



BSI Standards Publication

Health informatics — Device interoperability

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

National foreword

This British Standard is the UK implementation of EN ISO/IEEE 11073-10472:2025. It is identical to ISO/IEEE 11073-10472:2024. It supersedes BS EN ISO 11073-10472:2012, which is withdrawn.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 2025
Published by BSI Standards Limited 2025

ISBN 978 0 539 31273 7

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 October 2025.

Amendments/corrigenda issued since publication

Date	Text affected
------	---------------

English Version

Health informatics - Device interoperability - Part 10472:
Personal Health Device Communication - Device
Specialization - Medication Monitor (ISO/IEEE 11073-
10472:2024)

Informatique de santé - Interopérabilité des dispositifs
- Partie 10472: Communication entre dispositifs de
santé personnels - Spécialisation des dispositifs -
Moniteur de surveillance de médication (ISO/IEEE
11073-10472:2024)

Medizinische Informatik - Interoperabilität von
Geräten - Teil 10472: Kommunikation von Geräten für
die persönliche Gesundheit - Gerätespezifikation -
Medikamentenmonitoring (ISO/IEEE 11073-
10472:2024)

This European Standard was approved by CEN on 30 September 2024.

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

European foreword

This document (EN ISO/IEEE 11073-10472:2025) 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 April 2026, and conflicting national standards shall be withdrawn at the latest by April 2026.

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 11073-10472:2012.

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 11073-10472:2024 has been approved by CEN as EN ISO/IEEE 11073-10472:2025 without any modification.

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 www.iso.org/patents. 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 www.iso.org/members.html.

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

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

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.

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 <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.

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 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

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

² Available at: <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 [IEEE Xplore](#) or [contact IEEE](#).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 [IEEE SA Website](#).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 [IEEE Xplore](#). 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.

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: <https://ieeexplore.ieee.org/browse/standards/collection/ieee>.

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

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

Participants

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

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

Karsten Aalders
 Charles R. Abbruscato
 Nabil Abujbara
 Maher Abuzaïd
 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
 Rudy Belliardi
 Daniel Bernstein
 George A. Bertos
 Chris Biernacki
 Ola Björnsne
 Thomas Blackadar
 Thomas Bluethner
 Douglas P. Bogia
 Xavier Boniface
 Shannon Boucousis
 Lyle 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
 Jinhua Chung
 John A. Cogan
 John T. Collins
 Cory Condek
 Todd H. Cooper
 Sandra Costanzo
 Douglas Coup

Nigel Cox
 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
 Hyoungdo Do
 Fangjie Dong
 Jonathan Dougherty
 Xiaolian Duan
 Sourav Dutta
 Jakob Ehrensvarð
 Fredrik Einberg
 Javier Escayola Calvo
 Mark Estes
 Leonardo Estevez
 Bosco T. Fernandes
 Christoph Fischer
 Morten Flintrop
 Russell Foster
 Eric Freudenthal
 Matthias Frohner
 Ken Fuchs
 Jing Gao
 Marcus Garbe
 John Garguilo
 Liang Ge
 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
 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
 Zhiyong Huang
 David Hughes
 Robert D. Hughes
 Jiyoung Huh
 Hugh Hunter
 Philip O. Isaacson
 Atsushi Ito
 Michael Jaffe
 Praduman Jain
 Hu Jin
 Danny Jochelson
 Akiyoshi Kabe
 Steve Kahle
 Tomio Kamioka
 James J. Kang
 Kei Kariya
 Andy Kaschl
 Junzo Kashiwara
 Ralph Kent
 Laurie M. Kermes
 Sanjay R. Kharche
 Ahmad Kheirandish
 Junhyung Kim
 Minh 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
 Srikanth Madhurbootheswaran
 Miriam L. Makhoul
 M. Sabarimalai Manikandan
 Romain Marmot
 Sandra Martinez
 Miguel Martínez de EsproncedaCámara
 Peter Mayhew
 Jim McCain
 LászlóMeleg
 Alexander Mense
 Behnaz Minaei
 Jinsei Miyazaki
 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
 Thomas Norgall
 Yoshiteru Nozoe
 Abraham Ofek
 Brett Olive
 Begonya Otal
 Marco Paleari
 Bud Panjwani
 Carl Pantiskas
 Harry P. Pappas
 Hanna Park
 Jong-Tae Park
 Myungeun 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 Roche
 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

Hermann 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
 Arton 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

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

Stuart Kerry
 Raymond Krasinski
 Erik Moll
 Rajesh Murthy
 Bansri 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*

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

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

*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.

