

Health informatics—Personal health device communication

Part 10417: Device Specialization— Glucose Meter

IEEE Engineering in Medicine and Biology Society

Sponsored by the
IEEE 11073™ Standards Committee



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

IEEE Std 11073-10417™-2015
(Revision of
IEEE Std 11073-10417-2011)

This is a Redline Document produced by Techstreet, a business of Thomson Reuters.

This document is intended to provide users with an indication of changes from one edition to the next. It includes a full-text version of the new document, plus an indication of changes from the previous version.

Redlines are designed to save time and improve efficiencies by using the latest software technology to find and highlight document changes. More professionals are using valuable new technologies like redlines, to help improve outcomes in a fastpaced global business world.

Because it may not be technically possible to capture all changes accurately, it is recommended that users consult previous editions as appropriate. In all cases, only the current base version of this publication is to be considered the official document.

Redline Processing Notes:

1. ~~Red Text~~ - Red strikethrough text denotes deletions.
2. Blue Text - Blue underlined text denotes modifications and additions.

Health informatics—Personal health device communication

Part 10417: Device Specialization— Glucose Meter

Sponsor

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

Approved 11 June 2015

IEEE-SA Standards Board

Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, a normative definition of communication between personal telehealth glucose meter devices and compute engines (e.g., cell phones, personal computers, personal health appliances, and set top boxes) is established by this standard in a manner that enables plug-and-play interoperability. Appropriate portions of existing standards are leveraged, including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards. 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 glucose meters is defined in this standard.

Keywords: glucose meter, IEEE 11073-10417™, medical device communication, personal health devices

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

Copyright © 2015 by The Institute of Electrical and Electronics Engineers, Inc. All rights reserved. Published 2 July 2015. 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 9746-3 STD20244
Print: ISBN 978-0-7381-9747-0 STDPD20244

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*
Raymond A. Strickland, *Vice-Chair*
Craig Carlson, *Vice-Chair*

Karsten Aalders
Charles R. Abbruscato
Nabil Abujbara
Maher Abuzaid
James Agnew
Haidar Ahmad
Manfred Aigner
Jorge Alberola
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
David Chiu
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
Eyal Dassau
David Davenport
Russell Davis
Sushil K. Deka
Ciro de la Vega
Pedro de-las-Heras-Quiros
Jim DelloStritto
Matthew d'Entremont
Lane Desborough
Kent Dicks
Hyoungdo Do
Xiaolian Duan
Brian Dubreuil
Sourav Dutta
Jakob Ehrensvar
Fredrik Einberg
Roger M. Ellingson
Michihiro Enokida
Javier Escayola Calvo
Mark Estes
Leonardo Estevez
Roger Feeley
Bosco T. Fernandes
Christoph Fischer
Morten Flintrup
Joseph W. Forler
Russell Foster

Eric Freudenthal
Matthias Frohner
Ndifor Cyril Fru
Ken Fuchs
Jing Gao
Xuemei 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
Nathaniel Hamming
Rickey L. Hampton
Sten Hanke
Jordan Hartmann
Kai Hassing
Marc Daniel Haunschild
Wolfgang Heck
Nathaniel Heintzman
Charles Henderson
Jun-Ho Her
Takashi Hibino
Timothy L. Hirou
Allen Hobbs
Alex Holland
Arto Holopainen
Kris Holtzclaw
Robert Hoy
Frank Hsu
Anne Huang
Sen-Der Huang
Zhiqiang Huang
Ron Huby
David Hughes

Robert D. Hughes
Jiyoung Huh
Hugh Hunter
Hitoshi Ikeda
Yutaka Ikeda
Philip O. Isaacson
Atsushi Ito
Michael Jaffe
Praduman Jain
Wei Jin
Danny Jochelson
Chris Johnson
Phaneeth Junga
Akiyoshi Kabe
Steve Kahle
Tomio Kamioka
Kei Kariya
Andy Kaschl
Junzo Kashiwara
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
Qiong Li
Ying Li
Patrick Lichter
Jisoon Lim
Joon-Ho Lim
John Lin
Wei-Jung Lo
Charles Lowe
Don Ludolph
Christian Luszick
Bob MacWilliams
Srikanth Madhurbotheswaran
Miriam L. Makhoul

Romain Marmot
Sandra Martinez
Miguel Martínez de Espronceda
Cámara
Peter Mayhew
Jim McCain
László Meleg
Alexander Mense
Ethan Metsger
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
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
Lucian Pestritu
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 Sopensky
Rajagopalan Srinivasan
Andreas Stauber
Nicholas Steblay
Beth Stephen
Lars Steubesand
John (Ivo) Stivorc
Raymond A. Strickland
Chandrasekaran Subramaniam
Hermann Suominen
Lee Surprenant
Ravi Swami
Ray Sweidan
Jin Tan
Haruyuyki Tatsumi
John W. Thomas
Jonas Tirén
Alexandra Todiruta
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
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
Yaxi Yan
Ricky Yang
Melanie S. Yeung

Done-Sik Yoo
Jianchao Zeng
Jason Zhang
Zhiqiang Zhang
Thomas Zhao
Miha Zoubek
Szymon Zyskoter

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

John Ballingall
Giberto Barrón
Lyle G. Bullock, Jr.
Keith Chow
Joseph El Youssef
Randall Groves
Kai Hassing
Werner Hoelzl

