INTERNATIONAL STANDARD

ISO/IEEE 11073-10425

Second edition
2019-03

Health informatics — Personal health device communication —

Part 10425:
Device specialization — Continuous glucose monitor (CGM)

Informatique de santé — Communication entre dispositifs de santé personnels —

Partie 10425: Spécialisation du dispositif — Glucomètre continu (CGM)

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted (see www.iso.org/directives).

IEEE Standards documents are developed within the IEEE Societies and the Standards Coordinating Committees of the IEEE Standards Association (IEEE-SA) Standards Board. The IEEE develops its standards through a consensus development process, approved by the American National Standards Institute, which brings together volunteers representing varied viewpoints and interests to achieve the final product. Volunteers are not necessarily members of the Institute and serve without compensation. While the IEEE administers the process and establishes rules to promote fairness in the consensus development process, the IEEE does not independently evaluate, test, or verify the accuracy of any of the information contained in its standards.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

ISO/IEEE 11073-10425 was prepared by the IEEE 11073 Standards Committee of the IEEE Engineering in Medicine and Biology Society (as IEEE Std 11073-10425-2017) 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 11073-10425:2016), which has been technically revised.

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 the communication between continuous glucose monitor (CGM) devices and managers (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. 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 optionality in base frameworks in favor of interoperability. This standard defines a common core of communication functionality of CGM devices. In this context, CGM refers to the measurement of the level of glucose in the body on a regular (typically 5 minute) basis through a sensor continuously attached to the person.

Keywords: continuous glucose monitor, IEEE 11073-10425™, medical device communication, personal health devices

Important Notices and Disclaimers Concerning IEEE Standards Documents

IEEE documents are made available for use subject to important notices and legal disclaimers. These notices and disclaimers, or a reference to this page, appear in all standards and may be found under the heading "Important Notices and Disclaimers Concerning IEEE Standards Documents." They can also be obtained on request from IEEE or viewed at http://standards.ieee.org/IPR/disclaimers.html.

Notice and Disclaimer of Liability Concerning the Use of IEEE Standards Documents

IEEE Standards documents (standards, recommended practices, and guides), both full-use and trial-use, are developed within IEEE Societies and the Standards Coordinating Committees of the IEEE Standards Association ("IEEE-SA") Standards Board. IEEE ("the Institute") develops its standards through a consensus development process, approved by the American National Standards Institute ("ANSI"), which brings together volunteers representing varied viewpoints and interests to achieve the final product. IEEE Standards are documents developed through scientific, academic, and industry-based technical working groups. Volunteers in IEEE working groups are not necessarily members of the Institute 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 Standards do not guarantee or ensure safety, security, health, or environmental protection, or ensure against interference with or from other devices or networks. 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.

IEEE does not warrant or represent the accuracy or content of the material contained in its standards, and expressly disclaims all warranties (express, implied and statutory) not included in this or any other document relating to the standard, including, but not limited to, the warranties of: merchantability; fitness for a particular purpose; non-infringement; and quality, accuracy, effectiveness, currency, or completeness of material. In addition, IEEE disclaims any and all conditions relating to: results; and workmanlike effort. IEEE standards documents are supplied "AS IS" and "WITH ALL FAULTS."

Use of an IEEE standard is wholly voluntary. The existence of an IEEE standard does not imply that there are no other ways to produce, test, measure, purchase, market, or provide other goods and services related to the scope of the IEEE standard. Furthermore, the viewpoint expressed at the time a standard is approved and issued is subject to change brought about through developments in the state of the art and comments received from users of the standard.

In publishing and making its standards available, IEEE is not suggesting or rendering professional or other services for, or on behalf of, any person or entity nor is IEEE undertaking to perform any duty owed by any other person or entity to another. Any person utilizing any IEEE Standards document, should rely upon his or her own independent judgment in the exercise of reasonable care in any given circumstances or, as appropriate, seek the advice of a competent professional in determining the appropriateness of a given IEEE standard.

IN NO EVENT SHALL IEEE BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, OR CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO: PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES; LOSS OF USE, DATA, OR PROFITS; OR BUSINESS INTERRUPTION) HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, STRICT LIABILITY, OR TORT (INCLUDING NEGLIGENCE OR OTHERWISE) ARISING IN ANY WAY OUT OF THE PUBLICATION, USE OF, OR RELIANCE UPON ANY STANDARD, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE AND REGARDLESS OF WHETHER SUCH DAMAGE WAS FORESEEABLE.

