ICS 01.040.35, 35.240.80 SLOVENSKÁ TECHNICKÁ NORMA Máj 2018

STN	**Zdravotnícke informácie Komunikácia zdravotníckeho prístroja na mieste zdravotnej starostlivosti Časť 10101: Nomenklatúra (ISO/IEEE 11073-10101: 2004) Zmena A1**	**STN EN ISO 11073-10101/A1** 84 8037

Health informatics - Point-of-care medical device communication - Part 10101: Nomenclature (ISO/IEEE 11073-10101:2004)

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

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 04/18

Obsahuje: EN ISO 11073-10101:2005/A1:2017, ISO/IEEE 11073-10101:2004/Amd 1:2017

126392

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11073-10101:2005/A1

November 2017

ICS 01.040.35; 35.240.80

English Version

Health informatics - Point-of-care medical device communication - Part 10101: Nomenclature - Amendment 1: Additional definitions (ISO/IEEE 11073-10101:2004/Amd 1:2017)

Informatique de santé - Communication entre dispositifs médicaux sur le site des soins - Partie 10101: Nomenclature - Amendement 1 (ISO/IEEE 11073-10101:2004/Amd 1:2017)

Medizinische Informatik - Kommunikation patientennaher medizinischer Geräte - Teil 10101: Nomenklatur - Änderung 1 (ISO/IEEE 11073-10101:2004/Amd 1:2017)

This amendment A1 modifies the European Standard EN ISO 11073-10101:2005; it was approved by CEN on 13 April 2017.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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 amendment 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

Ref. No. EN ISO 11073-10101:2005/A1:2017 E

Contents

Page

European foreword

This document (EN ISO 11073-10101:2005/A1:2017) 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 Amendment to the European Standard EN ISO 11073-10101:2005 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2018, and conflicting national standards shall be withdrawn at the latest by May 2018.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN 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.

Endorsement notice

The text of ISO/IEEE 11073-10101:2004/Amd1:2017 has been approved by CEN as EN ISO 11073-10101:2005/A1:2017 without any modification.

INTERNATIONAL STANDARD

ISO/IEEE 11073-10101

First edition
2004-12-15

AMENDMENT 1
2017-10

Health informatics — Point-of-care medical device communication —

Part 10101: **Nomenclature**

AMENDMENT 1: Additional definitions

Informatique de santé — Communication entre dispositifs médicaux sur le site des soins —

Partie 10101: Nomenclature

AMENDEMENT 1: Définitions supplementaires

Reference number
ISO/IEEE 11073-10101:2004/Amd 1:2017(E)

ISO/IEEE 11073-10101:2004/Amd 1:2017(E)

COPYRIGHT PROTECTED DOCUMENT

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 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.

Amendment 1 to ISO/IEEE 11073-10101:2004/Amd 1:2017 was prepared by the 11073 Committee of the Engineering in Medicine and Biology Society of the IEEE (as IEEE 11073-10101:2004). It was adopted by Technical Committee ISO/TC 215, *Health informatics*, in parallel with its approval by the ISO/IEC national 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/IEC national bodies.

IEEE Std 11073-10101a™-2015
(Amendment to
ISO/IEEE 11073-10101:2004)

Health informatics—Point-of-care medical device communication

Part 10101: Nomenclature

Amendment 1: Additional Definitions

Sponsor

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

Approved 5 December 2015

IEEE-SA Standards Board

Abstract: Within the context of the ISO/IEEE 11073 family of standards for point-of-care (POC) medical device communication (MDC), the nomenclature defined by the base ISO/IEEE 11073-10101:2004 nomenclature standard is extended by this amendment. Significant extensions to support haemodynamics, respiration, ventilation and anesthesia monitoring, blood gas, urine, fluid-related metrics, and neurology, as well as units of measurements and measurement sites, are included. Formal definitions for observation identifiers used by the IEEE 11073 Personal Health Device standards and additional attributes for reporting their regulatory and certification status are also captured and provided. Information attributes to support alert communication and accurate medical device time synchronization and timekeeping are also defined.

