



EESTI STANDARDI EESSÕNA NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 11073-30300:2005 sisaldab Euroopa standardi EN ISO 11073-30300:2005 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11073-30300:2005 consists of the English text of the European standard EN ISO 11073-30300:2005.
Käesolev dokument on jõustatud 29.09.2005 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.	This document is endorsed on 29.09.2005 with the notification being published in the official publication of the Estonian national standardisation organisation.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.
Käsitlusala: The scope of this standard is to define an IrDA-based transport profile for medical device communication that uses short- range infrared, as a companion standard to ISO/IEEE 11073-30200, which specifies a cableconnected physical layer. This standard also supports use cases consistent with industry practice for handheld personal digital assistants (PDAs) and network APs that support IrDA-infrared communication.	Scope: The scope of this standard is to define an IrDA-based transport profile for medical device communication that uses short- range infrared, as a companion standard to ISO/IEEE 11073-30200, which specifies a cableconnected physical layer. This standard also supports use cases consistent with industry practice for handheld personal digital assistants (PDAs) and network APs that support IrDA-Infrared communication.
ICS 35.240.80	
Võtmesõnad:	

EUROPEAN STANDARD

EN ISO 11073-30300

NORME EUROPÉENNE

EUROPÄISCHE NORM

August 2005

35.240.80 **English Version** Health informatics - Point-of-care medical device communication - Part 30300: Transport profile - Infrared wireless (ISO/IEEE 11073-30300:2004) Informatique de santé - Communication entre dispositifs médicaux sur le site des soins - Partie 30300: Profil de transport - Faisceau information (ISO/IEEE 11073-Medizinische Informatik - Kommunikation patientennaher medizinischer Geräte - Teil 30300: Transportprofil drahtlose Infrarotübertragung 30300:2004) 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

oreword

The text of ISO/IEEE 11073-30300:2004 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 11073-30300:2005 by Technical Committee CEN/TC 251 "Health informatics", the secretariat of which is held by NEN.

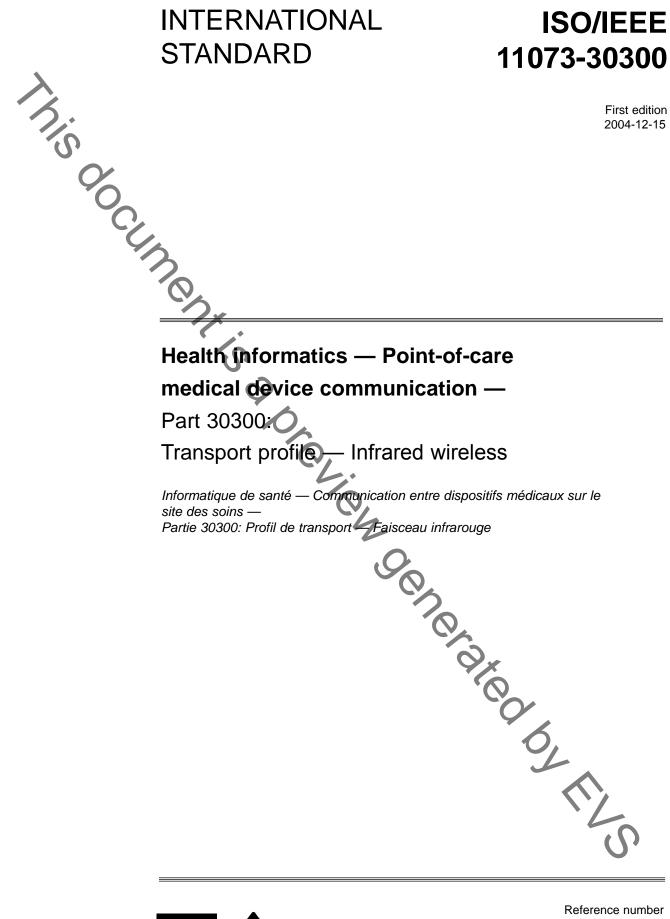
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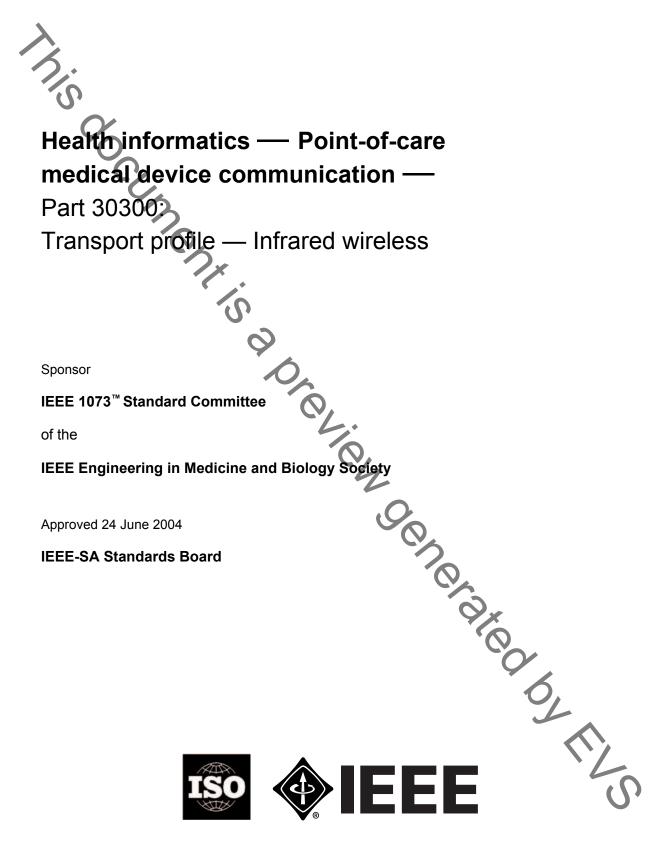
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ISO/IEEE 11073-30300:2004(E)

