INTERNATIONAL STANDARD

ISO/IEEE 11073-30200

First edition
2004-12-15

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

Part 30200:
Transport profile — Cable connected

Informatique de santé — Communication entre dispositifs médicaux sur le site des soins —
Partie 30200: Profil de transport — Connection par câble

Reference number
ISO/IEEE 11073-30200:2004(E)

Health informatics — Point-of-care medical device communication — Part 30200: Transport profile — Cable connected

Sponsor

IEEE 1073™ Standard Committee

of the

IEEE Engineering in Medicine and Biology Society

Approved 30 January 2000

IEEE-SA Standards Board

Abstract: A connection-oriented transport profile and physical layer suitable for medical device communications in legacy devices is established. Communications services and protocols consistent with specifications of the Infrared Data Association are defined. These communication services and protocols are optimized for use in patient-connected bedside medical devices.
Keywords: bedside, Infrared Data Association, IrDA, legacy device, medical device, medical device communications, MIB, patient, SNTP

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Published 15 December 2004. Printed in the United States of America.

Print: ISBN 0-7381-4519-X SH95303
PDF: ISBN 0-7381-4520-3 SS95303

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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 11073-30200:2004(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 11073-30200:2004(E), Health informatics — Point-of-care medical device communication — Part 30200: Transport profile — Cable connected.

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.

ISO/IEEE 11073-30200:2004(E) defines a communications transport profile. This profile is for a cable-connected local area network (LAN) for the interconnection of computers and medical devices. This standard is suitable for new device designs, but is particularly targeted to modifications of legacy devices.

The term "legacy devices" refers to equipment that is

— Already in use in clinical facilities
— In active production at the facilities of medical device manufacturers, or
— Beyond the initial stages of engineering development

Specifically, this standard describes connection-oriented communications services and protocols consistent with standards of the Infrared Data Association (IrDA), adapted as appropriate for ISO/IEEE 11073 applications and optimized for use in patient-connected bedside medical devices.

ISO/IEEE 11073-30200:2004(E) is one part of the family of ISO/IEEE 11073 standards. It is compatible with the upper layer ISO/IEEE 11073 standards.

The primary users of this standard are technical personnel who are creating or interfacing with a medical device communications system. Familiarity with the ISO/IEEE 11073 family of standards is recommended. Familiarity with communications and networking technologies is also recommended.

This standard is intended to satisfy the following objectives:

a) Allow compatibility with existing medical device communications designs to minimize design risk, contain product costs, and simplify field upgrades
b) Specify hardware and software elements that are available from multiple vendors
c) Make use of other computer industry communication technology to allow for continuous cost decreases
d) Meet the requirements of IEEE Std 1073™-1996
e) Be compatible with the current published and draft ISO/IEEE standard upper layers

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 guide was completed, the Legacy Device Working Group of the IEEE 1073 Committee had the following membership:

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When the IEEE-SA Standards Board approved this standard on 30 January 2000, it had the following membership:

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1. Overview

This standard is divided into 11 clauses, as follows:

- Clause 1 provides an overview 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 goals for this standard.
- Clause 5 provides an overview of network topology and layering.
- Clause 6 provides a profile of the physical layer.
- Clause 7 provides a profile of the data link layer.
- Clause 8 provides a profile of the network layer.
- Clause 9 provides a profile of the transport layer.
- Clause 10 describes the optional time synchronization service.
- Clause 11 provides labeling and conformance requirements.

This standard also contains 15 annexes, as follows:

- Annex A describes the physical layer.
- Annex B provides information on the maximum cable length.
- Annex C provides examples of physical link media.
- Annex D provides example schematics for modular adapters.
- Annex E provides a detailed rationale for pin assignments.
- Annex F describes the use of 10BASE-T with this standard.
- Annex G provides a discussion of power delivery considerations.
- Annex H provides examples of simple bedside communications controller (BCC) and device communications controller (DCC) designs.
- Annex I provides an example of an isolated BCC design.
- Annex J provides an optical isolator design example.
- Annex K provides marking guidelines.
- Annex L provides protocol examples, particularly of connection establishment.

— Annex M defines the Infrared Data Association (IrDA) profile specifications adapted from the IrDA implementation guidelines.
— Annex N provides guidelines for using the SNTP time synchronization protocol.
— Annex O provides bibliographical references.

1.1 Scope

The scope of this standard is an IrDA-based, cable-connected local area network (LAN) for the interconnection of computers and medical devices. This standard is suitable for new device designs, but is particularly targeted to modifications of legacy devices.

