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**Medizinische Informatik –
Kommunikation patientennaher medizinischer Geräte –
Teil 30300: Transportprofil – drahtlose Infrarotübertragung
(ISO/IEEE 11073-30300:2004);
Englische Fassung EN ISO 11073-30300:2005**

Health informatics –
Point-of-care medical device communication –
Part 30300: Transport profile – Infrared wireless (ISO/IEEE 11073-30300:2004);
English version EN ISO 11073-30300:2005

Informatique de santé –
Communication entre dispositifs médicaux sur le site des soins –
Partie 30300: Profil de transport – Faisceau infrarouge (ISO/IEEE 11073-30300:2004);
Version anglaise EN ISO 11073-30300:2005

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Normenausschuss Medizin (NAMed) im DIN

Nationales Vorwort

Diese Norm enthält unter Berücksichtigung des Präsidialbeschlusses 13/1998 den englischen Originaltext der europäischen Norm EN ISO/IEEE 11073-30300, Ausgabe 2005-08. Die Europäische Norm wurde in der WG IV „Technology for Interoperability“ des CEN/TC 251 „Medizinische Informatik“ übernommen und im Rahmen eines gemeinsamen Projektes zwischen ISO und IEEE erarbeitet. Der NA 063-07-02 AA „Interoperabilität“ des Fachbereichs 7 „Medizinische Informatik“ des Normenausschusses Medizin im DIN hat an der Erarbeitung mitgewirkt.

Für die im Abschnitt 2 zitierten Normen wird im Folgenden auf die entsprechende Deutsche Norm hingewiesen:

IEC 60825-1 siehe DIN EN 60825-1 + Berichtigung 1

ISO/IEEE 11073-30200 siehe DIN EN ISO 11073-30200

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Zusammenfassung

Die ISO/IEEE11073-Standardfamilie ermöglicht die Datenübertragung zwischen Medizingeräten und Computersystemen. Sie erlaubt die automatisierte, detaillierte Erfassung von patientenbezogenen Vitaldaten und Funktionsparametern durch die Verwendung von Überwachungs- und Therapiegeräten — beispielsweise auf einer Intensivstation oder im Operationssaal. Die primären Ziele dabei sind:

- Bereitstellung von „Plug-and-Play“-Funktionalität und Interoperabilität mit Patienten verbundener Medizingeräte für Realzeitanwendungen.
- Vereinfachung des effizienten Austausches gemessener Vitaldaten von Patienten und Betriebsdaten der verwendeten Medizingeräte.

„Echtzeit“ bedeutet, dass Daten von mehreren Medizingeräten zeitgenau erfasst und in Bruchteilen von Sekunden dargestellt oder verarbeitet werden können, werden können. „Plug and Play“ beinhaltet, dass eine medizinische Fachkraft lediglich die Verbindung zum Gerät herstellen muss, worauf das System automatisch — ohne weiteren menschlichen Eingriff — das neu angeschlossene Medizingerät erkennt, Kommunikationsparameter sowie gegebenenfalls die Applikation konfiguriert und danach die Kommunikation von Daten aufnimmt.

Gegenstand dieser Norm ist ein verbindungsorientiertes Transportprofil für die Kommunikation medizinischer Geräte, welche Infrarot-Datenübertragung benutzen. Dieses Profil unterstützt drahtlose Infrarotkommunikation kurzer Reichweite zwischen medizinischen Geräten, Netzwerkzugangspunkten, Computern und anderen medizinischen Datenverarbeitungssystemen. Die Anwendung von IrDA-Infrarotübertragung bietet sich insbesondere an für mobile und portable „Point of Care“-Analysegeräte (z. B. Glukose-Meßgeräte) und andere medizinische Geräte, die lediglich kurzzeitige „Point-and-Shoot“-Datenübertragung für die Verbindung zu einem Datenverarbeitungssystem benutzen. Die in dieser Norm festgelegten verbindungsorientierten Kommunikationsdienste und Protokolle stehen mit Spezifikationen der „Infrared Data Association“ (IrDA) im Einklang und sind für patientennahe Anwendungen am „Point of Care“ optimiert. Sie sind geeignet für Geräte-Neuentwicklungen, zielen aber insbesondere auch auf die Modifikation vorhandener Geräte ab. Unter „vorhandenen Geräten“ soll hierbei Ausrüstung verstanden werden, welche

- sich bereits in klinischen Einrichtungen im Einsatz befindet,
- bereits in der Produktion durch Hersteller medizinischer Geräte steht, oder
- deren erste Entwicklungsphasen abgeschlossen sind.