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Abstract: This standard establishes a connection-oriented transport profile and physical layer suitable for medical device communications that use short-range infrared wireless. This standard defines communications services and protocols that are consistent with specifications of the Infrared Data Association (IrDA) and are optimized for point-of-care (POC) applications at or near the patient.

Keywords: access point, bedside, device interfaces, infrared, Infrared Data Association, IrDA, legacy device, medical device, medical device communications, medical information bus, MIB, patient, Simple Network Time Protocol, SNTP, point-of-care, POC, point-of-care testing, POCT, wireless

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Print: ISBN 0-7381-4093-7 SH95258 PDF: ISBN 0-7381-4094-5 SS95258

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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

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ISO/IEEE 11073-30300:2004(E) was prepared by IEEE 1073 Committee of the IEEE Engineering in Medicine and Biology Society.

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IEEE Introduction

This introduction is not part of ISO/IEEE 11073-30300:2004(E), Health informatics — Point-of-care medical device communication — Part 30300: Transport profile — Infrared wireless.

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.

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Errata

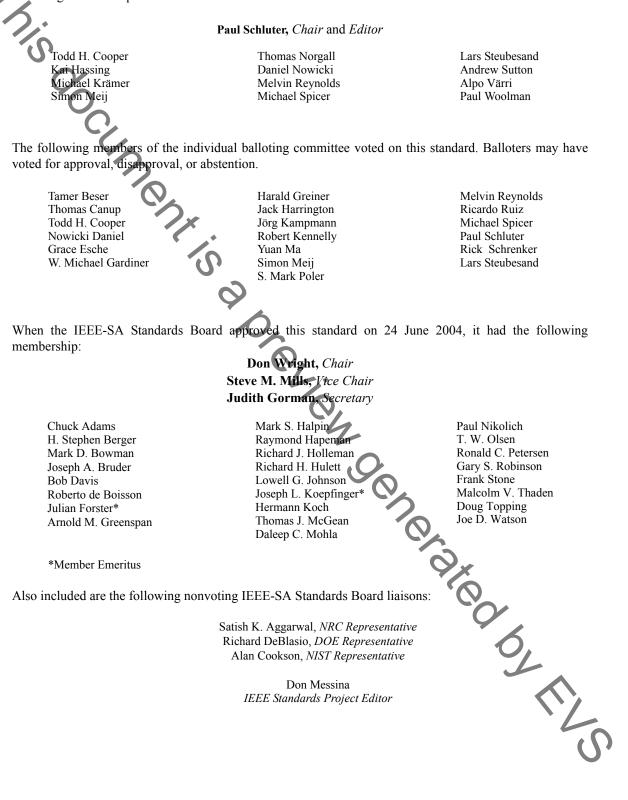
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Interpretations

Current interpretations can be accessed at the following URL: <u>http://standards.ieee.org/reading/ieee/interp/index.html</u>.