Contents

1. Overview1

1.1 Scope1

1.2 Purpose1

1.3 Word usage.....1

1.4 Context2

2. Normative references2

3. Definitions, acronyms, and abbreviations2

3.1 Definitions2

3.2 Acronyms and abbreviations3

4. Introduction to ISO/IEEE 11073 personal health devices3

4.1 General3

4.2 Introduction to IEEE 11073-20601 modeling constructs4

4.3 Compliance with other standards4

5. Medication monitor device concepts and modalities.....5

5.1 General5

5.2 Model usage examples6

5.3 Medication dispensed7

5.4 Status reporter.....7

5.5 User feedback8

5.6 Usage patterns8

6. Medication monitor domain information model9

6.1 Overview9

6.2 Class extensions9

6.3 Object instance diagram9

6.4 Types of configuration10

6.5 Medical device system object.....11

6.6 Numeric objects.....15

6.7 Real-time sample array objects.....25

6.8 Enumeration objects25

6.9 PM-store objects.....29

6.10 Scanner objects.....32

6.11 Class extension objects.....32

6.12 Medication monitor information model extensibility rules32

7. Medication monitor service model.....33

7.1 General33

7.2 Object access services33

7.3 Object access event report services34

8. Medication monitor communication model35

8.1 Overview35

8.2 Communications characteristics35

8.3 Association procedure35

8.4 Configuring procedure.....37

8.5 Operating procedure44

8.6 Time synchronization45

9. Test associations.....45

9.1 Behavior with standard configuration45

9.2 Behavior with extended configurations	45
10. Conformance	45
10.1 Applicability	45
10.2 Conformance specification	46
10.3 Levels of conformance	46
10.4 Implementation conformance statements (ICSs)	46
Annex A (informative) Bibliography	52
Annex B (normative) Any additional ASN.1 definitions	53
Annex C (normative) Allocation of identifiers	54
Annex D (informative) Message sequence examples	55
Annex E (informative) Protocol data unit examples	57
E.1 General	57
E.2 Association information exchange	57
E.3 Configuration information exchange	60
E.4 GET MDS attributes service	62
E.5 Data reporting	63
E.6 Disassociation	64
Annex F (informative) Revision history	65

Health Informatics—Device Interoperability— Part 10472: Personal Health Device Communication—Device Specialization—Medication Monitor

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 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, information models and application profile. 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.

1.2 Purpose

This standard addresses a need for an openly defined, independent standard for controlling information exchange to and from personal health devices and managers (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 Word usage

The word *shall* indicates mandatory requirements strictly to be followed in order to conform to the standard and from which no deviation is permitted (*shall* equals *is required to*).^{1,2}

The word *should* indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others; or that a certain course of action is preferred but not necessarily required (*should* equals *is recommended that*).

The word *may* is used to indicate a course of action permissible within the limits of the standard (*may* equals *is permitted to*).

The word *can* is used for statements of possibility and capability, whether material, physical, or causal (*can* equals *is able to*).

¹ The use of the word *must* is deprecated and cannot be used when stating mandatory requirements; *must* is used only to describe unavoidable situations.

² The use of *will* is deprecated and cannot be used when stating mandatory requirements; *will* is only used in statements of fact.

1.4 Context

See ISO/IEEE 11073-20601™ for an overview of the environment within which this standard is written.³

This standard defines the device specialization for the medication monitor, being a specific agent type, and it provides a description of the device concepts, its capabilities, and its implementation according to this standard.

