BSI Standards Publication

Health informatics — Device interoperability

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

bsi.

Documents
Document Sharing Hub

Full document details: BS EN ISO/IEEE 11073-10404:2022

National foreword

This British Standard is the UK implementation of EN ISO/IEEE 11073-10404:2022. It is identical to ISO/IEEE 11073-10404:2022. It supersedes BS EN ISO 11073-10404:2011, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its committee manager.

Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.

This publication is provided as is, and is to be used at the recipient's own risk.

The recipient is advised to consider seeking professional guidance with respect to its use of this publication.

This publication is not intended to constitute a contract. Users are responsible for its correct application.

© The British Standards Institution 2023
Published by BSI Standards Limited 2023

ISBN 978 0 539 22274 6

ICS 35.240.80

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 January 2023.

Amendments/corrigenda issued since publication

Date	Text affected

Documents
Document Sharing Hub

Full document details: BS EN ISO/IEEE 11073-10404:2022

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO/IEEE 11073-10404

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 santé personnels - Spécialisation des dispositifs - Oxymètre de pouls (ISO/IEEE 11073-10404:2022)

Medizinische Informatik - Kommunikation von Geräten für die persönliche Gesundheit - Teil 10404: Gerätespezifikation - Pulsoximeter (ISO/IEEE 11073-10404:2022)

This European Standard was approved by CEN on 4 December 2022.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

© 2022 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members.

Ref. No. EN ISO/IEEE 11073-10404:2022 E

Documents
Document Sharing Hub

Full document details: BS EN ISO/IEEE 11073-10404:2022

European foreword

This document (EN ISO/IEEE 11073-10404:2022) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2023, and conflicting national standards shall be withdrawn at the latest by June 2023.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 11073-10404:2011.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO/IEEE 11073-10404:2022 has been approved by CEN as EN ISO/IEEE 11073-10404:2022 without any modification.

AVA Documents
Document Sharing Hub

Full document details: BS EN ISO/IEEE 11073-10404:2022

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.

Documents
Document Sharing Hub

© IEEE 2021 – All rights reserved

Full document details: BS EN ISO/IEEE 11073-10404:2022

Documents
Document Sharing Hub

Full document details: BS EN ISO/IEEE 11073-10404:2022

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

Documents
Document Sharing Hub

Full document details: BS EN ISO/IEEE 11073-10404:2022

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.

Copyright © 2021 IEEE. All rights reserved.

Documents
Document Sharing Hub

Full document details: BS EN ISO/IEEE 11073-10404:2022

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.

Copyright © 2021 IEEE. All rights reserved.

AVA Documents
Document Sharing Hub

Full document details: BS EN ISO/IEEE 11073-10404:2022

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.

Copyright © 2021 IEEE. All rights reserved.

Documents
Document Sharing Hub

Full document details: BS EN ISO/IEEE 11073-10404:2022

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.

Copyright © 2021 IEEE. All rights reserved.

Documents
Document Sharing Hub

Full document details: BS EN ISO/IEEE 11073-10404:2022

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 Björsne
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. Deka
Ciro de la Vega
Pedro de-las-Heras-Quiros
Jim Dello Stritto
Kent Dicks
Hyoungho Do
Jonathan Dougherty
Xiaolian Duan
Sourav 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
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 Kashihara
Colin Kennedy
Ralph Kent
Laurie M. Kermes
Ahmad Kheirandish
Junhyung Kim

Copyright © 2021 IEEE. All rights reserved.