Translations

The IEEE consensus development process involves the review of documents in English only. In the event that an IEEE standard is translated, only the English version published by IEEE should be considered 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, or 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 his or her views should be considered the personal views of that individual rather than the formal position of IEEE.

Comments on standards

Comments for revision of IEEE Standards documents are welcome from any interested party, regardless of membership affiliation with IEEE. However, IEEE does not provide consulting information or advice pertaining to IEEE Standards documents. Suggestions for changes in documents should be in the form of a proposed change of text, together with appropriate supporting comments. Since IEEE standards represent a consensus of concerned interests, it is important that any responses to comments and questions also receive the concurrence of a balance of interests. For this reason, IEEE and the members of its societies and Standards Coordinating Committees are not able to provide an instant response to comments or questions except in those cases where the matter has previously been addressed. For the same reason, IEEE does not respond to interpretation requests. Any person who would like to participate in revisions to an IEEE standard is welcome to join the relevant IEEE working group.

Comments on standards should be submitted to the following address:

> Secretary, IEEE-SA Standards Board
> 445 Hoes Lane
> Piscataway, NJ 08854 USA

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 imply 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.

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, IEEE does not waive any rights in copyright to the documents.

Photocopies

Subject to payment of the appropriate fee, 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. 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 ten years. When a document is more than ten 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 the IEEE Xplore at http://ieeexplore.ieee.org/ or contact IEEE at the address listed previously. For more information about the IEEE-SA or IEEE's standards development process, visit the IEEE-SA Website at http://standards.ieee.org.

Errata

Errata, if any, for all IEEE standards can be accessed on the IEEE-SA Website at the following URL: http://standards.ieee.org/findstds/errata/index.html. Users are encouraged to check this URL for errata periodically.

Patents

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 http://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.

Participants

At the time this standard was submitted to the IEEE-SA Standards Board for approval, the Personal Health Device Working Group had the following membership:

Daidi Zhong, *Chair*
Michael J. Kirwan, *Chair*
Nathaniel M. Hamming, *Vice Chair*
Akib Uddin, *Vice Chair*

Karsten Aalders	Seungchul Chae	Ken Fuchs
Charles R. Abbruscato	Rahul Chauhan	Jing Gao
Nabil Abujbara	James Cheng	Xuemei Gao
Maher Abuzaid	Peggy Chien	Marcus Garbe
James Agnew	David Chiu	John Garguilo
Haidar Ahmad	Jinyong Choi	Rick Geimer
Manfred Aigner	Chia-Chin Chong	Igor Gejdos
Jorge Alberola	Saeed A. Choudhary	Ferenc Gerbovics
Murtaza Ali	Jinhan Chung	Nicolae Goga
Rolf Ambuehl	Malcolm Clarke	Julian Goldman
David Aparisi	John A. Cogan	Raul Gonzalez Gomez
Paolo Ariano	John T. Collins	Chris Gough
Lawrence Arne	Cory Condek	Channa Gowda
Diego B. Arquillo	Todd H. Cooper	Charles M. Gropper
Serafin Arroyo	David Cornejo	Amit Gupta
Muhammad Asim	Douglas Coup	Jeff Guttmacher
Merat Bagha	Nigel Cox	Rasmus Haahr
Doug Baird	Hans Crommenacker	Christian Habermann
David Baker	Tomio Crosley	Michael Hagerty
Anindya Bakshi	Allen Curtis	Jerry Hahn
Ananth Balasubramanian	Ndifor Cyril Fru	Robert Hall
Sunlee Bang	Jesús Daniel Trigo	Rickey L. Hampton
M. Jonathan Barkley	Eyal Dassau	Sten Hanke
Gilberto Barrón	David Davenport	Aki Harma
David Bean	Russell Davis	Jordan Hartmann
John Bell	Sushil K. Deka	Kai Hassing
Rudy Belliardi	Ciro de la Vega	Marc Daniel Haunschild
Kathryn M. Bennett	Pedro de-las-Heras-Quiros	Wolfgang Heck
Daniel Bernstein	Jim DelloStritto	Nathaniel Heintzman
George A. Bertos	Matthew d'Entremont	Charles Henderson
Chris Biernacki	Kent Dicks	Jun-Ho Her
Ola Björsne	Hyoungho Do	Helen B. Hernandez
Thomas Blackadar	Alistair Donaldson	Takashi Hibino
Marc Blanchet	Xiaolian Duan	Timothy L. Hirou
Thomas Bluethner	Brian Dubreuil	Allen Hobbs
Douglas P. Bogia	Sourav Dutta	Alex Holland
Xavier Boniface	Jakob Ehrensvard	Arto Holopainen
Shannon Boucousis	Fredrik Einberg	Kris Holtzclaw
Julius Broma	Michihiro Enokida	Robert Hoy
Lyle G. Bullock	Javier Escayola Calvo	Frank Hsu
Bernard Burg	Mark Estes	Anne Huang
Chris Burns	Leonardo Estevez	Sen-Der Huang
Anthony Butt	Roger Feeley	Zhiqiang Huang
Jeremy Byford-Rew	Hailing Feng	Ron Huby
Satya Calloji	Bosco T. Fernandes	David Hughes
Xiaoying Cao	Christoph Fischer	Robert D. Hughes
Carole C. Carey	Morten Flintrup	Jiyoung Huh
Craig Carlson	Joseph W. Forler	Hugh Hunter
Santiago Carot-Nemesio	Russell Foster	Hitoshi Ikeda
Randy W. Carroll	Eric Freudenthal	Yutaka Ikeda
Simon Carter	Matthias Frohner	Philip O. Isaacson