Noriyuki Ikeuchi
Atsushi Ito
Piotr Karocki
Patrick Keith-Hynes
Patrick Kinney
Robert Kircher
Michael J. Kirwan
Nick S. A. Nikjoo

Henry Pinto
Melvin I. Reynolds
Bartien Sayogo
Lars Schmitt
Raymond A. Strickland
Walter Struppler
Jan Wittenber
Oren Yuen

When the IEEE-SA Standards Board approved this standard on 11 June 2015, it had the following membership:

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

Masayuki Ariyoshi
Ted Burse
Stephen Dukes
Jean-Philippe Faure
J. Travis Griffith
Gary Hoffman
Michael Janezic

Joseph L. Koepfinger*
David J. Law
Hung Ling
Andrew Myles
T. W. Olsen
Glenn Parsons
Ronald C. Petersen
Annette D. Reilly

Stephen J. Shellhammer
Adrian P. Stephens
Yatin Trivedi
Phillip Winston
Don Wright
Yu Yuan
Daidi Zhong

*Member Emeritus

Julie Alessi, *IEEE-SA Content Production and Management*

Kathryn Bennett, *IEEE-SA Operational Program Management*

Introduction

This introduction is not part of IEEE Std 11073-10417™-2015, Health informatics—Personal health device communication—Part 10417: Device Specialization—Glucose Meter.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. This document uses the optimized framework created in IEEE Std 11073-20601-2015^a and describes a specific, interoperable communication approach for glucose meters. 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.

^aFor information on references, see 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
3.2 Acronyms and abbreviations	3
4. Introduction to ISO/IEEE 11073 personal health devices	4
4.1 General	4
4.2 Introduction to IEEE 11073-20601 modeling constructs.....	4
5. Glucose meter device concepts and modalities	5
5.1 General	5
6. Glucose meter domain information model	6
6.1 Overview	6
6.2 Class extensions.....	7
6.3 Object instance diagram	7
6.4 Types of configuration.....	8
6.5 Medical device system object.....	9
6.6 Numeric objects.....	12
6.7 Real-time sample array objects.....	20
6.8 Enumeration objects	20
6.9 PM-store objects.....	25
6.10 Scanner objects	29
6.11 Class extension objects	29
6.12 Glucose meter information model extensibility rules	29
7. Glucose meter service model.....	29
7.1 General	29
7.2 Object access services.....	29
7.3 Object access event report services	30
8. Glucose meter communication model	32
8.1 Overview	32
8.2 Communication characteristics.....	32
8.3 Association procedure	32
8.4 Configuring procedure.....	34
8.5 Operating procedure	38
8.6 Time synchronization	39
9. Test associations	39
9.1 Behavior with standard configuration.....	39
9.2 Behavior with extended configurations	39
10. Conformance	40
10.1 Applicability	40

10.2 Conformance specification	40
10.3 Levels of conformance	40
10.4 Implementation conformance statements	41
Annex A (informative) Bibliography	45
Annex B (normative) Any additional ASN.1 definitions	46
B.1 Device and sensor status bit mapping	46
Annex C (normative) Allocation of identifiers.....	47
C.1 General.....	47
C.2 Definitions of terms and codes.....	47
C.3 Systematic derivations of terms and codes	48
Annex D (informative) Message sequence examples.....	51
Annex E (informative) Protocol data unit examples	53
E.1 General	53
E.2 Association information exchange	53
E.3 Configuration information exchange.....	56
E.4 GET MDS attributes service	59
E.5 Data reporting.....	61
E.6 Disassociation	62

Health informatics—Personal health device communication

Part 10417: Device Specialization— Glucose Meter

IMPORTANT NOTICE: ~~This IEEE Standards~~ is 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 ~~the IEEE Standards~~ documents are responsible for determining and complying with all appropriate safety, security, environmental, health, and interference protection practices ~~or~~ and all applicable laws and regulations ~~requirements.~~

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

Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of communication between personal telehealth glucose meter devices and compute engines (e.g., cell phones, personal computers, personal health appliances, and 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, 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 for personal telehealth glucose meters.

1.2 Purpose

This standard addresses ~~a~~ the need for an openly defined, independent standard ~~for controlling 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 ~~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 IEEE Std 11073-20601^a~~TM-2010~~ 2014¹ for an overview of the environment within which this standard is written.

This standard defines the device specialization for the ~~glucose meter~~ insulin pump, 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 IEEE Std 11073-20601^a~~TM-2010 and ISO/IEEE 11073-20601:2010,2014~~² which in turn draws information from both ISO/IEEE 11073-10201:2004 [B3]³ and ISO/IEEE 11073-20101:2004 [B4]. The medical device encoding rules (MDERs) used within this standard are fully described in ~~ISO/~~Annex F of IEEE Std 11073-20601 ~~2010-2014~~.

¹ Information on references can be found in Clause 2.

² ISO/IEEE publications are available from the ISO Central Secretariat, 1, ch. de la Voie-Creuse, Case postale 56, CH-1211, Geneva 20, Switzerland (<http://www.iso.ch/>). ISO/IEEE publications are also available in the United States from the Institute of Electrical and Electronics Engineers, 445 Hoes Lane, Piscataway, NJ 08854-4141, USA (<http://standards.ieee.org/>).

³ The numbers in brackets correspond to those of the bibliography in Annex A.

