cogan
John T. Collins
Cory Condek
Todd H. Cooper
David Cornejo
Douglas Coup
Nigel Cox
Hans Crommenacker
Tomio Crosley
Allen Curtis
Jesús Daniel Trigo
David Davenport
Russell Davis
Sushil K. Dekka
Ciro de la Vega
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Jim Dello Stritto
Kent Dicks
Hyoungdo Do
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Xiaolian Duan
Sourav Dutta
Jakob Ehrensvar
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Javier Escayola Calvo
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Xinyi Hong
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Di Hu
Anne Huang
Zhiqiang Huang
Zhiyong Huang
Ron Huby
David Hughes
Robert D. Hughes
Jiyoung Huh
Hugh Hunter
Philip O. Isaacson
Atsushi Ito
Michael Jaffe
Praduman Jain
Danny Jochelson
Akiyoshi Kabe
Steve Kahle
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James J. Kang
Kei Kariya
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Min-Joon Kim	Abraham Ofek	Lars Steubesand
Taekon Kim	Brett Olive	John (Ivo) Stivorice
Tetsuya Kimura	Begonya Ota	Raymond A. Strickland
Michael J. Kirwan	Marco Paleari	Chandrasekaran Subramaniam
Alfred Kloos	Bud Panjwani	Hermann Suominen
Jeongmee Koh	Carl Pantiskas	Lee Surprenant
Jean-Marc Koller	Harry P. Pappas	Ravi Swami
John Koon	Hanna Park	Ray Sweidan
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Pierre Landau	Peter Piction	Gary Tschautscher
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Soundharya Nagasubramanian	Redmond Shouldice	Jason Zhang
Alex Neefus	Sternly K. Simon	Jie Zhao
Trong-Nghia Nguyen-Dobinsky	Marjorie Skubic	Thomas Zhao
Michael E. Nidd	Robert Smith	Daidi Zhong
Jim Niswander	Ivan Soh	Hongyuan Zhong
Hongliang Niu	Motoki Sone	Yuanhong Zhong
Hiroaki Niwamoto	Emily Sopensky	Miha Zoubek
Thomas Norgall	Rajagopalan Srinivasan	Szymon Zyskoter

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The following members of the individual balloting committee voted on this standard. Balloters may have voted for approval, disapproval, or abstention.

Bjoern Andersen
Lyle Bullock
Keith Chow
Malcolm Clarke
Kenneth Fuchs
David Fuschi
Randall Groves
Robert Heile

Werner Hoelzl
Noriyuki Ikeuchi
Atsushi Ito
Raj Jain
Piotr Karocki
Martin Kasparick
Raymond Krasinski
H. Moll

Iulian Profir
Beth Pumo
Stefan Schlichting
Janek Schumann
Walter Struppler
Oren Yuen
Janusz Zalewski
Daidi Zhong

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Paul Nikolich
Damir Novosel
Jon Walter Rosdahl

Dorothy Stanley
Mehmet Ulema
Lei Wang
Sha Wei
Philip B. Winston
Daidi Zhong
Jingyi Zhou

*Member Emeritus

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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 11073-20601-2019TM 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.

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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^{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.

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This standard defines specialized nomenclature codes that will be collected in IEEE Std 11073-10101-2019TM. 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.

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.