

SLOVENSKI STANDARD SIST EN ISO 11073-10441:2017

01-september-2017

Zdravstvena informatika - Komunikacija osebnih medicinskih naprav - 10441. del: Specialne naprave - Monitor aktivnost in kardiovaskularni fitnes (ISO / IEEE 11.073 -10.441: 2015)

Health informatics - Personal health device communication - Part 10441: Device specialization - Cardiovascular fitness and activity monitor (ISO/IEEE 11073-10441:2015)

iTeh STANDARD PREVIEW

Medizinische Informatik - Kommunikation von Geräten für die persönliche Gesundheit -Teil 10441: Gerätespezifikation - Monitor für die Herz-Kreislauf-Fitness und -Aktivität (ISO/IEEE 11073-10441:2015)

SIST EN ISO 11073-10441:2017

https://standards.iteh.ai/catalog/standards/sist/a73d2327-c7c0-47ae-b62c-

Informatique de santé - Communication entre dispositifs de santé personnels - Partie 10441: Spécialisation des dispositifs - Moniteur d'activité et de forme cardiovasculaire (ISO/IEEE 11073-10441:2015)

Ta slovenski standard je istoveten z: EN ISO 11073-10441:2017

ICS:

11.040.55 Diagnostična oprema Diagnostic equipment

35.240.80 Uporabniške rešitve IT v IT applications in health care

> zdravstveni tehniki technology

SIST EN ISO 11073-10441:2017 en,fr,de

iTeh STANDARD PREVIEW (standards.iteh.ai)

SIST EN ISO 11073-10441:2017 https://standards.iteh.ai/catalog/standards/sist/a73d2327-c7c0-47ae-b62ca59da873ed8f/sist-en-iso-11073-10441-2017

EUROPEAN STANDARD NORME EUROPÉENNE **EUROPÄISCHE NORM**

EN ISO 11073-10441

February 2017

ICS 11.040.55; 35.240.80

English Version

Health informatics - Personal health device communication - Part 10441: Device specialization -Cardiovascular fitness and activity monitor (ISO/IEEE 11073-10441:2015)

Informatique de santé - Communication entre dispositifs de santé personnels - Partie 10441: Spécialisation des dispositifs - Moniteur d'activité et de forme cardiovasculaire (ISO/IEEE 11073-10441:2015)

Medizinische Informatik - Kommunikation von Geräten für die persönliche Gesundheit - Teil 10441: Gerätespezifikation - Monitor für die Herz-Kreislauf-Fitness und -Aktivität (ISO/IEEE 11073-10441:2015)

This European Standard was approved by CEN on 16 January 2017.

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. standards.iteh.ai)

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 log/standards/sist/a73d2327-c7c0-47ae-b62c-

a59da873ed8f/sist-en-iso-11073-10441-2017 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: Avenue Marnix 17, B-1000 Brussels

EN ISO 11073-10441:2017 (E)

Contents	Page
European foreword	3

iTeh STANDARD PREVIEW (standards.iteh.ai)

<u>SIST EN ISO 11073-10441:2017</u> https://standards.iteh.ai/catalog/standards/sist/a73d2327-c7c0-47ae-b62c-a59da873ed8f/sist-en-iso-11073-10441-2017

EN ISO 11073-10441:2017 (E)

European foreword

The text of ISO/IEEE 11073-10441:2015 has been prepared by Technical Committee ISO/TC 215 "Health informatics" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 11073-10441:2017 by 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 August 2017, and conflicting national standards shall be withdrawn at the latest by August 2017.

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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

(standards.iteh.ai)

SIST Endorsement notice

https://standards.iteh.ai/catalog/standards/sist/a73d2327-c7c0-47ae-b62c-

The text of ISO/IEEE 11073-10441:2015 has been approved by CEN as EN ISO 11073-10441:2017 without any modification.

iTeh STANDARD PREVIEW (standards.iteh.ai)

SIST EN ISO 11073-10441:2017 https://standards.iteh.ai/catalog/standards/sist/a73d2327-c7c0-47ae-b62ca59da873ed8f/sist-en-iso-11073-10441-2017

INTERNATIONAL ISO/IEEE STANDARD 11073-10441

First edition 2015-03-01

Health informatics — Personal health device communication —

Part 10441:

Device specialization — Cardiovascular fitness and activity monitor

Teh ST Informatique de santé — Communication entre dispositifs de santé personnels —

Partie 10441: Spécialisation des dispositifs — Moniteur d'activité et de forme cardiovasculaire

SIST EN ISO 11073-10441:2017

https://standards.iteh.ai/catalog/standards/sist/a73d2327-c7c0-47ae-b62c-a59da873ed8f/sist-en-iso-11073-10441-2017



ISO/IEEE 11073-10441:2015(E)

iTeh STANDARD PREVIEW (standards.iteh.ai)