This standard reproduces relevant portions of the nomenclature found in ISO/IEEE 11073-10101:2004 [B2] and adds new nomenclature codes for the purposes of this standard. Among this standard ~~ISO/IEEE 11073-20601:2010~~, and IEEE Std 11073-20601-~~2010~~ [2014](#), all required nomenclature codes for implementation are documented.

~~NOTE 1—IEEE Std 11073-20601a-2010 is an amendment to ISO/IEEE 11073-20601:2010. It contains new material and corrections and does not copy the content of ISO/IEEE 11073-20601:2010. Throughout this standard, a reference to IEEE Std 11073-20601a-2010 refers to the document that is obtained after applying this new material and corrections to ISO/IEEE 11073-20601:2010.³~~

NOTE—In this standard, ISO/IEEE 11073-104zz is used to refer to the collection of device specialization standards that utilize IEEE Std 11073-20601 ~~a-2010~~ [2014](#), where zz can be any number from 01 to 99, inclusive.⁴

2. Normative references

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

IEEE Std 11073-20601~~a~~TM-~~2010~~ [2014](#), Health informatics—Personal health device communication—Application

⁴ Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement the 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*:~~Glossary of Terms & Definitions~~ [Online](#) should be consulted for terms not defined in this clause.⁷

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.

~~ISO/IEEE 11073-20601:2010, Health informatics—Personal health device communication Application profile—Optimized Exchange Protocol.~~⁶

⁵ The IEEE standards or products referred to in this clause are trademarks of the Institute of Electrical and Electronics Engineers, Inc.

⁶ IEEE publications are available from the Institute of Electrical and Electronics Engineers, 445 Hoes Lane, Piscataway, NJ 08854-4141, USA (<http://standards.ieee.org/>).

⁷ [IEEE Standards Dictionary Online subscription is available at:](#)
http://www.ieee.org/portal/innovate/products/standard/standards_dictionary.html.

~~⁶ ISO/IEEE publications are available from the ISO Central Secretariat, 1, ch. de la Voie-Creuse, Case postale 56, CH 1211, Geneva 20, Switzerland (<http://www.iso.ch/>). ISO/IEEE publications are also available in the United States from the Institute of Electrical and Electronics Engineers, 445 Hoes Lane, Piscataway, NJ 08854-4141, USA (<http://standards.ieee.org/>).~~

~~⁷ The IEEE Standards Dictionary: Glossary of Terms & Definitions is available at <http://shop.ieee.org/>.~~

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

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

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.](#)

glucose meter: A medical device for determining the approximate concentration of glucose in the blood.

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.

occlusion: [Total obstruction of the infusion set that prevents administering insulin.](#)

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
AST	alternative site testing
DIM	domain information model
EUI-64	extended unique identifier (64 bits)
HbA1c	hemoglobin bound to glucose (the A1c form)
HCP	health care ~~professional~~ provider
ICS	implementation conformance statements
ISF	~~interstitial fluid~~ insulin sensitivity factor
MDC	medical device communication
MDER	medical device encoding rules
MDS	medical device system
MOC	managed object class
OID	object identifier
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 IEEE Std 11073-20601~~a-2010~~ [2014](#) for a description of the guiding principles for this series of ISO/IEEE 11073 Personal Health Device standards.

IEEE Std 11073-20601~~a-2010~~ [2014](#) supports the modeling and implementation of an extensive set of personal health devices. This standard defines aspects of the glucose meter device. It describes all aspects necessary to implement the application layer services and data exchange protocol between an ISO/IEEE 11073 PHD glucose meter agent and a manager. This standard defines a subset of the objects and functionality contained in IEEE Std 11073-20601~~a-2010~~ [2014](#) and ~~it~~ extends and adds definitions where appropriate. All new definitions are given in Annex B in Abstract Syntax Notation One (ASN.1). Nomenclature codes referenced in this standard, which are not defined in IEEE Std 11073-20601~~a-2010~~ [2014](#), 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 IEEE Std 11073-20601~~a-2010~~ [2014](#), 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 IEEE Std 11073-20601~~a-2010~~ [2014](#) 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 ~~the~~ data that an agent can communicate to a manager. Communication between the agent and the manager is defined by the application protocol in [the](#) IEEE Std 11073-20601~~a-2010~~ [2014](#).

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 IEEE Std 11073-20601~~a-2010~~ [2014](#) 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 IEEE Std 11073-20601~~a-2010~~ [2014](#).

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.

5. Glucose meter device concepts and modalities

5.1 General

This clause presents the general concepts of glucose meters. In the context of personal health devices in this family of standards, a glucose meter is a device that measures the concentration of glucose in the blood. Glucose, or the concentration of blood sugar in the blood, is the primary source of energy for the body's cells. The glucose level is tightly regulated in the human body and is normally maintained between approximately 70 mg/dL and 150 mg/dL (4 mmol/L and 8 mmol/L). The total amount of glucose in the circulating blood is, therefore, approximately 3.5 g to 7.5 g (assuming an ordinary adult blood volume of 5 L). Glucose levels rise after meals and are usually lowest in the morning, before the first meal of the day.

In a healthy adult male of 75 kg with a blood volume of 5 L, a blood glucose level of 100 mg/dL (5.5 mmol/L) corresponds to a total of approximately 5 g (1/5 oz and equivalent to a commercial sugar packet) of glucose in the blood and approximately 45 g (1.5 oz) in the total body fluid (which includes blood and interstitial fluid) and on average will be approximately 60% of the total body weight in men.

