FINAL DRAFT
International Standard

ISO/IEEE
FDIS
11073-10419

Health informatics — Device interoperability —

Part 10419: Personal health device communication, device specialization, insulin pump

ISO/TC **215**

Secretariat: **ANSI**

Voting begins on:
2026-07-14

Voting terminates on:
2026-12-01

This document has not been edited by the ISO Central Secretariat.

FAST TRACK PROCEDURE

ISO/CEN PARALLEL PROCESSING

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

Reference number
ISO/IEEE FDIS 11073-10419:2026(en)

© IEEE 2026



COPYRIGHT PROTECTED DOCUMENT

© IEEE 2026

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

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

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

Published in Switzerland

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards 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 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.

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 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 11073-10419 was prepared by the *IEEE 11073 Standards Committee of the IEEE Engineering in Medicine and Biology Society* (as IEEE Std 11073-10419™-2023), in collaboration with the European Committee for Standardization (CEN), in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement), 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 third edition cancels and replaces the second edition (ISO/IEEE 11073-10419:2019), which has been technically revised.

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

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

© IEEE 2024 – All rights reserved

IEEE Std 11073-10419™-2023
(Revision of IEEE Std 11073-10419-2017)

Health informatics—Device interoperability

Part 10419: Personal Health Device Communication—Device Specialization—Insulin Pump

Developed by the

IEEE 11073™ Standards Committee
of the
IEEE Engineering in Medicine and Biology Society

6 December 2023

IEEE SA Standards Board

Recognized as an American National Standard

Copyright © 2024 IEEE. All rights reserved.

Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, a normative definition of communication between personal telehealth insulin pump devices and compute engines (e.g., cell phones, personal computers, personal health appliances, set top boxes) in a manner that enables plug-and-play interoperability, is established in this standard. 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 insulin pump devices is defined.

Keywords: IEEE 11073-10419™, insulin pump, medical device communication, personal health devices

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

Copyright © 2024 by The Institute of Electrical and Electronics Engineers, Inc.
All rights reserved. Published 23 February 2024. 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 979-8-8557-0452-5 STD26728
Print: ISBN 979-8-8557-0453-2 STDPD26728

IEEE prohibits discrimination, harassment, and bullying.
For more information, visit http://www.ieee.org/web/aboutus/whatis/policies/p9-26.html.
No part of this publication may be reproduced in any form, in an electronic retrieval system or otherwise, without the prior written permission of the publisher.

Copyright © 2024 IEEE. All rights reserved.

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.

Copyright © 2024 IEEE. All rights reserved.

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.

[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.

Copyright © 2024 IEEE. All rights reserved.

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.

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.

[3] Available at: https://ieeexplore.ieee.org/browse/standards/collection/ieee.
[4] Available at: https://standards.ieee.org/standard/index.html.

Copyright © 2024 IEEE. All rights reserved.

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.

[5] Available at: https://standards.ieee.org/about/sasb/patcom/materials.html.

Copyright © 2024 IEEE. All rights reserved.

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 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
Rudy Belliardi
Daniel Bernstein
George A. Bertos
Chris Biernacki
Ola Björsne
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
Jinhan 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
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 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
Danny Jochelson
Akiyoshi Kabe
Steve Kahle
Tomio Kamioka
James J. Kang
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

Copyright © 2024 IEEE. All rights reserved.

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 Espronceda Cámara
Peter Mayhew
Jim McCain
László Meleg
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
Tong Bi 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
Kwang Seok 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
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
Hongbo Zhao
Shibai Zhao
Yu Zhao
Liang Zheng
Yuanhong Zhong
Qing Zhou
Miha Zoubek
Szymon Zyskoter

Copyright © 2024 IEEE. All rights reserved.

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

Amelia Andersdotter
Bjoern Andersen
Lyle G. Bullock, Jr.
Keith Chow
Malcolm Clarke
Joseph El Youssef
David Fuschi
Randall Groves
Werner Hoelzl
Noriyuki Ikeuchi
Atsushi Ito
Piotr Karocki
Raymond Krasinski
Joerg-Uwe Meyer
H. Moll
Nick S. A. Nikjoo
Iulian Profir
Beth Pumo
Walter Struppler
Ganesh Subramanian
Oren Yuen

When the IEEE SA Standards Board approved this standard on 6 December 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

Copyright © 2024 IEEE. All rights reserved.

Introduction

This introduction is not part of IEEE 11073-10419-2023, Health informatics—Device interoperability—Part 10419: Personal Health Device Communication—Device Specialization—Insulin Pump.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. This document uses the optimized framework created in ISO/IEEE 11073-20601[6] and describes a specific, interoperable communication approach for insulin pumps. These standards align with and draw on the existing clinically focused standards to provide support for communication of data from clinical or personal health devices.

