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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

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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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/IEEE 11073-30300:2004(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 11073-30300:2004(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, 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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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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Kai Hassing	Daniel Nowicki	Andrew Sutton
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The following members of the individual balloting committee voted on this standard. Balloters may have voted for approval, disapproval, or abstention.

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When the IEEE-SA Standards Board approved this standard on 24 June 2004, it had the following membership:

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Alan Cookson, *NIST Representative*

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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 11073-30200[1] 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.

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[1]Information 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.

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[2]This 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[TM], 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[TM], 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]

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

[4]CEN 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).

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

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

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

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

[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.

[11]IrDA 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™, *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.

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[12]ISO/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/).

[13]NCCLS 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.)

[14]Notes 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 bed-side 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
ASYNC 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	*Point-of-Care Connectivity; Approved Standard*
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:

   a)   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.

   b)   The standard shall specify hardware and software elements that are available from multiple vendors.

   c)   The standard shall use existing, standards-based computer industry communication technology to allow for continuous cost decreases.

   d)   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 load-
        ing 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 com-
puter, 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.
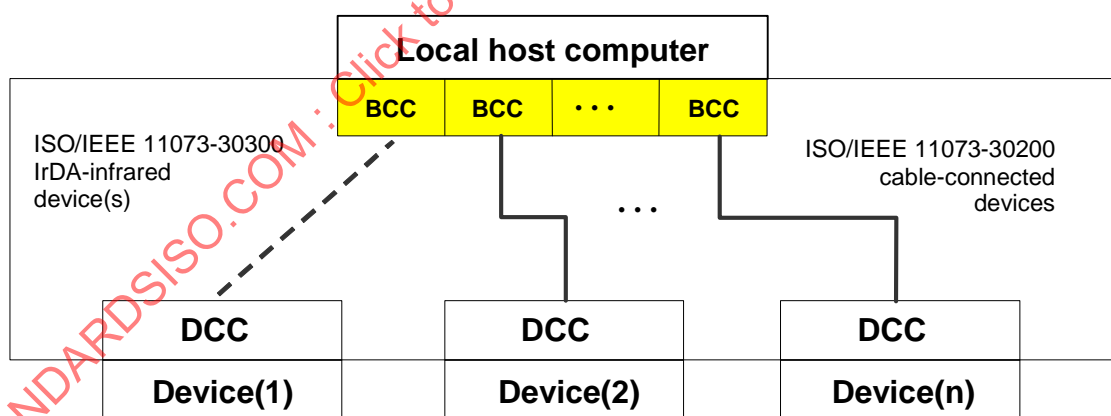
Figure 1—Connection topology with a local host

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 dis-
cover multiple secondary stations and then communicate with them one at a time.
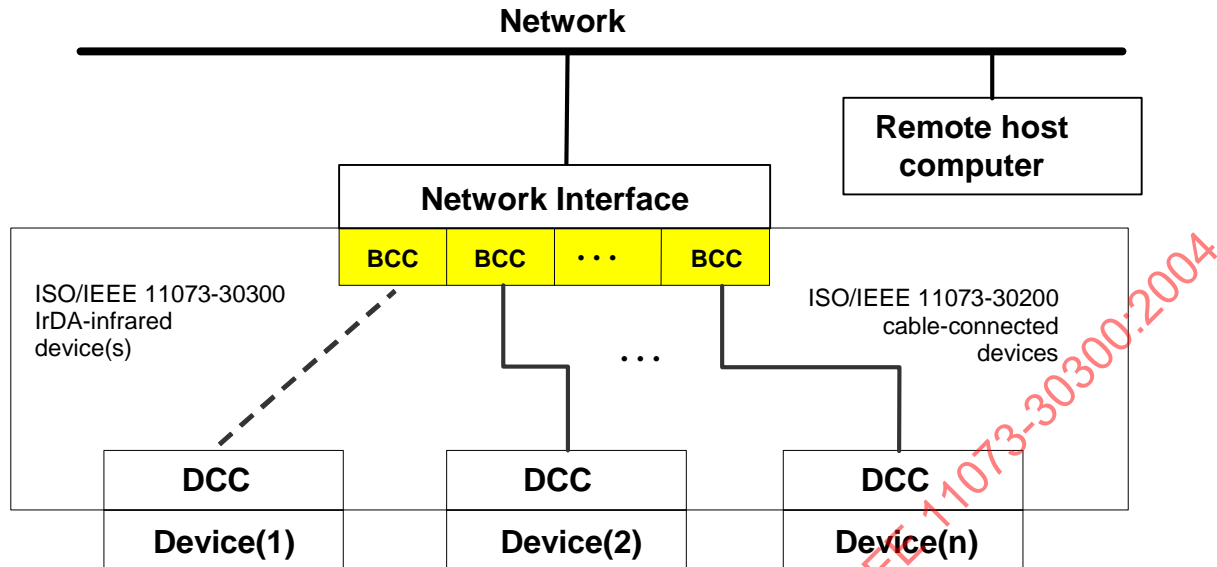
Figure 2—Connection topology with a remote host

5.2 Protocol layering

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

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.

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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]

[15]The 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.

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[16]The 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.

5.4 Client-server models for medical device communication

Three cases of client-server and primary-secondary are also considered.

Case I summarizes how IrDA-compatible PDAs participate as the client-initiator (as an IrDA primary) and the AP participates as (or represents) the server in a client-server relationship (as an IrDA secondary). This client-server model is endorsed by the NCCLS POCT1, especially for POC devices based on industry standard platforms.

Case II summarizes how a POC device participates as the client-initiator (as an IrDA secondary) and the AP participates as (or represents) the server in a client-server relationship (as an IrDA primary). This client-server model is also endorsed by the NCCLS POCT1, especially for memory-limited POC devices that can support only a secondary-only IrDA protocol stack.

Case III summarizes how an ISO/IEEE 11073-30200 DCC participates as the data-server (as an IrDA secondary) and the BCC participates as the client-initiator (as an IrDA primary). A step-by-step protocol walk-through for this case is provided in ISO/IEEE 11073-30200. This case is expanded to include the IrDA-infrared physical layer by this standard.