This standard is based on ISO/IEEE 11073:20601, which in turn draws information from both ISO/IEEE 11073-10201:2004 [B6]⁴ and ISO/IEEE 11073-20101:2004 [B7]. The medical device encoding rules (MDER) used within this standard are fully described in ISO/IEEE 11073-20601.

The object classes and attributes in this standard are identified by nomenclature codes. Each code consists of a reference identifier (RefID) string and an integer code value. By using a consistent nomenclature, interoperability is enhanced as all implementations maintain the same semantic meaning for the numeric codes. This standard leverages the existing nomenclature codes in IEEE Std 11073-10101™. Meanwhile, it defines specialized nomenclature codes that will be collected in future revisions of IEEE Std 11073-10101. Between this standard, IEEE Std 11073-10101, ISO/IEEE 11073-20601, and other IEEE Std 11073-104zz, 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 working groups and other stakeholders, and any corrective action will be published as corrigenda.

NOTE—In this standard, IEEE 11073-104zz is used to refer to the collection of device specialization standards that utilize ISO/IEEE 11073-20601, where zz can be any number from 01 to 99, inclusive.⁵

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used, so 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.

ISO/IEEE 11073-10101™, Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.⁶

ISO/IEEE 11073-20601™, Health informatics—Personal health device communication—Application profile—Optimized Exchange Protocol.^{7,8}

3. Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this document, the following terms and definitions apply. The *IEEE Standards Dictionary Online* should be consulted for terms not defined in this clause.⁹

³ Information on references can be found in Clause 2.

⁴ The numbers in brackets correspond to those of the bibliography in Annex A.

⁵ Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement the standard.

⁶ ISO publications are available from the International Organization for Standardization (<https://www.iso.org/>) and the American National Standards Institute (<https://www.ansi.org/>).

⁷ IEEE publications are available from the Institute of Electrical and Electronics Engineers, Inc., (<https://standards.ieee.org/>).

⁸ The IEEE standards or products referred to in this clause are trademarks of The Institute of Electrical and Electronics Engineers, Inc.

⁹ *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.

agent: A node that collects and transmits personal health data to an associated manager.

class: In object-oriented modeling, it describes the attributes, methods, and events that objects instantiated from the class utilize.

compute engine: *See:* **manager**.

device: A term used to refer to a physical apparatus implementing either an agent or a manager role.

handle: An unsigned 16-bit number that is locally unique and identifies one of the object instances within an agent.

manager: A node receiving data from one or more agent systems. Some examples of managers include a cellular phone, health appliance, set top box, or a computer system.

obj-handle: *See:* **handle**.

object: In object-oriented modeling, a particular instantiation of a class. The instantiation realizes attributes, methods, and events from the class.

personal health device: A device used in personal health applications.

personal telehealth device: *See:* **personal health device**.

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 statements
MDC	medical device communication
MDER	medical device encoding rules
MDS	medical device system
MOC	managed object class
PDU	protocol data unit
PHD	personal health device
VMO	virtual medical object
VMS	virtual medical system

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 managers and with computerized health-care information systems. See ISO/IEEE 11073-20601 for a description of the guiding principles for this series of ISO/IEEE 11073 Personal Health Device standards.

ISO/IEEE 11073-20601 supports the modeling and implementation of an extensive set of personal health devices. This standard defines aspects of the medication monitor device. It describes all aspects necessary to implement the application layer services and data exchange protocol between an ISO/IEEE 11073 PHD medication monitor agent and a manager. This standard defines a subset of the objects and functionality contained in ISO/IEEE 11073-20601 and extends and adds definitions where appropriate. All new definitions are given in Annex B in Abstract Syntax Notation One (ASN.1) [B8]. Nomenclature codes referenced in this standard, which are not defined in ISO/IEEE 11073-20601, are normatively defined in Annex C.

4.2 Introduction to IEEE 11073-20601 modeling constructs

4.2.1 General

The ISO/IEEE 11073 series of standards, and in particular ISO/IEEE 11073-20601, 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 ISO/IEEE 11073-20601 for a detailed description of the modeling constructs.

4.2.2 Domain information model

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 the manager is defined by the application protocol in ISO/IEEE 11073-20601.