Als Teil der ISO/IEEE 11073-Standardfamilie ist diese Norm kompatibel mit entsprechenden Standards für die höheren Protokollschichten (11073.1xxx und 11073.2xxx). Sie ist darüber hinaus vollständig kompatibel mit (und weitgehend abgeleitet von) der „Device and Access Point Specification“ des CLSI-Standards für Point-Of-Care Connectivity POCT1-A und geeignet, dessen anwendungsnahes „Device Messaging Layer“-Protokoll für „Point of Care“-Analysegeräte zu unterstützen. Sie stellt eine Alternative zu anderen Transportsystem-Standards (11073.3xxx) dar, insbesondere zu ISO/IEEE 11073-30200 Medizinische Informatik — Kommunikation patientennaher medizinischer Geräte — Teil 30200: Transportprofil — drahtgebundene Übertragung (ISO/IEEE 11073-30200:2004; Englische Fassung EN ISO 11073-30200:2005³). Beide Normen benutzen die gleichen IrDA-basierten Transportprotokolle. Hierdurch werden Entwicklungskosten reduziert und die Implementierung einfacher, preiswerter Adapter für den Kabel-zu-Infrarot-Übergang erleichtert. Gegenüber ISO/IEEE 11073-30200 weist diese Norm außerdem folgende wesentliche Erweiterungen auf:

- a) Sie definiert zwei zusätzliche Client-Server-Modelle für die Interaktion medizinischer Geräte, die das CLSI POCT1-A-Kommunikationsmodell unterstützen.
- b) Sie enthält Spezifikationen und Empfehlungen zur Funktion eines Netzwerk-Zugangspunkts als Übergang zwischen der IrDA-TinyTP-Verbindung zum medizinischen Gerät und einer TCP/IP-Verbindung zu einem entfernten netzwerkbasierten Host sowie zur Information, die an einem Netzwerk-Zugangspunkt bezüglich der Dienste eines oder mehrerer solcher Hosts registriert wird.

Über seine eigentliche Aufgabe hinaus ist es ein Hauptzweck dieser Norm, gemeinsame Zugangspunkte für die Unterstützung von ISO/IEEE 11073- und POCT1-A-kompatiblen medizinischen Geräten sowie von tragbaren „Personal Digital Assistants“ zu ermöglichen, ungeachtet der Unterschiede hinsichtlich ihrer höheren Protokollschichten und klinischen Anwendungen.

Nationaler Anhang NA (informativ)

Literaturhinweise

DIN EN ISO 11073-30300:2006-09, *Medizinische Informatik — Kommunikation patientennaher medizinischer Geräte — Teil 30300: Transportprofil — drahtlose Infrarotübertragung (ISO/IEEE 11073-30300:2004); Englische Fassung EN ISO 11073-30300:2005*

DIN EN 60825-1:2003-10, *Sicherheit von Laser-Einrichtungen — Teil 1: Klassifizierung von Anlagen, Anforderungen und Benutzer-Richtlinien (IEC 60825-1:1993 + A1:1997 + A2:2001); Deutsche Fassung EN 60825-1:1994 + A1:2002 + A2:2001*

DIN EN 60825-1 Berichtigung 1: 2004-06, *Berichtigungen zu DIN EN 60825-1 (VDE 0837 Teil 1):2003-10*

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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
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Medizinische Informatik - Kommunikation patientennaher
medizinischer Geräte - Teil 30300: Transportprofil -
drahtlose Infrarotübertragung
(ISO/IEEE 11073-30300:2004)

This European Standard was approved by CEN on 16 August 2005.