[6]For information on references, see Clause 2.

Copyright © 2024 IEEE. All rights reserved.

Contents

1. Overview 13
1.1 Scope 13
1.2 Purpose 13
1.3 Word usage 14
1.4 Context 14

2. Normative references 14

3. Definitions, acronyms, and abbreviations 15
3.1 Definitions 15
3.2 Acronyms and abbreviations 16

4. Introduction to ISO/IEEE 11073 personal health devices 17
4.1 General 17
4.2 Introduction to ISO/IEEE 11073-20601 modeling constructs 18
4.3 Compliance with other standards 18

5. Insulin pump device concepts and modalities 19
5.1 General 19
5.2 Device types 20
5.3 Collected data 20
5.4 Stored data 26
5.5 Scheduled data 26

6. Insulin pump domain information model 26
6.1 Overview 26
6.2 Object instance diagram 27
6.3 Types of configuration 28
6.4 Profiles 29
6.5 Medical device system object 29
6.6 Numeric objects 32
6.7 Real-time sample array objects 53
6.8 Enumeration objects 53
6.9 PM-store objects 59
6.10 Schedule-store objects 64
6.11 Scanner objects 72
6.12 Class extension objects 73
6.13 Insulin pump information model extensibility rules 73

7. Insulin pump service model 73
7.1 General 73
7.2 Object access services 73
7.3 Object access event report services 75

8. Insulin pump communication model 75
8.1 Overview 75
8.2 Communications characteristics 76
8.3 Association procedure 76
8.4 Configuring procedure 78
8.5 Operating procedure 80
8.6 Time synchronization 80

9. Test associations 80
9.1 Behavior with standard configuration 81
9.2 Behavior with extended configurations 81

Copyright © 2024 IEEE. All rights reserved.

10. Conformance 81
10.1 Applicability 81
10.2 Conformance specification 81
10.3 Levels of conformance 82
10.4 Implementation conformance statements 82

Annex A (informative) Bibliography 91

Annex B (normative) Any additional ASN.1 definitions 92

Annex C (normative) Allocation of identifiers 93
C.1 General 89
C.2 Definitions of terms and codes 89
C.3 Systematic derivations of terms and codes 91

Annex D (informative) Message sequence examples 104

Annex E (informative) Protocol data unit examples 106
E.1 General 106
E.2 Association information exchange 106
E.3 Configuration information exchange 109
E.4 GET MDS attributes service 114
E.5 Data reporting 115
E.6 Disassociation 116

Annex F (informative) Revision History 117

Copyright © 2024 IEEE. All rights reserved.

Health informatics—Device interoperability

Part 10419: Personal health device communication—Device Specialization—Insulin Pump

1. Overview

1.1 Scope

The scope of this standard is to establish a normative definition of communication between personal telehealth insulin pump devices (agents) 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 work done in other ISO/IEEE 11073 standards including existing terminology, information profiles, application profile standards, and transport standards. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability. This standard defines a common core functionality of personal telehealth insulin pump devices.

In the context of personal health devices, an insulin pump is a medical device used for the administration of insulin in the treatment of diabetes mellitus, also known as continuous subcutaneous insulin infusion (CSII) therapy.

This standard provides the data modeling according to the ISO/IEEE 11073-20601 standard, and does not specify the measurement method.

1.2 Purpose

This standard addresses the need for an openly defined, independent standard that support information exchange to and from personal health devices and compute engines (e.g., cell phones, personal computers, personal health appliances, and 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.

Copyright © 2024 IEEE. All rights reserved.

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*).[7,8]

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*).

1.4 Context

See ISO/IEEE 11073-20601[9] for an overview of the environment within which this standard is written.

This standard defines the device specialization for the insulin pump [B1][10] being a specific agent type, and provides a description of the device concepts, its capabilities, and its implementation according to this standard.

This standard is based on ISO/IEEE 11073-20601, which in turn draw information from both ISO/IEEE 11073-10201:2004 [B2] and ISO/IEEE 11073-20101:2004 [B3]. The medical device encoding rules (MDER) used within this standard are fully described in ISO/IEEE 11073-20601.

This standard defines specialized nomenclature codes that will be collected in IEEE Std 11073-10101. Between this standard, IEEE Std 11073-10101, IEEE Std 11073-20601 and other IEEE Std 11073-104xx, all required nomenclature codes for implementation are documented. New codes may be defined in newer versions/revisions of each of these documents. In the case of a conflict, where one term code has been assigned to two separate semantic concepts with different RefIDs, in general the oldest definition that is in actual use should take precedence. The same policy applies when one RefID has two different code values assigned in different specifications. The resolution of such conflicts will be determined through joint action by the responsible workgroups and other stakeholders and any corrective action published as corrigenda.