The failure to maintain blood glucose in the normal range leads to conditions of persistently high (hyperglycemia) or low (hypoglycemia) blood sugar. Diabetes mellitus, which is characterized by persistent hyperglycemia from several causes, is the most prominent disease related to the failure to regulate blood sugar. Fructose and galactose are also sugars found in the blood; however, only glucose levels are regulated via insulin and glucagon.

Countries that use the metric system generally use mmol/L. The United States uses mg/dL. To convert blood glucose readings, utilize the following conversions:

Divide the mg/dL by 18.02 to get mmol/L (or multiply by 0.0555)

Multiply the mmol/L by 18.02 to get mg/dL (or divide by 0.0555)

The glucose meters considered in this specialization are typically handheld instruments that require a sample of blood or body fluid to perform the glucose measurement. The glucose concentration measured by various techniques can be classified into different types defined by three elements: sample type, sample source, and concentration reference method. Table 1 shows all the glucose concentration types defined in this standard.

Table 1—Glucose concentration types

Sample type	Sample source	Reference method
Blood	Capillary	Whole blood
		Plasma
	Venous	Whole blood
		Plasma
	Arterial	Whole blood
		Plasma
	Undetermined	Whole blood
		Plasma
Interstitial fluid	N/A	N/A
Control solution	N/A	N/A
NOTE—The blood glucose concentration may be indirectly derived from an interstitial fluid (ISF) sample, which is a common technique used in continuous glucose monitoring. A control solution is normally used for glucose meter quality control.		

In addition to glucose measurement, glucose meters generally provide a means for the user to associate information on meals, exercise, and medications with a glucose measurement. Advanced devices may also allow users to customize device settings and to provide additional information related to their diabetes treatment and disease management.

Glucose meters are usually small, portable devices that are carried around by the user so that blood glucose measurements may be taken as needed, whether or not the user is in a network environment where communications with a manager can be established. Hence, measurement data are typically logged within the meter and can be retrieved at a later time, either in whole or in part, when the meter is connected to a manager network. There are two typical use cases for the transfer of measurement data to a manager:

- By the user in a non-health-care environment. A user may connect the meter to a personal manager device such as a personal computer or a portable communications device such as a cell phone. In this case, the user would download the most recent logged measurement data from the meter for near-term trend analysis or for transfer of data to an external electronic health network service. The transfer of data would happen immediately on connection with the manager application and require no initiation by the user. This is a temporary storage model of the meter.
- By a health care professional in an office or clinic environment. The health care professional would download all logged measurement data from the meter for longer-term analysis, such as the data logged since the patient's last appointment. The transfer of data would be controlled entirely by the manager application and would not necessarily happen automatically when a connection is established. This is a long-term storage model of the meter.

This standard supports configurations that allow for support of both temporary and long-term storage models.

6. Glucose meter domain information model

6.1 Overview

This clause describes the domain information model of the glucose meter.

6.2 Class extensions

In this standard, no class extensions are defined with respect to IEEE Std 11073-20601~~a-2010~~ [2014](#).

6.3 Object instance diagram

The object instance diagram of the glucose meter domain information model, which is 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 6.11. See 6.5 through 6.11 for descriptions of the different glucose meter objects (e.g., the glucose meter medical device system (MDS) object, the glucose numeric object, and the enumeration object). See 6.12 for rules for extending the glucose meter information model beyond elements as described in this standard. Each clause that describes an object of the glucose meter 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 an 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 IEEE Std 11073-20601~~a-2010~~ [2014](#).
- The methods available on the object.

- The potential events generated by the object. The 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 IEEE Std 11073-20601~~a-2010~~ [2014](#) 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 on an agent.

The attributes can be either static, dynamic, or observational as specified in IEEE Std 11073-20601~~a-2010~~ [2014](#).

