ICS 35.240.80 SLOVENSKÁ TECHNICKÁ NORMA August 2014

STN	**Zdravotnícka informatika. Komunikácia s osobným zdravotným prístrojom. Časť 10418: Prístroj. Medzinárodne normalizovaný (INR) monitor (ISO/IEEE 11073-10418: 2014).**	**STN EN ISO 11073-10418** 84 8037

Health informatics - Personal health device communication - Part 10418: Device specialization - International Normalized Ratio (INR) monitor (ISO/IEEE 11073-10418:2014)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Obsahuje: EN ISO 11073-10418:2014, ISO/IEEE 11073-10418:2014

119136

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11073-10418

March 2014

ICS 35.240.80

English Version

Health informatics - Personal health device communication - Part 10418: Device specialization - International Normalized Ratio (INR) monitor (ISO/IEEE 11073-10418:2014, Corrected version 2014-05-01)

Informatique de santé - Communication entre dispositifs médicaux sur le site des soins - Partie 10418: Spécialisation des dispositifs - Surveillance du rapport normalisé international (INR) (ISO/IEEE 11073-10418:2014, Version corrigée 2014-05-01)

Medizinische Informatik - Kommunikation von Geräten für die persönliche Gesundheit - Teil 10418: Gerätespezifikation - Monitor für den international standardisierter Thromboplastinzeit-Quotient (INR) (ISO/IEEE 11073-10418:2014, korrigierte Fassung 2014-05-01)

This European Standard was approved by CEN on 14 December 2013.

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.

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, 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

Contents

Page

Foreword

This document (EN ISO 11073-10418:2014) 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 September 2014, and conflicting national standards shall be withdrawn at the latest by September 2014.

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.

Endorsement notice

The text of ISO/IEEE 11073-10418:2014, Corrected version 2014-05-01 has been approved by CEN as EN ISO 11073-10418:2014 without any modification.

INTERNATIONAL STANDARD

ISO/IEEE 11073-10418

First edition
2014-03-01

Corrected version
2014-05-01

Health informatics — Personal health device communication —

Part 10418: Device specialization: International Normalized Ratio (INR) monitor

Informatique de santé — Communication entre dispositifs de santé personnels

Partie 10418: Spécialisation de dispositif: surveillance du rapport normalisé international (INR)

Reference number
ISO/IEEE 11073-10418:2014(E)

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. Neither the ISO Central Secretariat nor IEEE accepts any liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies and IEEE members. In the unlikely event that a problem relating to it is found, please inform the ISO Central Secretariat or IEEE at the address given 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 version published 2014

Published in Switzerland

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 11073-10418 was prepared by the Substations Committee of the IEEE Power Engineering Society of the IEEE (as IEEE 11073-10418-2011). It was adopted by Technical Committee ISO/TC 215, *Respiratory and anaesthetic equipment*, 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*

— *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 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*

This corrected version of ISO 11073-10417:2014 incorporates the following correction:

— the text "Authorized licensed use limited to: IEEE Standards Staff and authorized IEEE Sponsor Ballot Participants. Downloaded on May 28,2013 at 14:27:23 UTC from IEEE Xplore. Restrictions apply." has been deleted from the footer.

