Health informatics - Device interoperability - Part 10201: Point-of-care medical device communication - Domain information model (ISO/IEEE 11073- 10201:2020)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO/IEEE 11073-10201:2020 sisaldab Euroopa standardi EN ISO/IEEE 11073-10201:2020 ingliskeelset teksti.	This Estonian standard EVS-EN ISO/IEEE 11073-10201:2020 consists of the English text of the European standard EN ISO/IEEE 11073-10201:2020.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 03.06.2020.	Date of Availability of the European standard is 03.06.2020.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 35.240.80

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO/IEEE 11073-10201

June 2020

ICS 35.240.80

Supersedes EN ISO 11073-10201:2005

English Version

Health informatics - Device interoperability - Part 10201: Point-of-care medical device communication - Domain information model (ISO/IEEE 11073-10201:2020)

Informatique de santé - Interopérabilité des dispositifs - Partie 10201: Communication entre dispositifs médicaux sur le site des soins - Modèle d'informations du domaine (ISO/IEEE 11073-10201:2020)

Medizinische Informatik - Kommunikation patientennaher medizinischer Geräte - Teil 10201: Bereichs-Informationsmodell (ISO/IEEE 11073-10201:2020)

This European Standard was approved by CEN on 2 May 2020.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, 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/IEEE 11073-10201:2020 E

European foreword

This document (EN ISO/IEEE 11073-10201:2020) 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 2020, and conflicting national standards shall be withdrawn at the latest by December 2020.

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.

This document supersedes EN ISO 11073-10201:2005.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO/IEEE 11073-10201:2020 has been approved by CEN as EN ISO/IEEE 11073-10201:2020 without any modification.

Introduction

This introduction is not part of IEEE Std 11073-10201-2018, Health informatics—Point-of-care medical device communication—Part 10201: Domain Information Model.

ISO/IEEE 11073 standards enable communication between different medical devices and between medical devices and other IT systems for information and for command and control. The primary goals are to:

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

— Facilitate the efficient exchange of patient related data and medical device related data, acquired at the point-of-care (POC), in all health care environments

“Real-time” means that data from multiple devices can be retrieved, time correlated, and displayed or processed in fractions of a second.

“Plug-and-play” means that when a device or system is connected to another device or system, detection, configuration, and the initiation of communication all occur automatically andwithout any other human interaction.

“Efficient exchange of medical device data” means that information that is captured at the POC (e.g., patient vital signs data) can be archived, retrieved, and processed by many different types of applications without extensive software and equipment support, and without needless loss of information. This standard is especially targeted at acute and continuing care devices, such as patient monitors, ventilators, infusion pumps, ECG devices, etc. It is a member of a family of standards that can be layered together to provide connectivity optimized for the specific devices being interfaced.

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted (see www.iso.org/directives).

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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

ISO/IEEE 11073-10201 was prepared by the IEEE 11073 Standards Committee of the IEEE Engineering in Medicine and Biology Society (as IEEE Std 11073-10201-2018) and drafted in accordance with its editorial rules. It was adopted, under the "fast-track procedure" defined in the Partner Standards Development Organization cooperation agreement between ISO and IEEE, by Technical Committee ISO/TC 215, *Health informatics*.

This second edition cancels and replaces the first edition (ISO/IEEE 11073-10201:2004), which has been technically revised.

A list of all parts in the ISO/IEEE 11073 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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 Notices and Disclaimers Concerning IEEE Standards Documents." They can also be obtained on request from IEEE or viewed at http://standards.ieee.org/ipr/disclaimers.html.

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. IEEE Standards are documents developed through scientific, academic, and industry-based technical working groups. Volunteers in IEEE working groups 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 Standards do not guarantee or ensure safety, security, health, or environmental protection, or ensure against interference with or from other devices or networks. Implementers and users of IEEE Standards documents are responsible for determining and complying with all appropriate safety, security, environmental, health, and interference protection practices and all applicable laws and regulations.

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. A current 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 IEEE Xplore at http://ieeexplore.ieee.org/ 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 IEEE standard was completed, the Point-of-Care Devices Working Group had the following membership:

John Rhoads, *Chair*
Michael Faughn, *Subgroup Chair*

Bjoern Anderson
Malcolm Clarke
Todd Cooper
Chris Courville
Kenneth Fuchs
John Garguilo
Frank Golatowski
David Gregorczyk
Kai Hassing
John Hatcliff
Stefan Karl
Martin Kasparick
Koichiro Matsumoto
Joerg-Uwe Meyer
Stephan Poehlsen
Tracy Rausch
Stefan Schlichting
Paul Schluter
Masato Tanaka
Eugene Vasserman
Stan Wiley
Jan Wittenber

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

Bjoern Andersen
Michael Bayer
Keith Chow
Malcolm Clarke
Michael Faughn
David Fuschi
David Gregorczyk
Randall Groves
Kai Hassing
Werner Hoelzl
Noriyuki Ikeuchi
Atsushi Ito
Stefan Karl
Piotr Karocki
Martin Kasparick
H. Moll
John Rhoads
Stefan Schlichting
Paul Schluter
Walter Struppler
Ganesh Subramanian
Thomas Tullia
Jan Wittenber
Oren Yuen
Daidi Zhong

When the IEEE-SA Standards Board approved this standard on 5 December 2018, it had the following membership:

Jean-Philippe Faure, *Chair*
Gary Hoffman, *Vice Chair*
John D. Kulick, *Past Chair*
Konstantinos Karachalios, *Secretary*

Ted Burse
Guido R. Hiertz
Christel Hunter
Joseph L. Koepfinger*
Thomas Koshy
Hung Ling
Dong Liu
Xiaohui Liu
Kevin Lu
Daleep Mohla
Andrew Myles
Paul Nikolich
Ronald C. Petersen
Annette D. Reilly
Robby Robson
Dorothy Stanley
Mehmet Ulema
Phil Wennblom
Philip Winston
Howard Wolfman
Jingyi Zhou

*Member Emeritus

Contents

Health informatics—Point-of-care medical device communication

Part 10201: Domain Information Model

1. Scope

The scope of this project is to define a general object-oriented information model that may be used to structure information and identify services used in point-of-care (POC) medical device communications. The scope is primarily focused on acute care medical devices and the communication of patient vital signs information.

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used, so 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.

ISO/IEC 8824-1, Information technology — Abstract Syntax Notation One (ASN.1) — Part 1: Specification of basic notation.[1]

ISO/IEEE 11073-10101, Health informatics — Point-of-care medical device communication — Part 10101: Nomenclature.[2]

ISO/IEEE 11073-20101, Health informatics — Point-of-care medical device communication — Part 20101: Application profiles – Base standard.

OMG® Unified Modeling Language® (OMG UML®) 2.5.1.[3]

[1] ISO/IEC documents are available from the International Organization for Standardization (http://www.iso.org/), the International Electrotechnical Commission (http://www.iec.ch), and the American National Standards Institute (http://www.ansi.org/).
[2] ISO/IEEE documents are available from the International Organization for Standardization (http://www.iso.org/) and the Institute of Electrical and Electronics Engineers (http://standards.ieee.org/).
[3] The OMG UML standard can be freely downloaded at https://www.omg.org/spec/UML/