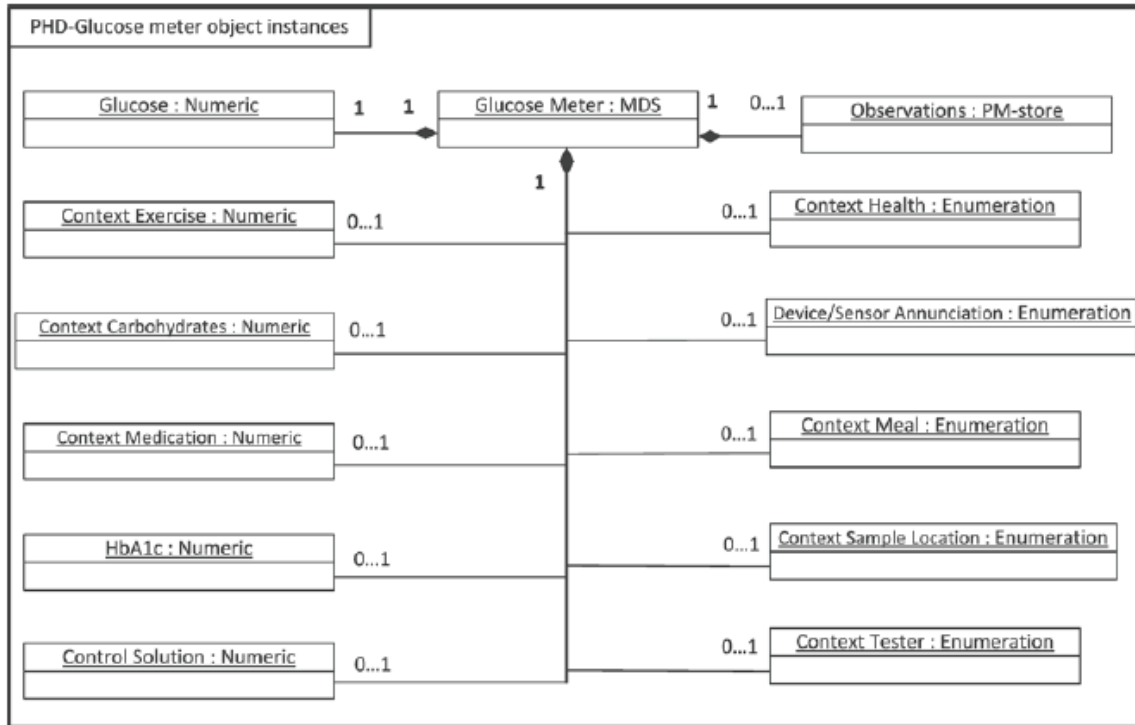


Figure 1—Glucose meter—domain information model

6.4 Types of configuration

6.4.1 General

As specified in IEEE Std 11073-20601a-2010 [2014](#), there are two styles of configuration available. Subclauses 6.4.2 and 6.4.3 briefly introduce standard and extended configurations.

6.4.2 Standard configuration

Standard configurations are defined in the ISO/IEEE 11073-104zz specializations (such as this standard) and are assigned a well-known identifier (Dev-Configuration-Id). The usage of a standard configuration is negotiated at association time between the agent and the manager. If the manager acknowledges that it understands and wants to operate using the configuration, then the agent can begin sending measurements immediately. If the manager does not understand the configuration, the agent provides the configuration prior to transmitting measurement information.

~~Two~~ The standard ~~configurations are defined in this standard. Standard~~ configuration 1700 (0x06A4) ~~contains only a glucose numeric object as defined in 6.6.2~~ is deprecated with the release of this version of the 10417 standard.

Standard configuration 1701 (0x06A5) contains a glucose numeric object and a control solution numeric object as defined in 6.6.7.

A new standard configuration 1702 (0x06A6) is introduced in this version of standard 10417. The new standard configuration contains a glucose numeric object, a control solution object, and a meal context object, and recommends the use of Base-Offset-Time attributes for time reporting.

As defined in 8.3.1 of IEEE Std 11073-20601-2014, if the extended configuration of the specialization implemented by an agent is one that makes use of PM stores and only reports measurements using segment data events and if the standard configuration does not support PM stores, an agent is not required to support the corresponding standard configuration. As defined in 7.4.3.6.1 of 20601, Managers released based on this specification shall support both standard configurations 1701 (0x06A5) and 1702 (0x06A6).

6.4.3 Extended configuration

In extended configurations, the agent's configuration is not predefined in a standard. The agent determines which objects, attributes, and values will be used in a configuration and assigns a configuration identifier. When the agent associates with a manager, it negotiates an acceptable configuration. Typically, the manager does not recognize the agent's configuration on the first connection, so the manager responds that the agent needs to send the configuration information as a configuration event report. If, however, the manager already understands the configuration, either because it was preloaded in some way or the agent had previously associated with the manager, then the manager responds that the configuration is known and no further configuration information needs to be sent.

6.5 Medical device system object

6.5.1 MDS object attributes

Table 2 summarizes the attributes of the glucose meter MDS object. The nomenclature code to identify the MDS object class is MDC_MOC_VMS_MDS_SIMP.

Table 2—MDS object attributes

Attribute name	Value	Qualifier
Handle	0	M
System-Type	Attribute not present. See IEEE Std 11073-20601-2014.	C
System-Type-Spec-List	{MDC_DEV_SPEC_PROFILE_GLUCOSE, 2}	M
System-Model	{"Manufacturer", "Model"}	M
System-Id	Extended unique identifier (64 bits) (EUI-64)	M
Dev-Configuration-Id	Extended configs: 0x4000–0x7FFF Standard config: 0x06A6 (1702) Standard config: 0x06A5 (1701)	M
Attribute-Value-Map	See IEEE Std 11073-20601-2014.	C
Production-Specification	See IEEE Std 11073-20601-2014.	O
Mds-Time-Info	See IEEE Std 11073-20601-2014.	C
Date-and-Time	See IEEE Std 11073-20601-2014.	C
Base-Offset-Time	See IEEE Std 11073-20601-2014.	R
Relative-Time	See IEEE Std 11073-20601-2014.	C
HiRes-Relative-Time	See IEEE Std 11073-20601-2014.	C
Date-and-Time-Adjustment	See IEEE Std 11073-20601-2014.	C
Power-Status	<i>onBattery or onMains</i>	O
Battery-Level	See IEEE Std 11073-20601-2014.	O
Remaining-Battery-Time	See IEEE Std 11073-20601-2014.	O
Reg-Cert-Data-List	See IEEE Std 11073-20601-2014.	O
Confirm-Timeout	See IEEE Std 11073-20601-2014.	O
NOTE—See IEEE Std 11073-20601-2014 for information on whether an attribute is static or dynamic.		