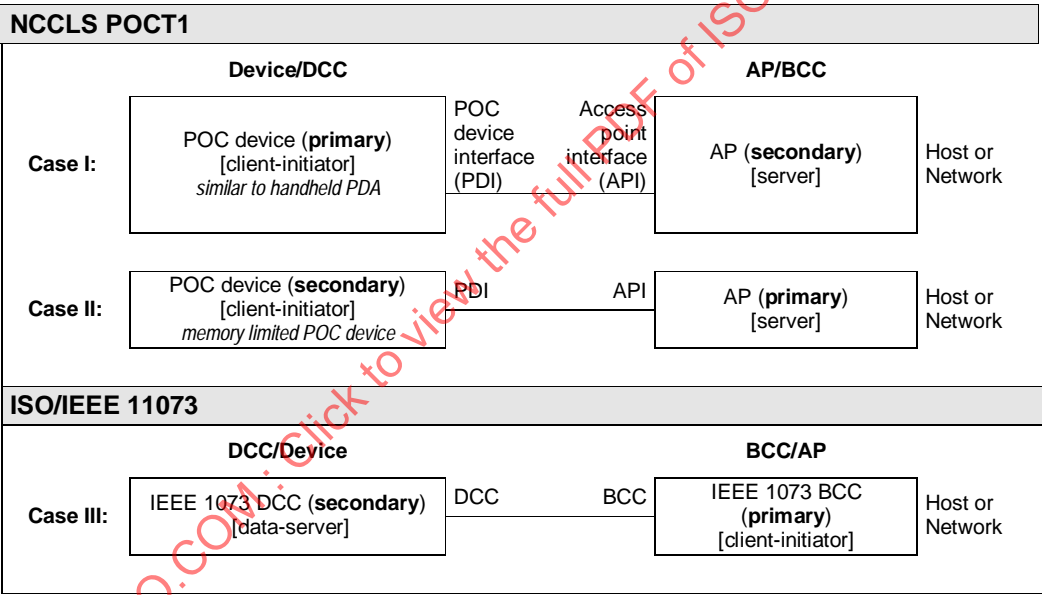**Figure 4—Client-server models for medical device communication**

6. Physical layer

The physical layer defines the optical and signal encoding used by the infrared physical layer, as specified by the IrDA serial infrared physical layer specification (IrPHY). Unless otherwise stated, the required, recommended, optional and default options and parameters specified by IrPHY shall apply to this standard.

The IrDA IrPHY defines a point-to-point, narrow angle ($\pm$ 15° half-angle cone) infrared[17] data transmission standard designed to operate over a distance of 0 to 1 m and at signaling rates of 9600 Bd[18] to 4 MBd. A recent extension to IrPHY called Very Fast Infrared (VFIR) supports a signaling rate of 16 MBd.

6.1 IrDA transceiver power options

The IrDA IrPHY defines two transceiver power options: standard power and low power. Low power uses roughly one-tenth the power of standard power and is appropriate for battery-powered devices. The range for the three combinations of standard power (StdPwr) and low power (LowPwr) are shown in Table 1.

Table 1—IrDA-infrared link distance specifications

	Link distance lower limit (m)	Minimum link distance upper limit (m)[a]
LowPwr to **LowPwr**	0	0.2
StdPwr to **LowPwr**	0	0.3
StdPwr to **StdPwr**	0	1.0

[a]The "minimum link distance, upper limit" defined in IrPHY is the *maximum* distance over which reliable communication is guaranteed.

DCCs or BCCs may use either power option. If power consumption is not an issue, it is recommended that BCCs implement the standard power option due to its greater range.

6.2 Signaling rates

The IrDA-infrared signaling rates utilized by this standard are shown in Table 2. Similar to ISO/IEEE 11073-30200, the 2400 Bd signaling rate is not supported. The signaling rate of 9600 Bd is mandatory, because negotiation of IrDA parameters is performed at that rate.

Unlike ISO/IEEE 11073-30200, signaling rates greater than 115.2 kBd are permitted. It should be recognized, however, that the majority of POC devices will use the slower Serial Infrared (SIR) signaling rates and that the availability of multiple SIR rates should not be sacrificed in order to support the faster Medium Infrared (MIR), Fast Infrared (FIR), and VFIR rates. Like many other IrDA communication parameters, the signaling rate is negotiated, the fastest common rate is used by the both entities, and communication at 9600 Bd is always possible.

Additional information about the IrDA-infrared physical layer and how it is used by this standard is provided in the following informative annexes:

— Annex A: Key physical layer parameters, SIR encoding example, electromagnetic interference (EMI)/radio frequency interference (RFI), eye safety, and other topics.

— Annex C: Sample ISO/IEEE 11073-30200 cable-connected-to-IrDA-infrared transceiver design.

— Annex D: Marking guidelines for an ISO/IEEE 11073-30300 infrared transceiver port.

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[17]Peak wavelength lies between 0.85 µm to 0.90 µm.

[18]Although the IrDA specifications permit operation at 2400 Bd, it is not supported by ISO/IEEE 11073-30200 or by this standard.

Table 2—ISO/IEEE 11073-30300 signaling rates and framing

Signaling rate	IrDA name	Frame wrapper and encoding	Nominal pulse duration	Status[a]
2.4 kBd	SIR[b]	Async RZI	1.63–78.13 μs	X
9.6 kBd	SIR	Async RZI	1.63–19.53 μs	M
19.2 kBd	SIR	Async RZI	1.63–9.77 μs	R
38.4 kBd	SIR	Async RZI	1.63–4.88 μs	R
57.6 kBd	SIR	Async RZI	1.63–3.26 μs	R
115.2 kBd	SIR	Async RZI	1.63 μs	R
576.0 kBd	MIR[c]	Sync HDLC RZI	434.0 ns	O
1115.2 kBd	MIR	Sync HDLC RZI	217.0 ns	O
4.0 MBd	FIR[d]	Sync 4PPM	125 .0 ns	O
16.0 MBd	VFIR[ee]	Sync HHH(1,13)	41.7 ns	O

[a]Status: M, mandatory; R, recommended; O, optional; X, not supported.
[b]SIR, asynchronous (Async) return to zero, inverted, (RZI), pulse duration 3/16 bit time at 115 kBd or signaling rate; CCITT CRC-16.
[c]MIR, synchronous (Sync) high-level data link control (HDLC) RZI, bit-stuffing after 5 ones; CCITT CRC-16.
[d]FIR, four-slot pulse position modulation (PPM); IEEE CRC-32. Consecutive pulse-pairs are valid.
[e]VFIR, rate-2/3-(1,13) run-length limited (RLL) code; IEEE CRC-32. This code, called the HHH(1,13) code within IrDA, is named after its authors, Hirt et al. [B2].

7. Data link layer

The data link layer is adopted from the serial IrLAP (and IrLAP-VFIR if VFIR is implemented). IrLAP implements ISO/OSI layer 2, the data link layer.