Documents
Document Sharing Hub

Full document details: BS EN ISO/IEEE 11073-10404:2022

Minho Kim
Min-Joon Kim
Taekon Kim
Tetsuya Kimura
Michael J. Kirwan
Alfred Kloos
Jeongmee Koh
Jean-Marc Koller
John Koon
Patty Krantz
Raymond Krasinski
Alexander Kraus
Ramesh Krishna
Geoffrey Kruse
Falko Kuester
Rafael Lajara
Pierre Landau
Jaechul Lee
JongMuk Lee
Kyong Ho Lee
Rami Lee
Sungkee Lee
Woojae Lee
Qiong Li
Xiangchen Li
Yingsong Li
Zhuofang Li
Patrick Lichter
Lin Lin
Jisoon Lim
Joon-Ho Lim
Liang Liu
Xiaoming Liu
Wei-Jung Lo
Charles Lowe
Don Ludolph
Christian Luszick
Bob MacWilliams
Srikkanth Madhurbootheswaran
Miriam L. Makhlouf
Romain Marmot
Sandra Martinez
Miguel Martínez de EsproncedaCámara
Peter Mayhew
Jim McCain
LászlóMeleg
Alexander Mense
Behnaz Minaei
Jinsei Miyazaki
Erik Moll
Darr Moore
Carsten Mueglitz
Soundharya Nagasubramanian
Alex Neefus
Trong-Nghia Nguyen-Dobinsky
Michael E. Nidd
Jim Niswander
Hongliang Niu
Hiroaki Niwamoto
Thomas Norgall
Yoshiteru Nozoe
Abraham Ofek
Brett Olive
BegonyaOtal
Marco Paleari
Bud Panjwani
Carl Pantiskas
Harry P. Pappas
Hanna Park
Jong-Tae Park
Myungeun Park
Soojun Park
Phillip E. Pash
TongBi Pei
Soren Petersen
James Petisce
Peter Piction
Michael Pliskin
Varshney Prabodh
Jeff Price
Harald Prinzhorn
Harry Qiu
Tanzilur Rahman
Phillip Raymond
Terrie Reed
Barry Reinhold
Brian Reinhold
Melvin I. Reynolds
John G. Rhoads
Jeffrey S. Robbins
Chris Roberts
Moskowitz Robert
Stefan Robert
Scott M. Robertson
Timothy Robertson
Patricia Roder
David Rosales
Bill Saltzstein
Giovanna Sannino
Jose A. Santos-Cadenas
Stefan Sauermann
John Sawyer
AloisSchloegl
Paul S. Schluter
Mark G. Schnell
Richard A. Schrenker
Antonio Scorpiniti
KwangSeok Seo
Riccardo Serafin
Sid Shaw
Frank Shen
Min Shih
Mazen Shihabi
Redmond Shouldice
Sternly K. Simon
Marjorie Skubic
Robert Smith
Ivan Soh
Motoki Sone
Emily Sopensky
Rajagopalan Srinivasan
Nicholas Steblay
Lars Steubesand
John (Ivo) Stivoric
Raymond A. Strickland
ChandrasekaranSubramaniam
Hermanni Suominen
Lee Surprenant
Ravi Swami
Ray Sweidan
Na Tang
Yi Tang
Haruyuyki Tatsumi
Isabel Tejero
Tom Thompson
Jonas Tirén
Janet Traub
Gary Tschautscher
Masato Tsuchid
Ken Tubman
Akib Uddin
Sunil Unadkat
Fabio Urbani
Philipp Urbauer
Laura Vanzago
Alpo Värri
Andrei Vasilateanu
Dalimar Velez
Martha Velezis
Rudi Voon
Barry Vornbrock
Isobel Walker
David Wang
Linling Wang
Jerry P. Wang
Yao Wang
Yi Wang
Steve Warren
Fujio Watanabe
Toru Watsuji
David Weissman
Kathleen Wible
Paul Williamson
Jan Wittenber
Jia-Rong Wu
Will Wykeham
Ariton Xhafa
Ricky Yang
Shaoqin Ye
Melanie S. Yeung
Qiang Yin
Done-Sik Yoo
Zhi Yu
Jianchao Zeng
Jason Zhang
Jie Zhao
Thomas Zhao
Daidi Zhong
Hongyuan Zhong
Yuanhong Zhong
Miha Zoubek
Szymon Zyskoter

Copyright © 2021 IEEE. All rights reserved.

Documents
Document Sharing Hub

Full document details: BS EN ISO/IEEE 11073-10404:2022

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

Copyright © 2021 IEEE. All rights reserved.

Documents
Document Sharing Hub

Full document details: BS EN ISO/IEEE 11073-10404:2022

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.

Copyright © 2021 IEEE. All rights reserved.

Documents
Document Sharing Hub

Full document details: BS EN ISO/IEEE 11073-10404:2022

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

Copyright © 2021 IEEE. All rights reserved.

Documents
Document Sharing Hub

Full document details: BS EN ISO/IEEE 11073-10404:2022

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

Copyright © 2021 IEEE. All rights reserved.

Documents
Document Sharing Hub

Full document details: BS EN ISO/IEEE 11073-10404:2022

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.

