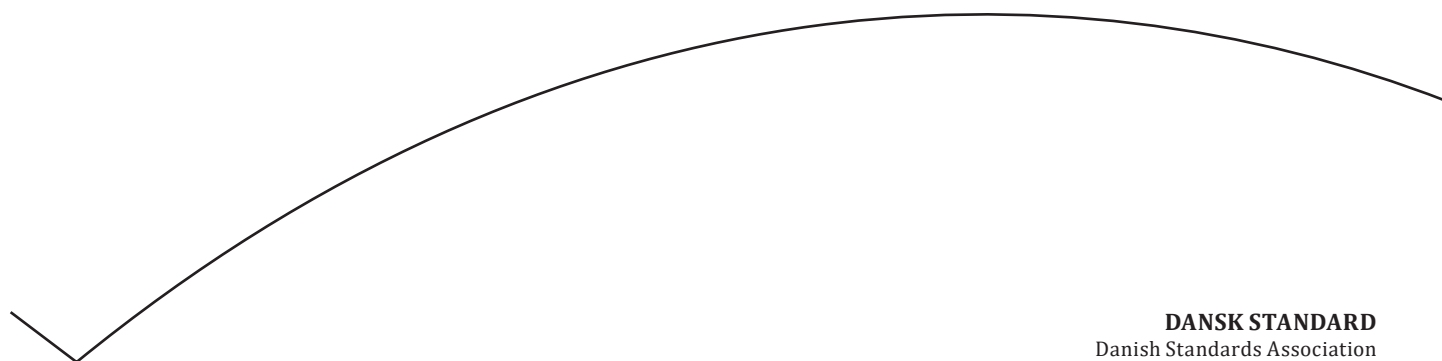


Sundhedsinformatik – Interoperabilitet mellem enheder – Del 10404: Kommunikation med personligt sundhedsudstyr – Udstyrsspecifikation – Pulsoximeter

Health informatics – Device interoperability –
Part 10404: Personal health device communication –
Device specialization – Pulse oximeter



DANSK STANDARD
Danish Standards Association

Göteborg Plads 1
DK-2150 Nordhavn
Tel: +45 39 96 61 01
dansk.standard@ds.dk
www.ds.dk

DS projekt: M363492

ICS: 35.240.80

Første del af denne publikations betegnelse er:

DS/ISO, hvilket betyder, at det er en international standard, der har status som dansk standard.

Denne publikations overensstemmelse er:

IDT med: ISO/IEEE 11073-10404:2022

DS-publikationen er på engelsk.

DS-publikationstyper

Dansk Standard udgiver forskellige publikationstyper.

Typen på denne publikation fremgår af forsiden.

Der kan være tale om:

Dansk standard

- standard, der er udarbejdet på nationalt niveau, eller som er baseret på et andet lands nationale standard, eller
- standard, der er udarbejdet på internationalt og/eller europæisk niveau, og som har fået status som dansk standard

DS-information

- publikation, der er udarbejdet på nationalt niveau, og som ikke har opnået status som standard, eller
- publikation, der er udarbejdet på internationalt og/eller europæisk niveau, og som ikke har fået status som standard, fx en teknisk rapport, eller
- europæisk præstandard

DS-håndbog

- samling af standarder, eventuelt suppleret med informativt materiale

DS-hæfte

- publikation med informativt materiale

Til disse publikationstyper kan endvidere udgives

- tillæg og rettelsesblade

DS-publikationsform

Publikationstyperne udgives i forskellig form som henholdsvis

- | | |
|------------------------|---|
| • fuldtekstpublikation | (publikationen er trykt i sin helhed) |
| • godkendelsesblad | (publikationen leveres i kopi med et trykt DS-omslag) |
| • elektronisk | (publikationen leveres på et elektronisk medie) |

DS-betegnelse

Alle DS-publikationers betegnelse begynder med DS efterfulgt af et eller flere præfikser og et nr., fx **DS 383**, **DS/EN 5414** osv. Hvis der efter nr. er angivet et **A** eller **Cor**, betyder det, enten at det er et **tillæg** eller et **rettelsesblad** til hovedstandard, eller at det er indført i hovedstandard.

DS-betegnelse angives på forsiden.

Overensstemmelse med anden publikation:

Overensstemmelse kan enten være IDT, EQV, NEQ eller MOD

- | | |
|---------------|---|
| • IDT: | Når publikationen er identisk med en given publikation. |
| • EQV: | Når publikationen teknisk er i overensstemmelse med en given publikation, men præsentationen er ændret. |
| • NEQ: | Når publikationen teknisk eller præsentationsmæssigt ikke er i overensstemmelse med en given standard, men udarbejdet på baggrund af denne. |
| • MOD: | Når publikationen er modificeret i forhold til en given publikation. |

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*



Reference number
ISO/IEEE 11073-10404:2022(E)

© IEEE 2021



COPYRIGHT PROTECTED DOCUMENT

© IEEE 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from IEEE at the address below.