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 the manager. Protocol messages within the ISO/IEEE 11073 series of standards are defined in ASN.1. The messages defined in ISO/IEEE 11073-20601 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 ISO/IEEE 11073-20601. The security of this communication is largely determined by, but not limited to, the physical security of the device along with the inherent security of the underlying transports. Additional security may be defined by future revisions of ISO/IEEE 11073-20601.

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, 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 [B1] base standards with respect to electrical and mechanical safety, and any device-specific standard as might be defined in the IEC 60601-2 [B2] series of standards. Software aspects may apply through standards such as IEC 62304 [B3]. 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 [B5] and IEC 80001-1 [B4]. 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. Medication monitor device concepts and modalities

5.1 General

This clause presents the general concepts of medication monitor devices. In the context of personal health devices in this family of standards, a medication monitor is a device that provides a record of the person's usage of medication. The medication monitor is expected to enable improvements in a person's compliance to taking medication as prescribed.

NOTE—The scope is purposely broad to cover a wide spectrum of device implementations in the area of medication adherence and to allow basic standards to be applied early in the development of this new application. It is anticipated that subsequent releases may build on this basis as processes mature, additional needs may be identified, and potentially related global standards emerge; for example, for medication nomenclature.

Currently it is widely estimated that only 30% to 60% of people adhere to a prescribed regimen including many people that stop taking medication early in the therapy. Consequences of non-compliance can be severe. It is estimated that many hospital and care home admissions are avoidable when compliance improves. Readers interested in investigating the subject further are referred to the wide range of studies that have been conducted. References and bibliographies can be found at the following locations:

- The Cochrane Collaboration¹⁰
- The Healthcare Compliance Packaging Council¹¹
- The National Institute for Clinical Excellence¹² (NICE) is publishing extensive Medicines Concordance and Adherence Guidelines

In the literature, the terms “adherence,” “compliance,” “compliance,” and “concordance” are used interchangeably to describe the same problem—a person not adhering to medication advice.

The medication monitor enables improvements in two of the main causes of poor compliance: memory, and feedback. Consumers, care givers, and health professionals have access to an objective diary of medication related events and are notified of exceptional situations when appropriate.

The goal of this medication monitor specialization is to provide a common interface representing the medical regimen by recording the location of the medication dispensed within the medication package, dosage, estimated time of ingestion, etc. This interface is generic and independent of the nature of the dispensing/monitoring mechanisms.

A medication monitor is usually integrated into one of several types of packaged medication, as follows:

- Blister packs

¹⁰ www.cochrane.org

¹¹ www.hcpc-europe.org and www.unitdose.org for USA

¹² <http://www.nice.org.uk/>

- Carded blister packs
- Bottles
- Mechanical dispensers
- Compartmented trays or cassettes
- Inhalers
- Vial packs, syringe packs, etc.
- Simple insulin injection device (this is not intended for the much more sophisticated insulin pumps)

Devices may be either designed for a single course of medication (disposable) or for refilling and re-usage. A blister pack is typically designed for one-time usage, whereas a mechanical dispenser may be refilled many times.

In some cases, the medication monitor may be separate from the medication package and rely on the consumer to record dosage events rather than have this done automatically when, for example, a pill is removed from a blister.

Devices may be mobile, traveling with the consumer, or they may be located in the person's home at all times.

The actual method used to assess when a dose is dispensed varies depending on the device type. A carded blister pack has means to detect when and which pill is removed from a blister. A smart bottle cap may just record when the cap is removed. An even simpler device may be a reminder feature attached to a pack of medication and, when acknowledged by pressing a button, that event is taken to be a dosage event.

This standard also supports reporting exception conditions that may make the medicine useless; for example, storage outside a temperature range or medication end-of-life. Other data that may be reported could, for example, include the time at which a package seal was broken.

5.2 Model usage examples

5.2.1 General

This clause shows how the object model described within this standard could be applied to some real-world device implementations. These are only meant to be example proof points of how a particular situation could be implemented with this model. The examples are presented as a demonstration of the possible ways in which an application might be implemented, and are not intended to be prescriptive nor exhaustive.