Copyright © 2021 IEEE. All rights reserved.

Documents
Document Sharing Hub

Full document details: BS EN ISO/IEEE 11073-10404:2022

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.

Copyright © 2021 IEEE. All rights reserved.

Documents
Document Sharing Hub

Full document details: BS EN ISO/IEEE 11073-10404:2022

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.

Copyright © 2021 IEEE. All rights reserved.

Documents
Document Sharing Hub

Full document details: BS EN ISO/IEEE 11073-10404:2022

IEEE Std 11073-20601-2019 supports the modeling and implementation of an extensive set of personal health devices. This standard defines aspects of the pulse oximeter device. It describes all aspects necessary to implement the application layer services and data exchange protocol between an ISO/IEEE 11073 PHD pulse oximetry agent and a manager. This standard defines a subset of the objects and functionality contained in IEEE Std 11073-20601-2019, extending and adding definitions where appropriate.

All nomenclature codes referenced in this standard are collected in Annex C. Annex C may contain definitions of codes that are used by this standard and that are not yet present in the referenced versions of IEEE Std 11073-10101-2019 and IEEE Std 11073-20601-2019.

4.2 Introduction to IEEE 11073-20601 modeling constructs

4.2.1 General

The ISO/IEEE 11073 series of standards, and in particular IEEE Std 11073-20601-2019, is based on an object-oriented systems management paradigm. The overall system model is divided into three principal components: the domain information model (DIM), the service model, and the communication model. See IEEE Std 11073-20601-2019 for a detailed description of the modeling constructs.

4.2.2 Domain information model (DIM)

The DIM is a hierarchical model that describes an agent as a set of objects. These objects and their attributes represent the elements that control behavior and report on the status of the agent and data that an agent can communicate to a manager. Communication between the agent and manager is defined by the application protocol in IEEE Std 11073-20601-2019.

4.2.3 Service model

The service model defines the conceptual mechanisms for the data exchange services. Such services are mapped to messages that are exchanged between the agent and manager. Protocol messages within the ISO/IEEE 11073 series of standards are defined in ASN.1. The messages defined in IEEE Std 11073-20601-2019 can coexist with messages defined in other standard application profiles defined in the ISO/IEEE 11073 series of standards.

4.2.4 Communication model

In general, the communication model supports the topology of one or more agents communicating over logical point-to-point connections to a single manager. For each logical point-to-point connection, the dynamic system behavior is defined by a connection state machine as specified in IEEE Std 11073-20601-2019.

4.2.5 Implementing the models

An agent implementing this standard shall implement all mandatory elements of the information, service, and communication models as well as all conditional elements where the condition is met. The agent should implement the recommended elements, and it may implement any combination of the optional elements. A manager implementing this standard shall utilize at least one of the mandatory, conditional, recommended, or optional elements. In this context, “utilize” means to use the element as part of the primary function of the manager device. For example, a manager whose primary function is to display data would need to display a piece of data in the element in order to utilize it.

4.3 Compliance with other standards

Devices that comply with this standard may also be required to comply with other domain- and device-specific standards that supersede the requirements of this standard with respect to issues including safety,

Copyright © 2021 IEEE. All rights reserved.

Documents
Document Sharing Hub

Full document details: BS EN ISO/IEEE 11073-10404:2022

reliability, and risk management. A user of this standard is expected to be familiar with all other such standards that apply and to comply with any higher specifications thus imposed.

Typically, medical devices should comply with the IEC 60601-1 [B2] base standards with respect to electrical and mechanical safety and any device-specific standard as might be defined in the IEC 60601-2 [B3] series of standards. Software aspects may apply through standards such as IEC 62304/EN 62304 [B4]. Devices that comply with this standard implement higher layers of network software and utilize lower layers as appropriate to the application. The requirements on performance of such applications and conformance are defined elsewhere and are outside the scope of this standard. Moreover, the use of any medical equipment is subject to risk assessment and risk management appropriate to the application. Some relevant examples are ISO 14971:2007 [B8] and IEC 80001-1 [B5]. The requirements of such risk assessment, risk management, and conformance are outside the scope of this standard. The applicable versions of the referenced safety related standards may differ per country.