Institute of Electrical and Electronics Engineers, Inc
3 Park Avenue, New York
NY 10016-5997, USA

Email: stds.ipr@ieee.org
Website: www.ieee.org

Published in Switzerland

This is a preview of "DS/ISO/IEEE 11073-10...". Click here to purchase the full version from the ANSI store.

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted (see www.iso.org/directives).

IEEE Standards documents are developed within the IEEE Societies and the Standards Coordinating Committees of the IEEE Standards Association (IEEE-SA) Standards Board. The IEEE develops its standards through a consensus development process, approved by the American National Standards Institute, which brings together volunteers representing varied viewpoints and interests to achieve the final product. Volunteers are not necessarily members of the Institute and serve without compensation. While the IEEE administers the process and establishes rules to promote fairness in the consensus development process, the IEEE does not independently evaluate, test, or verify the accuracy of any of the information contained in its standards.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

ISO/IEEE 11073-10404 was prepared by the *IEEE 11073 Standards Committee of the IEEE Engineering in Medicine and Biology Society* (as IEEE Std 11073-10404-2020) and drafted in accordance with its editorial rules. It was adopted, under the "fast-track procedure" defined in the Partner Standards Development Organization cooperation agreement between ISO and IEEE, by Technical Committee ISO/TC 215, *Health informatics*.

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

A list of all parts in the ISO/IEEE 11073 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

This is a preview of "DS/ISO/IEEE 11073-10...". Click [here](#) to purchase the full version from the ANSI store.

This is a preview of "DS/ISO/IEEE 11073-10...". [Click here to purchase the full version from the ANSI store.](#)

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

The Institute of Electrical and Electronics Engineers, Inc.
3 Park Avenue, New York, NY 10016-5997, USA

Copyright © 2021 by The Institute of Electrical and Electronics Engineers, Inc.
All rights reserved. Published 7 January 2021. Printed in the United States of America.

IEEE is a registered trademark in the U.S. Patent & Trademark Office, owned by The Institute of Electrical and Electronics Engineers, Incorporated.

PDF: ISBN 978-1-5044-6458-1 STD24061
Print: ISBN 978-1-5044-6459-8 STDPD24061

IEEE prohibits discrimination, harassment, and bullying.

For more information, visit <https://www.ieee.org/about/corporate/governance/p9-26.html>.

No part of this publication may be reproduced in any form, in an electronic retrieval system or otherwise, without the prior written permission of the publisher.

This is a preview of "DS/ISO/IEEE 11073-10...". Click here to purchase the full version from the ANSI store.

Important Notices and Disclaimers Concerning IEEE Standards Documents

IEEE Standards documents are made available for use subject to important notices and legal disclaimers. These notices and disclaimers, or a reference to this page (<https://standards.ieee.org/ipr/disclaimers.html>), appear in all standards and may be found under the heading “Important Notices and Disclaimers Concerning IEEE Standards Documents.”

Notice and Disclaimer of Liability Concerning the Use of IEEE Standards Documents

IEEE Standards documents are developed within the IEEE Societies and the Standards Coordinating Committees of the IEEE Standards Association (IEEE SA) Standards Board. IEEE develops its standards through an accredited consensus development process, which brings together volunteers representing varied viewpoints and interests to achieve the final product. IEEE Standards are documents developed by volunteers with scientific, academic, and industry-based expertise in technical working groups. Volunteers are not necessarily members of IEEE or IEEE SA, and participate without compensation from IEEE. While IEEE administers the process and establishes rules to promote fairness in the consensus development process, IEEE does not independently evaluate, test, or verify the accuracy of any of the information or the soundness of any judgments contained in its standards.

IEEE makes no warranties or representations concerning its standards, and expressly disclaims all warranties, express or implied, concerning this standard, including but not limited to the warranties of merchantability, fitness for a particular purpose and non-infringement. In addition, IEEE does not warrant or represent that the use of the material contained in its standards is free from patent infringement. IEEE standards documents are supplied “AS IS” and “WITH ALL FAULTS.”

Use of an IEEE standard is wholly voluntary. The existence of an IEEE Standard does not imply that there are no other ways to produce, test, measure, purchase, market, or provide other goods and services related to the scope of the IEEE standard. Furthermore, the viewpoint expressed at the time a standard is approved and issued is subject to change brought about through developments in the state of the art and comments received from users of the standard.

