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

Part 30300:NDARD PREVIEW

Transport profile ds infrared wireless

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Part 30300:

Transport profile — Infrared wireless

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IEEE Engineering in Medicine and Biology Society 30300-2004

Approved 24 June 2004

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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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ISO Foreword

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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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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.

Notice to users

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Interpretations

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

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

Part 30300:

Transport profile — infrared wireless

1. Overview iTeh STANDARD PREVIEW

This standard is divided into eleven clauses, as follows: s.iteh.ai)

- 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 and/sist/78135776-9927-4335-
- 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 IrDA-infrared 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.

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1.3 Standards compatibility

ISO/IEEE 11073-30300:2004

This standard is one part of the family of ISO/IEEE 11073 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 dards.iteh.ai)

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
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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/).

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

 $^{^{10}}$ The numbers in brackets correspond to the bibliographical items listed in Annex I.

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