(New)

Attribute name	Value	Qual.
Handle	0	M
System-Type	Attribute not present. See IEEE Std 11073-20601a-2010.	C
System-Type-Spec-List	{MDC_DEV_SPEC_PROFILE_GLUCOSE, 2}.	M
System-Model	{"Manufacturer", "Model"}	M
System-Id	Extended unique identifier (64 bits) (EUI-64)	M
Dev-Configuration-Id	Standard config: 0x06A4 (1700) Standard config: 0x06A5 (1701) Extended configs: 0x4000–0x7FFF	M
Attribute-Value-Map	See IEEE Std 11073-20601a-2010.	C
Production-Specification	See IEEE Std 11073-20601a-2010.	O
Mds-Time-Info	See IEEE Std 11073-20601a-2010.	C
Date-and-Time	See IEEE Std 11073-20601a-2010.	C
Relative-Time	See IEEE Std 11073-20601a-2010.	C
HiRes-Relative-Time	See IEEE Std 11073-20601a-2010.	C
Date-and-Time-Adjustment	See IEEE Std 11073-20601a-2010.	C
Power-Status	<i>onBattery or onMains</i>	O
Battery-Level	See IEEE Std 11073-20601a-2010.	O
Remaining-Battery-Time	See IEEE Std 11073-20601a-2010.	O
Reg-Cert-Data-List	See IEEE Std 11073-20601a-2010.	O
Confirm-Timeout	See IEEE Std 11073-20601a-2010.	O

(Deleted)

~~NOTE—See IEEE Std 11073-20601a-2010 for information on whether an attribute is static or dynamic.~~

In the response to a Get MDS object command, only implemented attributes and their corresponding values are returned.

See IEEE Std 11073-20601a-2010 [2014](#) for descriptive explanations of the individual attributes as well as for information on attribute ID and attribute type.

The Dev-Configuration-Id attribute holds a locally unique 16-bit identifier that identifies the device configuration instance. [The Device Configuration Identifiers for standard configurations are listed in Table 2.](#) For a glucose meter agent with extended configuration, this identifier is chosen in the range of extended-config-start to extended-config-end (see IEEE Std 11073-20601a-2010 [2014](#)) as shown in Table 2.

The agent sends the Dev-Configuration-Id during the Associating state (see 8.3) to identify its configuration for the duration of the association. If the manager already holds the configuration information relating to the Dev-Configuration-Id, it recognizes the Dev-Configuration-Id. Then the Configuring state (8.4) is skipped, and the agent and manager enter the Operating state. If the manager does not recognize the Dev-Configuration-Id, the agent and manager enter the Configuring state.

If an agent implements multiple IEEE 11073-104zz specializations, System-Type-Spec-List is a list of type/version pairs, each referencing the respective device specialization and version of that specialization.

6.5.2 MDS object methods

Table 3 defines the methods (actions) of the glucose meter agent's MDS object. These methods are invoked using the Action service. In Table 3, the Subservice type name column defines the name of the method; the Mode column defines whether the method is invoked as an unconfirmed action (i.e., roiv-cmip-action from IEEE Std 11073-20601a-2010 [2014](#)) or a confirmed action (i.e., roiv-cmip-confirmed-action); the Subservice type (action-type) column defines the nomenclature code to use in the action-type field of an action request and response (see IEEE Std 11073-20601a-2010 [2014](#)); the Parameters (action-info-args) column defines the associated ASN.1 data structure (see IEEE Std 11073-20601a-2010 [2014](#) for ASN.1 definitions) to use in the action message for the action-info-args field of the request; and the Results (action-info-args) column defines the structure to use in the action-info-args of the response.

Table 3—MDS object methods

Service	Subservice type name	Mode	Subservice type (action-type)	Parameters (action-info-args)	Results (action-info-args)
ACTION	Set-Time	Confirmed	MDC_ACT_SET_TIME	SetTimeInvoke	—
ACTION	Set-Base-Offset-Time	Confirmed	MDC_ACT_SET_BO_TIME	SetBOTimeInvoke	—

— Set-Time

This method allows the manager to set a real-time clock in the agent with the absolute time. The agent indicates whether the Set-Time command is valid using the mds-time-capab-set-clock bit in the Mds-Time-Info attribute (see IEEE Std 11073-20601a-2010 [2014](#)).

— Set-Base-Offset-Time

This method allows the manager to set a real-time clock in the agent with the base time and offset. The agent indicates whether the Set-Base-Offset-Time command is valid using the mds-time-capab-set-clock bit in the Mds-Time-Info attribute (see IEEE Std 11073-20601-2014).

If the agent supports the Base-Offset-Time-Stamp attribute, this method shall be implemented.

Agents following only this device specialization and no others shall send event reports using agent-initiated measurement data transmission. Agents following this device specialization as well as others shall send event reports in the appropriate fashion. During the association procedure (see 8.3), data-req-mode-capab shall be set to the appropriate value for the event report style. As a result, the manager shall assume the glucose meter agent does not support any of the MDS-Data-Request features (see IEEE Std 11073-20601~~a-2010~~ [2014](#) for additional information). Thus, implementation of the MDS-Data-Request method/action is not required in this standard and is not shown in Table 3.

6.5.3 MDS object events

Table 4 defines the events that can be sent by the glucose meter MDS object.