In publishing and making its standards available, IEEE is not suggesting or rendering professional or other services for, or on behalf of, any person or entity, nor is IEEE undertaking to perform any duty owed by any other person or entity to another. Any person utilizing any IEEE Standards document, should rely upon his or her own independent judgment in the exercise of reasonable care in any given circumstances or, as appropriate, seek the advice of a competent professional in determining the appropriateness of a given IEEE standard.

IN NO EVENT SHALL IEEE BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, OR CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO: THE NEED TO PROCURE SUBSTITUTE GOODS OR SERVICES; LOSS OF USE, DATA, OR PROFITS; OR BUSINESS INTERRUPTION) HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, STRICT LIABILITY, OR TORT (INCLUDING NEGLIGENCE OR OTHERWISE) ARISING IN ANY WAY OUT OF THE PUBLICATION, USE OF, OR RELIANCE UPON ANY STANDARD, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE AND REGARDLESS OF WHETHER SUCH DAMAGE WAS FORESEEABLE.

Translations

The IEEE consensus development process involves the review of documents in English only. In the event that an IEEE standard is translated, only the English version published by IEEE is the approved IEEE standard.

Official statements

A statement, written or oral, that is not processed in accordance with the IEEE SA Standards Board Operations Manual shall not be considered or inferred to be the official position of IEEE or any of its committees and shall not be considered to be, nor be relied upon as, a formal position of IEEE. At lectures, symposia, seminars, or educational courses, an individual presenting information on IEEE standards shall make it clear that the presenter's views should be considered the personal views of that individual rather than the formal position of IEEE, IEEE SA, the Standards Committee, or the Working Group.

Comments on standards

Comments for revision of IEEE Standards documents are welcome from any interested party, regardless of membership affiliation with IEEE or IEEE SA. However, **IEEE does not provide interpretations, consulting information, or advice pertaining to IEEE Standards documents.**

Suggestions for changes in documents should be in the form of a proposed change of text, together with appropriate supporting comments. Since IEEE standards represent a consensus of concerned interests, it is important that any responses to comments and questions also receive the concurrence of a balance of interests. For this reason, IEEE and the members of its Societies and Standards Coordinating Committees are not able to provide an instant response to comments, or questions except in those cases where the matter has previously been addressed. For the same reason, IEEE does not respond to interpretation requests. Any person who would like to participate in evaluating comments or in revisions to an IEEE standard is welcome to join the relevant IEEE working group. You can indicate interest in a working group using the Interests tab in the Manage Profile & Interests area of the [IEEE SA myProject system](#). An IEEE Account is needed to access the application.

Comments on standards should be submitted using the [Contact Us](#) form.

Laws and regulations

Users of IEEE Standards documents should consult all applicable laws and regulations. Compliance with the provisions of any IEEE Standards document does not constitute compliance to any applicable regulatory requirements. Implementers of the standard are responsible for observing or referring to the applicable regulatory requirements. IEEE does not, by the publication of its standards, intend to urge action that is not in compliance with applicable laws, and these documents may not be construed as doing so.

Data privacy

Users of IEEE Standards documents should evaluate the standards for considerations of data privacy and data ownership in the context of assessing and using the standards in compliance with applicable laws and regulations.

Copyrights

IEEE draft and approved standards are copyrighted by IEEE under US and international copyright laws. They are made available by IEEE and are adopted for a wide variety of both public and private uses. These include both use, by reference, in laws and regulations, and use in private self-regulation, standardization, and the promotion of engineering practices and methods. By making these documents available for use and adoption by public authorities and private users, IEEE does not waive any rights in copyright to the documents.

Photocopies

Subject to payment of the appropriate licensing fees, IEEE will grant users a limited, non-exclusive license to photocopy portions of any individual standard for company or organizational internal use or individual, non-commercial use only. To arrange for payment of licensing fees, please contact Copyright Clearance Center, Customer Service, 222 Rosewood Drive, Danvers, MA 01923 USA; +1 978 750 8400; <https://www.copyright.com/>. Permission to photocopy portions of any individual standard for educational classroom use can also be obtained through the Copyright Clearance Center.

This is a preview of "DS/ISO/IEEE 11073-10...". Click here to purchase the full version from the ANSI store.

Updating of IEEE Standards documents

Users of IEEE Standards documents should be aware that these documents may be superseded at any time by the issuance of new editions or may be amended from time to time through the issuance of amendments, corrigenda, or errata. An official IEEE document at any point in time consists of the current edition of the document together with any amendments, corrigenda, or errata then in effect.