NOTE—In this standard, ISO/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.[11]

2. Normative references

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

[7] The use of the word *must* is deprecated and cannot be used when stating mandatory requirements; *must* is used only to describe unavoidable situations.
[8] The use of *will* is deprecated and cannot be used when stating mandatory requirements; *will* is used only in statements of fact.
[9] Information on references can be found in Clause 2.
[10] The numbers in brackets correspond to those of the bibliography in Annex A.
[11] Notes in text, tables, and figures of a standard are given for information only and do not contain requirements needed to implement this standard.

Copyright © 2024 IEEE. All rights reserved.

IEEE Std 11073-10101, Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.[12,13]

IEEE Std 11073-20601, Health informatics—Device InteroperabilkityPersonal health device communication—Application Profile—Optimized Exchange Protocol.

See Annex A for all informative material referenced by this standard.

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.[14]

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

artificial pancreas (AP): A system combining diabetes devices to provide similar functionality as a pancreas. Examples include linking a continuous glucose monitor to an insulin pump to automatically reduce or increase insulin infusion based upon specified thresholds of measured interstitial glucose.

basal insulin: Insulin required to cover the basic insulin needs of the body.

basal rate: Rate of continuously delivered insulin to cover the basic insulin needs of the body.

basal rate profile: Profile defining the time-dependent course of the basal rate over a periodic time interval (e.g., 24 h, beginning at midnight).

blood glucose: Glucose concentration in the blood.

bolus: A single dose of a medication typically administered by infusion. *See also:* **bolus insulin**.

bolus insulin: Insulin required to cover the intake of food or to correct high blood glucose levels.

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

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

correction bolus: A bolus to correct high blood glucose levels. *See also:* **bolus**.

daily basal dose: Total amount of basal insulin delivered in 24 h, beginning at midnight.

device: A physical apparatus implementing either an agent or a manager role.

extended bolus: A bolus given over an extended period of time with a specified duration. *See also:* **bolus**.

[12] The IEEE standards or products referred to in this clause are trademarks of the Institute of Electrical and Electronics Engineers, Inc.
[13] IEEE publications are available from the Institute of Electrical and Electronics Engineers, (http://standards.ieee.org/). After IEEE-SASB approval of IEEE P11073-20601, the IEEE published standard will be adopted by ISO/IEC as the latest version of ISO/IEC/IEEE 11073-20601.
[14] *IEEE Standards Dictionary Online* is available at: http://dictionary.ieee.org. An IEEE Account is required for access to the dictionary, and one can be created at no charge on the dictionary sign-in page.

Copyright © 2024 IEEE. All rights reserved.

fast bolus: A bolus given over a very short period that can be considered as having infinitesimal duration and specified by amount of infusion. *See also:* **bolus**.

glucagon: Naturally occurring hormone released by the pancreas when glucose levels are low.

glucose: Commonly referred to as "sugar," it is the major source of energy used by the body cells**.**

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

infusion set: A tubing system with cannula that interfaces the insulin reservoir to the body.

insulin: Naturally occurring hormone required for carbohydrate metabolism. Insulin regulates the way sugar, fat, and proteins are moved into the cells and the way they are stored or used for energy.

insulin on board: The amount of currently active insulin within the person with diabetes (PWD) body.

insulin to carbohydrate ratio (I:CHO): Amount of carbohydrate covered or disposed of by a single unit of insulin.

insulin sensitivity factor (ISF): An estimated amount of blood glucose reduced by a single unit of insulin. Also known as a *correction factor*.

international unit (IU): Unit of measurement used in pharmacology for the measurement of the amount of a substance.

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 computer system.

meal bolus: A bolus to compensate for meal intake. *See also:* **bolus**.

multi-wave bolus: A bolus combining a fast bolus with an extended bolus; one part of the bolus amount is delivered immediately while the other is delivered over a specific period of time.

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.

occlusion: Total obstruction of the infusion set that prevents administering insulin.

personal health device (PHD): A device used in personal health applications.

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

piston rod: Mechanical apparatus to propel the plunger of the insulin reservoir.

priming: The filling of the fluidic path with insulin (e.g., after replacement of the reservoir and/or infusion set).

reservoir: The insulin supply of an insulin pump.

temporary basal rate: Temporary adjustment of the basal rate.

total daily dose: The total amount of insulin delivered during one day (i.e., 24 h, beginning at midnight). This amount contains basal insulin as well as bolus insulin.

3.2 Acronyms and abbreviations

Copyright © 2024 IEEE. All rights reserved.