Table 4—Glucose meter MDS object events

Service	Subservice type name	Mode	Subservice type (event-type)	Parameters (event-info)	Results (event-reply-info)
EVENT REPORT	MDS-Configuration-Event	Confirmed	MDC_NOTI_CONFIG	ConfigReport	ConfigReport Rsp
	MDS-Dynamic-Data-Update-Fixed	Confirmed	MDC_NOTI_SCAN_REPORT_FIXED	ScanReportInfoFixed	—
	MDS-Dynamic-Data-Update-Var	Confirmed	MDC_NOTI_SCAN_REPORT_VAR	ScanReportInfoVar	—
	MDS-Dynamic-Data-Update-MP-Fixed	Confirmed	MDC_NOTI_SCAN_REPORT_MP_FIXED	ScanReportInfoMP Fixed	—
	MDS-Dynamic-Data-Update-MP-Var	Confirmed	MDC_NOTI_SCAN_REPORT_MP_VAR	ScanReportInfoMP Var	—

— MDS-Configuration-Event

This event is sent by the glucose meter agent during the configuring procedure if the manager does not already know the glucose meter agent's configuration from past associations or because the manager has not been implemented to recognize the configuration according to the glucose meter device specialization. The event provides static information about the supported measurement capabilities of the glucose meter agent.

— MDS-Dynamic-Data-Update-Var

This event provides dynamic measurement data from the glucose meter agent for the glucose numeric object. These data are reported using a generic attribute list variable format. The event is sent as an unsolicited message by the agent (i.e., an agent-initiated measurement data transmission). See 8.5.3 for more information on unsolicited event reporting.

— MDS-Dynamic-Data-Update-Fixed

This event provides dynamic measurement data from the glucose meter agent for the glucose numeric object. These data are reported in the fixed format defined by the Attribute-Value-Map attribute of the object(s). The event is sent as an unsolicited message by the agent (i.e., an agent-initiated measurement data transmission). See 8.5.3 for more information on unsolicited event reporting.

— MDS-Dynamic-Data-Update-MP-Var

This is the same as MDS-Dynamic-Data-Update-Var but allows inclusion of data from multiple people.

— MDS-Dynamic-Data-Update-MP-Fixed

This is the same as MDS-Dynamic-Data-Update-Fixed but allows inclusion of data from multiple people.

NOTE—IEEE Std 11073-20601~~a-2010~~ [2014](#) requires that managers support all of the MDS object events listed ~~above~~ [Table 4](#).

6.5.4 Other MDS services

6.5.4.1 GET service

A glucose meter agent shall support the GET service, which is provided by the MDS object to retrieve the values of all implemented MDS object attributes. The GET service can be invoked as soon as the glucose meter agent receives the Association Response and moves to the Associated state, including the Operating and Configuring substates.

The manager may request the MDS object attributes of the glucose meter agent; in which case, the manager shall send the “Remote Operation Invoke | Get” message (see roiv-cmip-get in IEEE Std 11073-20601~~a-2010~~ [2014](#)) with the reserved MDS handle value of 0. The glucose meter agent shall report its MDS object attributes to the manager using the “Remote Operation Response | Get” message (see rors-cmip-get in IEEE Std 11073-20601~~a-2010~~ [2014](#)). See Table 5 for a summary of the GET service including some message fields.

Table 5 — Glucose meter MDS object GET service

Service	Remark	Field	Value	Qualifier
roiv-cmip-get	Manager GET service request of agents MDS attributes.	obj-handle	0	M
		attribute-id-list	Dynamic	O
rors-cmip-get	Agent GET service response to GET service request by manager.	obj-handle	0	M
		attribute-list	Dynamic	M

See 8.5.2 for details on the procedure for getting the MDS object attributes.

6.5.4.2 SET service

The glucose meter specialization does not require an implementation to support the MDS object SET service.

6.6 Numeric objects

6.6.1 General

The glucose meter DIM (see Figure 1) contains numeric objects that represent aspects of blood glucose and associated medical context. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU. Table 6 shows attributes that are common to all the numeric types of the glucose meter agent.

Table 6—Common glucose numeric object attributes

Attribute name	Extended configuration	
	Value	Qualifier
Handle	See IEEE Std 11073-20601-2014.	M
Type	Defined in each table below.	M
Supplemental-Types	See IEEE Std 11073-20601-2014.	NR
Metric-Spec-Small	mss-avail-intermittent mss-avail-stored-data mss-upd-aperiodic mss-msmt-aperiodic mss-acc-agent-initiated mss-cat-manual	M
Metric-Structure-Small	See IEEE Std 11073-20601-2014.	NR
Measurement-Status	See IEEE Std 11073-20601-2014.	NR
Metric-Id	See IEEE Std 11073-20601-2014.	C
Metric-Id-List	See IEEE Std 11073-20601-2014.	NR
Metric-Id-Partition	See IEEE Std 11073-20601-2014.	NR
Unit-Code	See IEEE Std 11073-20601-2014.	M
Attribute-Value-Map	See IEEE Std 11073-20601-2014.	C
Source-Handle-Reference	See IEEE Std 11073-20601-2014.	NR
Label-String	See IEEE Std 11073-20601-2014.	O
Unit-LabelString	See IEEE Std 11073-20601-2014.	O
Absolute-Time-Stamp	See IEEE Std 11073-20601-2014.	C
Base-Offset-Time-Stamp	See IEEE Std 11073-20601-2014.	R
Relative-Time-Stamp	See IEEE Std 11073-20601-2014.	O
HiRes-Time-Stamp	See IEEE Std 11073-20601-2014.	C
Measure-Active-Period	See IEEE Std 11073-20601-2014.	C
Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	C
Compound-Simple-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	C
Compound-Basic-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Compound-Nu-Observed-Value	See IEEE Std 11073-20601-2014.	NR
Accuracy	See IEEE Std 11073-20601-2014.	R

(New)