Keywords: alert communication, anesthesia, blood gas, codes, Continua, fluid-related metrics, haemodynamics, IEEE 11073-10101a, IHE PCD, information model, ISO/IEEE 11073-10101, measurement sites, medical device certification, medical device communication, neurology, nomenclature, NTP, ontology, patient, PCHA, Personal Connected Health Alliance, POC, point-of-care, respiration, semantics, service model, terminology, time synchronization, timekeeping, units of measure, urine, ventilation

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

PDF: ISBN 978-1-5044-0119-7 STD20525
Print: ISBN 978-1-5044-0120-3 STDPD20525

Important Notices and Disclaimers Concerning IEEE Standards Documents

IEEE documents are made available for use subject to important notices and legal disclaimers. These notices and disclaimers, or a reference to this page, appear in all standards and may be found under the heading "Important Notice" or "Important Notices and Disclaimers Concerning IEEE Standards Documents."

Notice and Disclaimer of Liability Concerning the Use of IEEE Standards Documents

IEEE Standards documents (standards, recommended practices, and guides), both full-use and trial-use, are developed within IEEE Societies and the Standards Coordinating Committees of the IEEE Standards Association ("IEEE-SA") Standards Board. IEEE ("the Institute") develops its standards through a consensus development process, approved by the American National Standards Institute ("ANSI"), which brings together volunteers representing varied viewpoints and interests to achieve the final product. Volunteers are not necessarily members of the Institute and participate without compensation from IEEE. While IEEE administers the process and establishes rules to promote fairness in the consensus development process, IEEE does not independently evaluate, test, or verify the accuracy of any of the information or the soundness of any judgments contained in its standards.

IEEE does not warrant or represent the accuracy or content of the material contained in its standards, and expressly disclaims all warranties (express, implied and statutory) not included in this or any other document relating to the standard, including, but not limited to, the warranties of: merchantability; fitness for a particular purpose; non-infringement; and quality, accuracy, effectiveness, currency, or completeness of material. In addition, IEEE disclaims any and all conditions relating to: results; and workmanlike effort. IEEE standards documents are supplied "AS IS" and "WITH ALL FAULTS."

Use of an IEEE standard is wholly voluntary. The existence of an IEEE standard does not imply that there are no other ways to produce, test, measure, purchase, market, or provide other goods and services related to the scope of the IEEE standard. Furthermore, the viewpoint expressed at the time a standard is approved and issued is subject to change brought about through developments in the state of the art and comments received from users of the standard.

In publishing and making its standards available, IEEE is not suggesting or rendering professional or other services for, or on behalf of, any person or entity nor is IEEE undertaking to perform any duty owed by any other person or entity to another. Any person utilizing any IEEE Standards document, should rely upon his or her own independent judgment in the exercise of reasonable care in any given circumstances or, as appropriate, seek the advice of a competent professional in determining the appropriateness of a given IEEE standard.

IN NO EVENT SHALL IEEE BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, OR CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO: PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES; LOSS OF USE, DATA, OR PROFITS; OR BUSINESS INTERRUPTION) HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, STRICT LIABILITY, OR TORT (INCLUDING NEGLIGENCE OR OTHERWISE) ARISING IN ANY WAY OUT OF THE PUBLICATION, USE OF, OR RELIANCE UPON ANY STANDARD, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE AND REGARDLESS OF WHETHER SUCH DAMAGE WAS FORESEEABLE.

Translations

The IEEE consensus development process involves the review of documents in English only. In the event that an IEEE standard is translated, only the English version published by IEEE should be considered the approved IEEE standard.

Official statements

A statement, written or oral, that is not processed in accordance with the IEEE-SA Standards Board Operations Manual shall not be considered or inferred to be the official position of IEEE or any of its committees and shall not be considered to be, or be relied upon as, a formal position of IEEE. At lectures, symposia, seminars, or educational courses, an individual presenting information on IEEE standards shall make it clear that his or her views should be considered the personal views of that individual rather than the formal position of IEEE.

Comments on standards

Comments for revision of IEEE Standards documents are welcome from any interested party, regardless of membership affiliation with IEEE. However, IEEE does not provide consulting information or advice pertaining to IEEE Standards documents. Suggestions for changes in documents should be in the form of a proposed change of text, together with appropriate supporting comments. Since IEEE standards represent a consensus of concerned interests, it is important that any responses to comments and questions also receive the concurrence of a balance of interests. For this reason, IEEE and the members of its societies and Standards Coordinating Committees are not able to provide an instant response to comments or questions except in those cases where the matter has previously been addressed. For the same reason, IEEE does not respond to interpretation requests. Any person who would like to participate in revisions to an IEEE standard is welcome to join the relevant IEEE working group.