5. Pulse oximeter device concepts and modalities

5.1 General

This clause presents the general concepts of pulse oximeter equipment. In the context of PHDs in the ISO/IEEE 11073 family of standards, a pulse oximeter, also called an oximeter, provides a noninvasive estimate of functional oxygen of arterial haemoglobin (SpO_2) from a light signal interacting with tissue, by using the time-dependent changes in tissue optical properties that occur with pulsatile blood flow (see Draft Guidance for Industry and FDA Staff **Error! Reference source not found.**). Applying the Beer-Lambert law of light absorption through such an arterial network, the fraction of oxygenation of arterial haemoglobin can be estimated. This estimate, normally expressed as a percentage by multiplying that fraction by 100, is known as SpO_2. Occasionally, this estimate may be referenced as $\%SpO_2$. ISO 80601-2-61:2017 [B9] contains additional information applicable to pulse oximetry.

5.2 Device types

Pulse oximeter systems with applicability in the personal health space may take on a variety of configurations and sensor compositions, and their configurations have suitability in different personal health application spaces. Pulse oximeter equipment comprises a pulse oximeter monitor, a pulse oximeter probe, and a probe cable extender, if provided. Some oximeters are all-in-one assemblies, where the optical probe, processing, and display components are in a single package. Other oximeters may consist of separate sensor and processing/display components. Still others may place the sensor and signal processing in one component, and send that information into an external component for display and storage. Pulse oximeters may place sensors in numerous locations on the body and use transconductance and reflectance of the light path. This standard assumes all measurements are equal and provides a single measure with no differentiation of location. In addition, other configurations may add storage capability into the system. This implies that different information models may be best suited for each particular device configuration.

5.3 General concepts

5.3.1 Noninvasive measurement

The scope of this specialization covers the intended use of pulse oximeter equipment, which includes, but is not limited to, the estimation of arterial oxygen haemoglobin saturation and pulse rate. This standard is not applicable to pulse oximeter equipment intended for use in laboratory research applications or to oximeters that require a blood sample (see ISO 80601-2-61:2017 [B9]). This standard does not cover measurement of oxygenation via blood extraction. This standard is not applicable to pulse oximeter equipment solely intended for foetal use.

The sensing mechanism may use either transmissive or reflective methods to measure blood oxygenation.

Copyright © 2021 IEEE. All rights reserved.

Documents
Document Sharing Hub

Full document details: BS EN ISO/IEEE 11073-10404:2022

In addition, blood oxygenation is usually determined as a ratio of the absorbance of two different wavelengths of light, although more wavelengths may be used.

5.3.2 Acquisition modes

5.3.2.1 General

Pulse oximeters are used to measure SpO_2 within a variety of use scenarios.

5.3.2.2 Spot-check

In a spot-check scenario, a user may simply want to take a single, fully processed reading for transmission to a manager. For example, the user would attach the oximeter, whereupon the agent would take an oximetry and pulse rate reading. The agent would then begin communication with a manager and send that single reading. The manager may acknowledge the transmission so the agent can subsequently disassociate and return to its prior state.

5.3.2.3 Continuous monitoring

A continuous monitoring situation involves the pulse oximeter device measuring the user's oxygenation for some period of time greater than that needed to acquire a single measurement. Multiple measurements may be taken to acquire trending information.

5.3.2.4 Stored-and-forwarded measurements

Stored-and-forwarded measurements could be considered as a specialized, continuous monitoring application where the pulse oximetry device is not always in communication with a manager, and the oximeter records data over several minutes or hours. In this case, oximetry data are stored in the device for the duration of the study session and subsequently transferred to the manager at an appropriate time. This measurement communication style is distinct from the situation where temporarily stored measurements are transferred when the communication link is restored.

5.4 Collected data

5.4.1 General

This subclause describes the nature of the data that have been collected based on the acquisition modes described in 5.3.2.

5.4.2 Percentage of arterial haemoglobin oxygen saturation

5.4.2.1 SpO_2

Every oximeter sends at least one expression of SpO_2. This is the primary measurement of a pulse oximeter. It is important to note that this measurement is determined through various signal processing techniques and can be expressed in different ways. Each method and expression has its applicability in particular application spaces (e.g., vital signs monitoring and diagnostic sleep studies). Often the reported SpO_2 has been processed with a variety of techniques in order to present the data for use in a number of ways.