IrLAP provides the following features:

— Dynamic address and address conflict resolution

— Error recovery mechanism

— Station discovery and identification procedure

— Connectionless and connection-oriented data transfer and other services

— Negotiation of connection characteristics

This standard follows some of the recommendations of IrDA Lite [B6] for IrLAP.

IrLAP capabilities not specified here may be implemented, but are out of the scope for an ISO/IEEE 11073-30300 interface. Examples of these capabilities are sniffing, connectionless data transfer, test frames, role exchange, and 2400 Bd operation.

This standard requires that each port on a multiport BCC/AP represent a separate instance of the transport profile stack.

7.1 IrDA primary and secondary roles

ISO/IEEE 11073 and the NCCLS POCT1 use different conventions for the IrDA primary and secondary roles played by a DCC/device and a BCC/AP with infrared capability.

7.1.1 ISO/IEEE 11073

ISO/IEEE 11073 connections use the following conventions for assigning IrDA primary and secondary roles:

— A DCC/device with infrared capability shall act as an IrDA secondary station.

— A BCC/AP with infrared capability shall act as an IrDA primary station.

7.1.2 NCCLS POCT1

NCCLS POCT1 connections use the following conventions for assigning IrDA primary and secondary roles:

— A DCC/device with infrared capability is strictly free to participate as either an IrDA primary or secondary station.

— A BCC/AP with infrared capability shall be able to operate as either an IrDA primary or secondary[19], in response to the IrDA secondary or primary role of the DCC/device that attempts to communicate with it.[20]

7.2 IrLAP frame

IrLAP, when used with IrPHY SIR, defines a physical layer frame wrapper and a data link frame. The physical layer uses the ASYNC frame wrapper. The ASYNC frame wrapper has a beginning of frame (BOF), end of frame (EOF), and frame check sequence (FCS) fields. This frame encloses the IrLAP data link frame, shown in Figure 5. IrLAP defines a transparency algorithm that allows the use of the framing characters (BOF and EOF) inside the data frame.

Address	Control	Information
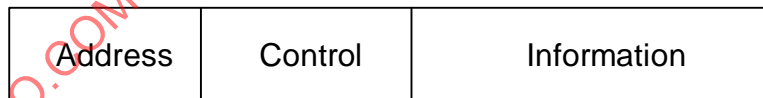
Figure 5—IrLAP frame

IrLAP and IrPHY also define synchronous HDLC frame wrappers for 576 kBd and 1.152 MBd (MIR) and a synchronous frame wrapper using four-slot PPM for 4 MBd (FIR). IrLAP-VFIR defines extensions and modifications to IrLAP to support 16 MBd (VFIR). The IrLAP data link frame shown in Figure 5 is the IrLAP payload supported by all four framing methods (SIR, MIR, FIR and VFIR).

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[19]It should be noted that many IrDA devices are capable of participating as IrDA primary or secondary stations and that the additional firmware required to provide IrDA secondary functionality (e.g., responding to discovery frames) is relatively modest when compared to the firmware required to implement an IrDA primary stack.

[20]Requiring that a BCC/AP be able to participate as an IrDA secondary station is consistent with industry standard practice for the majority of IrDA-compatible devices. IrDA primary devices contend for access to the infrared medium only when they have something to transfer; this approach minimizes infrared traffic that could interfere with other infrared devices. IrDA primary devices can rapidly gain access to data services of the BCC/AP without having to wait for the discovery polling interval of the latter.

7.3 Procedure model

The simplified procedure model in Figure 6 illustrates the different procedures within an IrDA communication.

```
┌──────────┐     ┌──────────┐     ┌─────────────┐     ┌──────────────┐
│ Discover │ ──▶ │ Connect  │ ──▶ │ Information │ ──▶ │  Disconnect  │
│          │     │          │     │  transfer   │     │              │
└──────────┘     └──────────┘     └─────────────┘     └──────────────┘
     ▲                ▲                                        │
     │                │                                        │
     └────────────────┴────────────────────────────────────────┘
```

Figure 6—IrDA communication procedure model

7.3.1 Discovery

A primary station (the initiator) performs a discovery procedure to detect all available secondary devices. The secondary device (the responder) responds with address information and minimal device information (service hints and a device nickname). The discovery phase is done with a fixed set of communication parameters (e.g., 9600 Bd).

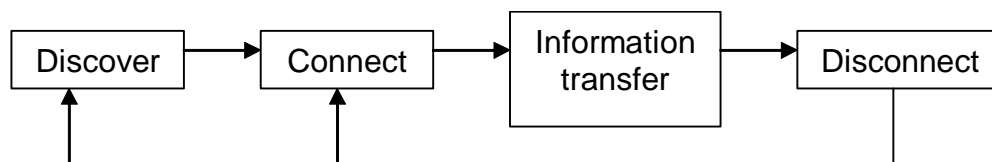Discovery begins when the initiator broadcasts a discovery command frame. This command frame specifies the number of time slots for the discovery process: more time slots means more devices can be discovered and reduces the likelihood of collisions between responders during discovery.

In ISO/IEEE 11073-30200, a cable-connected BCC/AP port may use a relatively short discovery polling interval (~ one second) to detect nearby secondary devices since the discovery procedure cannot interfere with other infrared devices in the room. An infrared BCC/AP port should use a somewhat longer discovery polling interval (~ two seconds) to minimize unnecessary interaction with other infrared devices in its vicinity. The discovery polling interval shall comply with the media access rules described in the IrDA IrLAP specification. Specifically, a BCC/AP or DCC/device in the contention state shall ensure that there is no activity on the link for a time period greater than 500 ms (560 ms to 600 ms recommended) before attempting to transmit (usually the exchange station identification [XID] discovery frame).

An infrared secondary ISO/IEEE 11073 device, in applications where a permanent connection is required, shall respond to all discovery command frames issued by the BCC. An infrared secondary NCCLS POCT1 device, on the other hand, shall respond to discovery command frames issued by an AP only if (1) the POCT device needs to communicate with the AP or (2) a sufficient amount of time has elapsed since the previous transmission. The purpose of the latter requirement is to prevent subsequent rediscovery of the device immediately after it has sent its data.

7.3.2 Negotiation and connection

The primary station establishes a connection by negotiating the maximum communication capabilities (e.g., signaling speed, data size, window size) supported by both devices. In the case of a multiport BCC, this may be constrained by available system bandwidth and the bandwidth requirements at other ports on the BCC.

After acknowledgment from the secondary station, both stations switch to the new communication parameters.

7.3.3 Information transfer

The primary station periodically polls the secondary station for data or status information. The stations communicate using a reliable data transport service. Stations may also use an unreliable expedited data transport service for time synchronization.