IEEE STANDARDS ASSOCIATION IEEE

Health informatics—Personal health device communication

Part 10418: Device specialization—International Normalized Ratio (INR) monitor

IEEE Engineering in Medicine and Biology Society

Sponsored by the
IEEE 11073™ Standards Committee

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

IEEE Std 11073-10418™-2011

9 November 2011

IEEE Std 11073-10418™-2011

Health informatics—Personal health device communication

Part 10418: Device specialization—International Normalized Ratio (INR) monitor

Sponsor

IEEE 11073™ Standards Committee

of the

IEEE Engineering in Medicine and Biology Society

Approved 10 September 2011

IEEE-SA Standards Board

Abstract: A normative definition of communication between personal telehealth International Normalized Ratio (INR) devices (agents) 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. Work done in other ISO/IEEE 11073 standards is leveraged, including existing terminology, information profiles, 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 functionality of INR devices is defined in this standard. In the context of personal health devices, the measurement of the prothrombin time (PT) that is used to assess the level of anticoagulant therapy and its presentation as the International Normalized Ratio compared to the prothrombin time of normal blood plasma is referred to in INR monitoring. Applications of the INR monitor include the management of the therapeutic level of anticoagulant used in the treatment of a variety of conditions. The data modeling and its transport shim layer according to ISO/IEEE 11073-20601:2010 are provided by this standard, and the measurement method is not specified.

Keywords: IEEE 11073-10418, International Normalized Ratio (INR) monitor, medical device communication, personal health devices

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

PDF: ISBN 978-0-7381-6704-6 STD97137
Print: ISBN 978-0-7381-6705-3 STDPD97137

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 or the soundness of any judgments contained in its standards.

Use of an IEEE Standard is wholly voluntary. The 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 this, or any other IEEE Standard document.

The IEEE does not warrant or represent the accuracy or content of the material contained herein, 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 herein 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 five years for revision or reaffirmation, or every ten years for stabilization. When a document is more than five years old and has not been reaffirmed, or more than ten years old and has not been stabilized, 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 this document available, the IEEE is not suggesting or rendering professional or other services for, or on behalf of, any person or entity. Nor is the IEEE undertaking to perform any duty owed by any other person or entity to another. Any person utilizing this, and any other IEEE Standards document, should rely upon his or her 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.

Interpretations: Occasionally questions may arise regarding the meaning of portions of standards as they relate to specific applications. When the need for interpretations is brought to the attention of IEEE, the Institute will initiate action to prepare appropriate responses. Since IEEE Standards represent a consensus of concerned interests, it is important to ensure that any interpretation has also received 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 interpretation requests except in those cases where the matter has previously received formal consideration. 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 interpretation of the 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, explanation, or interpretation of the IEEE.

Comments for revision of IEEE Standards are welcome from any interested party, regardless of membership affiliation with IEEE. Suggestions for changes in documents should be in the form of a proposed change of text, together with appropriate supporting comments. Recommendations to change the status of a stabilized standard should include a rationale as to why a revision or withdrawal is required. Comments and recommendations on standards, and requests for interpretations should be addressed to:

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

Introduction

This introduction is not part of IEEE Std 11073-10418-2011, Health informatics—Personal health device communication—Part 10418: Device specialization—International Normalized Ratio (INR) monitor.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of the communication between medication monitoring devices and managers (e.g., cell phones, personal computers, personal health appliances, and set top boxes) in a manner that enables plug-and-play interoperability. It leverages appropriate portions of existing standards including ISO/IEEE 11073 terminology and information models. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting ambiguity in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for personal telehealth INR devices. In this context, the measurement of the prothrombin time (PT) that is used to assess the level of anticoagulant therapy and its presentation as the International Normalized Ratio (INR) compared with the PT of normal blood plasma is referred to in INR monitoring. Applications of the INR monitor include the management of the therapeutic level of anticoagulant used in the treatment of a variety of conditions.

Notice to users

Laws and regulations

Users of these documents should consult all applicable laws and regulations. Compliance with the provisions of this standard 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

This document is copyrighted by the IEEE. It is made available 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 this document available for use and adoption by public authorities and private users, the IEEE does not waive any rights in copyright to this document.

Updating of IEEE documents

Users of IEEE standards 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. 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 Standards Association web site at http://ieeexplore.ieee.org/xpl/standards.jsp, or contact the IEEE at the address listed previously.

For more information about the IEEE Standards Association or the IEEE standards development process, visit the IEEE-SA web site at http://standards.ieee.org.

Errata

Errata, if any, for this and all other standards can be accessed at the following URL: http://standards.ieee.org/findstds/errata/index.html. Users are encouraged to check this URL for errata periodically.

