BRITISH STANDARD

BS EN ISO
11073-20101:

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

Part 20101: Application profiles — Base standard

The European Standard EN ISO 11073-20101:2005 has the status of a British Standard

ICS 35.240.80

BSI
British Standards

This British Standard is the official English language version of EN ISO 11073-20101:2005. It is identical with ISO/IEEE 11073-20101:2004.

The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the *BSI Catalogue* under the section entitled "International Standards Correspondence Index", or by using the "Search" facility of the *BSI Electronic Catalogue* or of British Standards Online.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, the EN ISO title page, the EN ISO foreword page, the ISO/IEEE title pages, pages ii to ix, a blank page, pages 1 to 78, an inside back cover and a back cover.

The BSI copyright notice displayed in this document indicates when the document was last issued.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 5 December 2005

ISBN 0 580 46540 3

Amendments issued since publication

Amd. No.	Date	Comments

EUROPÄISCHE NORM

August 2005

ICS 35.240.80

English Version

Health informatics - Point-of-care medical device communication - Part 20101: Application profiles - Base standard (ISO/IEEE 11073-20101:2004)

Informatique de santé - Communication entre dispositifs médicaux sur le site des soins - Partie 20101: Profils d'applications - Norme de base (ISO/IEEE 11073-20101:2004)

Medizinische Informatik - Kommunikation patientennaher medizinischer Geräte - Teil 20101: Anwendungsprofil - Basisnorm

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.

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

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

Ref. No. EN ISO 11073-20101:2005: E

Foreword

The text of ISO/IEEE 11073-20101:2004 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 11073-20101:2005 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 11073-20101:2004 has been approved by CEN as EN ISO 11073-20101:2005 without any modifications.

INTERNATIONAL STANDARD

ISO/IEEE 11073-20101

First edition
2004-12-15

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

Part 20101:

Application profiles — Base standard

Informatique de santé — Communication entre dispositifs médicaux sur le site des soins —
Partie 20101: Profils d'applications — Norme de base

Reference number
ISO/IEEE 11073-20101:2004(E)

blank

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

Part 20101:

Application profiles — Base standard

Sponsor

IEEE 1073™ Standard Committee

of the

IEEE Engineering in Medicine and Biology Society

Approved 24 June 2004

IEEE-SA Standards Board

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 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. 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.

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 11073-20101:2004(E) was prepared by IEEE 1073 Committee of the IEEE Engineering in Medicine and Biology Society.

IEEE Introduction

This introduction is not part of ISO/IEEE 11073-20101:2004(E), Health informatics — Point-of-care medical device communication — Part 20101: Application profiles — Base standard.

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.

Notice to users

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
Francis Cantraine
Todd H. Cooper
Michael Flötotto
Ken Fuchs
Kai Hassing
Gunther Hellmann
Ron Kirkham
Michael Krämer
Alberto Macerata
Simon Meij
Angelo Rossi Mori
Thomas Norgall
Thomas Penzel
Francesco Pinciroli
Rick Revello
Melvin Reynolds
Lief Rystrøm
Michael Spicer
Lars Steubesand
Andrew Sutton
Alpo Värri
Jan Wittenber
Paul Woolman
Christoph Zywietz

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

Thomas Canup
Michael Chilbert
Todd H. Cooper
James (Bob) Davis
George Economakos
Grace Esche
Kenneth Fuchs
Kai Hassing
Tom Kannally
Robert Kennelly
Randy Krohn
Yeou-Song Lee
Daniel Nowicki
Melvin Reynolds
Ricardo Ruiz-Fernández
Michael Spicer
M. Michael Shabot
Lars Steubesand
Jan Wittenber
Gin-Shu Young

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

*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

blank

Health informatics — Point-of-care medical device communication —
Part 20101:
Application profiles — Base standard

1. Overview

This standard is divided into eight clauses, as follows:

- Clause 1 provides the scope of this standard.
- Clause 2 lists references to other standards that are useful in applying this standard.
- Clause 3 provides definitions and abbreviations.
- Clause 4 provides conventions.
- Clause 5 provides the rationale for this standard.
- Clause 6 provides a communication, i.e., protocol and service, model.
- Clause 7 provides an information, i.e., object, model.
- Clause 8 provides conformance requirements.

This standard also contains nine annexes, as follows:

- Annex A defines the specialized medical device encoding rules (MDER). (normative)
- Annex B describes the allocation of object identifiers. (normative)
- Annex C provides references to time synchronization protocols applied by this standard.
- Annex D includes state transition diagrams as part of the dynamic model.
- Annex E provides abstract syntax, which offers extensions to leveraged standards, such as minimal open systems interconnection (mOSI), that are specific to this standard. (normative)
- Annex F includes examples of a number of protocol data unit (PDU) examples.
- Annex G describes a specialization of Abstract Syntax Notation One (ASN.1).
- Annex H deals with compatibility of ASN.1 between the 1988/90 and 1994 versions.
- Annex I provides a bibliography of useful references.

1.1 Scope

The scope of this standard is upper layer [i.e., the International Organization for Standardization's (ISO's) open systems interconnection (OSI) application, presentation layer, and session layer] services and protocols for information exchange under the ISO/IEEE 11073 standards for medical device communications (MDC).

This standard is the base standard of the ISO/IEEE 11073-20000 medical device application profiles (MDAP), as harmonized through the Committee for European Normalization (CEN) and the ISO.

1.2 Purpose

The purpose of this standard is to define MDC upper layer application, i.e., ISO A-type profiles for interchange of data, which are defined by the medical device data language (MDDL) format, or ISO F-type profiles (ISO/IEEE 11073-10000 series).

1.3 Goals

The primary goal of MDAP standards is to support MDC upper layer data interchange, based on MDDL, among a wide range, by type and scale, of future and current devices for use in point-of-care (POC) settings in the acute care sections of hospitals.

1.4 Audience

The primary user of the MDAP standards is a software engineer who is creating a MDC system or attempting to establish an interface to one.

Because this family of standards is based largely upon international standardization profiles, familiarity with a range of related standards and technologies is useful if not necessary. The following are recommended as a minimum background:

a) ISO/IEEE 11073 architecture, especially IEEE Std 1073™,[1] ISO/IEEE 11073-10201, and lower layer standards (e.g., ISO/IEEE 11073-30200)

b) ISO's OSI layered architecture, primarily the upper layers, i.e., application, presentation, and session

c) Systems management

d) Object-oriented analysis and design

e) Machine language theory

2. References

This standard shall be used in conjunction with the following publications. When the following standards are superceded by an approved revision, the revision shall apply.

IEEE Std 1073, IEEE Standard for Medical Device Communications—Overview and Framework.[2]

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

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