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

Part 30300: Transport profile — Infrared wireless

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ICS 35.240.80

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- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep UK interests informed;
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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 59 and a back cover.

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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 infrarouge (ISO/IEEE 11073-
30300:2004)

Medizinische Informatik - Kommunikation patientennaher
medizinischer Geräte - Teil 30300: Transportprofil -
drahtlose Infrarotübertragung

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Foreword

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.

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of an identical text or by endorsement, at the latest by February 2006, and conflicting national standards shall be withdrawn at the latest by February 2006.

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The text of ISO/IEEE 11073-30300:2004 has been approved by CEN as EN ISO 11073-30300:2005 without any modifications.

EN ISO 11073-30300:2005

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STANDARD

ISO/IEEE
11073-30300

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**Health informatics — Point-of-care
medical device communication —
Part 30300:
Transport profile — Infrared wireless**

*Informatique de santé — Communication entre dispositifs médicaux sur le
site des soins —
Partie 30300: Profil de transport — Faisceau infrarouge*



Reference number
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**Health informatics — Point-of-care
medical device communication —
Part 30300:
Transport profile — Infrared wireless**

Sponsor

IEEE 1073™ Standard Committee

of the

IEEE Engineering in Medicine and Biology Society

Approved 24 June 2004

IEEE-SA Standards Board



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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.

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 11073-30300:2004(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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Health informatics — Point-of-care medical device communication —

Part 30300:

Transport profile — infrared wireless

1. Overview

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.

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- 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.

1.3 Standards compatibility

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.