In response to the various physiological phenomena and situations, SpO_2 measurements may be expressed in a variety of ways. Additional modalities for expressing SpO_2 are often used that are better suited to expose or suppress various physiological or environmental phenomena, as seen in 5.4.2.2. The following subclause outlines three expressions of SpO_2 that may be used by a device manufacturer to convey blood oxygenation level.

Copyright © 2021 IEEE. All rights reserved.

Documents
Document Sharing Hub

Full document details: BS EN ISO/IEEE 11073-10404:2022

It is also conceivable that pulse oximeter equipment may deliver a single SpO_2 that is determined by one of these modalities. Furthermore, several of these distinct expressions may be transmitted concurrently during a measurement session. The manager, upon receiving this collection of information, may choose to display another subset of these expressions. It is required for a pulse oximeter agent to support at least one instance of this measurement.

5.4.2.2 Alternative expressions of SpO_2

One case of SpO_2 measurement involves a user wearing a sensor during unintentional or moderate activity. The result of this activity may be intermittent loss of signal acquisition. The most common expression of SpO_2 may be too sensitive to these effects and could result in a fluctuating (and, therefore, misleading) reading. An SpO_2 measurement modality known as "slow-response" modality has a characteristic that "smooths out" a series of measurements in some fashion, perhaps by changing an averaging parameter or by employing a different algorithm. This modality is defined in this standard.

During a sleep study, an apnea event results in a rapid desaturation of blood oxygenation. This SpO_2 measurement can be expressed by a "fast-response" modality that uses a technique that more effectively captures such events. The technique may vary among device manufacturers, but a distinct expression able to capture these rapid changes is defined in this standard.

The terms *slow-response* and *fast-response* are relative to a particular implementation and are not intended to show a comparison across devices or vendors. Note that these are descriptive terms intentionally left unspecific to allow more flexible interpretations within a particular implementation.

A pulse oximeter will often send SpO_2 measurements periodically; e.g., once every second. In addition, pulse oximeters may begin outputting measurements as soon as it has a reasonable estimate of functional haemoglobin oxygenation. Subsequent measurements may, in some fashion, converge on the oximeter's best estimate. An additional modality, the "spot-check" modality, fulfills the desire to be able to perform and display a single SpO_2 measurement that is also its best estimate of functional haemoglobin oxygenation. In other words, a spot-check is not simply the first measurement, but the first *best* measurement. The specific manner in which this measurement is produced is specific to the pulse oximeter implementation. Once that measurement is transmitted, the measurement session is complete.

5.4.3 Pulse rate

The heart rate measured by a pulse oximeter is produced by a heartbeat, but also requires ejection of blood by the heart and generation of an arterial and tissue pressure wave that is detectable by photoplethysmographic means. Therefore, the pulse rate may be a less reliable measure of heart rate than that of directly measuring by electrocardiograph (ECG). As described in 5.4.2.1 and 5.4.2.2, the reported value or values may be determined in a variety of ways, and corresponding modalities of "slow-response," "fast-response," and "spot-check" are defined for pulse rate measurements. It is required for a pulse oximeter agent to support at least one instance of this feature.

5.4.4 Pulsatile occurrence

If a precisely timestamped occurrence of a pulse is transmitted to a manager, that information can be used in conjunction with other reported physiological events to derive another physiological measurement. Other application spaces may wish to indicate pulsatile occurrence with less precision for purposes of displaying, for instance, a flashing heart icon. It is not required for a pulse oximeter agent to support this feature.

5.4.5 Plethysmogram

There are applications where it is desired to visualize the sequence of samples related to the time-varying light absorption due to the effects of pulsatile blood flow. Often these samples are taken from a single wavelength light source, usually the wavelength less affected by changes in oxygen saturation. It is not required for a pulse oximeter agent to support this feature.

Copyright © 2021 IEEE. All rights reserved.

Documents
Document Sharing Hub

Full document details: BS EN ISO/IEEE 11073-10404:2022

5.4.6 Pulsatile quality and signal characterization

Pulse oximeter manufacturers have many ways to characterize the quality of the pulsatile wave. Unfortunately, no industry-wide standard currently exists to quantify the characteristics of the signal. However, signal amplitude metrics among the different vendors provide quantities that can be found to have a linear relationship. One notable characteristic is the amplitude of the signal modulation. Other methods to characterize the quality of the pulsatile wave may be employed. It is not required for a pulse oximeter to support this feature.

