

International Standard

ISO/IEEE 11073-10472

Health informatics — Device interoperability —

Second edition 2024-09

Part 10472: Personal health device Teh Standards communication — Device specialization — Medication monitor

Informatique de santé — Interopérabilité des dispositifs —

Partie 10472: Communication entre dispositifs de santé personnels — Spécialisation des dispositifs — Moniteur de surveillance de médication

iTeh Standards (https://standards.iteh.ai) Document Preview

ISO/IEEE 11073-10472:2024

https://standards.iteh.ai/catalog/standards/iso/5dce412f-417e-46ef-ae91-c4bad7053808/iso-ieee-11073-10472-2024



COPYRIGHT PROTECTED DOCUMENT

© IEEE 2024

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: <u>www.ieee.org</u> Published in Switzerland

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 document 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.

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at <u>www.iso.org/patents</u>. ISO shall not be held responsible for identifying any or all such patent rights.

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 11073-10472 was prepared by the IEEE 11073 Standards Committee of the IEEE Engineering in Medicine and Biology Society (as IEEE Std 11073-10472) 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 11073-10472:2012), which has been technically revised.

The main changes are as follows:

- added support for Base-Offset-Time;
- defined new standard configurations based on BaseOffsetTime;
- updated Clause 2 to include ISO/IEEE 11073-20601 and IEEE Std 11073-10101;
- updated version of this device specialization;
- updated the association details based on new version;
- updated the wording in 6.3 regarding the Observational;

— updated the examples in 8.4.2 and Annex E, to indicate the support of BaseOffsetTime;

— updated the qualifier in MDS and other objects to recommend BaseOffsetTime; also updated the description of the qualifiers in 6.5;

- added some text to 6.12 to further elaborate the DIM extensibility rule;
- corrected the use condition of GET MDS at E.4.1;

— updated the text in 8.5.2 regarding attribute-id-list, in order to be compliant with ISO/IEC 11073-20601;

- added subclause 3.4—Compliance with other standards;
- removed the year in bibliography to represent the latest version;
 - extended Table 1 to specify qualifier details for all possible configurations;
- updated the wording at 1.3 and 4.1 regarding the precedence of nomenclature between
- 11073-10101, 11073-20601, 11073-104xx and this standard;
 - updated the usage of nomenclature-version. Tied it with the corresponding protocol-version.

A list of all parts in the ISO 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 <u>www.iso.org/members.html</u>.

iTeh Standards (https://standards.iteh.ai) Document Preview

ISO/IEEE 11073-10472:2024

https://standards.iteh.ai/catalog/standards/iso/5dce412f-417e-46ef-ae91-c4bad7053808/iso-ieee-11073-10472-2024

Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, a normative definition of communication between personal telehealth medication monitor devices and compute engines (e.g., cell phones, personal computers, personal health appliances, set top boxes) is established by this standard in a manner that enables plug-and-play interoperability. Appropriate portions of existing standards including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards are leveraged. The use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability are specified. A common core of communication functionality for personal telehealth medication monitor devices is defined in this standard.

Keywords: device communication, IEEE 11073-10472[™], medication monitor, personal health devices

iTeh Standards (https://standards.iteh.ai) Document Preview

ISO/IEEE 11073-10472:2024

1ttps://standards.iteh.ai/catalog/standards/iso/5dce412f-417e-46ef-ae91-c4bad7053808/iso-ieee-11073-10472-2024

The Institute of Electrical and Electronics Engineers, Inc.

3 Park Avenue, New York, NY 10016-5997, USA

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

PDF: ISBN 978-1-5044-9754-1 STD26191 Print: ISBN 978-1-5044-9755-8 STDPD26191

IEEE prohibits discrimination, harassment, and bullying.

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

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.

© IEEE 2024 – All rights reserved

Copyright © 2023 by The Institute of Electrical and Electronics Engineers, Inc. All rights reserved. Published 11 July 2023. Printed in the United States of America.