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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.

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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.

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 11073-30300:2004 has been approved by CEN as EN ISO 11073-30300:2005 without any modifications.

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.

- 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.

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, 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 802.3TM, 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 1073TM, 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 Varembe, 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/>).

⁶IEEE publications are available from the Institute of Electrical and Electronics Engineers, Inc., 445 Hoes Lane, Piscataway, NJ 08854, USA (<http://standards.ieee.org/>).

⁷The IEEE standards or products referred to in this clause are trademarks of the Institute of Electrical and Electronics Engineers, Inc.

⁸IETF publications are available from the Internet Engineering Task Force (<http://www.ietf.org/>).

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 100TM, *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 Varembe, 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.

3.1.6 beginning of frame (BOF): An octet specified by Infrared Link Access Protocol (IrLAP) that marks the beginning of a frame.

3.1.7 Category-5 (CAT-5) balanced cable: The designation of 100 Ω unshielded twisted pair (UTP) cables and associated connecting hardware whose transmission characteristics are specified up to 100 MHz. (ANSI/TIA/EIA-568-A)

3.1.8 common access point (AP): An AP that can service ISO/IEEE 11073, National Committee for Clinical Laboratory Standards *Point-of-Care Connectivity; Approved Standard* (NCCLS POCT1), and handheld personal digital assistant (PDA) devices.

3.1.9 Connectivity Industry Consortium (CIC): A consortium, no longer in existence, that was organized to specify, recommend, and develop communication protocols for point-of-care (POC) diagnostic medical devices.

3.1.10 cyclic redundancy check (CRC): The result of a calculation carried out on the octets within an Infrared Link Access Protocol (IrLAP) frame; it is also called a frame check sequence (FCS). The CRC is appended to the transmitted frame. At the receiver, the calculation creating the CRC may be repeated, and the result compared to that encoded in the signal.

3.1.11 data manager (DM): Typically, a network server that performs such functions as point-of-care (POC) data storage and forwarding, quality assurance and quality control, and other POC instrument and data management functions.

3.1.12 device communications controller (DCC): A communications interface associated with a medical device. A DCC may support one or more physically distinct devices acting as a single network communications unit. Its purpose is to provide a point-to-point communication link to a bedside communications controller (BCC).

3.1.13 device manager: In the context of this standard, a network server that gathers, processes, stores, and forwards data from ISO/IEEE 11073 instruments and devices, typically using one or more networked access points (APs).

NOTE—A device manager is not a required component for an ISO/IEEE 11073 compatible infrastructure.

3.1.14 docking station: A mechanical and electrical interface that supports the use of a point-of-care (POC) device, typically employing legacy mechanical interfaces, connectors, protocols, and power delivery methods.

3.1.15 electromagnetic compatibility (EMC): The ability of a device, equipment, or system to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbances to anything in that environment.

3.1.16 electromagnetic interference (EMI): Signals emanating from external sources (e.g., power supplies and transmitters) or internal sources (e.g., adjacent electronic components, energy sources) that disrupt or prevent operation of electronic systems.

3.1.17 electrostatic discharge (ESD): The sudden transfer of charge between bodies of differing electrostatic potentials that may produce voltages or currents that could destroy or damage electrical components.

3.1.18 frame check sequence (FCS): The result of a calculation performed on a series of octets to verify their integrity (i.e., that the octets were transferred without error). For Infrared Data Association (IrDA) communications, the FCS may be a 16-bit cyclic redundancy check (CRC).

3.1.19 high-level data link control (HDLC): A standard protocol defined by the International Organization for Standardization (ISO) for bit-oriented, frame-delimited data communications.

3.1.20 information access service (IAS): A component of Infrared Link Management Protocol (IrLMP) that provides for simple retrieval of device capability and configuration information.

3.1.21 Infrared Data Association (IrDA): An industry organization that has developed a set of infrared data communications specifications. The abbreviation is commonly used to refer to the set of specifications.

3.1.22 Infrared Link Access Protocol (IrLAP): The link access protocol specified by the Infrared Data Association (IrDA) that provides for reliable, ordered transfer of data between two devices.

