

First edition

2016-06-15

Corrected version

2018-03

Health informatics — Personal health device communication —

Part 10419:

Device specialization — Insulin pump

*Informatique de santé — Communication entre dispositifs de santé
personnels —*

Partie 10419: Spécialisation du dispositif — Pompe à insuline



Reference number
ISO/IEEE 11073-10419:2016(E)



COPYRIGHT PROTECTED DOCUMENT

© IEEE 2015

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO or IEEE at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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

stds.ipr@ieee.org
www.ieee.org

This is a preview of "ISO/IEEE 11073-10419...". [Click here to purchase the full version from the ANSI store.](#)

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.

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.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is called to the possibility that implementation of this standard may require the use of subject matter covered by patent rights. By publication of this standard, no position is taken with respect to the existence or validity of any patent rights in connection therewith. ISO/IEEE is not responsible for identifying essential patents or patent claims for which a license may be required, for conducting inquiries into the legal validity or scope of patents or patent claims or determining whether any licensing terms or conditions provided in connection with submission of a Letter of Assurance or a Patent Statement and Licensing Declaration Form, 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 ISO or the IEEE Standards Association.

ISO/IEEE 11073-10419 was prepared by the IEEE 11073 Standards Committee of the IEEE Engineering in Medicine and Biology Society (as IEEE Std 11073-10419-2015). It was adopted by Technical Committee ISO/TC 215, *Health informatics*, in parallel with its approval by the ISO member bodies, under the "fast-track procedure" defined in the Partner Standards Development Organization cooperation agreement between ISO and IEEE. IEEE is responsible for the maintenance of this document with participation and input from ISO member bodies.

This corrected version of ISO/IEEE 11073-10419:2016 incorporates the following corrections:

- corrected footers and formatting.

ISO/IEEE 11073 consists of the following parts, under the general title *Health informatics* — *Personal health device communication* (text in parentheses gives a variant of subtitle):

- *Part 10101: (Point-of-care medical device communication) Nomenclature*

- *Part 10102: (Point-of-care medical device communication) Nomenclature: Annotated ECG*

cardiac

- *Part 10201: (Point-of-care medical device communication) Domain information model*
- *Part 10404: Device specialization — Pulse oximeter*
- *Part 10406: Device specialization — Basic electrocardiograph (ECG) (1- to 3-lead ECG)*
- *Part 10407: Device specialization — Blood pressure monitor*
- *Part 10408: Device specialization — Thermometer*
- *Part 10415: Device specialization — Weighing scale*
- *Part 10417: Device specialization — Glucose meter*
- *Part 10418: Device specialization — International Normalized Ratio (INR) monitor*
- *Part 10420: Device specialization — Body composition analyzer*
- *Part 10421: Device specialization — Peak expiratory flow monitor (peak flow)*
- *Part 10471: Device specialization — Independant living activity hub*
- *Part 10472: Device specialization — Medication monitor*
- *Part 20101: (Point-of-care medical device communication) Application profiles — Base standard — Part 20601: Application profile — Optimized exchange protocol*
- *Part 30200: (Point-of-care medical device communication) Transport profile — Cable connected — Part 30300: (Point-of-care medical device communication) Transport profile — Infrared wireless — Part 30400: (Point-of-care medical device communication) Interface profile — Cabled Ethernet — Part 90101: (Point-of-care medical device communication) Analytical instruments — Point-of-care test — Part 91064: (Standard communication protocol) Computer-assisted electrocardiography*
- *Part 92001: (Medical waveform format) — Encoding rules [Technical Specification]*

This is a preview of "ISO/IEEE 11073-10419...". Click [here](#) to purchase the full version from the ANSI store.

Health informatics—Personal health device communication

Part 10419: Device Specialization— Insulin Pump

Sponsor

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

Approved 16 February 2015

IEEE-SA Standards Board

This is a preview of "ISO/IEEE 11073-10419...". Click here to purchase the full version from the ANSI store.

Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, a normative definition of communication between personal telehealth insulin pump devices and compute engines (e.g., cell phones, personal computers, personal health appliances, set top boxes) in a manner that enables plug-and-play interoperability, is established in this standard. Appropriate portions of existing standards including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards are leveraged. The use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability are specified. A common core of communication functionality for personal telehealth insulin pump devices is defined.