Interpretations

Current interpretations can be accessed at the following URL: http://standards.ieee.org/findstds/interps/index.html.

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 with respect to the existence or validity of any patent rights in connection therewith. 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.

Contents

Health informatics—Personal health device communication

Part 10418: Device specialization—International Normalized Ratio (INR) monitor

IMPORTANT NOTICE: This standard is not intended to ensure safety, security, health, or environmental protection. Implementers of the standard are responsible for determining appropriate safety, security, environmental, and health practices or regulatory requirements.

1. Overview

1.1 Scope

The scope of this standard is to establish a normative definition of communication between personal telehealth International Normalized Ratio (INR) devices (agents) and managers (e.g. cell phones, personal computers, personal health appliances, and set top boxes) in a manner that enables plug-and-play interoperability. It leverages work done in other ISO/IEEE 11073 standards including existing terminology, information profiles, application profile standards, and transport standards. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability. This standard defines a common core of functionality of INR devices.

In the context of personal health devices, INR monitoring refers to the measurement of the prothrombin time (PT) that is used to assess the level of anticoagulant therapy and its presentation as the International Normalized Ratio compared to the prothrombin time of normal blood plasma. Applications of the INR monitor include the management of the therapeutic level of anticoagulant used in the treatment of a variety of conditions.

This standard provides the data modeling and its transport shim layer according to IEEE Std 11073-20601a™-2010[1] and does not specify the measurement method.

[1] Information on references can be found in Clause 2.

1.2 Purpose

This standard addresses a need for an openly defined, independent standard for controlling information exchange to and from personal health devices (agents) and managers (e.g., cell phones, personal computers, personal health appliances, and set top boxes). Interoperability is key to growing the potential market for these devices and to enabling people to be better informed participants in the management of their health.

1.3 Context

See IEEE Std 11073-20601a-2010 for an overview of the environment within which this standard is written.

This standard defines the device specialization for the INR monitor, being a specific agent type, and it provides a description of the device concepts, its capabilities, and its implementation according to this standard.

This standard is based on IEEE Std 11073-20601a-2010, which in turn draws information from both ISO/IEEE 11073-10201:2004 [B9][2] and ISO/IEEE 11073-20101:2004 [B10]. The medical device encoding rules (MDERs) used within this standard are fully described in IEEE Std 11073-20601a-2010.

This standard reproduces relevant portions of the nomenclature found in ISO/IEEE 11073-10101:2004 [B8] and adds new nomenclature codes for the purposes of this standard. Between this standard and IEEE Std 11073-20601a-2010, all required nomenclature codes for implementation are documented.

NOTE 1—IEEE Std 11073-20601a-2010 is an amendment to ISO/IEEE 11073-20601:2010. It contains new material and corrections and does not copy the content of ISO/IEEE 11073-20601:2010. Throughout this standard, a reference to IEEE Std 11073-20601a-2010 refers to the document that is obtained after applying this new material and corrections to ISO/IEEE 11073-20601:2010.[3]

NOTE 2—In this standard, ISO/IEEE 11073-104zz is used to refer to the collection of device specialization standards that utilize IEEE Std 11073-20601a-2010, where zz can be any number from 01 to 99, inclusive.

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used, so that each referenced document is cited in text and its relationship to this document is explained). For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments or corrigenda) applies.

IEEE Std 11073-20601a™-2010, Health informatics—Personal health device communication—Application Profile—Optimized Exchange Protocol—Amendment 1.[4,5]

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

See Annex A for all informative material referenced by this standard.

[2] The numbers in brackets correspond to those of the bibliography in Annex A.

[3] Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement the standard.

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

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

[6] ISO/IEEE publications are available from the ISO Central Secretariat, 1, ch. de la Voie-Creuse, Case Postale 56, CH-1211, Geneva 20, Switzerland (http://www.iso.ch/). ISO/IEEE publications are also available in the United States from the Institute of Electrical and Electronics Engineers, 445 Hoes Lane, Piscataway, NJ 0885