3.1.23 Infrared Link Management Protocol (IrLMP): The link management protocol specified by Infrared Data Association (IrDA) that supports multiplexing of the Infrared Link Access Protocol (IrLAP) layer and simple retrieval of device capability and configuration information.

3.1.24 local area network (LAN): A communication network to interconnect a variety of intelligent devices (e.g., personal computers [PCs], workstations, printers, file storage devices) that can transmit data over a limited area, typically within a facility. *See also: service access point (SAP).*

3.1.25 medical information bus (MIB): The informal name for the ISO/IEEE 11073 family of standards.

3.1.26 octet: A group of eight adjacent bits.

3.1.27 personal digital assistant (PDA): The name given to the class of consumer electronic devices that handle functions such as management of calendars, contact lists, and task lists.

3.1.28 point of care (POC): The environment immediately surrounding a patient.

3.1.29 point-of-care (POC) device: A medical device typically used in patient care areas. In the context of the National Committee for Clinical Laboratory Standards *Point-of-Care Connectivity; Approved Standard* (NCCLS POCT1), a device that is capable of performing blood chemistry and other measurements in patient-care areas.

3.1.30 point-of-care (POC) device interface (PDI): Specifies the interface (principally output) of a POC device or its docking station to an access point (AP).

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 device communications controller (DCC).

3.1.31 primary station: As defined by Infrared Link Access Protocol (IrLAP), the station on the data link that assumes responsibility for the organization of data flow and for unrecoverable data link error conditions. It issues commands to the secondary stations and gives them permission to transmit.

3.1.32 protocol data unit (PDU): Information delivered as a unit between peer entities that contains control information and, optionally, data.

3.1.33 quality of service (QoS): Four negotiated parameters constituting the QoS for a link: signaling speed, maximum turnaround time, data size, and disconnect threshold.

3.1.34 radio frequency (RF): (A) (Loosely) The frequency in the portion of the electromagnetic spectrum that is between the audio-frequency portion and the infrared portion. (B) A frequency useful for radio transmission.

NOTE to (B)—The present practicable limits of RF are roughly 10 kHz to 100 000 MHz. Within this frequency range electromagnetic radiation may be detected and amplified as an electric current at the wave frequency.

3.1.35 radio frequency interference (RFI): *See:* **radio interference (RI).**

3.1.36 radio interference (RI): Degradation of the reception of a wanted signal caused by radio frequency (RF) disturbance. *Synonym:* **radio frequency interference (RFI).**

NOTES

1—RF disturbance is an electromagnetic disturbance having components in the RF range.

2—The English words *interference* and *disturbance* are often used indiscriminately. The expression *radio frequency interference* (RFI) is also commonly applied to an RF disturbance or an unwanted signal.

3.1.37 secondary station: As defined by Infrared Link Access Protocol (IrLAP), any station on the data link that does not assume the role of the primary station. It will initiate transmission only as a result of receiving explicit permission to do so from the primary station.

3.1.38 service access point (SAP): An address or port at which a connection to an upper layer protocol entity can be established.

3.1.39 service data unit (SDU): Information that is delivered as a unit between peer service access points (SAPs). *See:* **service access point (SAP).**

3.1.40 set normal response mode (SNRM): A high-level data link control (HDLC) message sent by a bedside communications controller (BCC) to a device communications controller (DCC) when a successful connection to the network has occurred.

3.1.41 Tiny Transport Protocol (TinyTP): The transport protocol specified by Infrared Data Association (IrDA) that provides multiple, concurrent, reliable, bidirectional communication streams on an IrDA link with robust flow control.

3.1.42 Transmission Control Protocol/Internet Protocol (TCP/IP): A transport protocol that provides reliable, bidirectional, stream-oriented network communication. TCP/IP is one of the foundation protocols of the Internet.

3.1.43 unshielded twisted pair (UTP): The type of Category-5 (CAT-5) cabling used in ISO/IEEE 11073-30200.