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 (<u>https://standards.ieee.org/ipr/disclaimers.html</u>), 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 IEEE Societies and subcommittees of IEEE Standards Association (IEEE SA) Board of Governors. 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 IEEE Standards documents do not guarantee safety, security, health, or environmental protection, or guarantee against interference with or from other devices or networks. 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 their 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 balloting 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. Statements made by volunteers may not represent the formal position of their employer(s) or affiliation(s).

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 subcommittees of the IEEE SA Board of Governors 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.¹ An IEEE Account is needed to access the application.

Comments on standards should be submitted using the Contact Us form.²

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

ISO/IEEE 11073-10472:2024

IEEE draft and approved standards are copyrighted by IEEE under U.S. 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, neither IEEE nor its licensors 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.

¹ Available at: <u>https://development.standards.ieee.org/myproject-web/public/view.html#landing</u>.

 $^{^2 \} Available \ at: \ \underline{https://standards.ieee.org/content/ieee-standards/en/about/contact/index.html}.$

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 <u>IEEE Xplore</u> or <u>contact IEEE</u>.³ 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 <u>IEEE SA Website</u>.⁴ 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 <u>IEEE Xplore</u>. Users are encouraged to periodically check for errata.

Patents

IEEE standards are developed in compliance with the IEEE SA Patent Policy.5

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.

ttps://standards.iteh.ai/catalog/standards/iso/5dce412f-417e-46ef-ae91-c4bad7053808/iso-ieee-11073-10472-2024 IMPORTANT NOTICE

Technologies, application of technologies, and recommended procedures in various industries evolve over time. The IEEE standards development process allows participants to review developments in industries, technologies, and practices, and to determine what, if any, updates should be made to the IEEE standard. During this evolution, the technologies and recommendations in IEEE standards may be implemented in ways not foreseen during the standard's development. 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.

³ Available at: <u>https://ieeexplore.ieee.org/browse/standards/collection/ieee</u>.

⁴ Available at: <u>https://standards.ieee.org/standard/index.html</u>.

⁵ Available at: <u>https://standards.ieee.org/about/sasb/patcom/materials.html</u>.

Participants

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

Nigel Cox

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 Ananth Balasubramanian Sunlee Bang M. Jonathan Barkley Gilberto Barrón David Bean John Bell Olivia Bellamou-Huet Rudv Belliardi Daniel Bernstein George A. Bertos Chris Biernacki Ola Björsne Thomas Blackadar h.ai/catalog/standards Thomas Bluethner Douglas P. Bogia Xavier Boniface Shannon Boucousis Lvle G. Bullock. Jr. Bernard Burg Chris Burns Jeremy Byford-Rew Satya Calloji Carole C. Carey Craig Carlson Santiago Carot-Nemesio Seungchul Chae Yao Chen Jing Cheng Peggy Chien David Chiu Jinyong Choi Chia-Chin Chong Jinhan Chung John A. Cogan John T. Collins Cory Condek Todd H. Cooper Sandra Costanzo **Douglas** Coup