7.3.4 Disconnect

Both stations, primary or secondary, can normally disconnect the connection. In addition there are timeout mechanisms on both sides to detect a broken or aborted connection. All communication parameters are reset to negotiation values upon disconnect.

7.4 Minimum data link layer requirements

The minimum data link layer services support the capabilities of device discovery, connect, data transfer, and disconnect.

7.4.1 Minimum data link layer services

The status of the data link layer service primitives provided by a BCC or DCC is specified in Table 3 as M for mandatory or C for conditional.

Table 3—Data link layer services

Service	BCC	DCC
Discovery		
IrLAP_Discovery.request(general address bit)	M	C [pri]
IrLAP_Discovery.confirm(list of discovery logs)	M	C [pri]
IrLAP_Discovery.indication(discovery log)	C [a]	C [sec]
Connect		
IrLAP_Connect.request(target device address, requested quality of service [QoS], sniff[b])	M	C [nbs]
IrLAP_Connect.confirm(connection handle, returned QoS)	M	C [nbs]
IrLAP_Connect.indication(source device address, connection handle, returned QoS)	C [nbs]	M
IrLAP_Connect.response(source device address, connection handle, requested QoS)	C [nbs]	M
Data		
IrLAP_Data.request(connection handle, user data, expedited unreliable flag = false)	M	M
IrLAP_Data.indication(connection handle, user data, expedited unreliable flag = false)	M	M
IrLAP_Data.request(connection handle, user data, expedited unreliable flag = true)	C [sntp]	C [sntp]
IrLAP_Data.indication(connection handle, user data, expedited unreliable flag = true)	C [sntp]	C [sntp]

Table 3—Data link layer services *(continued)*

Service	BCC	DCC
Disconnect		
IrLAP_Disconnect.request(connection handle)	M	M
IrLAP_Disconnect.indication(connection handle, unacknowledged data)	M	M
[pri] Discovery services required in a DCC that participates as an IrDA primary station. [sec] Discovery services required in a DCC that participates as an IrDA secondary station. [nbs] Connect services required in a BCC or DCC that supports a network/bedside service, such as SNTP. [sntp] The expedited unreliable IrLAP_Data services are required for the LM_UData/TTP_UData service in a BCC or DCC that supports SNTP.		

[a]Discovery service required in a BCC that participates as an IrDA secondary station.
[b]Use of the sniffing feature is out of the scope of this standard.

7.4.2 Negotiation

At a minimum, the IrLAP negotiation parameters in Table 4 shall be supported.

Table 4—IrLAP minimum negotiation parameters

Parameter	Infrared	*Cable-Connected*[a]
Signaling speed	9600 Bd	*9600 Bd*
Maximum turnaround time	500 ms	*500 ms*
Data size[b]	64 octets	*64 octets*
Window size	1 frame window	*1 frame window*
Additional BOFs	10 BOFs	*0 BOFs*
Link disconnect time	40 s	*3 s*
Link threshold time	3 s	*0 s*

[a]ISO/IEEE 11073-30200. The cable-connected parameters are shown here for information only.
[b]The data size parameter is the maximum number of data octets allowed in any received frame. A data
   size parameter of 64 octets is required for negotiation. A larger data size may also be required to sup-
   port the range of transfer protocol data unit (PDU) sizes provided by this profile.

7.4.3 Link disconnect time

IrLAP supports the negotiation of the link disconnect time, which is the time a station will wait without receiving valid frames before it disconnects the link. IrLAP stations using infrared may support a variety of link disconnect times, ranging from 3 s to 40 s. In general, for medical device applications, a shorter link disconnect time should be used, consistent with the intended uses of the device.

7.4.4 Contention state

In the contention state, 11 BOFs shall be used on every frame. The first 10 BOFs shall be FFh. The 11th BOF shall be C0h.

7.4.5 Signaling speed

A station shall operate at 9600 Bd. A station may operate at other signaling speeds, as shown on Table 2 (in 6.2). It is recommended that a BCC/AP be able to support several SIR speeds (e.g., 19 200 Bd, 38 400 Bd, 57 600 Bd, or 115 200 Bd, in addition to 9600 Bd) because the majority of devices (DCCs) will use signaling rates in this range. A station may support signaling rates greater than 115.2 kBd.

7.4.6 SIR interaction pulse (SIP)

In order to guarantee coexistence with slower (SIR) systems, higher speed systems (MIR, FIR and VFIR) shall emit a 1.6 µs SIP at least once every 500 ms so that slower (SIR) speed stations will recognize, and not interfere with, the higher speed stations. The SIP is described in IrPHY.

7.4.7 Data size

The maximum size of a PDU is negotiated at the time of the connection. The IrLAP data size parameter is negotiated independently for each direction of the link; therefore, the primary and secondary stations may support different maximum PDU sizes.

The negotiated signaling speed and turnaround time may constrain the actual data size by limiting the amount of time available to transfer the frame. If the requested data size cannot be supported, the link shall be renegotiated.

7.4.8 Poll interval

When a primary station transmits an information frame, IrLAP permits the turnaround time to be as short as the negotiated minimum turnaround time.

When a primary station has no information frame to transmit, it shall wait for some interval before issuing a receive ready (RR) poll frame. The polling interval is not specified in IrLAP, but shall be bounded by the negotiated minimum and maximum turnaround times. IrLAP does not provide a mechanism for negotiating the polling interval, represented by the *P-Timer-Expired* event in the transmit (XMIT) state of the primary role state machine.

In some applications, the DCC may consume the bulk of the available bandwidth at low signaling speeds. In the event that the BCC were to frequently wait for 500 ms to issue a poll frame, a substantial proportion of the potential bandwidth goes unused. If the BCC were to simply issue a poll frame after the minimum turnaround time, it could drive the device to spend an inordinate amount of time servicing an inactive communications link. Therefore, it is reasonable to allow the BCC (as a IrDA primary station) to negotiate an intermediate polling interval that optimizes bandwidth usage without interfering with device performance.

Table 5—Maximum turnaround time

Signaling speed (Bd)	Timing
9600	Stations are restricted to a fixed maximum turnaround time of 500 ms.
19 200	
38 400	
57 600	
115 200	Stations select a maximum turnaround time during negotiation.

A DCC (as a IrDA secondary station) may advertise the preference to be polled at a shorter interval than 500 ms. The available selections are shown in Table 6. The preferred polling interval is advertised through the information access service (IAS), see Clause 8.