Participants

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



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

Transport profile — infrared wireless

1. Overview

Part 30300:

This standard is divided into eleven 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 nine annexes, as follows:

- Annex A describes the Infrared Data Association (IrDA) infrared physical layer,
- Annex B provides an overview of the ISO/IEEE 11073-30200¹ cable-connected physical layer.
- Annex C provides an example of an ISO/IEEE 11073-30200 cable-connected infrared adapter.
- Annex D provides marking guidelines.
- Annex E defines the IrDA profile specifications adapted from the IrDA implementation guidelines.
- Annex F defines networked access points (APs) for NCCLS *Point-of-Care Connectivity; Approved Standard* (NCCLS POCT1) diagnostic devices.
- Annex G provides guidelines for networked APs for ISO/IEEE 11073 devices.

¹Information on references can be found in Clause 2.

- Annex H discusses lower layer compatibility with other medical communication standards.
- Annex I provides bibliographical references.

1.1 Scope

The scope of this standard is to define an IrDA-based transport profile for medical device communication that uses short-range infrared, as a companion standard to ISO/IEEE 11073-30200, which specifies a cable-connected physical layer. This standard also supports use cases consistent with industry practice for handheld personal digital assistants (PDAs) and network APs that support IrDA-infrared communication.

1.2 Purpose

The purpose of this standard is to provide connection-oriented communication services and protocols consistent with IrDA specifications, using short-range infrared as the physical layer. This standard extends and complements ISO/IEEE 11073-30200, which specifies a cable-connected physical layer. The use of IrDAinfrared is appropriate for mobile and portable point-of-care (POC) clinical lab instruments (e.g., glucose meters) and other medical devices that require intermittent point-and-shoot connectivity to a data repository.

This standard utilizes the work embodied in the Connectivity Industry Consortium (CIC) and NCCLS POCT1 device and AP interface specification (Appendix A), which is part of an overall effort to standardize communication for POC medical devices using a single transport protocol (IrDA Tiny Transport Protocol [TinyTP]) running over two physical layers: cable-connected and infrared.

1.3 Standards compatibility

This standard is one part of the family of ISO/IEEE 1073 standards. It is a companion standard to ISO/IEEE 11073-30200. Both standards describe connection-oriented communications services and protocols consistent with standards of the IrDA.

Like ISO/IEEE 11073-30200, this standard is designed to be compatible with the ISO/IEEE 11073 upper layer standards such as the ISO/IEEE 11073-10000 and ISO/IEEE 11073-20000 families of standards. It is also fully compatible with (and is largely based on) Appendix A of the NCCLS POCT1 and is capable of supporting other upper layer medical device communication standards, such as the NCCLS POCT1 device messaging layer for POC diagnostic devices.

Finally, this standard specifies and provides recommendations for how a network AP acts as a relay between the IrDA TinyTP connection to the medical device and a Transmission Control Protocol/Internet Protocol (TCP/IP) connection to a remote host on the network.² This is an essential first step toward deploying the ISO/IEEE 11073 family of standards on the widely used TCP/IP and other standard Internet protocols.

1.4 Audience

The primary users of this standard are technical personnel who are creating or interfacing to 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.

²This standard provides a normative specification regarding network APs for NCCLS POCT1 devices in Annex F and informative guidance regarding network APs for ISO/IEEE 11073 devices. A future ISO/IEEE 11073 internetworking standard may include other profiles based on User Datagram Protocol/Internet Protocol (UDP/IP) as well as TCP/IP.

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.

ANSI/TIA/EIA-232-F, Interface Between Terminal Equipment and Data Circuit-Terminating Equipment Employing Serial Binary Data Interchange.³

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

CENELEC EN 60825-1/A11 (amendment to CENELEC version of IEC 60825-1, Safety of Laser Products —Part 1: Equipment Classification, Requirements and User's Guide).⁴

IEC 60417-1, Graphical Symbols for Use on Equipment—Part 1: Overview and Application.⁵

IEC 60825-1, Safety of laser products—Part I: Equipment classification, requirements and user's guide, as amended (reported at TC 76 Meeting, Frankfurt, Germany, October 31, 1997).

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.^{6, 7}

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

ISO/IEEE 11073-30200, Health informatics — Point-of-care-medical device communication — Part 30200: Transport profile — Cable connected.