Every IEEE standard is subjected to review at least every 10 years. When a document is more than 10 years old and has not undergone a revision process, it is reasonable to conclude that its contents, although still of some value, do not wholly reflect the present state of the art. Users are cautioned to check to determine that they have the latest edition of any IEEE standard.

In order to determine whether a given document is the current edition and whether it has been amended through the issuance of amendments, corrigenda, or errata, visit [IEEE Xplore](#) or [contact IEEE](#). For more information about the IEEE SA or IEEE's standards development process, visit the IEEE SA Website.

Errata

Errata, if any, for all IEEE standards can be accessed on the [IEEE SA Website](#). Search for standard number and year of approval to access the web page of the published standard. Errata links are located under the Additional Resources Details section. Errata are also available in [IEEE Xplore](#). Users are encouraged to periodically check for errata.

Patents

IEEE Standards are developed in compliance with the [IEEE SA Patent Policy](#).

Attention is called to the possibility that implementation of this standard may require use of subject matter covered by patent rights. By publication of this standard, no position is taken by the IEEE with respect to the existence or validity of any patent rights in connection therewith. If a patent holder or patent applicant has filed a statement of assurance via an Accepted Letter of Assurance, then the statement is listed on the IEEE SA Website at <https://standards.ieee.org/about/sasb/patcom/patents.html>. Letters of Assurance may indicate whether the Submitter is willing or unwilling to grant licenses under patent rights without compensation or under reasonable rates, with reasonable terms and conditions that are demonstrably free of any unfair discrimination to applicants desiring to obtain such licenses.

Essential Patent Claims may exist for which a Letter of Assurance has not been received. The IEEE is not responsible for identifying Essential Patent Claims for which a license may be required, for conducting inquiries into the legal validity or scope of Patents Claims, or determining whether any licensing terms or conditions provided in connection with submission of a Letter of Assurance, if any, or in any licensing agreements are reasonable or non-discriminatory. Users of this standard are expressly advised that determination of the validity of any patent rights, and the risk of infringement of such rights, is entirely their own responsibility. Further information may be obtained from the IEEE Standards Association.

IMPORTANT NOTICE

IEEE Standards do not guarantee or ensure safety, security, health, or environmental protection, or ensure against interference with or from other devices or networks. IEEE Standards development activities consider research and information presented to the standards development group in developing any safety recommendations. Other information about safety practices, changes in technology or technology implementation, or impact by peripheral systems also may be pertinent to safety considerations during implementation of the standard. Implementers and users of IEEE Standards documents are responsible for determining and complying with all appropriate safety, security, environmental, health, and interference protection practices and all applicable laws and regulations.

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
Muhammad Asim
Kit August
Doug Baird
David Baker
Anindya Bakshi
Abira Balanadarasan
Ananth Balasubramanian
Sunlee Bang
M. Jonathan Barkley
Gilberto Barrón
David Bean
John Bell
Olivia Bellamou-Huet
Rudy Belliardi
Kathryn M. Bennett
Daniel Bernstein
George A. Bertos
Chris Biernacki
Ola Björnsne
Thomas Blackadar
Marc Blanchet
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
Pedro de-las-Heras-Quiros
Jim Dello Stritto
Kent Dicks
Hyoungdo Do
Jonathan Dougherty
Xiaolian Duan
Sourav Dutta
Jakob Ehrensvar
Fredrik Einberg
Javier Escayola Calvo
Mark Estes
Leonardo Estevez
Hailing Feng
Bosco T. Fernandes
Christoph Fischer
Morten Flintrup
Joseph W. Forler
Russell Foster
Eric Freudenthal
Matthias Frohner
Ken Fuchs
Jing Gao
Qi Gao
Marcus Garbe
John Garguilo
Rick Geimer
Igor Gejdos
Ferenc Gerbovics
Alan Godfrey
Nicolae Goga
Julian Goldman
Raul Gonzalez Gomez
Chris Gough
Channa Gowda
Charles M. Gropper

Amit Gupta
Jeff Guttmacher
Rasmus Haahr
Christian Habermann
Michael Hagerty
Jerry Hahn
Robert Hall
Shu Han
Nathaniel Hamming
Rickey L. Hampton
Sten Hanke
Aki Harma
Jordan Hartmann
Kai Hassing
Avi Hauser
Wolfgang Heck
Nathaniel Heintzman
Charles Henderson
Jun-Ho Her
Helen B. Hernandez
Timothy L. Hirou
Allen Hobbs
Alex Holland
Arto Holopainen
Kris Holtzclaw
Xinyi Hong
Robert Hoy
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
Tomio Kamioka
James J. Kang
Kei Kariya
Andy Kaschl
Junzo Kashiara
Colin Kennedy
Ralph Kent
Laurie M. Kermes
Ahmad Kheirandish
Junhyung Kim

This is a preview of "DS/ISO/IEEE 11073-10...". Click here to purchase the full version from the ANSI store.