5.5 Derived data

5.5.1 Limit indications

Pulse oximeters may implement indicators based on monitoring physiological values as falling outside predefined limits. The commonly implemented indicators include reaching the thresholds of a high or low SpO_2, or reaching the thresholds of a high or low pulse rate.

5.5.2 Pulsatile status

Pulse oximeters may provide status indications of certain characteristics of a pulsatile wave or irregularities in the waveform.

5.5.3 Device and sensor status

Pulse oximeters may provide status indications pertaining to sensor malfunction or dislodgement as well as various signal anomalies.

5.6 Stored data

As stated in 5.3.2.4, a pulse oximeter may be used over one or more sessions of several hours without being in contact with a manager to send its data. After the session or sessions are completed, the pulse oximeter agent connects to a manager. The manager is able to select which of the agent's stored sessions to retrieve. The agent then transmits the manager's selection in one or several blocks of messages for processing by a manager or other processing apparatus. The manager is also able to choose a set of sessions for deletion.

5.7 Device configurations

Although agents typically have a static configuration, it is permissible and desirable for an agent to support multiple configurations, one of which would be active at any given time. Pulse oximeters may have a rich set of features that can be combined into a collection of different configurations, one of which can be selected by the manager during configuration.

Two general categories of configurations exist. The first category is known as the set of standard configurations. These are intended to describe a relatively limited feature set of a single device specialization, which have predefined configuration identity (ID) codes. Managers may be pre-loaded with these configurations, in which case the configuration process is eliminated and immediate operation is allowed. The second category involves the set of extended configurations. These configurations are more flexible in that they may include concepts particular to one or more device specializations or include other features as defined in this standard.

Copyright © 2021 IEEE. All rights reserved.

Documents
Document Sharing Hub

Full document details: BS EN ISO/IEEE 11073-10404:2022

6. Pulse oximeter DIM

6.1 Overview

This clause describes the DIM of the pulse oximeter.

6.2 Class extensions

In this standard, no class extensions are defined with respect to IEEE Std 11073-20601-2019.

6.3 Object instance diagram

The object instance diagram of the pulse oximeter DIM's numeric objects, defined for the purposes of this standard, is shown in Figure 1.