Daidi Zhong, Chair Malcolm Clarke, Vice-chair Raymond Krasinski, Secretary

Hans Crommenacker Tomio Crosley Allen Curtis Jesús Daniel Trigo David Davenport Russell Davis Sushil K. Deka Ciro de la Vega Jim Dello Stritto Kent Dicks Hyoungho Do Fangjie Dong Jonathan Dougherty Xiaolian Duan Sourav Dutta Jakob Ehrensvard Fredrik Einberg Javier Escayola Calvo Mark Estes Leonardo Estevez Bosco T. Fernandes Christoph Fischer Morten Flintrup Russell Foster Eric Freudenthal Matthias Frohner Ken Fuchs Jing Gao Marcus Garbe John Garguilo Liang Ge Rick Geimer Igor Geidos 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 Nathaniel Heintzman Charles Henderson Jun-Ho Her Timothy L. Hirou Allen Hobbs Alex Holland Arto Holopainen Kris Holtzclaw Robert Hoy Anne Huang Guiling Huang Haofei Huang Zhivong Huang David Hughes Robert D. Hughes Jivoung Huh Hugh Hunter Philip O. Isaacson Atsushi Ito Michael Jaffe Praduman Jain Hu Jin Danny Jochelson Akiyoshi Kabe Steve Kahle Tomio Kamioka James J. Kangeee-11073-10472-2024 Kei Kariya Andy Kaschl Junzo Kashihara Ralph Kent Laurie M. Kermes Sanjay R. Kharche Ahmad Kheirandish Junhyung Kim Minho Kim Min-Joon Kim Taekon Kim Tetsuya Kimura Michael J. Kirwan Alfred Kloos Edward Koch Jeongmee Koh Jean-Marc Koller John Koon Patty Krantz 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 Jing Li Qiong Li Xiangchen Li Xiaoyu Li Patrick Lichter Jisoon Lim Wei-Jung Lo Charles Lowe Ling Luo Don Ludolph Christian Luszick **Bob MacWilliams** Srikkanth Madhurbootheswaran Miriam L. Makhlouf M. Sabarimalai Manikandan Romain Marmot Sandra Martinez Miguel Martínez de EsproncedaCámara Peter Mayhew Jim McCain LászlóMeleg Alexander Mense Behnaz Minaei Jinsei Mivazaki Madhu Mohan Erik Moll Darr Moore Chris Morel Carsten Mueglitz Soundharya Nagasubramanian Alex Neefus Trong-Nghia Nguyen-Dobinsky Michael E. Nidd Jim Niswander Hiroaki Niwamoto hai/catalog/standards Thomas Norgall Yoshiteru Nozoe Abraham Ofek Brett Olive Begonya Otal Marco Paleari Bud Panjwani Carl Pantiskas Harry P. Pappas Hanna Park

Phillip E. Pash TongBi Pei Soren Petersen James Petisce Peter Piction Michael Pliskin Varshney Prabodh Jeff Price Harald Prinzhorn Lifei Qian Harry Qiu Tanzilur Rahman Lin Ran Phillip Raymond Terrie Reed Barry Reinhold Brian Reinhold John G. Rhoads Jeffrey S. Robbins Chris Roberts Moskowitz Robert Stefan Robert Scott M. Robertson Timothy Robertson Sean Rocke David Rosales Bill Saltzstein Giovanna Sannino Jose A. Santos-Cadenas Stefan Sauermann John Sawyer Alois Schloegl 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

Hermanni Suominen Lee Surprenant Ravi Swami Ray Sweidan Na Tang Haruyuyki Tatsumi Isabel Tejero Chn 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 Isobel Walker David Wang Jerry P. Wang Shiwei Wang Yao Wang Yi Wang Steve Warren Fujio Watanabe Toru Watsuji Kathleen Wible Paul Williamson Jia-Rong Wu Will Wykeham Ariton Xhafa Ricky Yang Melanie S. Yeung Qiang Yin Done-Sik Yoo Zhi Yu Jianchao Zeng Jason Zhang Zerui Zhang Shibai Zhao Yu Zhao Liang Zheng Yuanhong Zhong Qing Zhou Miha Zoubek Szymon Zyskoter

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

Robert Aiello Pradeep Balachandran Pin Chang Malcolm Clarke Javier Espina

Jong-Tae Park

Myungeun Park

Michael Faughn Ken Fuchs Charles M. Gropper Werner Hoelzl Piotr Karocki

Stuart Kerry Raymond Krasinski Erik Moll Rajesh Murthy Bansi Patel

Scott M. Robertson Stefan Schlichting Harry Solomon Walter Struppler John Vergis Yu Yuan Oren Yuen Daidi Zhong

When the IEEE SA Standards Board approved this standard on 30 March 2023, it had the following membership:

David J. Law, Chair Ted Burse, Vice Chair Gary Hoffman, Past Chair Konstantinos Karachalios, Secretary