5.2.2 Sequenced medication monitor example types

This subclause details medication monitor examples where the position of the medication are significant (or at least make sense) and the amount of medication at that position is fixed. What is meant by fixed amount is that the medication amount in a location does not change once the device is loaded. This still allows for the medication amounts to vary from location to location.

These devices could be modeled with the fixed-dosage medication dispensed object.

- Carded blister holding a (finite) number of sequenced (numbered) doses. Doses could be tablets, capsules, ampoules, vials, pre-filled syringes, sachets, etc.
- Carded blister containing multiple medications, e.g., a maintenance dose to take daily, and an emergency stronger dose to take as needed.
- Compartmented, refillable drug container. The typical device comprises a calendar means, labeled morning, mid-day, evening, night, weekdays Monday through Sunday, and eventually week numbers.
- Compartmented disposable container. Each compartment contains multiple pills to be taken together.
- Revolver-like medication dispenser. By the means of a user twist, a revolver mechanism is rotated one notch and a single dose can be dispensed. By the nature of the design, each dose is removed in a strict sequence.

5.2.3 Non-sequenced medication monitor example types

Medication monitor examples where dose positions are not applicable and the amount of medication is determined at dosage dispensing time. These devices could be modeled using the following variable-dosage medication dispensed events.

- Standard medication bottle with a switch in the lid. This type considers a removed lid to be a single medication event.
- Simple blister holder with a switch. This type considers a removed and re-inserted blister to be a single medication event.
- Motorized/automated medication dispenser. Various types allow dispensing of a dose from a container into a bin at pre-set times. When the bin is opened and the dose taken out, this is considered to be a dose event.
- Inhaler with a variable dose. The typical (asthma-) inhaler allows for a variable dose by the means of an aerosol being dispensed in “x number of puffs” or a solid drug being dispensed in number of “twists”.
- Injection device. The typical (insulin-) injection pen comprises means of recording an injection dose.
- An “infusion”: variable amount of drug administered as a fluid or gas. Possibly, the maker defines the quantity, e.g., 10 cc to be equivalent to a dose. So dispensing of 20 cc is recorded as two 10 cc doses at the same time.

5.3 Medication dispensed

The medication monitor shall always include a mechanism for recording medication dispensed events and providing an indication of the time and date that a medication is removed from its package. There is no intention to mandate that the medication monitor should also be able to detect that the medication is actually ingested, injected, inhaled, or otherwise absorbed into the person’s body.

The modeling of these medication dispensed events is done via two different objects depending on the physical type of the medication. The fixed-dosage medication dispensed object is used for cases where the dosage is not changeable and does not vary during dispensing (e.g., pills). The variable-dosage medication dispensed object is used when the dosage may vary and/or be changeable at dispensing (e.g., gases or liquids).

5.4 Status reporter

The medication monitor may include a mechanism that reports status. The specific status may include any of the following:

- Medication not dispensed as expected: the medication was not dispensed within the regimen allowed timing. Conceptually, a regimen would be a preferred time interval for the medication. This status would be raised when the regimen is violated by no medication having been taken within the specified time interval.
- Medication dispensed unexpectedly: the medication was dispensed outside the regimen allowed timing. Conceptually, a regimen would be a preferred time interval for the medication. This status would be raised when the regimen is violated by the medication having been taken outside the specified time interval.
- Medication unfit: the medication monitor has determined that the medication has become unfit.
- Tampering: the medication monitor has determined that tampering has occurred.
- Optimum environmental conditions have been exceeded high/low: environmental conditions such as temperature, for example, have been exceeded.
- Expiration: the medication has expired and is beyond specified use by date.
- Non-compliance yellow/red: the medication monitor has determined that the person’s usage is not in compliance. Non-compliance generally means that the medication regimen is not being followed adequately. The severity of non-compliance is indicated in two levels. Yellow is the first level and indicates that consumer advising may be indicated. Red is the second level and indicates that consumer intervention is indicated.
- Course completed: the full course of loaded medication has been dispensed.