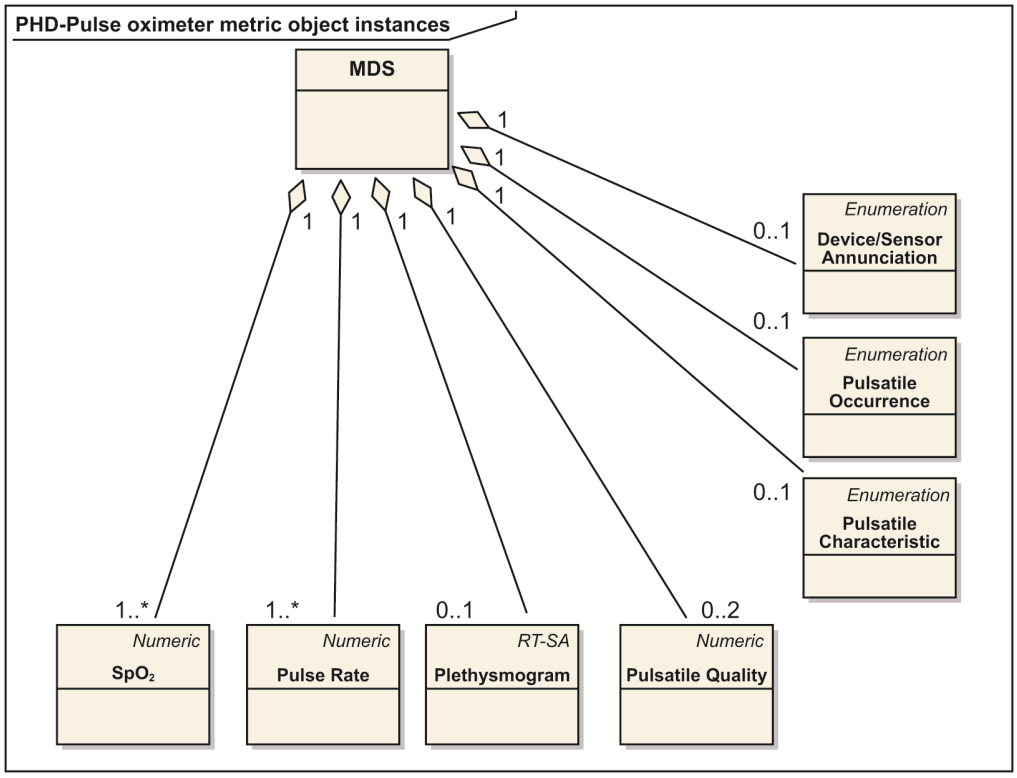

Figure 1—Pulse oximeter DIM for metric objects

The objects of the DIM, as shown in Figure 1, are described in the following subclauses: medical device system (MDS) object (see 6.5), the numeric objects (see 6.6), the real-time sample array (RT-SA) objects (see 6.7), and the enumeration objects (see 6.8). Figure 2 illustrates the PM-store objects (see 6.9), and the scanner objects (see 6.10) are shown in Figure 4. See 6.11 for rules for extending the pulse oximeter information model beyond elements as described in this standard. Each subclause that describes an object of the pulse oximeter contains the following information:

— The nomenclature code used to identify the class of the object. One example where this code is used is the configuration event, where the object class is reported for each object. This allows the manager to determine whether the class of the object being specified is a numeric, RT-SA, enumeration, scanner, or PM-store class.

Copyright © 2021 IEEE. All rights reserved.

Documents
Document Sharing Hub

Full document details: BS EN ISO/IEEE 11073-10404:2022

— The attributes of the object. Each object has attributes that represent and convey information on the physical device and its data sources. Each object has a Handle attribute that identifies the object instance within an agent. Attribute values are accessed and modified using methods such as GET and SET. Attribute types are defined using ASN.1. The ASN.1 definitions for new attribute types specific to this standard are in Annex B, and the ASN.1 definitions for existing attribute types referenced in this standard are in IEEE Std 11073-20601-2019.

— The methods available on the object.

— The potential events generated by the object. Data are sent to the manager using events.

— The available services such as getting or setting attributes.

The attributes for each class are defined in tables that specify the name of the attribute, its value, and its qualifier. The qualifiers are as follows:

— M – Attribute is Mandatory, C – Attribute is Conditional and depends on the condition stated in the Remark or Value column (if IEEE Std 11073-20601-2019 is referenced, then it contains the conditions), R – Attribute is Recommended, O – Attribute is Optional, NR – Attribute is Not Recommended and NA — Attribute is Not Allowed. Mandatory attributes shall be implemented by an agent. Conditional attributes shall be implemented if the condition applies and may be implemented otherwise. Recommended attributes should be implemented by the agent. Optional attributes may be implemented on an agent. Not recommended attributes should not be implemented by the agent. If any attribute defined in the DIM of IEEE Std 11073-20601-2019 is not included in the definition of that object in this standard, it shall not be included in that object by an implementation. Vendor-specific attributes are allowed as described in 6.12.

An attribute is further qualified as static, dynamic, or observational. Static attributes shall not change value during the life of an association. Dynamic attributes have a value that may change during the life of an association. The dynamic attribute value should be sent at configuration time and shall be sent at or before the time when the value would be needed for interpreting a reported observation. Observational attributes have a value that may change during the life of an association. When a set of observational attribute values are received, these values are combined with the available context information (i.e., all related dynamic and static attribute values) to represent the observation at the observation time.

6.4 Types of configuration

6.4.1 General

As specified in IEEE Std 11073-20601-2019, two styles of configuration are available. The following subclauses briefly introduce standard and extended configurations.

6.4.2 Standard configuration

Standard configurations are defined in the ISO/IEEE 11073-104zz specializations (such as this standard) and are assigned a well-known identifier (Dev-Configuration-Id). The usage of a standard configuration is negotiated at configuration time between the agent and manager. If the manager acknowledges that it recognizes and wants to operate using the configuration, then the agent can begin sending measurements immediately. If the manager does not understand the configuration, the agent provides the configuration prior to transmitting measurement information.

6.4.3 Extended configuration

In extended configurations, the agent's configuration is not predefined in a standard. The agent determines which objects, attributes, and values that it wants to use in a configuration and assigns a configuration identifier. When the agent associates with a manager, it negotiates an acceptable configuration. Typically,

Copyright © 2021 IEEE. All rights reserved.

Documents
Document Sharing Hub

Full document details: BS EN ISO/IEEE 11073-10404:2022