3.2 Acronyms and abbreviations

ACK	acknowledgment (TCP message)
AEL	accessible emission level
AP	access point
API	access point interface
ASYNCR or Async	asynchronous
BCC	bedside communications controller
BOF	beginning of frame
BPWR	bedside communications controller power
CAT-5	Category 5
CIC	Connectivity Industry Consortium

CPU	central processing unit
CRC	cyclic redundancy check
CS	connection sense
DCC	device communications controller
DM	data manager
DPWR	device communications controller power
DTR	data terminal ready
EMC	electromagnetic compatibility
EMI	electromagnetic interference
EOF	end of frame
ESD	electrostatic discharge
EUI	extended unique identifier
FCS	frame check sequence
FIR	IrDA Fast Infrared (at the negotiated speed of 4 MBd)
GND	ground
GPS	global positioning system
HDLC	high-level data link control
IAS	information access service
IP	Internet Protocol
IR	infrared
IrDA	Infrared Data Association
IrLAP	Infrared Link Access Protocol
IrLMP	Infrared Link Management Protocol
IrPHY	Infrared physical layer specification
LAN	local area network
LAP	LAN access point
LM	link management
LowPwr	low power
LSAP	link service access point
LSB	least significant bit
MDDL	medical device data language
MGR	manager
MIB	medical information bus
MIR	IrDA Medium Infrared (at the negotiated speeds of 576 kBd or 1152 kBd)
MTU	maximum transfer unit
NCCLS	National Committee for Clinical Laboratory Standards
NTP	Network Time Protocol
PC	personal computer
PDA	personal digital assistant
PDI	POC device interface
PDU	protocol data unit
POC	point of care or point-of-care
POCT1	<i>Point-of-Care Connectivity; Approved Standard</i>
PPM	pulse position modulation
PSH	push
QoS	quality of service

RAC	Registration Authority Committee
RD	receive data
RFC	request for comments
RFI	radio frequency interference
RJ	registered jack
RLL	run-length limited
RR	receive ready
RTS	request to send
RxD	receive data
RZI	return to zero, inverted
SAP	service access point
SAR	segmentation and reassembly
SDU	service data unit
SIP	SIR interaction pulse
SIR	IrDA Serial Infrared (at the negotiated speeds of 9600 Bd to 115.2 kBd)
SNMP	Simple Network Management Protocol
SNRM	set normal response mode
SNTP	Simple Network Time Protocol
StdPwr	standard power
SYNC	synchronize (TCP message)
sync	synchronous
TCP/IP	Transmission Control Protocol/Internet Protocol
TD	transmit data
TinyTP	Tiny Transport Protocol
TTP	TinyTP
TTPSAP	TinyTP service access point
TxD	transmit data
UA	unnumbered acknowledgment
UART	universal asynchronous receiver/transmitter
UDP	User Datagram Protocol
UTP	unshielded twisted pair
VFIR	IrDA Very Fast Infrared (at the negotiated speed of 16 MBd)
XID	exchange station identification
XMIT	transmit

4. Goals for this standard

The following are the main goals for this standard:

- The standard shall define a short-range, point-to-point infrared wireless communication link, suitable for portable medical devices used at the POC at or near the vicinity of the patient.
- The standard shall specify hardware and software elements that are available from multiple vendors.
- The standard shall use existing, standards-based computer industry communication technology to allow for continuous cost decreases.
- The standard should use the same IrDA-based transport protocols as ISO/IEEE 11073-30200 to reduce software development costs and to facilitate the development of simple, low-cost cable-connected-to-infrared adapters.

- e) The standard shall support the requirements of IEEE Std 1073 as well as the current published and draft IEEE/ANSI standard upper layers.
- f) The standard should define at least one implementation of a network AP and, in particular, provide a normative specification of an AP for NCCLS POCT1 devices.

5. Architecture

This clause is intended to define ISO/IEEE 11073-30300 network topology, protocol layering, and the client-server relationships that exist between a medical device and the host monitor or system.