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

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

Copyright © 2015 by The Institute of Electrical and Electronics Engineers, Inc.
All rights reserved. Published 10 April 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 978-0-7381-9610-7 STD20158
Print: ISBN 978-0-7381-9611-4 STDPD20158

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*
Melanie S. Yeung, *Vice-Chair*

Karsten Aalders	Saeed A. Choudhary	Nicolae Goga
Charles R. Abbruscato	Jinhan Chung	Julian Goldman
Nabil Abujbara	Malcolm Clarke	Raul Gonzalez Gomez
Maher Abuzaid	John A. Cogan	Chris Gough
Manfred Aigner	John T. Collins	Channa Gowda
Jorge Alberola	Cory Condek	Charles M. Gropper
Murtaza Ali	Todd H. Cooper	Amit Gupta
Rolf Ambuehl	David Cornejo	Jeff Guttmacher
David Aparisi	Douglas Coup	Rasmus Haahr
Lawrence Arne	Nigel Cox	Christian Habermann
Diego B. Arquilo	Hans Crommenacker	Michael Hagerty
Serafin Arroyo	Tomio Crosley	Jerry Hahn
Muhammad Asim	David Culp	Robert Hall
Merat Bagha	Allen Curtis	Nathaniel Hamming
Doug Baird	Ndifor Cyril Fru	Rickey L. Hampton
David Baker	Jesús Daniel Trigo	Sten Hanke
Anindya Bakshi	Eyal Dassau	Jordan Hartmann
Ananth Balasubramanian	David Davenport	Kai Hassing
Sunlee Bang	Russell Davis	Marc Daniel Haunschild
M. Jonathan Barkley	Ed Day	Wolfgang Heck
Gilberto Barrón	Sushil K. Deka	Charles Henderson
David Bean	Ciro de la Vega	Jun-Ho Her
John Bell	Pedro de-las-Heras-Quiros	Takashi Hibino
Rudy Belliardi	Jim DelloStritto	Timothy L. Hirou
Kathryn M. Bennett	Matthew d'Entremont	Allen Hobbs
Daniel Bernstein	Lane Desborough	Alex Holland
George A. Bertos	Kent Dicks	Arto Holopainen
Chris Biernacki	Hyoungdo Do	Robert Hoy
Ola Björnsne	Xiaolian Duan	Frank Hsu
Thomas Blackadar	Brian Dubreuil	Anne Huang
Marc Blanchet	Jakob Ehrensvar	Sen-Der Huang
Thomas Bluethner	Fredrik Einberg	Zhiqiang Huang
Douglas P. Borgia	Roger M. Ellingson	Ron Huby
Xavier Boniface	Michihiro Enokida	David Hughes
Shannon Boucousis	Javier Escayola Calvo	Robert D. Hughes
Julius Broma	Leonardo Estevez	Jiyoung Huh
Lyle G. Bullock, Jr.	Roger Feeley	Hugh Hunter
Bernard Burg	Bosco T. Fernandes	Hitoshi Ikeda
Chris Burns	Christoph Fischer	Yutaka Ikeda
Anthony Butt	Morten Flintrup	Philip O. Isaacson
Jeremy Byford-Rew	Joseph W. Forler	Atsushi Ito
Satya Calloji	Russell Foster	Michael Jaffe
Carole C. Carey	Eric Freudenthal	Praduman Jain
Santiago Carot-Nemesio	Matthias Frohner	Danny Jochelson
Randy W. Carroll	Ken Fuchs	Chris Johnson
Simon Carter	Jing Gao	Phaneeth Junga
Seungchul Chae	Marcus Garbe	Akiyoshi Kabe
Rahul Chauhan	John Garguilo	Steve Kahle
James Cheng	Rick Geimer	Tomio Kamioka
Peggy Chien	Igor Gejdos	Kei Kariya
Chia-Chin Chong	Ferenc Gerbovics	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
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 Saueremann
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 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
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
Junjie Yang
Ricky Yang
Melanie S. Yeung
Done-Sik Yoo
Jason Zhang
Zhiqiang Zhang
Thomas Zhao
Daidi Zhong
Miha Zoubek
Szymon Zysko

This is a preview of "ISO/IEEE 11073-10419...". Click here to purchase the full version from the ANSI store.