<u>SIST EN ISO 11073-10441:2017</u> https://standards.iteh.ai/catalog/standards/sist/a73d2327-c7c0-47ae-b62c-a59da873ed8f/sist-en-iso-11073-10441-2017



COPYRIGHT PROTECTED DOCUMENT

© IEEE 2013

Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO or IEEE at the respective address below.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Institute of Electrical and Electronics Engineers, Inc. 3 Park Avenue, New York • NY 10016-5997, USA E-mail stds.ipr@ieee.org
Web www.ieee.org

ISO/IEEE 11073-10441:2015(E)

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 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 11073-10441 was prepared by the 11073 Committee of the Engineering in Medicine and Biology Society of the IEEE (as IEEE 11073-10441-2013). 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.

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 00103: Overview
- 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

ISO/IEEE 11073-10441:2015(E)

- 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 10441: Device specialization Cardiovascular fitness and activity monitor
- Part 10442: (Point-of-care medical device communication) Device specialization Strength fitness equipment
- Part 10471: Device specialization Independent living activity hub
- Part 10472: Device specialization Medication monitor
- Part 20101: (Point-of-care medical device communication) Application profiles Base standard (standards.iteh.ai)
- 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



Health Informatics—Personal health device communication

Part 10441: Device specialization— Cardiovascular fitness and activity monitor

iTeh STANDARD PREVIEW (standards.iteh.ai)

SIST EN ISO 11073-10441:2017

IEEE Engineering in Medicine and Biology Society beach

Sponsored by the IEEE 11073™ Standards Committee

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

iTeh STANDARD PREVIEW (standards.iteh.ai)

<u>SIST EN ISO 11073-10441:2017</u> https://standards.iteh.ai/catalog/standards/sist/a73d2327-c7c0-47ae-b62c-a59da873ed8f/sist-en-iso-11073-10441-2017

IEEE Std 11073-10441[™]-2013

(Revision of IEEE Std 11073-10441-2008)

Health informatics—Personal health device communication

Part 10441: Device specialization— Cardiovascular fitness and activity monitor

iTeh STANDARD PREVIEW (standards.iteh.ai)

Sponsor

IEEE 11073TM Standards Committee ISO 11073-10441:2017
of the https://standards.iteh.ai/catalog/standards/sist/a73d2327-c7c0-47ae-b62c-

IEEE Engineering in Medicine and Biology Society 441-2017

Approved 6 February 2013

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 cardiovascular fitness and activity monitor devices and managers (e.g., cell phones, personal computers, personal health appliances, and set top boxes) is established in 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 is specified. A common core of communication functionality for personal telehealth cardiovascular fitness and activity monitor devices is defined in this standard.

Keywords: activity monitor, cardiovascular fitness, IEEE 11073-10441[™], medical device communication, personal health devices

iTeh STANDARD PREVIEW (standards.iteh.ai)

<u>SIST EN ISO 11073-10441:2017</u> https://standards.iteh.ai/catalog/standards/sist/a73d2327-c7c0-47ae-b62c-a59da873ed8f/sist-en-iso-11073-10441-2017

Copyright © 2013 by The Institute of Electrical and Electronics Engineers, Inc. All rights reserved. Published 29 March 2013. 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 978-0-7381-8267-4 STD98161 Print: ISBN 978-0-7381-8268-1 STDPD98161

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.

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

Notice and Disclaimer of Liability Concerning the Use of IEEE Documents: IEEE Standards documents are developed within the IEEE Societies and the Standards Coordinating Committees of the IEEE Standards Association (IEEE-SA) Standards Board. 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 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.

Use of an IEEE Standard is wholly voluntary. IEEE disclaims liability for any personal injury, property or other damage, of any nature whatsoever, whether special, indirect, consequential, or compensatory, directly or indirectly resulting from the publication, use of, or reliance upon any IEEE Standard document.

IEEE does not warrant or represent the accuracy or content of the material contained in its standards, and expressly disclaims any express or implied warranty, including any implied warranty of merchantability or fitness for a specific purpose, or that the use of the material contained in its standards is free from patent infringement. IEEE Standards documents are supplied "AS IS"

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. 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 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.

Standards.iteh.ai

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 the official position of IEEE or any of its committees and shall not be considered to be, nor 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 to ensure 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. Any person who would like to participate in evaluating comments or revisions to an IEEE standard is welcome to join the relevant IEEE working group at http://standards.ieee.org/develop/wg/.

Comments on standards should be submitted to the following address:

Secretary, IEEE-SA Standards Board 445 Hoes Lane Piscataway, NJ 08854-4141 USA

Photocopies: Authorization to photocopy portions of any individual standard for internal or personal use is granted by The Institute of Electrical and Electronics Engineers, Inc., provided that the appropriate fee is paid to Copyright Clearance Center. To arrange for payment of licensing fee, 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.