

SLOVENSKI STANDARD SIST EN ISO 11073-10201:2005

01-november-2005

Zdravstvena informatika – Komunikacija medicinskih naprav na mestu oskrbe – 10201. del: Informacijski model domene (ISO/IEEE 11073-10201:2004)

Health informatics - Point-of-care medical device communication - Part 10201: Domain information model (ISO/IEEE 11073-10201:2004)

Medizinische Informatik - Kommunikation patientennaher medizinischer Geräte - Teil 10201: Bereichs-Informations (nodelln dards.iteh.ai)

Informatique de santé - Communication entre dispositifs médicaux sur le site des soins - Partie 10201: Modele d'information du domaine (ISO/IEEE 11073-10201:2004)

Ta slovenski standard je istoveten z: EN ISO 11073-10201:2005

ICS:

35.240.80 Uporabniške rešitve IT v

zdravstveni tehniki

IT applications in health care

technology

SIST EN ISO 11073-10201:2005

en

iTeh STANDARD PREVIEW (standards.iteh.ai)

EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM EN ISO 11073-10201

August 2005

ICS 35.240.80

English Version

Health informatics - Point-of-care medical device communication - Part 10201: Domain information model (ISO/IEEE 11073-10201:2004)

Informatique de santé - Communication entre dispositifs médicaux sur le site des soins - Partie 10201: Modèle d'information du domaine (ISO/IEEE 11073-10201:2004) Medizinische Informatik - Kommunikation patientennaher medizinischer Geräte - Teil 10201: Bereichs-Informationsmodell

This European Standard was approved by CEN on 16 August 2005.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom, and Sixty 9421b52f-03c2-4258-b06f-

3f1712410533/sist-en-iso-11073-10201-2005



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

Management Centre: rue de Stassart, 36 B-1050 Brussels

EN ISO 11073-10201:2005 (E)

Foreword

The text of ISO/IEEE 11073-10201:2004 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 11073-10201:2005 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 February 2006, and conflicting national standards shall be withdrawn at the latest by February 2006.

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

Endorsement notice

The text of ISO/IEEE 11073-10201:2004 has been approved by CEN as EN ISO 11073-10201:2005 without any modifications dards.iteh.ai)

INTERNATIONAL STANDARD

ISO/IEEE 11073-10201

First edition 2004-12-15

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

Parth 0204:NDARD PREVIEW

Domain information model

SIST EN ISO 11073-10201:2005 htt/Informatique de santé sta Communication entre dispositifs médicaux sur le site des soins 410533/sist-en-iso-11073-10201-2005 Partie 10201: Modèle d'information du domaine



iTeh STANDARD PREVIEW (standards.iteh.ai)

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

Part 10201:

Domain information model

Sponsor iTeh STANDARD PREVIEW

IEEE 1073™ Standard Committee ndards.iteh.ai)

of the <u>SIST EN ISO 11073-10201:2005</u>

https://standards.iteh.ai/catalog/standards/sist/9421b52f-03c2-4258-b06f-

IEEE Engineering in Medicine and Biology Society 201-2005

Approved 24 June 2004

IEEE-SA Standards Board



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 the 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 the IEEE at the address given below.

Abstract: Within the context of the ISO/IEEE 11073 family of standards for point-of-care (POC) medical device communication (MDC), this standard provides an abstract object-oriented domain information model that specifies the structure of exchanged information, as well as the events and services that are supported by each object. All elements are specified using abstract syntax (ASN.1) and may be applied to many different implementation technologies, transfer syntaxes, and application service models. Core subjects include medical, alert, system, patient, control, archival, communication, and extended services. Model extensibility is supported, and a conformance model and statement template is provided.

Keywords: abstract syntax, alarm, alert, ASN.1, information model, medical device communications, medical information bus, MIB, point-of-care, POC, object-oriented, patient, remote control

(standards.iteh.ai)

<u>SIST EN ISO 11073-10201:2005</u> https://standards.iteh.ai/catalog/standards/sist/9421b52f-03c2-4258-b06f-3f1712410533/sist-en-iso-11073-10201-2005

This ISO/IEEE document is an International Standard and is copyright-protected by ISO and the IEEE. Except as permitted under the applicable laws of the user's country, neither this ISO/IEEE standard nor any extract from it may be reproduced, stored in a retrieval system or transmitted in any form or by any means, electronic, photocopying, recording or otherwise, without prior written permission being secured.

Requests for permission to reproduce should be addressed to either ISO or the IEEE at the addresses 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 Standards Association Manager, Standards Intellectual Property 445 Hoes Lane Piscataway, NJ 08854 E-mail: stds.ipr@ieee.org Web: www.ieee.org

Copyright © 2004 ISO/IEEE. All rights reserved.

Published 15 December 2004. 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.