Comments on standards should be submitted to the following address:

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

Laws and regulations

Users of IEEE Standards documents should consult all applicable laws and regulations. Compliance with the provisions of any IEEE Standards document does not imply compliance to any applicable regulatory requirements. Implementers of the standard are responsible for observing or referring to the applicable regulatory requirements. IEEE does not, by the publication of its standards, intend to urge action that is not in compliance with applicable laws, and these documents may not be construed as doing so.

Copyrights

IEEE draft and approved standards are copyrighted by IEEE under U.S. and international copyright laws. They are made available by IEEE and are adopted for a wide variety of both public and private uses. These include both use, by reference, in laws and regulations, and use in private self-regulation, standardization, and the promotion of engineering practices and methods. By making these documents available for use and adoption by public authorities and private users, IEEE does not waive any rights in copyright to the documents.

Photocopies

Subject to payment of the appropriate fee, IEEE will grant users a limited, non-exclusive license to photocopy portions of any individual standard for company or organizational internal use or individual, non-commercial use only. To arrange for payment of licensing fees, please contact Copyright Clearance Center, Customer Service, 222 Rosewood Drive, Danvers, MA 01923 USA; +1 978 750 8400. Permission to photocopy portions of any individual standard for educational classroom use can also be obtained through the Copyright Clearance Center.

Updating of IEEE Standards documents

Users of IEEE Standards documents should be aware that these documents may be superseded at any time by the issuance of new editions or may be amended from time to time through the issuance of amendments, corrigenda, or errata. An official IEEE document at any point in time consists of the current edition of the document together with any amendments, corrigenda, or errata then in effect.

Every IEEE standard is subjected to review at least every ten years. When a document is more than ten years old and has not undergone a revision process, it is reasonable to conclude that its contents, although still of some value, do not wholly reflect the present state of the art. Users are cautioned to check to determine that they have the latest edition of any IEEE standard.

In order to determine whether a given document is the current edition and whether it has been amended through the issuance of amendments, corrigenda, or errata, visit the IEEE-SA Website at http://ieeexplore.ieee.org/xpl/standards.jsp or contact IEEE at the address listed previously. For more information about the IEEE SA or IEEE's standards development process, visit the IEEE-SA Website at http://standards.ieee.org.

Errata

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

Patents

Attention is called to the possibility that implementation of this standard may require use of subject matter covered by patent rights. By publication of this standard, no position is taken by the IEEE with respect to the existence or validity of any patent rights in connection therewith. If a patent holder or patent applicant has filed a statement of assurance via an Accepted Letter of Assurance, then the statement is listed on the IEEE-SA Website at http://standards.ieee.org/about/sasb/patcom/patents.html. Letters of Assurance may indicate whether the Submitter is willing or unwilling to grant licenses under patent rights without compensation or under reasonable rates, with reasonable terms and conditions that are demonstrably free of any unfair discrimination to applicants desiring to obtain such licenses.

Essential Patent Claims may exist for which a Letter of Assurance has not been received. The IEEE is not responsible for identifying Essential Patent Claims for which a license may be required, for conducting inquiries into the legal validity or scope of Patents Claims, or determining whether any licensing terms or conditions provided in connection with submission of a Letter of Assurance, if any, or in any licensing agreements are reasonable or non-discriminatory. Users of this standard are expressly advised that determination of the validity of any patent rights, and the risk of infringement of such rights, is entirely their own responsibility. Further information may be obtained from the IEEE Standards Association.

Participants

At the time this standard was submitted to the IEEE-SA Standards Board for approval, the Upper Layers Working Group had the following membership:

Jan Wittenber, *Chair*
Paul Schluter and Todd Cooper, *Vice Chairs*

Malcolm Clarke
Steven Dain
Kenneth Fuchs
Norman Jones
Kenneth Marks
John Rhoads
Jeff Rinda
Stefan Schlichting
John Walsh
Daidi Zhong

The following members of the individual balloting committee voted on this standard. Balloters may have voted for approval, disapproval, or abstention.