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 16 February 2015, 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-Philippe Faure
Gary Hoffman

Michael Janezic
Jeffrey Katz
Joseph L. Koepfinger*
David 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 non-voting IEEE-SA Standards Board liaisons:

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

Don Messina
IEEE-SA Content Production and Management

Kathryn Bennett
IEEE-SA Technical Program Operations

Introduction

This introduction is not part of IEEE Std 11073-10419-2015, Health informatics—Personal health device communication—Part 10419: Device Specialization—Insulin Pump.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. This document uses the optimized framework created in ISO/IEEE 11073-20601:2010¹ and describes a specific, interoperable communication approach for insulin pumps. These standards align with and draw on the existing clinically focused standards to provide support for communication of data from clinical or personal health devices.

¹For information on references, see Clause 2.

Contents

1. Overview	1
1.1 Scope	1
1.2 Purpose	2
1.3 Context	2
2. Normative references.....	2
3. Definitions, acronyms, and abbreviations	3
3.1 Definitions	3
3.2 Acronyms and abbreviations	4
4. Introduction to ISO/IEEE 11073 personal health devices	5
4.1 General	5
4.2 Introduction to ISO/IEEE 11073-20601 modeling constructs	6
4.3 Compliance with other standards.....	6
5. Insulin pump device concepts and modalities	7
5.1 General	7
5.2 Device types	8
5.3 Collected data	8
5.4 Stored data.....	14
5.5 Scheduled data.....	15
6. Insulin pump domain information model	15
6.1 Overview	15
6.2 Class extensions.....	15
6.3 Object instance diagram	15
6.4 Types of configuration.....	17
6.5 Profiles.....	18
6.6 Medical device system object.....	18
6.7 Numeric objects.....	21
6.8 Real-time sample array objects.....	35
6.9 Enumeration objects	36
6.10 PM-store objects	41
6.11 Schedule-store objects	46
6.12 Scanner objects	55
6.13 Class extension objects	55
6.14 Insulin pump information model extensibility rules	56
7. Insulin pump service model.....	56
7.1 General	56
7.2 Object access services.....	56
7.3 Object access event report services	58
8. Insulin pump communication model	59
8.1 Overview	59
8.2 Communications characteristics	59
8.3 Association procedure	60
8.4 Configuring procedure.....	61
8.5 Operating procedure	63
8.6 Time synchronization	64

9. Test associations	64
9.1 Behavior with standard configuration.....	64
9.2 Behavior with extended configurations	64
10. Conformance	64
10.1 Applicability	64
10.2 Conformance specification	65
10.3 Levels of conformance	65
10.4 Implementation conformance statements	66
Annex A (informative) Bibliography	71
Annex B (normative) Any additional ASN.1 definitions	72
B.1 Device status and insulin pump status bit mapping	72
Annex C (normative) Allocation of identifiers.....	74
C.1 General.....	74
C.2 Definitions of terms and codes.....	74
C.3 Systematic derivations of terms and codes	76
Annex D (informative) Message sequence examples.....	85
Annex E (normative) Schedule-store class.....	87
E.1 Schedule-store class	87
E.2 Schedule-segment class.....	91
Annex F (normative) Schedule class ASN.1 definitions	97
F.1 ACTION-method-related data types	97
F.2 Data types for new object attributes and object services	97
F.3 Data protocol definitions	100
Annex G (informative) The schedule-store concept.....	102
G.1 General.....	102
G.2 Schedule-store object hierarchy	103
Annex H (informative) Scedule communication model.....	107
H.1 Operating procedure	107
Annex I (informative) Protocol data unit examples.....	112
I.1 General	112
I.2 Association information exchange	112
I.3 Configuration information exchange.....	116
I.4 GET MDS attributes service	120
I.5 Data reporting.....	121
I.6 Disassociation.....	122