IETF Network Working Group Report RFC-1305, Network Time Protocol (version 3) specification, implementation and analysis, Mills, D., University of Delaware, Mar. 1992.^{8,9}

IETF Network Working Group Report RFC-2030, Simple Network Time Protocol (SNTP) (version 4) for IPv4, IPv6 and OSI, Mills, D., University of Delaware, Oct. 1996.

IETF RFC-793, Transmission Control Protocol – DARPA Internet Program Protocol Specification, Postel, Jon (editor), University of Southern California, Information Sciences Institute, Sept. 1981. This and other related TCP/IP requests for comments (RFCs) are available as IETF publications. See also books about TCP/IP by Comer [B1]¹⁰ and other authors.

IrDA Serial Infrared Link Access Protocol (IrLAP).¹¹

³ANSI 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/). EIA publications are available from Global Engineering Documents, 15 Inverness Way East, Englewood, CO 80112, USA (http://global.ihs.com/).

⁴CEN publications are available from CEN publications are available from the European Committee for Standardization (CEN), 36, rue de Stassart, B-1050 Brussels, Belgium (http://www.cenorm.be).

⁵IEC 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, 25 West 43rd Street, 4th Floor, New York, NY 10036, USA (http://www.ansi.org/).

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

¹⁰The numbers in brackets correspond to the bibliographical items listed in Annex I.

¹¹IrDA publications are available at http://www.irda.org.

IrDA Serial Infrared Link Access Protocol Specification for 16 Mbit/s Addition (VFIR).

IrDA Serial Infrared Link Management Protocol.

IrDA Serial Infrared Physical Layer Specification, version 1.3, Oct. 15, 1998.

IrDA Tiny TP: A Flow-Control Mechanism for use with IrLMP.

ISO/IEC 8802-3, Information technology — Telecommunications and information exchange between systems — Local and metropolitan area networks — Specific requirements — Part 3: Carrier sense multiple access with collision detection (CSMA/CD) access method and physical layer specifications.¹²

NCCLS Point-of-Care Connectivity; Approved Standard. NCCLS document POCT1-A [ISBN 1-56238-450-3].¹³

3. Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this standard, the following terms and definitions apply. IEEE 100^{TM} , *The Authoritative Dictionary of IEEE Standards Terms and Definitions*, Seventh Edition [B4], should be referenced for terms not defined in this clause.

3.1.1 10BASE-T: ISO/IEC 8802-3 and IEEE Std 802.3 physical layer specification for Ethernet over two pairs of unshielded twisted pair (UTP) media at 10 Mbit/s.

3.1.2 access point (AP): A subsystem that consolidates data from one or more point-of-care (POC) devices onto another communication link.

NOTE—Examples of APs include a multiport concentrator or a dedicated single-port AP, typically connected to a local area network (LAN), or an AP that is part of a multifunctional device such as a patient monitor or personal computer (PC).¹⁴

3.1.3 access point (AP) interface: The interface (principally input) to an AP or concentrator.

NOTE—This term is used extensively in the National Committee for Clinical Laboratory Standards *Point- of-Care Connectivity; Approved Standard* (NCCLS POCT1) and is equivalent to an ISO/IEEE 11073 bedside communications controller (BCC).

3.1.4 baud (Bd): A unit of signaling speed, expressed as the number of times per second the signal can change the electrical state of the transmission line or other medium.

NOTE—Depending on the encoding strategies, a signal event may represent a single bit, more, or less, than one bit.

3.1.5 bedside communications controller (BCC): A communications controller, typically located at a patient bedside, that serves to interface between one or more medical devices associated with a single patient. The BCC may be embedded into local display, monitoring, or control equipment. Alternatively, it may be part of a communications router to a remote hospital host computer system.

 ¹²ISO/IEC publications are available from the ISO Central Secretariat, Case Postale 56, 1 rue de Varembé, CH-1211, Genève 20, Switzerland/Suisse (http://www.iso.ch/). ISO/IEC publications are also available in the United States from Global Engineering Documents, 15 Inverness Way East, Englewood, CO 80112, USA (http://global.ihs.com/). Electronic copies are available in the United States from the American National Standards Institute, 25 West 43rd Street, 4th Floor, New York, NY 10036, USA (http://www.ansi.org/).
 ¹³NCCLS documents are available from NCCLS, 940 West Valley Road, Suite 1440, Wayne, PA 19087-1898, USA. (NCCLS was

formerly known as the National Committee for Clinical Laboratory Standards.)

¹⁴Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement this standard.