INTERNATIONAL STANDARD

ISO/IEEE 11073-10419

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO/IEEE 11073-10419:2016
https://standards.iteh.ai/catalog/standards/sist/9d803bdc-613b-4382-bc74-d3cafe4069c9/iso-ieee-11073-10419-2016

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

© IEEE 2015

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO/IEEE 11073-10419:2016
https://standards.iteh.ai/catalog/standards/sist/9d803bdc-613b-4382-bc74-d3cafe4069c9/iso-ieee-11073-10419-2016

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

© IEEE 2015 – All rights reserved

Foreword

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

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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 11073-10419:2016
https://standards.iteh.ai/catalog/standards/sist/0d803bdc-613b-4382-bc74-d3cafe4069c9/iso-ieee-11073-10419-2016

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*

© IEEE 2015 – All rights reserved

— *Part 10103: (Point-of-care medical device communication) Nomenclature: Implantable device, 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*

iTeh STANDARD PREVIEW
(standards.iteh.ai)

— *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*

ISO/IEEE 11073-10419:2016
https://standards.iteh.ai/catalog/standards/sist/9d803bdc-613b-4382-bc74-d3cafe4069c9/iso-ieee-11073-10419-2016

— *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]

© IEEE 2015 – All rights reserved

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Approved 16 February 2015

IEEE-SA Standards Board

ISO/IEEE 11073-10419:2016
https://standards.iteh.ai/catalog/standards/sist/9d803bdc-613b-4382-bc74-d3cafe4069c9/iso-ieee-11073-10419-2016

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO/IEEE 11073-10419:2016
https://standards.iteh.ai/catalog/standards/sist/9d803bdc-613b-4382-bc74-d3cafe4069c9/iso-ieee-11073-10419-2016

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.

Copyright © 2015 IEEE. All rights reserved.

© IEEE 2015 – All rights reserved

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.”

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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.

ISO/IEEE 11073-10419:2016
https://standards.iteh.ai/catalog/standards/sist/8d8f3b1c-0b3b-4383-bed4-13e0b0f8c85e/iso-ieee-11073-10419-2016

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.

Copyright © 2015 IEEE. All rights reserved.

© IEEE 2015 – All rights reserved

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:

iTeh STANDARD PREVIEW

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

(standards.iteh.ai)

Laws and regulations

ISO/IEEE 11073-10419:2016
https://standards.iteh.ai/catalog/standards/sist/9d803bdc-613b-4382-bc74-d3cafe4069c9/iso-ieee-11073-10419-2016

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.

Copyright © 2015 IEEE. All rights reserved.

© IEEE 2015 – All rights reserved

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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.

ISO/IEEE 11073-10419:2016
https://standards.iteh.ai/catalog/standards/sist/9cf803bdc-613b-4382-bc74-d3cafa4069c9/iso-ieee-11073-10419-2016

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.

Copyright © 2015 IEEE. All rights reserved.

© IEEE 2015 – All rights reserved

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
Charles R. Abbruscato
Nabil Abujbara
Maher Abuzaid
Manfred Aigner
Jorge Alberola
Murtaza Ali
Rolf Ambuehl
David Aparisi
Lawrence Arne
Diego B. Arquilo
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
Kathryn M. Bennett
Daniel Bernstein
George A. Bertos
Chris Biernacki
Ola Björsne
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
Jesús Daniel Trigo
Eyal Dassau
David Davenport
Russell Davis
Ed Day
Sushil K. Deka
Ciro de la Vega
Pedro de-las-Heras-Quiros
Jim DelloStritto
Matthew d'Entremont
Lane Desborough
Kent Dicks
Hyoungho Do
Xiaolian Duan
Brian Dubreuil
Jakob Ehrensvard
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
Nathaniel Hamming
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
David Hughes
Robert D. 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

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO/IEEE 11073-10419:2016
https://standards.iteh.ai/catalog/standards/sist/9d803bdc-613b-4382-bc74-d3cafc4069c9/iso-ieee-11073-10419-2016

Copyright © 2015 IEEE. All rights reserved.

© IEEE 2015 – All rights reserved

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
Srikkanth 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 L. 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 Staubert
Nicholas Steblay
Beth Stephen
Lars Steubesand
John (Ivo) Stivoric
Raymond A. Strickland
Hermanni 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

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO/IEEE 11073-10419:2016
https://standards.iteh.ai/catalog/standards/sist/9d803bdc-613b-4[illegible]-d3cafe4069c9/iso-ieee-11073-10419-2016

Copyright © 2015 IEEE. All rights reserved.

© IEEE 2015 – All rights reserved

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*

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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

ISO/IEEE 11073-10419:2016
https://standards.iteh.ai/catalog/standards/sist/9d803bdc-613b-4e62-b1e3-d3cafe1d0e0c/iso-ieee-11073-10419-2016

*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

Copyright © 2015 IEEE. All rights reserved.

© IEEE 2015 – All rights reserved

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 11073-20601:2010[1] 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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO/IEEE 11073-10419:2016
https://standards.iteh.ai/catalog/standards/sist/9d803bdc-613b-4382-bc74-d3cafe4069c9/iso-ieee-11073-10419-2016

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

Copyright © 2015 IEEE. All rights reserved.

© IEEE 2015 – All rights reserved

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO/IEEE 11073-10419:2016
https://standards.iteh.ai/catalog/standards/sist/0d803bde-613b-4382-be74-d3cafc4069c9/iso-ieee-11073-10419-2016

Copyright © 2015 IEEE. All rights reserved.

© IEEE 2015 – All rights reserved

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO/IEEE 11073-10419:2016
https://standards.iteh.ai/catalog/standards/sist/9d803bdc-613b-4382-bc74-d3cafe4069c9/iso-ieee-11073-10419-2016

Copyright © 2015 IEEE. All rights reserved.

© IEEE 2015 – All rights reserved