The term "legacy devices" refers to equipment that is

— Already in use in clinical facilities
— In active production at the facilities of medical device manufacturers, or
— Beyond the initial stages of engineering development

In each of these cases, the degree of effort to add a standardized communications capability might normally be prohibitive, unless special care is taken in developing a suitable standard.

1.2 Purpose

The purpose of this standard is to provide connection-oriented communications services and protocols consistent with IrDA specifications and adapted as appropriate for ISO/IEEE 11073 applications.

1.3 Standards compatibility

This standard is one part of the family of ISO/IEEE 11073 standards. It is compatible with the ISO/IEEE upper layer standards.

1.4 Audience

The primary users of this standard are technical personnel who are creating or interfacing with a medical device communications system. Familiarity with the ISO/IEEE 11073 family of standards is recommended. Familiarity with communications and networking technologies is also recommended.

2. References

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

ANSI/TIA/EIA-232-F-1997, Interface Between Terminal Equipment and Data Circuit-Terminating Equipment Employing Serial Binary Data Interchange.[1]

ANSI/TIA/EIA-561-1990, Simple 8 Position Non-Synchronous Interface Between Data Terminal Equipment and Data Circuit-Terminating Equipment Employing Serial Binary Data Interchange.

[1]ANSI publications are available from the Sales Department, American National Standards Institute, 25 West 43rd Street, 4th Floor, New York, NY 10036, USA (http://www.ansi.org/).

ANSI/TIA/EIA-562-1989, Electrical Characteristics for an Unbalanced Digital Interface.

ANSI/TIA/EIA-568-A-1995, Commercial Building Telecommunications Cabling Standard.

IEC 60603-7: 1996, Connectors for Frequencies Below 3 MHz for Use with Printed Circuit Boards—Part 7: Detailed specification for connectors, 8-way, including fixed and free connectors with common mating features, with assessed quality.[2]

IEC 60417-1:1998, Graphical Symbols for Use on Equipment—Part 1: Overview and Application.

IEEE Std 802.3™, IEEE Standard for Local Area Networks—Carrier Sense Multiple Access with Collision Detection (CSMA/CD) Access Method and Physical Layer Specifications.[3, 4]

IEEE Std 1073™-1996, IEEE Standard for Medical Device Communications—Transport Profiles—Overview and Framework.

IEEE Std 1073.3.1™-1994, IEEE Standard for Medical Device Communications—Transport Profile—Connection Mode.[5]

IEEE Std 1073.4.1™-1994, IEEE Standard for Medical Device Communications—Physical Layer Interface—Cable Connected.[6]

IrDA, Link Management Protocol, Version 1.1, Jan. 23, 1996.[7]

IrDA, Serial Infrared Link Access Protocol (IrLAP), Version 1.1, June 16, 1996.

IrDA, Tiny TP: A Flow-Control Mechanism for use with IrLMP, Version 1.1, Oct. 20, 1996.

ISO/IEC 8877:1992(E), Information technology—Telecommunications and information exchange between systems—Interface connector and contact assignments for ISDN Basic Access Interface located at reference points S and T.

RFC-1305, Internet Engineering Task Force, Network Working Group Report, Mar. 1992, “Network Time Protocol Specification, Implementation and Analysis,” Mills, D., University of Delaware.[8, 9]

RFC-2030, Internet Engineering Task Force, Network Working Group Report, Oct. 1996, “Simple Network Time Protocol (SNTP) Version 4 for IPv4, IPv6 and OSI,” Mills, D., University of Delaware.

[2]IEC publications are available from the Sales Department of the International Electrotechnical Commission, Case Postale 131, 3, rue de Varembé, CH-1211, Genève 20, Switzerland/Suisse (http://www.iec.ch/). IEC publications are also available in the United States from the Sales Department, American National Standards Institute, 11 West 42nd Street, 13th Floor, New York, NY 10036, USA.

[3]IEEE publications are available from the Institute of Electrical and Electronics Engineers, 445 Hoes Lane, P.O. Box 1331, Piscataway, NJ 08855-1331, USA (http://www.standards.ieee.org/).

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

[5]IEEE Std 1073.3.1-1994 has been withdrawn; however, copies can be obtained from Global Engineering, 15 Inverness Way East, Englewood, CO 80112-5704, USA, tel. (303) 792-2181 (http://global.ihs.com/).

[6]IEEE Std 1073.4.1-1994 has been withdrawn; however, copies can be obtained from Global Engineering, 15 Inverness Way East, Englewood, CO 80112-5704, USA, tel. (303) 792-2181 (http://global.ihs.com/).

[7]IrDA publications are available at http://www.irda.org.

[8]Internet Engineering Task Force publications are available at http://www.ietf.org/.

[9]Information on the Network Time Protocol is available at http://www.eecis.udel.edu/~ntp/.