- Medication taken incorrectly: the medication monitor has determined that the person has taken the medication incorrectly.
- Consumer side effects: the medication monitor has determined that the person may be experiencing side effects. Side effects is a general term to indicate a range of perceived consumer abnormalities that a medication monitor may be able to detect.
- Course reloaded: the full course of medication has been reloaded.
- Medication monitor inoperable: the medication monitor is no longer able to perform adequately and should no longer be used.

For each of the recognized status conditions, the medication monitor would generate a status report of the occurrence and the time.

5.5 User feedback

It is often valuable for a health care professional to have an objective record of side effects in association with medicine usage. A major reason for non-compliance is the person's concern about side effects and efficacy in general. Recent studies indicate that the best improvements in compliance will be achieved when both consumer and healthcare professional are able to discuss side effects objectively. The medication monitor may support questions being posed to the user and the resulting answers conveyed to the manager. Objective recording of dosage events, combined with subjective quality of life data, can provide valuable feedback regarding the efficacy of treatment.

This feedback capability may be utilized in a number of ways.

For example:

- a) To reinforce correct usage
 - Yes/no to a correct procedure. For example, "Was the medication taken with water?"
- b) To provide a subjective impression of quality-of-life information.
 - A Hamilton scale (e.g., "How severe were headaches today?") on a scale of 1 = "none" to 5 = "continuous."
 - Yes/no answers to simple questions. For example, "Are you feeling well?" or "Did you have a headache today?"
 - A value within a visual analog scale. For example, "Indicate mood on a scale from very depressed to very happy? 0–100" or "How bad was the headache? 0–100."

The origin and text of the particular questions are solely a function of the medication monitoring device. There is no collaboration between the agent and the manager for this purpose in this standard. As the questions relate to the specific medication and person, they are expected to be static and only change in the cases of where the medication is changed (e.g., a carousel or reloadable device). The agent implementation specifics of how questions are presented to the person and answered are outside the scope of this standard. This standard is only concerned with the conveyance of the results.

See 6.5.1 for an explanation of how this information is correlated in the downstream information systems via the device's System-Id and/or Context-Id.

5.6 Usage patterns

Although a medication monitor can be used as a personal device to assist the user unaided, the expectation is that the recorded data will often be communicated to a healthcare service provider to enable advising and intervention.

Depending on the therapy and the medication monitor implementation, data may be read from the medication monitor frequently (e.g., daily or more) or infrequently (e.g., weekly or less). Devices may be permanently connected (e.g., with a static refillable medication dispenser) or connected occasionally (e.g., with a portable pill pack).

6. Medication monitor domain information model

6.1 Overview

This clause describes the domain information model of the medication monitor.

6.2 Class extensions

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

6.3 Object instance diagram

The object instance diagram of the medication monitor domain information model, defined for the purposes of this standard, is shown in Figure 1.

The objects of the DIM, as shown in Figure 1, are described in 6.5 to 6.10. This includes the medical device system (MDS) object (see 6.5), the numeric objects (see 6.6), the RT-SA objects (see 6.7), the enumeration objects (see 6.8), the PM-store objects (see 6.9), and the scanner objects (see 6.10). See 6.11 for rules for extending the medication monitor information model beyond elements as described in this standard. Each clause that describes an object of the medication monitor 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, real time sample array, enumeration, scanner, or PM-store class.
- 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 ISO/IEEE 11073-20601.
- 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 mean: M — Attribute is Mandatory, C — Attribute is Conditional and depends on the condition stated in the Remark or Value column (if ISO/IEEE 11073-20601 is referenced, then it contains the conditions), R — Attribute is Recommended, NR — Attribute is Not Recommended, and O — Attribute is Optional. 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. Not recommended attributes should not be implemented by the agent. Optional attributes may be implemented by the agent. For attributes with qualifiers set to R or NR, underlying requirements stated in the Remark and Value column in ISO/IEEE 11073-20601 shall be followed. If any attribute (from the DIM of ISO/IEEE 11073-20601) is not included in the definition of that object in this standard, it shall not be included in that object by an implementation, unless it is a vendor-specific attribute extended according to 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.