Attribute name	Extended configuration	
	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M
Type	Defined in each table below.	M
Supplemental-Types	See IEEE Std 11073-20601a-2010.	NR
Metric-Spec-Small	mss-avail-intermittent mss-avail-stored-data mss-upd-aperiodic mss-msmt-aperiodic mss-acc-agent-initiated mss-cat-manual	M
Metric-Structure-Small	See IEEE Std 11073-20601a-2010.	NR
Measurement-Status	See IEEE Std 11073-20601a-2010.	NR
Metric-Id	See IEEE Std 11073-20601a-2010.	C
Metric-Id-List	See IEEE Std 11073-20601a-2010.	NR
Metric-Id-Partition	See IEEE Std 11073-20601a-2010.	NR
Unit-Code	See IEEE Std 11073-20601a-2010.	M
Attribute-Value-Map	See IEEE Std 11073-20601a-2010.	C
Source-Handle-Reference	See IEEE Std 11073-20601a-2010.	NR
Label-String	See IEEE Std 11073-20601a-2010.	O
Unit-LabelString	See IEEE Std 11073-20601a-2010.	O
Absolute-Time-Stamp	See IEEE Std 11073-20601a-2010.	R
Relative-Time-Stamp	See IEEE Std 11073-20601a-2010.	O
HiRes-Time-Stamp	See IEEE Std 11073-20601a-2010.	C
Measure-Active-Period	See IEEE Std 11073-20601a-2010.	C
Simple-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	C
Compound-Simple-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	NR
Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	C
Compound-Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	NR
Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	NR
Compound-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	NR
Accuracy	See IEEE Std 11073-20601a-2010.	R

(Deleted)

Subclauses 6.6.2 through 6.6.6 describe the numeric objects that are defined for use in the glucose meter. Each object represents a specific aspect of blood glucose measurement or an associated medical context. The class is denoted by the Type attribute. The description of each numeric object defines the data or events it produces, the possible states, and where appropriate, its behavior. The respective tables define the numeric values generated by the agent in response to a change in state.

Sometimes, the interpretation of one attribute value in an object depends on other attribute values in the same object. For example, Unit-Code and Unit-LabelString provide context for the observed values. Whenever a contextual attribute changes, the agent shall report these changes to the manager using an MDS object event (see 6.5.3) prior to reporting any of the dependent values.

The numeric object does not support any methods, events, or other services.

For standard configurations, the optional attributes are initially not present. See IEEE Std 11073-20601a-2010 [2014](#) for descriptive explanations on the individual attributes as well as for information on attribute ID and attribute type.

6.6.2 Blood glucose

Table 7 summarizes the attributes of the blood glucose numeric object. The blood glucose numeric object shall be supported by a glucose meter agent.

Table 7—Blood glucose numeric object attributes

Attribute name	Extended configuration		Standard configuration (Dev-Configuration-Id = 0x06A5)		Standard configuration (Dev-Configuration-Id = 0x06A6)	
	Value	Qualifier	Values	Qualifier	Values	Qualifier
Handle	See IEEE Std 11073-20601-2014 {MDC_PART_SCADA, MDC_CONC_GLU_CAPILLARY_ WHOLEBLOOD or MDC_CONC_GLU_CAPILLARY_ PLASMA or MDC_CONC_GLU_VENOUS_ WHOLEBLOOD or MDC_CONC_GLU_VENOUS_PLASM A or MDC_CONC_GLU_ARTERIAL_WHO LEBLOOD or MDC_CONC_GLU_ARTERIAL_ PLASMA or MDC_CONC_GLU_UNDETERMINED WHOLEBLOOD or MDC_CONC_GLU_UNDETERMINED PLASMA or MDC_CONC_GLU_ISF}	M		M		M
Type			{MDC_PART_SCADA, MDC_CONC_GLU_ UNDETERMINED_ PLASMA}	M	{MDC_PART_SCADA, MDC_CONC_GLU_ UNDETERMINED_ PLASMA}	M
Metric-Spec- Small	mss-avail-intermittent mss-avail-stored- data mss-upd-aperiodic mss-msmt- aperiodic mss-acc-agent-initiated. The mss-cat-manual shall only be set if the reading is manually entered.	M	mss-avail-intermittent mss-avail- stored-data mss-upd-aperiodic mss- msmt-aperiodic mss-acc-agent- initiated	M	mss-avail-intermittent mss-avail-stored- data mss-upd-aperiodic mss-msmt-aperiodic mss-acc-agent- initiated	M
Unit-Code	MDC_DIM_MILLI_G_PER_DL or MDC_DIM_MILLI_MOLE_PERL	M	MDC_DIM_MILLI_G_PER_DL	M	MDC_DIM_MILLI_G_PER_DL	M
Attribute- Value-Map	See IEEE Std 11073-20601-2014.	C	MDC_ATTR_NU_VAL_OBS_BASIC, then MDC_ATTR_TIME_STAMP_ABS	M	MDC_ATTR_NU_VAL_OBS_BASIC, then MDC_ATTR_TIME_STAMP_BO	M
Absolute- Time-Stamp	See IEEE Std 11073-20601-2014.	C	If fixed format is used and the standard configuration is not adjusted, this attribute is mandatory; otherwise, the conditions from IEEE Std 11073- 20601-2014 apply.	C	If fixed format is used and the standard configuration is not adjusted, this attribute is mandatory; otherwise, the conditions from IEEE Std 11073-20601-2014 apply.	C

(New)