



## Health informatics—Personal health device communication

# Part 10404: Device specialization— Pulse oximeter

IEEE Engineering in Medicine and Biology Society

Developed by the IEEE 11073™ Standards Committee

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

**IEEE** 

STANDARDS

(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<sup>™</sup>, medical device communication, personal health devices, PHD, pulse oximeter

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.

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

### 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.

#### **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 <a href="https://standards.ieee.org/about/sasb/patcom/patents.html">https://standards.ieee.org/about/sasb/patcom/patents.html</a>. 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 Anindva 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 Björsne Thomas Blackadar Marc Blanchet Thomas Bluethner Douglas P. Bogia Xavier Boniface Shannon Boucousis Julius Broma Lyle G. Bullock, Jr. Bernard Burg Chris Burns

Craig Carlson Santiago Carot-Nemesio Randy W. Carroll Simon Carter Seungchul Chae Rahul Chauhan Peggy Chien David Chiu Jinyong Choi

Jeremy Byford-Rew

Satva Calloii

Xiaoving Cao

Carole C. Carey

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. Deka Ciro de la Vega

Pedro de-las-Heras-Ouiros Jim Dello Stritto Kent Dicks Hyoungho Do Jonathan Dougherty Xiaolian Duan Souray Dutta Jakob Ehrensvard 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 Oi 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 Akivoshi Kabe Steve Kahle Tomio Kamioka James J. Kang Kei Kariya Andy Kaschl Junzo Kashihara Colin Kennedy Ralph Kent Laurie M. Kermes Ahmad Kheirandish Junhyung Kim

Minho Kim Yoshiteru Nozoe Nicholas Steblay Min-Joon Kim Abraham Ofek Lars Steubesand Taekon Kim Brett Olive John (Ivo) Stivoric Tetsuya Kimura BegonyaOtal Raymond A. Strickland Michael J. Kirwan Marco Paleari ChandrasekaranSubramaniam Alfred Kloos Bud Panjwani Hermanni Suominen Carl Pantiskas Jeongmee Koh 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 Haruyuyki Tatsumi Alexander Kraus Soojun Park Phillip E. Pash Ramesh Krishna Geoffrey Kruse TongBi Pei Falko Kuester Soren Petersen

Isabel Tejero Tom Thompson Jonas Tirén Rafael Lajara James Petisce Janet Traub Pierre Landau Peter Piction Gary Tschautscher Jaechul Lee Michael Pliskin Masato Tsuchid Varshney Prabodh Ken Tubman JongMuk Lee Kyong Ho Lee Jeff Price Akib Uddin Rami Lee Harald Prinzhorn Sunil Unadkat Sungkee Lee Harry Qiu Fabio Urbani Tanzilur Rahman Philipp Urbauer Woojae Lee Qiong Li Phillip Raymond Laura Vanzago Terrie Reed Xiangchen Li Alpo Värri Barry Reinhold Andrei Vasilateanu Yingsong Li

Zhuofang Li Brian Reinhold Dalimar Velez Patrick Lichter Melvin I. Reynolds Martha Velezis Lin Lin John G. Rhoads Rudi Voon Jisoon Lim Jeffrey S. Robbins Barry Vornbrock Isobel Walker Joon-Ho Lim Chris Roberts Moskowitz Robert David Wang Liang Liu Xiaoming Liu Stefan Robert Linling Wang Wei-Jung Lo Jerry P. Wang Scott M. Robertson Charles Lowe Timothy Robertson Yao Wang

Don Ludolph Patricia Roder Yi Wang Christian Luszick David Rosales Steve Warren Bob MacWilliams Bill Saltzstein Fujio Watanabe Srikkanth Madhurbootheswaran Giovanna Sannino Toru Watsuii Miriam L. Makhlouf Jose A. Santos-Cadenas David Weissman Romain Marmot Stefan Sauermann Kathleen Wible Paul Williamson Sandra Martinez John Sawyer AloisSchloegl Jan Wittenber

Miguel Martínez de Paul S. Schluter EsproncedaCámara Jia-Rong Wu Peter Mayhew Mark G. Schnell Will Wykeham Ariton Xhafa Jim McCain Richard A. Schrenker LászlóMeleg Antonio Scorpiniti Ricky Yang Alexander Mense KwangSeok Seo Shaoqin Ye Behnaz Minaei Riccardo Serafin Melanie S. Yeung Sid Shaw Jinsei Miyazaki Qiang Yin Erik Moll Frank Shen Done-Sik Yoo Darr Moore Min Shih Zhi Yu

Carsten MueglitzMazen ShihabiJianchao ZengSoundharya NagasubramanianRedmond ShouldiceJason ZhangAlex NeefusSternly K. SimonJie ZhaoTrong-Nghia Nguyen-DobinskyMarjorie SkubicThomas Zhao

Michael E. NiddRobert SmithDaidi ZhongJim NiswanderIvan SohHongyuan ZhongHongliang NiuMotoki SoneYuanhong ZhongHiroaki NiwamotoEmily SopenskyMiha ZoubekThomas NorgallRajagopalan SrinivasanSzymon Zyskoter

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

Bjoern Andersen Iulian Profir Werner Hoelzl Lyle Bullock Noriyuki Ikeuchi Beth Pumo Keith Chow Atsushi Ito Stefan Schlichting Malcolm Clarke Raj Jain Janek Schumann Kenneth Fuchs Piotr Karocki Walter Struppler David Fuschi Martin Kasparick Oren Yuen Randall Groves Raymond Krasinski Janusz Zalewski H. Moll Daidi Zhong Robert Heile

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

Jingyi Zhou

David J. Law Dorothy Stanley Ted Burse Mehmet Ulema Doug Edwards Howard Li J. Travis Griffith Dong Liu Lei Wang Kevin Lu Sha Wei Grace Gu Guido R. Hiertz Paul Nikolich Philip B. Winston Joseph L. Koepfinger\* Damir Novosel Daidi Zhong

Jon Walter Rosdahl

\*Member Emeritus

John D. Kulick

### 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.

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

-

## Contents

1. Overview	
1.1 Scope	12
1.2 Purpose	12
1.3 Context	
2. Normative references	13
3. Definitions, acronyms, and abbreviations	
3.1 Definitions	
3.2 Acronyms and abbreviations	14
4. Introduction to ISO/IEEE 11073 personal health devices	
4.1 General	
4.2 Introduction to IEEE 11073-20601 modeling constructs	
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	
5.5 Derived data	
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	
6.9 PM-store objects	41
6.10 Scanner objects	45
6.11 Class extension objects	
6.12 Pulse oximeter information model extensibility rules	
7. Pulse oximeter service model	48
7.1 General	
7.2 Object access services	
7.3 Object access EVENT REPORT services	
8. Pulse oximeter communication model	57
8.1 Overview	
8.2 Communications characteristics	
8.3 Association procedure	
8.4 Configuring procedure	
8.5 Operating procedure	
8.6 Time synchronization	
U.U 11111 DYINUH UHLAHUH	۱ را د ا

9. Test associations	57
9.1 Behavior with standard configuration	57
9.2 Behavior with extended configurations	
10. Conformance	58
10.1 Applicability	58
10.2 Conformance specification	58
10.3 Levels of conformance	
10.4 Implementation conformance statements (ICSs)	
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<sup>TM2</sup> 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]<sup>3</sup> 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.

<sup>&</sup>lt;sup>2</sup> Information on references can be found in Clause 2.

<sup>&</sup>lt;sup>3</sup> The numbers in brackets correspond to the numbers in the bibliography in Annex A.