Table 6—Polling interval selections

0 ms
50 ms
100 ms
250 ms

The primary station shall poll at the maximum turnaround time unless a shorter polling interval is advertised by the secondary station. A primary station shall not poll faster than the advertised polling interval. A primary station shall not poll faster than the minimum turnaround time. A polling interval of 0 means that the secondary station will accept polling as fast as the minimum turnaround time.

NOTE—Selecting a shorter poll interval must not interfere with the maximum turnaround time that determines the time allotted to the DCC to transmit.

8. Network layer

The network link layer is adopted from the serial IrLMP, which implements ISO/OSI Layer 3.

IrLMP consists of the following components:

a) **IAS** maintains an information base with information about offered services and device information.

b) **Link management multiplexer** provides multiple connections over IrLAP.

This standard follows some of the recommendations of IrDA Lite [B6] for IrLMP.

IrLMP capabilities not specified here are out of the scope for an ISO/IEEE 11073-30300 interface. Examples of these capabilities are sniffing, connectionless data transfer, and exclusive mode.

8.1 Discovery information

IrLMP as service user for the IrLAP services provides the discovery information shown in Figure 7. This information is a maximum of 23 octets long.

Service hints	Device nickname

Figure 7—Discovery information field

Service hints are mandatory and contain at least 1 octet. They provide information about the general device class (e.g., computer, printer, or modem). More hint octets can be appended to the first one. An ISO/IEEE 11073-30300 BCC or DCC shall assert the reserved service hint bit 12, and the extension bit 7, as shown in Table 7. Other bits may be set if the BCC or DCC is can perform other functions (e.g., serve as a LAP).

Table 7—Service hint bit assignment

Octet 1		Octet 2	
Bit	**Function**	**Bit**	**Function**
1		8	
2		9	
3		10	
4		11	
5		12	ISO/IEEE 11073 = 1
6		13	
7	Extension = 1	14	

Not all IrDA devices that assert hint bit 12 are assured of supporting this standard. To be certain, the primary station should query the IAS of the secondary station for the IEEE:1073:3:3 object class (described in Table 10).

A BCC or DCC shall report a device nickname with the discovery information. The device nickname should be a short, recognizable name for the device. The device nickname shall begin with the prefix MIB followed by a space for an ISO/IEEE 11073 device. The format of the device nickname encoding is shown in Figure 8. This encoding shall include a character set code, as described in IrLMP. Examples of device nick-names are shown in Table 8.

Character set code (1 octet)	Name

Figure 8—Device nickname format

Table 8—Sample device nicknames

Name	Encoding	Octets	Length[a] (octet)
MIB BCC	ASCII	00 4D 49 42 20 42 43 43	8
MIB IV Pump	ASCII	00 4D 49 42 20 49 56 20 50 75 6D 70	12
MIB Ventilator	ASCII	00 4D 49 42 20 56 65 6E 74 69 6C 61 74 6F 72	15
MIB NIBP	ASCII	00 4D 49 42 20 4E 49 42 50	9
POCT Glucose[b]	ASCII	00 43 49 43 20 47 6C 75 63 6F 73 65	12

[a]IrLAP restricts the length of discovery information (device nickname plus service hints) to 23 octets.
[b]The NCCLS POCT1 uses POCT followed by a space as a standard device nickname prefix.

NOTE—Regarding discovery information implementation, some IrDA platforms may not allow specific service hint bits to be set with a device nickname. In such cases, at a minimum, a valid service hint or device nickname shall be set. However, use of both is preferred when possible.

8.2 Information access requirements

The information access requirements support the capabilities of a global identifier number, node type identification, and dynamic AP identification.

8.2.1 IASs

The IAS shall provide the following service primitives as described in Table 9. The status of an IAS is specified as M for mandatory or R for recommended.

Table 9—IAS requirements

IAS primitives	Status
LM_GetValueByClass.request(address, class name, attribute name)	M
LM_GetValueByClass.confirm(list of (object id, attribute value))	M
LM_GetValue.request(address, id, attribute name1, [attribute name2, ...])	R
LM_GetValue.confirm(list of attribute values)	R

8.2.2 Global identifier number

A BCC or DCC shall report a global identifier number in the IAS object database, as shown in Table 10. The global identifier number is the 64-bit global identifier (extended unique identifier 64 (EUI-64)] parameter for that BCC or DCC. This parameter consists of a 3-octet (24-bit) company identifier (company_id) number followed by a 5-octet (40-bit) extension identifier. The format, shown in Figure 9, follows the IrLMP conventions for an octet sequence.

The individual company_id number is assigned by the IEEE Registration Authority Committee (RAC) and represents a unique code for a particular manufacturing company or other organization.

The 40-bit extension identifier number is assigned by the particular manufacturer or other organization. It is the responsibility of the individual manufacturer to assign a unique (nonduplicate) extension identifier number to each BCC or DCC. For BCCs or adapters that cannot be individually serialized, a valid 3-octet (24-bit) IEEE company identifier shall be provided with the 5 octet (40 bit) extension identifier set to 0.

type = 2 (octet sequence)	length = 8	company identifier	extension identifier
1 octet	2 octets	3 octets	5 octets
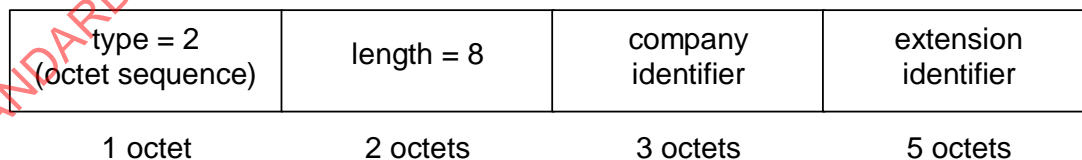
Figure 9—Global identifier format in IAS

No more than one 64-bit global identifier value shall be contained within each component that is manufactured. For legacy devices that use a communications protocol adapter, the global identifier can reside in the adapter.

The use of the EUI-64 global identifier number enables unique global identification of ISO/IEEE 11073 communication controllers. This allows for distinguishing between multiple devices of the same type that are connected to the same patient and facilitates device tracking and maintenance within an institution. It can also be used for medical device authentication and future AP options based on Internet Protocol (IP) (version 6).

8.2.3 Interface type

A BCC or DCC shall report the type of interface supported (BCC or DCC) using the NodeType attribute as shown in Table 10 or Table 11, respectively.

8.2.4 Port identifier number

A BCC or DCC shall report a unique port number value for each port on the device, as described in Table 10 or Table 11, respectively.