5.1 Topology

The ISO/IEEE 11073-30200 and ISO/IEEE 11073-30300 networks define a star topology, requiring each device to have its own connection directly into the network. On the communications network, there are two types of communications nodes allowed:

- a) The bedside communications controller (BCC) is the primary node and functions as the network controller and the hub of the star.
- b) Device communications controllers (DCCs) are secondary nodes and limited in number to the loading capacity of the BCC and/or number of physical ports.

The devices connect to the network through the DCC. The BCC can interface directly to a local host computer, as in Figure 1, or to a remote host computer over a network, as in Figure 2. The portion of the BCC performing ISO/IEEE 11073-30300 operations would be the same in both configurations. Note, however, that the BCC would also include internetworking functions in the latter case.

Unless otherwise noted, all references to a BCC in this standard refer only to components performing the functions of ISO/IEEE 11073-30300, as indicated in Figure 1 and Figure 2.

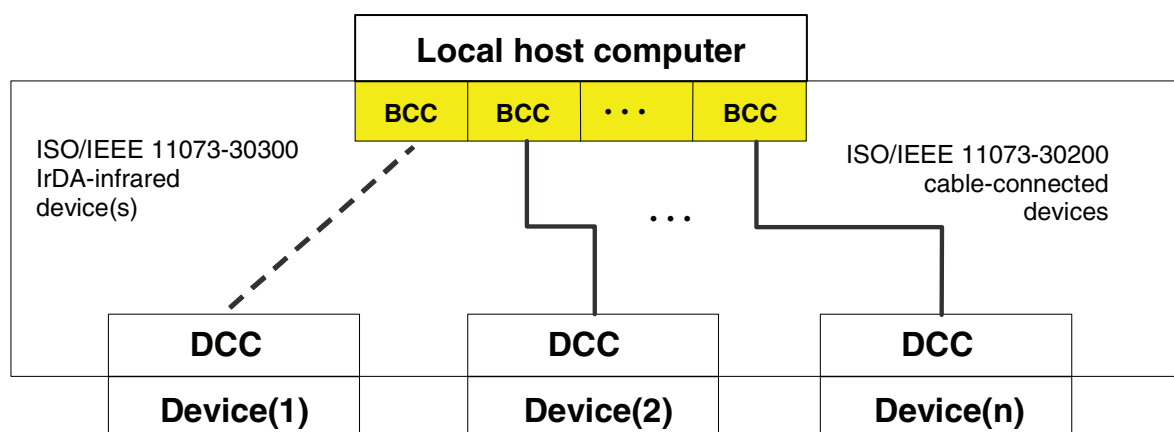


Figure 1—Connection topology with a local host

The cable-connected network described by ISO/IEEE 11073-30200 consists of individual point-to-point connections between the BCC and each DCC: it is not a multidrop network. Only a single DCC is supported on each physical port connection.

The IrDA-infrared wireless connections described by this standard specify how a primary station can discover multiple secondary stations and then communicate with them one at a time.