Joseph S. Levy Howard Li Gui Lin Johnny Daozhuang Lin Xiaohui Liu Kevin W. Lu Daleep C. Mohla Andrew Myles Paul Nikolich Annette D. Reilly Robby Robson Lei Wang F. Keith Waters Karl Weber Philip B. Winston Don Wright

iTeh Standards (https://standards.iteh.ai) Document Preview

ISO/IEEE 11073-10472:2024

https://standards.iteh.ai/catalog/standards/iso/5dce412f-417e-46ef-ae91-c4bad7053808/iso-ieee-11073-10472-2024

Sara R. Biyabani Doug Edwards Ramy Ahmed Fathy Guido R. Hiertz Yousef Kimiagar Joseph L. Koepfinger* Thomas Koshy John D. Kulick

*Member Emeritus

Introduction

This introduction is not part of IEEE Std 11073-10472-2023, IEEE Standard for Health Informatics—Device Interoperability—Part 10472: Personal Health Device Communication—Device Specialization—Medication Monitor.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of the communication between medication monitoring devices and managers (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 and information models. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting ambiguity in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for medication monitors. In this context, medication monitors are defined as devices that have the ability to determine and communicate (to a manager) measures of a user's adherence to a medication regime.

iTeh Standards (https://standards.iteh.ai) Document Preview

ISO/IEEE 11073-10472:2024

https://standards.iteh.ai/catalog/standards/iso/5dce412f-417e-46ef-ae91-c4bad7053808/iso-ieee-11073-10472-2024

Contents

1. Overview	1
1.1 Scope	1
1.2 Purpose	1
1.3 Word usage	
1.4 Context	2
2. Normative references	2
3. Definitions, acronyms, and abbreviations	2
3.1 Definitions	2
3.2 Acronyms and abbreviations	3
4. Introduction to ISO/IEEE 11073 personal health devices	3
4.1 General	
4.2 Introduction to IEEE 11073-20601 modeling constructs	
4.3 Compliance with other standards	
5. Medication monitor device concepts and modalities	5
5.1 General	
5.2 Model usage examples	
5.3 Medication dispensed	
5.4 Status reporter	7 7
5.4 Status reporter	Q
5.6 Usage patterns	
6. Medication monitor domain information model	9
6.1 Overview	
6.2 Class extensions	
6.3 Object instance diagram	9
6.4 Types of configuration	
6.5 Medical device system object	
6.6 Numeric objects	
6.7 Real-time sample array objects	
6.8 Enumeration objects	
6.9 PM-store objects	
6.10 Scanner objects	32
6.11 Class extension objects	
6.12 Medication monitor information model extensibility rules	
7. Medication monitor service model	
7.1 General	
7.2 Object access services	
7.3 Object access event report services	
8. Medication monitor communication model	
8.1 Overview	
8.2 Communications characteristics	
8.3 Association procedure	
8.4 Configuring procedure	
8.5 Operating procedure	
8.6 Time synchronization	
9. Test associations	45
9. Test associations	
9.1 Behavior with standard configuration	

9.2 Behavior with extended configurations
10. Conformance
10.1 Applicability
10.2 Conformance specification46
10.3 Levels of conformance
10.4 Implementation conformance statements (ICSs)
Annex A (informative) Bibliography
Annex B (normative) Any additional ASN.1 definitions
Annex C (normative) Allocation of identifiers
Annex D (informative) Message sequence examples
Annex E (informative) Protocol data unit examples
E.1 General
E.2 Association information exchange
E.3 Configuration information exchange
E.3 Configuration information exchange
E.3 Configuration information exchange60E.4 GET MDS attributes service62E.5 Data reporting63
E.3 Configuration information exchange

(https://standards.iteh.ai) Document Preview

ISO/IEEE 11073-10472:2024

https://standards.iteh.ai/catalog/standards/iso/5dce412f-417e-46ef-ae91-c4bad7053808/iso-ieee-11073-10472-2024