8.2.5 SAPs

An ISO/IEEE 11073 BCC that supports SNTP shall specify an IrDA TinyTP service endpoint, as shown in Table 10. A BCC may provide other service connection endpoints.

An ISO/IEEE 11073 DCC that supports the MDDL upper layers shall specify an IrDA TinyTP service endpoint, as shown in Table 11.

8.2.6 Supported objects and attributes

The IAS in a BCC or DCC shall support the objects and attributes listed in Table 10 or Table 11, respectively. The status of an object-attribute pair is specified as M for mandatory, R for recommended, or O for optional.

Table 10—Objects and attributes in a BCC

Object class	Attribute name	Value type	Description	Status
Device	DeviceName	user string	This attribute is described in IrLMP.	M
	IrLMPSupport	octet sequence	This attribute is described in IrLMP.	M
IEEE:1073:3:3[a]	GlobalID	octet sequence	Specifies the global identifier number for the BCC.	M[b]
	NodeType	integer	0 (= BCC)	M
	PortNumber	integer	Ascribes a specific number to each port on the BCC.	M
	PollInterval	integer	Specifies the preferred polling interval, in milliseconds. May be 0, 50, 100, or 250.	O[c]

Table 10—Objects and attributes in a BCC *(continued)*

Object class	Attribute name	Value type	Description	Status
IEEE:1073:3:3[a] :SNTP	IrDA:TinyTP: LsapSel[d]	integer	Specifies the service connection end-point for the SNTP upper layers to an IrDA TinyTP service.	R[e]

[a]If a BCC port is an infrared port, the IAS shall include the IEEE:1073:3:3 object class.
 If a BCC port is a cable-connected port, the IAS shall include the IEEE:1073:3:2 object class.
 If a BCC port is a cable-connected port that can support an infrared adapter, it is recommended that the BCC port either detect the adapter or allow the user to configure the presence of the adapter. Such configuration facilitates selection of the optimum IrDA communication parameters during the IrLAP negotiation phase.
 If a BCC port is a cable-connected port that can support an infrared adapter but cannot identify the physical layer being used, then both the IEEE:1073:3:2 and IEEE:1073:3:3 object classes shall be included in the IAS.
[b]For BCCs or adapters that cannot be individually serialized, a valid 3 octet (24 bit) IEEE company identifier shall be provided with the 5 octet (40 bit) extension identifier set to 0.
[c]If the capability is not supported by a BCC operating as an IrDA secondary station, the attribute shall be omitted from the IAS.
[d]LsapSel is an unsigned integer in the range 0x00–0x7F. With the exception of the special LsapSel values 0x00 (LM-IAS), 0x70 (connectionless data service), 0x71–0x7E (reserved), and 0x7F (reserved for broadcast), the assignment of LsapSel values is arbitrary.
[e]If the capability is not supported, the attribute shall be omitted from the IAS.

Table 11—Objects and attributes in a DCC

Object class	Attribute name	Value type	Description	Status
Device	DeviceName	user string	This attribute is described in IrLMP.	M
	IrLMPSupport	octet sequence	This attribute is described in IrLMP.	M
IEEE:1073:3:3[a]	GlobalID	octet sequence	Specifies the global identifier number for the DCC.	M[b]
	NodeType	integer	1 (= DCC)	M
	PortNumber	integer	Ascribes a specific number to each MIB DCC port on the medical device.	M
	PollInterval	integer	Specifies the preferred polling interval, in milliseconds. May be 0, 50, 100, or 250.	O[c]
IEEE:1073:3:3[a] :MDDL	IrDA:TinyTP: LsapSel[d]	integer	Specifies the service connection end-point for the ISO/IEEE11073 MDDL upper layers to an IrDA TinyTP service.	M[e]

[a]If a DCC port is an infrared port, the IAS shall include the IEEE:1073:3:3 object class.
 If a DCC port is a cable-connected port, the IAS shall include the IEEE:1073:3:2 object class.
 If a DCC port is a cable-connected port that can support an infrared adapter, it is recommended that the DCC port either detect the adapter or allow the user to configure the presence of the adapter. Such configuration facilitates selection of the optimum IrDA communication parameters during the IrLAP negotiation phase.
 If a DCC port is a cable-connected port that can support an infrared adapter but cannot identify the physical layer being used, then both the IEEE:1073:3:2 and IEEE:1073:3:3 object classes shall be included in the IAS.
[b]For DCCs or adapters that cannot be individually serialized, a valid 3 octet (24 bit) IEEE company identifier shall be provided with the 5 octet (40 bit) extension identifier set to 0.
[c]If the capability is not supported, the attribute shall be omitted from the IAS.
[d]LsapSel is an unsigned integer in the range 0x00–0x7F. With the exception of the special LsapSel values 0x00 (LM-IAS), 0x70 (connectionless data service), 0x71–0x7E (reserved), and 0x7F (reserved for broadcast), the assignment of LsapSel values is arbitrary.
[e]Mandatory for an ISO/IEEE 11073 DCC that supports MDDL; otherwise, the attribute shall be omitted from the IAS.

8.2.7 Extending the list of objects and attributes

The objects and attributes supported by the IAS may be extended by other ISO/IEEE 11073 family standards as well as other communication protocols. A standard that provides IAS extensions shall specify the object class, the attribute name, and the value type. The object class name should incorporate the name of the standard, e.g., IEEE:1073:3:3 and/or IEEE:1073:3:2.

Reasons for extending the IAS include the possibility of providing an link SAP (LSAP) that uses a protocol other than MDDL or SNTP. For example, NCCLS:POCT1:MGR:GENERIC or NCCLS:POCT1:MGR:*VENDOR*[21] would be used to indicate the availability of a generic or vendor-specific NCCLS POCT1 data manager (DM) on the network. The use of other LSAPs to establish connections to other services is out of the scope of this standard.

NOTE—If sessions are established on other LSAPs concurrent with MDDL, it is important to understand the impact of this connection on the throughput and latency performance of the MDDL connection. It may be necessary to service the MDDL connection at a higher priority in order to guarantee the desired level of throughput and/or latency. If SNTP is implemented, that link should be serviced as high-priority, low-latency. The impact of SNTP on throughput is negligible.

8.3 Minimum IrLMP multiplexer requirements

The minimum multiplexer requirements provide support for device discovery, connection, disconnection, status, and data transfer as described in Table 12. The status of the network layer service primitives provided by a primary or secondary station is M for mandatory, C for conditional, or O for optional.