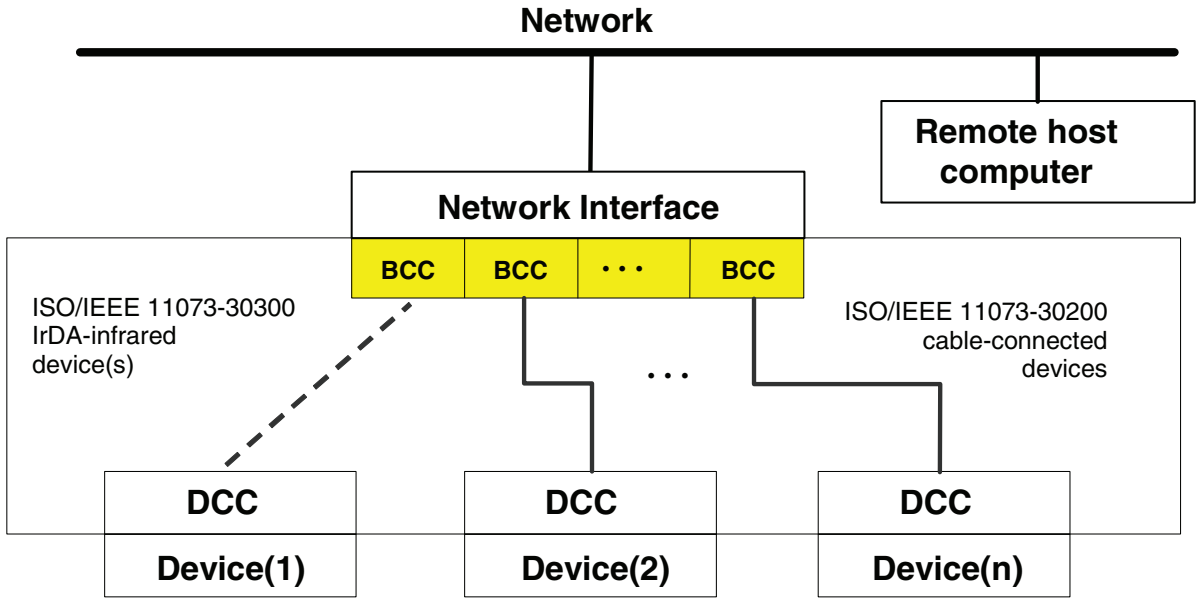


Figure 2—Connection topology with a remote host

5.2 Protocol layering

Layering is consistent with the IrDA standards, as shown in Figure 3.

Related ISO OSI layer		IrDA, ISO/IEEE 11073-30200, and ISO/IEEE 11073-30300 layers			
SAPs		IrLMP	MDDL SAP	SNTP SAP	Other SAPs
Transport	4	IAS	TinyTP: Tiny Transport Protocol		
Network	3	IrLMP: Link Management Protocol			
Data link	2	IrLAP: Link Access Protocol			
Physical link	1	Cable-connected		Infrared	
		ISO/IEEE 11073-30200		IrDA SIR, MIR, FIR, and VFIR	

Figure 3—IrDA, ISO/IEEE 11073-30200, and ISO/IEEE 11073-30300 layering

The components of the stack are briefly as follows:

- a) **Physical layer** defines optical and signal encoding used by the IrDA-infrared physical layer (see Clause 6).
- b) **Infrared Link Access Protocol (IrLAP)** provides a device-to-host connection for the reliable, ordered transfer of data, including device discovery procedures (see Clause 7).
- c) **Infrared Link Management Protocol (IrLMP)** provides multiplexing of the IrLAP layer (see Clause 8).
- d) **TinyTP** provides flow control on IrLMP connections (see Clause 9).
- e) **MDDL SAP** is a service access point (SAP) for the medical device data language (MDDL), as described in other ISO/IEEE 11073 standards.

- f) **Simple Network Time Protocol (SNTP) SAP** is a SAP for an optional time synchronization service (see Clause 10).
- g) **Other SAPs** support other medical device communication protocols, such as those developed by the NCCLS and other standards organizations, as well as nonstandard, often proprietary, protocols.

Service primitives are specified for some of the layers. This definition of service does not imply any specific interface implementation. These primitives do not constitute an application programming interface. Conformance to this standard is judged by performance at the communications port only.

5.3 IrDA primary and secondary roles

IrLAP communication partners act in one of two roles. There is one primary station and one or more secondary stations. The primary station discovers all available secondary stations and establishes a connection to specific stations. The primary station is always the initiator of data transfer; the secondary station reacts to commands from the primary.

At the lower IrLAP protocol layer, the primary station is always the initiator of the data transfer, and the secondary station reacts to commands from the primary. At the IrLMP and TinyTP layers, however, the master/slave nature of IrLAP is hidden from the application, and a symmetrical set of services is provided, regardless of whether a station participates as a primary or secondary.

ISO/IEEE 11073-30200 and IrDA-compatible PDAs use different conventions for assigning IrDA primary and secondary roles to devices and APs. Although operation as an IrDA primary or secondary is generally hidden from applications that use the IrDA IrLMP and TinyTP protocol layers, differences do exist and are addressed in this subclause.

5.3.1 ISO/IEEE 11073-30200

ISO/IEEE 11073-30200 uses the following IrDA primary and secondary conventions:

- The DCC participates as a IrDA secondary station and
- The BCC participates as an IrDA primary station.

