

Health informatics—Personal health device communication

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

IEEE Engineering in Medicine and Biology Society

Sponsored by the
IEEE 11073™ Standards Committee

Health informatics—Personal health device communication

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

Sponsor

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

Approved 21 August 2014

IEEE-SA Standards Board

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, and 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

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

Copyright © 2014 by The Institute of Electrical and Electronics Engineers, Inc.
All rights reserved. Published 10 October 2014. 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 978-0-7381-9318-2 STD98795
Print: ISBN 978-0-7381-9319-9 STDPD98795

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.

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 Notice” or “Important Notices and Disclaimers Concerning IEEE Standards Documents.”

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. Volunteers 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 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-SA Website at <http://ieeexplore.ieee.org/xpl/standards.jsp> 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 IEEE standard was completed, the Personal Health Devices Working Group had the following membership:

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

Charles R. Abbruscato
Nabil Abujbara
Maher Abuzaid
Manfred Aigner
Jorge Alberola
Karsten Alders
Murtaza Ali
Rolf Ambuehl
David Aparisi
Lawrence Arne
Diego B. Arquillo
Serafin Arroyo
Muhammad Asim
Merat Bagha
Doug Baird
David Baker
Anindya Bakshi
Ananth Balasubramanian
Sunlee Bang
M. Jonathan Barkley
Gilberto Barrón
David Bean
John Bell
Rudy Belliardi
Daniel Bernstein
George A. Bertos
Chris Biernacki
Ola Björnsne
Thomas Blackadar
Marc Blanchet
Thomas Bluethner
Douglas P. Bogia
Xavier Boniface
Shannon Boucousis
Julius Broma
Lyle G. Bullock, Jr.
Bernard Burg
Chris Burns
Anthony Butt
Jeremy Byford-Rew
Satya Calloji
Carole C. Carey
Santiago Carot-Nemesio
Randy W. Carroll
Simon Carter
Seungchul Chae
Rahul Chauhan
James Cheng
Peggy Chien
Chia-Chin Chong

Saeed A. Choudhary
Jinhan Chung
Malcolm Clarke
John A. Cogan
John T. Collins
Cory Condek
Todd H. Cooper
David Cornejo
Douglas Coup
Nigel Cox
Hans Crommenacker
Tomio Crosley
David Culp
Allen Curtis
Ndifor Cyril Fru
Eyal Dassau
David Davenport
Russell Davis
Ed Day
Sushil K. Dekka
Pedro de-las-Heras-Quiros
Jim DelloStitto
Matthew d'Entremont
Lane Desborough
Kent Dicks
Hyoungdo Do
Xiaolian Duan
Brian Dubreuil
Jakob Ehrensvar
Fredrik Einberg
Roger M. Ellingson
Michihiro Enokida
Javier Escayola Calvo
Leonardo Estevez
Roger Feeley
Bosco T. Fernandes
Christoph Fischer
Morten Flintrup
Joseph W. Forler
Russell Foster
Eric Freudenthal
Matthias Frohner
Ken Fuchs
Jing Gao
Marcus Garbe
John Garguilo
Rick Geimer
Igor Gejdos
Ferenc Gerbovics
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
Rickey L. Hampton
Sten Hanke
Jordan Hartmann
Kai Hassing
Marc Daniel Haunschild
Wolfgang Heck
Charles Henderson
Jun-Ho Her
Takashi Hibino
Timothy L. Hirou
Allen Hobbs
Alex Holland
Arto Holopainen
Robert Hoy
Frank Hsu
Anne Huang
Sen-Der Huang
Zhiqiang Huang
Ron Huby
Robert D. Hughes
David Hughes
Jiyoung Huh
Hugh Hunter
Hitoshi Ikeda
Yutaka Ikeda
Philip O. Isaacson
Atsushi Ito
Michael Jaffe
Praduman Jain
Danny Jochelson
Chris Johnson
Phaneeth Junga
Akiyoshi Kabe
Steve Kahle
Tomio Kamioka
Kei Kariya
Andy Kaschl
Junzo Kashiara

Kohichi Kashiwagi
Ralph Kent
Laurie M. Kermes
Ikuo Keshi
Junhyung Kim
Min-Joon Kim
Minho Kim
Taekon Kim
Tetsuya Kimura
Alfred Kloos
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
Yonghee Lee
Joe Lenart
Kathryn A. Lesh
Qiong Li
Ying Li
Patrick Lichter
Jisoon Lim
Joon-Ho Lim
John Lin
Jiajia Liu
Wei-Jung Lo
Charles Lowe
Don Ludolph
Christian Luszick
Bob MacWilliams
Srikanth Madhurbootheswaran
Romain Marmot
Sandra Martinez
Miguel Martínez de Espronceda
Cámara
Peter Mayhew
Jim McCain
László Meleg
Alexander Mense
Ethan Metsger
Yu Miao
Jinsei Miyazaki
Erik Moll
Darr Moore
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
Charles Palmer
Bud Panjwani
Carl Pantiskas
Harry P. Pappas
Mikey Paradis
Hanna Park
Jong-Tae Park
Myungeun Park
Soojun Park
Phillip E. Pash
TongBi Pei
Soren Petersen
James Petisce
Peter Piction
Michael Pliskin
Jeff Price
Harald Prinzhorn
John Quinlan
Arif Rahman
Tanzilur Rahman
Steve Ray
Phillip Raymond
Tim Reilly
Barry Reinhold
Brian Reinhold
Melvin I. Reynolds
John G. Rhoads
Jeffrey S. Robbins
Moskowitz Robert
Timothy Robertson
David Rosales
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
Liqun Shen
Bozhi Shi
Min Shih
Mazen Shihabi
Redmond Shouldice