Minho Kim	Yoshiteru Nozoe	Nicholas Steblay
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
Patty Krantz	Jong-Tae Park	Na Tang
Raymond Krasinski	Myungeun Park	Yi Tang
Alexander Kraus	Soojun Park	Haruyuyki Tatsumi
Ramesh Krishna	Phillip E. Pash	Isabel Tejero
Geoffrey Kruse	Tong Bi Pei	Tom Thompson
Falko Kuester	Soren Petersen	Jonas Tirén
Rafael Lajara	James Petisce	Janet Traub
Pierre Landau	Peter Piction	Gary Tschautscher
Jaechul Lee	Michael Pliskin	Masato Tsuchida
JongMuk Lee	Varshney Prabodh	Ken Tubman
Kyong Ho Lee	Jeff Price	Akib Uddin
Rami Lee	Harald Prinzhorn	Sunil Unadkat
Sungkee Lee	Harry Qiu	Fabio Urbani
Woojae Lee	Tanzilur Rahman	Philipp Urbauer
Qiong Li	Phillip Raymond	Laura Vanzago
Xiangchen Li	Terrie Reed	Alpo Värri
Yingsong Li	Barry Reinhold	Andrei Vasilateanu
Zhuofang Li	Brian Reinhold	Dalimar Velez
Patrick Lichter	Melvin I. Reynolds	Martha Velez
Lin Lin	John G. Rhoads	Rudi Voon
Jisoon Lim	Jeffrey S. Robbins	Barry Vornbrock
Joon-Ho Lim	Chris Roberts	Isobel Walker
Liang Liu	Moskowitz Robert	David Wang
Xiaoming Liu	Stefan Robert	Linling Wang
Wei-Jung Lo	Scott M. Robertson	Jerry P. Wang
Charles Lowe	Timothy Robertson	Yao Wang
Don Ludolph	Patricia Roder	Yi Wang
Christian Lusztick	David Rosales	Steve Warren
Bob MacWilliams	Bill Saltzstein	Fujio Watanabe
Srikkanth Madhurbootheswaran	Giovanna Sannino	Toru Watsuji
Miriam L. Makhoul	Jose A. Santos-Cadenas	David Weissman
Romain Marmot	Stefan Sauermann	Kathleen Wible
Sandra Martinez	John Sawyer	Paul Williamson
Miguel Martínez de	Alois Schloegl	Jan Wittenber
Espronceda Cámara	Paul S. Schluter	Jia-Rong Wu
Peter Mayhew	Mark G. Schnell	Will Wykeham
Jim McCain	Richard A. Schrenker	Ariton Xhafa
László Meleg	Antonio Scorpiniti	Ricky Yang
Alexander Mense	KwangSeok Seo	Shaoqin Ye
Behnaz Minaei	Riccardo Serafin	Melanie S. Yeung
Jinsei Miyazaki	Sid Shaw	Qiang Yin
Erik Moll	Frank Shen	Done-Sik Yoo
Darr Moore	Min Shih	Zhi Yu
Carsten Mueglitz	Mazen Shihabi	Jianchao Zeng
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

This is a preview of "DS/ISO/IEEE 11073-10...". Click here to purchase the full version from the ANSI store.

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

When the IEEE SA Standards Board approved this standard on 30 January 2020, it had the following membership:

Gary Hoffman, *Chair*
Vacant Position, *Vice Chair*
Jean-Philippe Faure, *Past Chair*
Konstantinos Karachalios, *Secretary*

Ted Burse
Doug Edwards
J. Travis Griffith
Grace Gu
Guido R. Hiertz
Joseph L. Koepfinger*
John D. Kulick

David J. Law
Howard Li
Dong Liu
Kevin Lu
Paul Nikolich
Damir Novosel
Jon Walter Rosdahl

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

*Member Emeritus

This is a preview of "DS/ISO/IEEE 11073-10...". [Click here to purchase the full version from the ANSI store.](#)

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

This is a preview of "DS/ISO/IEEE 11073-10...". Click here to purchase the full version from the ANSI store.

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 is a preview of "DS/ISO/IEEE 11073-10...". Click here to purchase the full version from the ANSI store.

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.