The BCC periodically performs IrDA discovery to see if a DCC is attached to the cable, possibly as frequently as every one or two seconds.

The IrDA secondary role assigned to the DCC and primary role assigned to the BCC are appropriate for the acute-care settings in which ISO/IEEE 11073-30200 is intended to be used, for the following reasons:

- a) The BCC can poll the DCC in a deterministic manner. This manner is critical in the acute-care setting where it is necessary to have second-by-second parameter and alarm updates from ventilators and heart-rate monitors.
- b) The BCC, as the client (initiator and controlling entity), requests data from the DCC, which acts as the data server (source of data) during the session. These roles fit the IrDA client-server model with the BCC participating as a primary and the DCC participating as a secondary station.
- c) DCCs are often memory constrained and thus benefit from the smaller secondary IrDA stack size.
- d) BCCs could broadcast to multiple DCCs.
- e) BCCs could communicate simultaneously (multicast) to multiple DCCs.¹⁵

¹⁵The IrDA standards specify how a primary station can *discover* multiple secondary stations and communicate with them one at a time. The IrDA standards currently do not specify how point-to-multipoint communication should be performed, but this capability could be added at a later date.

5.3.2 PDA and local area network (LAN) AP (LAP)

A PDA and a LAP use the following IrDA primary and secondary conventions:

- The PDA participates as an IrDA primary station and
- The LAP participates as an IrDA secondary station.

The PDA initiates the transaction as a client by performing IrDA discovery, and the LAP passively waits for the request on behalf of the server on the network in a client-server relationship.

The IrDA primary role assigned to the PDA and secondary role assigned to the LAP are also appropriate for POC data transfer for the following reasons:

- a) The PDA, as the initiator of the client-server data exchange, contends for access to the infrared medium only when it has something to transfer. This approach minimizes infrared traffic that could interfere with other infrared devices.
- b) The PDA, as the IrDA primary, can rapidly access the LAP services because it does not need to wait for the discovery polling interval (if the LAP was an IrDA primary station).
- c) These roles (PDA as primary and LAP as secondary) represent industry standard practice for the majority of IrDA-compatible devices (including printers and modems) described in the IrDA Point and Shoot Profile [B7].

Because handheld NCCLS POCT1 devices share many of the characteristics of PDAs, the ability to operate as an IrDA primary station is desirable, especially if both types of devices were to share the same AP infrastructure.

5.3.3 Common AP

Based on the discussion above, two conventions have been used for assigning IrDA primary and secondary roles for devices and APs. This subclause explores how both conventions can be incorporated into a common AP that can support ISO/IEEE 11073 medical information bus (MIB) devices, NCCLS POCT1 diagnostic devices, and handheld PDAs.

In order to support ISO/IEEE 11073-30300 infrared DCCs (devices) as IrDA secondaries and to support handheld PDAs or POC devices as IrDA primaries, the common AP should be able to function either as an IrDA primary or secondary station, depending on the type of device that attempts to communicate with it.¹⁶ It should be noted that many IrDA devices are capable of participating as IrDA primary or secondary stations, so implementing this capability in an AP should not be difficult.

Although supporting both roles places an additional burden on the common AP, it provides the greatest flexibility to the POC device designer, where limited memory size and processor capability may be major issues. A POC device that has ample memory can participate as an IrDA primary, consistent with how handheld PDAs communicate with LAPs. As an IrDA primary, the POC device would be able to rapidly establish a connection with the common AP because the POC device would not have to wait for the discovery polling interval.

A POC device that has limited memory could instead participate as an IrDA secondary, similar to an ISO/IEEE 11073-30200 DCC. A relatively short discovery polling interval (~ one second) could be used with the cable-connected RS-232 physical layer specified by this standard, allowing rapid discovery of the POC or MIB device.

¹⁶The general intent here is that a POC device can participate either as a primary or secondary, but not both. IrDA primary-secondary role exchange is not supported by ISO/IEEE 11073-30200 or by this standard.