

SLOVENSKI STANDARD SIST EN ISO 11073-10419:2016

01-december-2016

Zdravstvena informatika - Komunikacija osebnih medicinskih naprav - 10419. del: Specialne naprave - Inzulinska črpalka (ISO/IEEE 11073-10419:2016, popravljena različica 2018-03)

Health informatics - Personal health device communication - Part 10419: Device specialization - Insulin pump (ISO/IEEE 11073-10419:2016, Corrected version 2018-03)

Medizinsche Informatik - Kommunikation von Geräten für die persönliche Gesundheit - Teil 10419: Gerätespezifikation - Insulinpumpe (ISO/IEEE 11073-10419:2016)

(standards.iteh.ai)

Informatique de santé - Communication entre dispositifs de santé personnels - Partie 10419: Spécialisation du dispositif - Pompe à insuline (ISO/IEEE 11073-10419:2016)

78f55316f3ec/sist-en-iso-11073-10419-2016

Ta slovenski standard je istoveten z: EN ISO 11073-10419:2016

ICS:

35.240.80 Uporabniške rešitve IT v IT applications in health care

zdravstveni tehniki technology

SIST EN ISO 11073-10419:2016 en,fr,de

SIST EN ISO 11073-10419:2016

iTeh STANDARD PREVIEW (standards.iteh.ai)

EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

EN ISO 11073-10419

June 2016

ICS 35.240.80

English Version

Health informatics - Personal health device communication - Part 10419: Device specialization - Insulin pump (ISO/IEEE 11073-10419:2016, Corrected version 2018-03)

Informatique de santé - Communication entre dispositifs de santé personnels - Partie 10419: Spécialisation du dispositif - Pompe à insuline (ISO/IEEE 11073-10419:2016)

Medizinsche Informatik - Kommunikation von Geräten für die persönliche Gesundheit - Teil 10419: Gerätespezifikation - Insulinpumpe (ISO/IEEE 11073-10419:2016)

This European Standard was approved by CEN on 28 February 2016.

This European Standard was corrected and reissued by the CEN-CENELEC Management Centre on 21 November 2018.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

SIST EN ISO 11073-10419:2016

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION COMITÉ EUROPÉEN DE NORMALISATION EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

EN ISO 11073-10419:2016 (E)

Contents	Page
European foreword	3

iTeh STANDARD PREVIEW (standards.iteh.ai)

EN ISO 11073-10419:2016 (E)

European foreword

This document (EN ISO 11073-10419:2016) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 "Health informatics" the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2016, and conflicting national standards shall be withdrawn at the latest by December 2016.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

iTeh STA Endorsement notice VIEW

The text of ISO/IEEE 11073-10419:2016. Corrected version 2018-03 has been approved by CEN as EN ISO 11073-10419:2016 without any modification.

SIST EN ISO 11073-10419:2016

iTeh STANDARD PREVIEW (standards.iteh.ai)

SIST EN ISO 11073-10419:2016

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

iTeh STAND PREVIEW

Partie 10419: Spécialisation du dispositif — Pompe à insuline

(standards.iteh.ai)



iTeh STANDARD PREVIEW (standards.iteh.ai)

<u>SIST EN ISO 11073-10419:2016</u> https://standards.iteh.ai/catalog/standards/sist/5b243d61-9d3f-4c08-b145-78f55316f3ec/sist-en-iso-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

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.

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 of scope of patents or patent claims or determining whether any licensing terms of 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

- 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 Independent living activity hub
- Part 10472: Device specialization Medication monitor
- (standards.iteh.ai)
 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]

IEEE Std 11073-10419™-2015

Health informatics—Personal health device communication

Part 10419: Device Specialization— **Insulin Pump**

Sponsor

IEEE 11073™ Standards Committee

IEEE Engineering in Medicine and Biology Society REVIEW

(standards.iteh.ai)

Approved 16 February 2015

SIST EN ISO 11073-10419:2016

IEEE-SA Standards Board Standards Board Standards Standa 78f55316f3ec/sist-en-iso-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)

<u>SIST EN ISO 11073-10419:2016</u> https://standards.iteh.ai/catalog/standards/sist/5b243d61-9d3f-4c08-b145-78f55316f3ec/sist-en-iso-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.

Vi Copyright © 2015 IEEE. 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."

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, of 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.

vii Copyright © 2015 IEEE. 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:

Secretary, IEEE-SA Standards Board

445 Hoes Lane (standards.iteh.ai) Piscataway, NJ 08854 USA

SIST EN ISO 11073-10419:2016

Laws and regulations SIST EN ISO 11073-10419:2016

78f55316f3ec/sist-en-iso-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.

viii Copyright © 2015 IEEE. 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

Patents

(standards.iteh.ai)

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.