Susan Burgess
Keith Chow
Malcolm Clarke
Gion Durisch
Christoph Fischer
Kenneth Fuchs
John Garguilo
Joel Goergen
Randall Groves
Kai Hassing
Werner Hoelzl
Noriyuki Ikeuchi
Atsushi Ito
Piotr Karocki
Daniel Kraehenbuehl
Kenneth Marks
Melvin Reynolds
John Rhoads
Bartien Sayogo
Stefan Schlichting
Paul Schluter
Janek Schumann
Eugene Stoudenmire
Walter Struppler
John Walsh
J. Wiley
Jan Wittenber
Oren Yuen
Daidi Zhong

When the IEEE-SA Standards Board approved this standard on 5 December 2015, it had the following membership:

John D. Kulick, *Chair*
Jon Walter Rosdahl, *Vice Chair*
Richard H. Hulett, *Past Chair*
Konstantinos Karachalios, *Secretary*

Masayuki Ariyoshi
Ted Burse
Stephen Dukes
Jean-Philippe Faure
J. Travis Griffith
Gary Hoffman
Michael Janezic
Joseph L. Koepfinger*
David J. Law
Hung Ling
Andrew Myles
T. W. Olsen
Glenn Parsons
Ronald C. Petersen
Annette D. Reilly
Stephen J. Shellhammer
Adrian P. Stephens
Yatin Trivedi
Phillip Winston
Don Wright
Yu Yuan
Daidi Zhong

*Member Emeritus

Introduction

This introduction is not part of IEEE Std 11073-10101a™-2015, Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature—Amendment 1: Additional Definitions.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. They provide automatic and detailed electronic data capture of patient vital signs information and device operational data. The primary goals are to:

— Provide real-time plug-and-play interoperability for patient-connected medical devices

— Facilitate the efficient exchange of vital signs and medical device data, acquired at the point-of-care, in all health care environments

This amendment extends the nomenclature originally defined by the base IEEE Std 11073-10101:2004 nomenclature standard. It reflects the continued innovation in medical device and system design for the past decade and is based on a highly successful collaboration with the following organizations:

— Integrating the Healthcare Enterprise (IHE) Patient Care Devices (PCD) domain

— Personal Connected Health Alliance (PCHA, formerly Continua Health Alliance)

— ISO/TC 121, Anaesthetic and respiratory equipment, Subcommittee 4, Terminology and semantics

In addition, other vendors and standards development and profiling organizations have contributed to and have recognized the value of this work and the benefit it provides to the user and provider communities and to the patients that we ultimately serve.

This nomenclature amendment includes significant extensions to support:

— haemodynamics

— respiratory, ventilation and anesthesia monitoring

— blood gas, urine, fluid chemistry and other fluid-related metrics

— neurology

— units of measurements and measurement sites

— new medical device types, including infant warmers and incubators

This amendment also provides:

— formal definitions for observation identifiers used by IEEE 11073 Personal Health Devices

— attributes for reporting medical device regulatory and certification status

— attributes to support alert communication

— attributes to support accurate medical device time synchronization and timekeeping

NOTES as used in this amendment (preceding editorial instructions) are not meant to be included in the rollup or part of the editorial instructions. They are used solely to provide informative guidance and background to the reader as to why certain changes were made.

Contents

Health informatics—Point-of-care medical device communication

Part 10101: Nomenclature

Amendment 1: Additional Definitions

NOTE—The editing instructions contained in this **amendment** define how to merge the material contained therein into the existing base standard and its amendments to form the comprehensive standard.

The editing instructions are shown in ***bold italic***. Four editing instructions are used: change, delete, insert, and replace. ***Change*** is used to make corrections in existing text or tables. The editing instruction specifies the location of the change and describes what is being changed by using ~~strikethrough~~ (to remove old material) and underscore (to add new material). ***Delete*** removes existing material. ***Insert*** adds new material without disturbing the existing material. Insertions may require renumbering. If so, renumbering instructions are given in the editing instruction. ***Replace*** is used to make changes in figures or equations by removing the existing figure or equation and replacing it with a new one. Editing instructions, change markings, and this NOTE will not be carried over into future editions because the changes will be incorporated into the base standard.