Atsushi Ito
Michael Jaffe
Praduman Jain
Wei Jin
Danny Jochelson
Phaneeth Junga
Akiyoshi Kabe
Steve Kahle
Tomio Kamioka
James Jin Kang
Kei Kariya
Andy Kaschl
Junzo Kashihara
Kohichi Kashiwagi
Ralph Kent
Laurie M. Kermes
Ikuo Keshi
Junhyung Kim
Minho Kim
Min-Joon Kim
Taekon Kim
Tetsuya Kimura
Alfred Kloos
Jeongmee Koh
Jean-Marc Koller
John Koon
Patty Krantz
Raymond Krasinski
Alexander Kraus
Ramesh Krishna
Geoffrey Kruse
Falko Kuester
Rafael Lajara
Pierre Landau
Jaechul Lee
JongMuk Lee
Kyong Ho Lee
Rami Lee
Sungkee Lee
Woojae Lee
Yonghee Lee
Joe Lenart
Kathryn A. Lesh
Catherine Li
Qiong Li
Patrick Lichter
Jisoon Lim
Joon-Ho Lim
John Lin
Wei-Jung Lo
Charles Lowe
Don Ludolph
Christian Luszick
Bob MacWilliams
Srikkanth Madhurbootheswaran
Miriam L. Makhlouf
Romain Marmot
Sandra Martinez
Miguel Martínez de Espronceda
  Cámara
Peter Mayhew
Jim McCain
László Meleg
Alexander Mense

Jinsei Miyazaki
Erik Moll
Darr Moore
Carsten Mueglitz
Piotr Murawski
Soundharya Nagasubramanian
Jae-Wook Nah
Alex Neefus
Trong-Nghia Nguyen-Dobinsky
Michael E. Nidd
Tetsu Nishimura
Jim Niswander
Hiroaki Niwamoto
Thomas Norgall
Anand Noubade
Yoshiteru Nozoe
Abraham Ofek
Brett Olive
Begonya Otal
Marco Paleari
Charles Palmer
Bud Panjwani
Carl Pantiskas
Harry P. Pappas
Hanna Park
Jong-Tae Park
Myungeun Park
Soojun Park
Phillip E. Pash
TongBi Pei
Lucian Pestritu
Soren Petersen
James Petisce
Peter Piction
Michael Pliskin
Varshney Prabodh
Jeff Price
Harald Prinzhorn
Harry Qiu
Arif Rahman
Tanzilur Rahman
Steve Ray
Phillip Raymond
Tim Reilly
Barry Reinhold
Brian Reinhold
Melvin I. Reynolds
John G. Rhoads
Jeffrey S. Robbins
Chris Roberts
Moskowitz Robert
Timothy Robertson
David Rosales
Fatemeh Saki
Bill Saltzstein
Benedikt Salzbrunn
Giovanna Sannino
Jose A. Santos-Cadenas
Stefan Sauermann
John Sawyer
Guillaume Schatz
Alois Schloegl
Paul S. Schluter
Lars Schmitt