Table 12—Network layer services

Service	BCC	DCC
LM_DiscoverDevices.request(nr slots)	M	C [pri]
LM_DiscoverDevices.confirm(status, List of (device address, device info, method))	M	C [pri]
LM_DiscoverDevices.indication(device address, device info, method)	C [sec]	C [sec]
LM_Connect.request(called LSAP, requested QoS, client data)	M	C [nbs]
LM_Connect.confirm(called LSAP, resultant QoS, client data)	M	C [nbs]
LM_Connect.indication(calling LSAP, resultant QoS, client data)	C [nbs]	M
LM_Connect.response(calling LSAP, client data)	C [nbs]	M
LM_Disconnect.request(reason, client data)	O [a]	O [a]
LM_Disconnect.indication(reason, client data)	M	M
LM_Status.request()	M	M
LM_Status.indication(link status, lock status)	M	M
LM_Status.confirm(unacknowledged data flag)	M	M
LM_Data.request(data)	M	M
LM_Data.indication(data)	M	M

[21]Recommendations for *VENDOR* identification strings are provided in Appendix F of NCCLS POCT1.

Table 12—Network layer services *(continued)*

Service	BCC	DCC
LM_UData.request(data)	C [sntp]	C [sntp]
LM_UData.indication(data)	C [sntp]	C [sntp]
[pri] Discovery services required in a DCC that participates as an IrDA primary station. [sec] Discovery services required in a BCC or DCC that participates as an IrDA secondary station. [nbs] Connect services required in a BCC or DCC that supports a network/bedside service, such as SNTP. [sntp] The expedited unreliable LM_UData/TTP_UData service in a BCC or DCC that supports SNTP.		

[a]An IrLAP disconnect may be used in place of an IrLMP disconnect as described in IrDA Lite [B6].

9. Transport layer

The transport layer is adopted from IrDA TinyTP, which implements ISO/OSI Layer 4, the transport layer. This layer provides support for multiple transport connections with independent flow control.

TinyTP also defines a capability for data stream segmentation and reassembly (SAR). SAR may be used to achieve a larger maximum transfer unit (MTU), if both ends of the link support SAR.

9.1 MTU

The transport profile provides a delivery service for user data. Any client service data unit (SDU) not larger than the MTU shall be delivered by the transport profile. The MTU is determined according to Table 13. Data size is the negotiated IrLAP data size parameter. The MTU is determined independently for each direction of transfer.

Table 13—MTU size

Data size (bytes)	SAR supported	MTU (bytes)
Any	Yes	1496
64	No	64
128	No	128
256	No	256
512	No	512
1024	No	1024
2048	No	1496

The selected MTU may constrain the use of the transport profile by the client. An MTU smaller than 1024 bytes may be inadequate for some applications. IrLAP negotiates the most favorable link possible. If the negotiated link is inadequate for any client application, then the link fails.

9.2 Transport service requirements

The transport service requirements provide support for connection, disconnection, flow control, and data transfer as described in Table 14. The status of the transport layer service primitives provided by a BCC or DCC is specified as M for mandatory, C for conditional, or O for optional.

Table 14—Transport layer services

Service	BCC	DCC
TTP_Connect.request(called TinyTP SAP [TTPSAP], requested QoS, calling maximum SDU size, calling user data)	M	C [nbs]
TTP_Connect.confirm(called TTPSAP, resultant QoS, called maximum SDU size, called user data)	M	C [nbs]
TTP_Connect.indication(calling TTPSAP, resultant QoS, calling maximum SDU size, calling user data)	C [nbs]	M
TTP_Connect.response(calling TTPSAP, called maximum SDU size, called user data)	C [nbs]	M
TTP_Disconnect.request(user data)	O [a]	O [a]
TTP_Disconnect.indication(reason, user data)	M	M
TTP_LocalFlow.request(flow)	M	M
TTP_Data.request(user data)	M	M
TTP_Data.indication(user data, status)	M	M
TTP_UData.request(user data)	C [sntp]	C [sntp]
TTP_UData.indication(user data)	C [sntp]	C [sntp]
[nbs] Connect services required in a BCC or DCC that supports a network/bedside service, such as SNTP. [sntp] The expedited unreliable LM_UData/TTP_UData service in a BCC or DCC that supports SNTP.		

[a]An IrLAP disconnect may be used in place of an IrLMP disconnect as described in IrDA Lite [B6].

9.3 MDDL service

The MDDL SAP is provided by the DCC and used by the BCC to establish a connection for MDDL upper layer communications. This connection is established and confirmed using the TTP_Connect service identified in Table 14.

10. Time synchronization

Some applications of MIB may require precise synchronization of the DCC time-of-day clock with the BCC time-of-day clock. This shall be accomplished using the unicast communication mode of the Simple Network Time Protocol (SNTP) (version 4). The use of this time-synchronization service by BCCs and DCCs is identified in Table 15.

Table 15—SNTP services

Service	BCC	DCC
SNTP server	Recommended	N/A
SNTP client	N/A	Optional

NOTE–The method by which a BCC obtains its time directly impacts the quality of the time service provided to a DCC. However, that method is out of the scope of this document.

The SNTP protocol described in RFC-2030 is a subset of the complete Network Time Protocol (NTP) described in RFC-1305. RFC-2030 is the governing document regarding the SNTP protocol and message format.

For recommendations regarding the use of SNTP, see Annex O of ISO/IEEE 11073-30200.

SNTP uses a 48 octet NTP message format. In client-server mode, the client (DCC) sends a 48 octet SNTP request to the server (BCC), and the server responds with a 48-octet SNTP reply. These messages are sent and received using the TinyTP service primitives:

   TTP_UData.request(userData)

   TTP_UData.indication(userData)

The Udata service is an expedited, connection-oriented service. An expedited service is preferred over a reliable service in order to minimize communications latency.

NOTE—An implementation should strive to minimize delays that reduce the quality of the time synchronization. The IrDA TTP_Udata service primitives are mapped directly onto the IrLMP service primitives.

The SNTP service is connection-oriented and is assigned a separate SAP in order to prevent interference with the MDDL protocol. In order to support this capability, the IAS in a BCC shall support the SNTP object and attributes described in Clause 8.[22]

11. Labeling and conformance requirements

This clause defines the labeling and conformance requirements for this standard.

11.1 Labeling requirements

The information shown in Table 16 shall be provided with the documentation for a BCC or DCC**.**

Table 16—BCC and DCC capability profile

Capability	BCC	DCC	Supported
Number of ports			1, 2, 3 ...
IrDA-infrared optical power			Standard or low

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[22]This standard does not preclude a DCC from obtaining time information by using some other means, such as a built-in global positioning system (GPS) clock receiver.