Print: ISBN 0-7381-4089-9 SH95256 PDF: ISBN 0-7381-4090-2 SS95256

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.

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.

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. When a document is more than five years old and has not been reaffirmed, 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 the advice of a competent professional in determining the exercise of reasonable care in any given circumstances.

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 TEEE, 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. 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. Comments on standards and requests for interpretations should be addressed to:

Secretary, IEEE-SA Standards Board

445 Hoes Lane

Piscataway, NJ 08854 USA

NOTE — 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 shall not be responsible for identifying patents for which a license may be required by an IEEE standard or for conducting inquiries into the legal validity or scope of those patents that are brought to its attention.

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.

ISO/IEEE 11073-10201:2004(E)

iTeh STANDARD PREVIEW (standards.iteh.ai)

ISO 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.

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.

A pilot project between ISO and the IEEE has been formed to develop and maintain a group of ISO/IEEE standards in the field of medical devices as approved by Council resolution 43/2000. Under this pilot project, IEEE is responsible for the development and maintenance of these standards with participation and input from ISO member bodies.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. Neither ISO nor the IEEE shall be held responsible for identifying any or all such patent rights.

ISO/IEEE 11073-10201;2004(E) was prepared by IEEE 1073 Committee of the IEEE Engineering in Medicine and Biology Society.

(standards.iteh.ai)

IEEE Introduction

This introduction is not part of ISO/IEEE 11073-10201:2004(E), Health informatics — Point-of-care medical device communication — Part 10201: Domain information model.

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

"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 all the clinician has to do is make the connection — the systems automatically detect, configure, and communicate without any other human interaction.

"Efficient exchange of medical device data" means that information that is captured at the point-of-care (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. The standards are especially targeted at acute and continuing care devices, such as patient monitors, ventilators, infusion pumps, ECG devices, etc. They comprise a family of standards that can be layered together to provide connectivity optimized for the specific devices being interfaced.

(standards.iteh.ai)

Notice to users

<u>SIST EN ISO 11073-10201:2005</u> https://standards.iteh.ai/catalog/standards/sist/9421b52f-03c2-4258-b06f-3f1712410533/sist-en-iso-11073-10201-2005

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 shall not be responsible for identifying patents or patent applications for which a license may be required by to implement an IEEE standard or for conducting inquiries into the legal validity or scope of those patents that are brought to its attention.

Errata

Errata, if any, for this and all other standards can be accessed at the following URL: http://standards.ieee.org/reading/ieee/updates/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/reading/ieee/interp/index.html.

Participants

At the time this standard was completed, the working group of the IEEE 1073 Standard Committee had the following membership:

Todd H. Cooper, Chair

Wolfgang Bleicher	Jörg Kampmann	Melvin Reynolds
Francis Cantraine	Ron Kirkham	Paul Rubel
Thomas Canup	Michael Krämer	Lief Rystrom
Mats Cardell	Alberto Macerata	Paul Schluter
Michael Chilbert	Simon Meij	Michael Spicer
Michael Flötotto	Angelo Rossi Mori	Alpo Värri
Ken Fuchs	Thomas Norgall	Jan Wittenber
Kai Hassing	Daniel Nowicki	Paul Woolman
Gunther Hellmann	Thomas Penzel	Christoph Zywietz
	Francesco Pinciroli	

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

Thomas Canup	John Grider	Melvin Reynolds
Michael Chilbert	Kai Hassing	Michael Spicer
Keith Chow	Tom Kannally	Richard Schrenker
Todd H. Cooper	iTeh STAN Robert Kennelly PREVIEW	M. Michael Shabot
Grace Esche	Randall Krohn	Lars Steubesand
Kenneth Fuchs	(stan Yeou-Song Lee, eh.ai)	Gin-shu Young
	Stall Daniel Nowicki Cli. al	

SIST EN ISO 11073-10201:2005

When the IEEE-SA Standards Board approved this standard on 24 June 2004, it had the following membership:

Don Wright, Chair Steve M. Mills, Vice Chair Judith Gorman, Secretary

Chuck Adams	Mark S. Halpin	Paul Nikolich
H. Stephen Berger	Raymond Hapeman	T. W. Olsen
Mark D. Bowman	Richard J. Holleman	Ronald C. Petersen
Joseph A. Bruder	Richard H. Hulett	Gary S. Robinson
Bob Davis	Lowell G. Johnson	Frank Stone
Roberto de Marca Boisson	Joseph L. Koepfinger*	Malcolm V. Thaden
Julian Forster*	Hermann Koch	Doug Topping
Arnold M. Greenspan	Thomas J. McGean	Joe D. Watson
•	Daleep C. Mohla	

^{*}Member Emeritus

Also included are the following nonvoting IEEE-SA Standards Board liaisons:

Satish K. Aggarwal, NRC Representative Richard DeBlasio, DOE Representative Alan Cookson, NIST Representative

> Don Messina IEEE Standards Project Editor

Contents

1.	Scop	e		1
2.	Norn	native refe	erences	1
3.	Defi	nitions		4
4.	Abbı	eviations	and acronyms	8
5.	Gene	eral requir	ements	9
6.	DIM			9
	6.1	Genera	ıl	9
		6.1.1	Modeling concept	9
		6.1.2	Scope of the DIM	
		6.1.3	Approach	11
		6.1.4	Extension of the model	
	6.2	Packag	ge diagram–overview	12
	6.3	_	for the Medical Package	
		6.3.1	VMO (i.e., virtual medical object)	14
		6.3.2		
		6.3.3	VMD (i.e., virtual medical device) object	15
		6.3.4	Metric object	15
		6.3.5	Metric object	15
		6.3.6	Sample Array object	
		6.3.7	Real Time Sample Array object 3.10201-2005	
			Time Sample Array object and ards/sist/9421/b52f-03c2-4258-b06f	
		6.3.9	Distribution Sample Array object 1 1073-10201-2005	16
		6.3.10	Enumeration object	16
		6.3.11	Complex Metric object	
		6.3.12	PM-Store (i.e., persistent metric) object	
		6.3.13	PM-Segment object.	
	6.4		for the Alert Package	
		6.4.1	Alert object	
		6.4.2	Alert Status object	
		6.4.3	Alert Monitor object	
	6.5	Model	for the System Package	
			VMS (i.e., virtual medical system) object	
		6.5.2	MDS object	
		6.5.3	Simple MDS object	
		6.5.4	Hydra MDS object	
		6.5.5	Composite Single Bed MDS object	
		6.5.6	Composite Multiple Bed MDS object	
		6.5.7	Log object	
		6.5.8	Event Log object	
		6.5.9	Battery object	
		6.5.10	Clock object	
	6.6		for the Control Package	
	0.0	6.6.1	SCO	
		6.6.2	Operation object	
		6.6.3	Select Item Operation object	
		0.0.5	21111 Itom Operation objections	

	6.6.4 Set Value Operation object	23
	6.6.5 Set String Operation object	23
	6.6.6 Toggle Flag Operation object	23
	6.6.7 Activate Operation object	23
	6.6.8 Limit Alert Operation object	23
	6.6.9 Set Range Operation object	23
6.7	Model for the Extended Services Package	24
	6.7.1 Scanner object	24
	6.7.2 CfgScanner (i.e., configurable scanner) object	25
	6.7.3 EpiCfgScanner (i.e., episodic configurable scanner) object	25
	6.7.4 PeriCfgScanner (i.e., periodic configurable scanner) object	25
	6.7.5 FastPeriCfgScanner (i.e., fast periodic configurable scanner) object	26
	6.7.6 UcfgScanner (i.e., unconfigurable scanner) object	26
	6.7.7 Context Scanner object	26
	6.7.8 Alert Scanner object	26
	6.7.9 Operating Scanner object	26
6.8	Model for the Communication Package	26
	6.8.1 Communication Controller object	27
	6.8.2 DCC (i.e., device communication controller) object	27
	6.8.3 BCC (i.e., bedside communication controller) object	
	6.8.4 Device Interface object	
	6.8.5 MibElement object	
	6.8.6 Specialized MibElement object	
6.9	Model for the Archival Package D. A. D. D. D. D. J. X. J. D. D. D. J. X. J. D. D. J. X. J. D. D. J. X. J. D. D. D. D. D. D. J. X. J. D.	28
	Model for the Archival Package	29
	6.9.2 Patient Archive object. Archive object. Session Archive object.	29
	6.9.3 Session Archive object	30
	6.9.4 Physician object 6.9.5 Session Test object EN ISO 11073-10201.2005 6.9.6 https://sandary.object.objec	30
	6.9.5 Session Test object	30
	6.9.6 https://standards.tteh.ai/catalog/standards/sist/9421652f-03c2-4258-606f-	30
	6.9.7 Ancillary object	30
6.10	Model for the Patient Package	30
	6.10.1 Patient Demographics object	
6.11	DIM—dynamic model	31
	6.11.1 General	
	6.11.2 MDS communication finite state machine (FSM)	31
	6.11.3 Communicating systems—startup object interaction diagram	
	6.11.4 Communication Package—MibElement data access	
	6.11.5 Dynamic object relations	
	•	
DIM	object definitions	36
7.1	General	26
/.1	General	
	7.1.2 Common data types	
7.2	**	
1.2	Top object	
	7.2.2 Behavior	-
7.3	7.2.3 Notifications	
1.3	7.3.1 VMO	
	7.3.2 VMD object	
	7.3.4 Metric object	
	7.5.4 Metile object	30

7.