Mark G. Schnell
Richard A. Schrenker
Antonio Scorpiniti
Kwang Seok Seo
Riccardo Serafin
Sid Shaw
Frank Shen
Bozhi Shi
Min Shih
Mazen Shihabi
Redmond Shouldice
Sternly K. Simon
Marjorie Skubic
Robert Smith
Ivan Soh
Motoki Sone
Emily Sopensky
Rajagopalan Srinivasan
Andreas Staubert
Nicholas Steblay
Lars Steubesand
John (Ivo) Stivoric
Raymond A. Strickland
Chandrasekaran Subramaniam
Hermanni Suominen
Lee Surprenant
Ravi Swami
Ray Sweidan
Jin Tan
Yi Tang
Haruyuyki Tatsumi
John W. Thomas
Jonas Tirén
Alexandra Todiruta
Janet Traub
Gary Tschautscher
Masato Tsuchid
Ken Tubman
Yoshihiro Uchida
Sunil Unadkat
Fabio Urbani
Philipp Urbauer
Laura Vanzago
Alpo Värri
Dalimar Velez
Rudi Voon
Barry Vornbrock
Isobel Walker
David Wang
Jerry P. Wang
Yao Wang
Yi Wang
Steve Warren
Fujio Watanabe
Toru Watsuji
Mike Weng
Kathleen Wible
Paul Williamson
Jan Wittenber
Jia-Rong Wu
Will Wykeham
Ariton Xhafa
Dan Xiao
Yaxi Yan

Qifeng Yan	Qiang Yin	Zhiqiang Zhang
Junjie Yang	Done-Sik Yoo	Thomas Zhao
Ricky Yang	Jianchao Zeng	Miha Zoubek
Melanie S. Yeung	Jason Zhang	Szymon Zyskoter

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

Charles Barest	Nathaniel M. Hamming	Paul Schluter
Lyle G. Bullock	Werner Hoelzl	Steven Smith
Craig Carlson	Noriyuki Ikeuchi	Walter Struppler
Malcolm Clarke	Atsushi Ito	Karl Weber
David Fuschi	Piotr Karocki	Jan Wittenber
Randall Groves	Joerg-Uwe Meyer	Oren Yuen
	Bartien Sayogo	

When the IEEE-SA Standards Board approved this standard on 28 September 2017, it had the following membership:

Jean-Philippe Faure, *Chair*
Gary Hoffman, *Vice Chair*
John D. Kulick, *Past Chair*
Konstantinos Karachalios, *Secretary*

Chuck Adams	Thomas Kochy	Robby Robson
Masayuki Ariyoshi	Joseph L. Koepfinger*	Dorothy Stanley
Ted Burse	Kevin Lu	Adrian Stephens
Stephen Dukes	Daleep Mohla	Mehmet Ulema
Doug Edwards	Damir Novosel	Phil Wennblom
J. Travis Griffith	Ronald C. Petersen	Howard Wolfman
Michael Janezic	Annette D. Reilly	Yu Yuan

*Member Emeritus

Introduction

This introduction is not part of IEEE Std 11073-10425-2017, Health informatics—Personal health device communication—Part 10425: Device Specialization—Continuous Glucose Monitor (CGM).

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. This document uses the optimized framework created in ISO/IEEE 11073-20601:2016 and describes a specific, interoperable communication approach for continuous glucose monitors (CGMs).[1] These standards align with, and draw on, the existing clinically focused standards to provide support for communication of data from clinical or personal health devices (PHDs).

---

[1] Information on references can be found in Clause 2.

Contents

Health informatics—Personal health device communication

Part 10425: Device Specialization—Continuous Glucose Monitor (CGM)

1. Overview

1.1 Scope

This standard establishes a normative definition of communication between personal health continuous glucose monitor (CGM) 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 of communication functionality of CGM devices. In this context, CGM refers to the measurement of the level of glucose in the body on a regular (typically 5 minute) basis through a sensor continuously attached to the person.

1.2 Purpose

This standard addresses a need for an openly defined, independent standard for controlling information exchange to and from personal health devices (PHDs) and compute engines (e.g., cell phones, personal computers, personal health appliances, set top boxes). Interoperability is the key to growing the potential market for these devices and to enabling people to be better informed participants in the management of their health.

1.3 Context

See ISO/IEEE 11073-20601:2016 for an overview of the environment within which this standard is written.[2]

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

---

[2] Information on references can be found in Clause 2.