Sternly K. Simon
Marjorie Skubic
Robert Smith
Ivan Soh
Motoki Sone
Emily Sopenisky
Rajagopalan Srinivasan
Andreas Staubert
Nicholas Steblay
Beth Stephen
Lars Steubesand
John (Ivo) Stivoric
Raymond A. Strickland
Hermann Suominen
Lee Surprenant
Ravi Swami
Ray Sweidan
Jin Tan
Haruyuyki Tatsumi
John W. Thomas
Brad Tipler
Jonas Tirén
James Tomcik
Janet Traub
Jesús Daniel Trigo
Gary Tschautscher
Masato Tsuchid
Ken Tubman
Yoshihiro Uchida
Sunil Unadkat
Fabio Urbani
Philipp Urbauer
Laura Vanzago
Alpo Värri
Ciro de la Vega
Dalimar Velez
Naveen Verma
Rudi Voon
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
Junjie Yang
Ricky Yang
Melanie Yeung
Done-Sik Yoo
Jason Zhang
Zhiqiang Zhang
Thomas Zhao
Miha Zoubek
Szymon Zysko

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

Thomas Blackadar
Lyle G. Bullock, Jr.
Keith Chow
Sourav Dutta
Joseph El Youssef
Christoph Fischer
Hector Barron Gonzalez
Randall Groves
Kai Hassing
Wolfgang Heck

Werner Hoelzl
Noriyuki Ikeuchi
Atsushi Ito
Raj Jain
Piotr Karocki
Robert Kircher
JongMuk Lee
Jie Li
William Lumpkins
Greg Luri

Nick S. A. Nikjoo
Melvin I. Reynolds
Bartien Sayogo
Paul Schluter
Lars Schmitt
Eugene Stoudenmire
Walter Struppler
Jan Wittenber
Oren Yuen
Daidi Zhong

When the IEEE-SA Standards Board approved this standard on 21 August 2014, it had the following membership:

John Kulick, *Chair*
Jon Walter Rosdahl, *Vice Chair*
Richard H. Hulett, *Past Chair*
Konstantinos Karachalios, *Secretary*

Peter Balma
Farooq Bari
Ted Burse
Clint Chaplain
Stephen Dukes
Jean-Phillippe Faure
Gary Hoffman

Michael Janezic
Jeffrey Katz
Joseph L. Koepfinger*
David J. Law
Hung Ling
Oleg Logvinov
T. W. Olsen
Glenn Parsons

Ron Peterson
Adrian Stephens
Peter Sutherland
Yatin Trivedi
Phil Winston
Don Wright
Yu Yuan

*Member Emeritus

Also included are the following nonvoting IEEE-SA Standards Board liaisons:

Richard DeBlasio, *DOE Representative*
Michael Janezic, *NIST Representative*

Don Messina
IEEE-SA Content Publishing

Kathryn Bennett
IEEE-SA Technical Community Programs

Introduction

This introduction is not part of IEEE Std 11073-10425-2014, 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 11073-20601:2010 and describes a specific, interoperable communication approach for continuous glucose monitors (CGMs).^a 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).

^a Information on references can be found in Clause 2.

Contents

1. Overview	1
1.1 Scope	1
1.2 Purpose	1
1.3 Context	2
2. Normative references.....	2
3. Definitions, acronyms, and abbreviations	2
3.1 Definitions	2
3.1 Acronyms and abbreviations	3
4. Introduction to IEEE 11073™ personal health devices.....	4
4.1 General	4
4.2 Introduction to IEEE 11073-20601 modeling constructs.....	4
4.3 Compliance with other standards.....	5
5. Glucose monitoring concepts and modalities	5
5.1 General	5
5.2 Device types	7
5.3 CGM Agent to manager communication.....	7
5.4 Collected data	8
5.5 Stored data	10
6. Continuous glucose monitor domain information model	10
6.1 Overview	10
6.2 Class extensions.....	10
6.3 Object instance diagram	10
6.4 Types of configuration.....	11
6.5 Profiles.....	12
6.6 Medical device system object.....	12
6.7 Numeric objects.....	16
6.8 Real-time sample array objects.....	25
6.9 Enumeration objects	25
6.10 PM-store objects	29
6.11 Scanner objects.....	33
6.12 Class extension objects.....	33
6.13 CGM information model extensibility rules	33
7. Continuous glucose monitor service model.....	34
7.1 General	34
7.2 Object access services.....	34
7.3 Object access event report services	35
8. Continuous glucose monitor communication model	36
8.1 Overview	36
8.2 Communication characteristics.....	36
8.3 Association procedure	37
8.4 Configuring procedure.....	38
8.5 Operating procedure	40
8.6 Time synchronization	40

9. Test associations	40
9.1 Behavior with standard configuration.....	41
9.2 Behavior with extended configurations	41
10. Conformance	41
10.1 Applicability	41
10.2 Conformance specification	41
10.3 Levels of conformance	42
10.4 Implementation conformance statements	42
Annex A (informative) Bibliography	47
Annex B (normative) Any additional ASN.1 definitions	48
Annex C (normative) Allocation of identifiers.....	50
Annex D (informative) Message sequence examples.....	54
Annex E (informative) Protocol data unit examples	56

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

IMPORTANT NOTICE: IEEE Standards documents are not intended to ensure safety, security, health, or environmental protection, or ensure against interference with or from other devices or networks. Implementers 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.

This IEEE document is made available for use subject to important notices and legal disclaimers. These notices and disclaimers appear in all publications containing this document and may be found under the heading “Important Notice” or “Important Notices and Disclaimers Concerning IEEE Documents.” They can also be obtained on request from IEEE or viewed at <http://standards.ieee.org/IPR/disclaimers.html>.

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 (PCs), 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, and 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.