Table 16—BCC and DCC capability profile *(continued)*

Capability	BCC	DCC	Supported
EUI-64 GlobalID with unique extension identifier			Yes/No
EUI-64 GlobalID with extension identifier set to 0			Yes/No
IrDA conformance			Yes/No (Annex E)
IEEE:1073:3:3:MDDL			Yes/No
IEEE:1073:3:3:SNTP			Yes/No
NCCLS:POCT1:MGR:GENERIC			Yes/No
List other protocols or services ...			Yes/No
List protocols, method(s), and related RFCs used to configure a networked BCC/AP.		N/A	Yes/No

11.2 Conformance requirements

Conformance to the requirements described in this standard shall be ensured by means of conformance testing.

Conformance requirements for IrDA components can be found in Annex E.

Annex A

(informative)

IrDA physical layer parameters

This annex summarizes the key IrDA physical layer parameters, as specified by the IrDA IrPHY. Unless otherwise stated, the required, recommended, optional and default options and parameters for the IrDA IrPHY shall apply to this standard; the purpose of this annex is to provide an informative overview.

The IrDA IrPHY defines a point-to-point, narrow angle (± 15° half-angle cone) infrared[23] data transmission standard designed to operate over a distance of 0 to 1 m and at signaling rates of 9600 Bd[24] to 4 MBd. A recent extension to IrPHY called VFIR supports a signaling rate of 16 MBd.

A.1 IrDA physical layer optical requirements

For the transmitter, the output intensity at any point within a cone of half-angle 15° with respect to the optic axis shall fall between the specified minimum and maximum shown in Table A.1. The intensity at any point outside a cone of half-angle greater than 30° shall not exceed the minimum intensity value.

Table A.1—Key IrDA physical layer parameters

Peak wavelength: 0.85-0.95 μm	SIR/MIR/FIR StdPwr	SIR/MIR/FIR LowPwr[a]	VFIR StdPwr
Link distance, cm			
Lower limit	0	—	0
Upper limit (LowPwr to LowPwr)	—	20	—
Upper limit (LowPwr to StdPwr)	—	30	—
Upper limit (StdPwr to StdPwr)	100	—	100
Data rate			
Minimum	9.6 kBd	9.6 kBd	16 MBd
Maximum	4 MBd	4 MBd	16 MBd
Intensity, mW/Sr[b]			
Minimum (≤ 115 kBd)	40	3.6	—
Minimum (> 115 kBd)	100	9	100
Maximum (all data rates)	500	72	500
Irradiance[c]			
Minimum, μW/cm^2 (≤ 115 kBd)	4	9	—
Minimum, μW/cm^2 (> 115 kBd)	10	22.5	10

---

[23]Peak wavelength lies between 0.85 μm to 0.90 μm.

[24]Although the IrDA specifications permit operation at 2400 Bd, it is not supported by ISO/IEEE 11073-30200 or by this standard.

Table A.1—Key IrDA physical layer parameters *(continued)*

| Peak wavelength: 0.85-0.95 μm	SIR/MIR/FIR StdPwr	SIR/MIR/FIR LowPwr[a]	VFIR StdPwr
Maximum, mW/cm^2	500	500	500
Receiver latency, ms[d]	10	0.5	0.10

[a]Low power uses roughly one-tenth the power of standard power and is appropriate for battery-powered devices.
[b]The transmitter shall meet these requirements within a $\pm$ 15° half-angle cone. The intensity shall not exceed the specified minimum outside a $\pm$ 30° half-angle cone.
[c]The receiver shall meet these requirements within a $\pm$ 15° half-angle cone.
[d]Receiver latency is the time that the receiver is guaranteed to be ready to receive data after the transmitter stops transmitting.

The receiver shall be able to recognize a signal between the minimum irradiance (depending on the data rate and the power class [StdPwr/LowPwr]) shown in Table A.1 and the maximum of 500 mW/cm^2, at any point within a cone of half-angle 15° with respect to the optic axis, as depicted in Figure A.1.
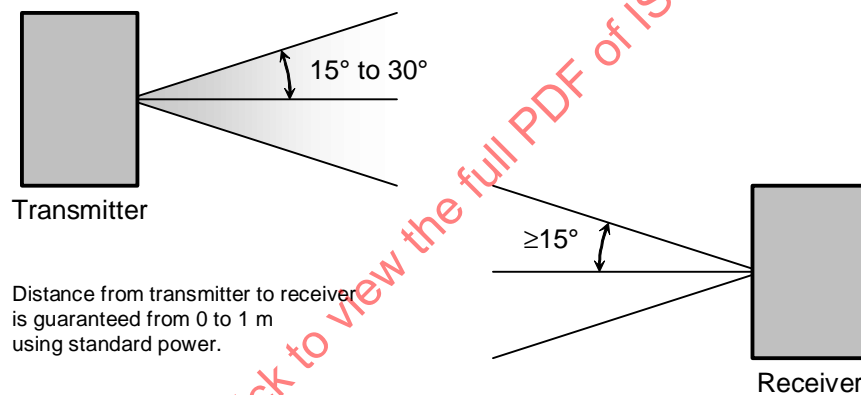
Figure A.1—IrDA physical layer viewing angle and distance

A.2 IrDA 3/16 encoding

This subclause describes octet frame encoding and 3/16 bit encoding used by IrDA IrPHY-SIR. The encoding methods used for data rates greater than 115 kBd are described in IrDA IrPHY and VFIR specifications referenced in Clause 2.

A BCC or DCC may support one or more of the following signaling speeds: 9600 Bd, 19 200 Bd, 38 400 Bd, 57 600 Bd, or 115 200 Bd. At a minimum, BCCs and DCCs shall support 9600 Bd.

The transmission between BCCs and DCCs shall consist of contiguous octets. The octets are transmitted asynchronously.

Octet encoding shall use start/stop encoding. Each octet shall be encoded to include a start bit (logic 0, represented by the presence of an optical pulse), followed by 8 data bits, followed by a stop bit (logic 1,

represented by the absence of an optical pulse). The bits of an octet are transmitted synchronously. The least significant bit (LSB) is transmitted first. The 8 data bits may be logic 0 or 1.

Each logic 0 bit is represented by an optical pulse that has a maximum duration of 3/16 of the bit time, as shown in Figure A.2. The minimum pulse duration is 3/16 of the bit time for 115.2 kBd (1.63 µs) and may also be used at slower signaling rates. If a discrete universal asynchronous receiver/transmitter (UART) and infrared encoder are used, the infrared pulses would nominally begin at the center of each UART bit period, which is the optimum time for the encoder to sample the output of the UART.
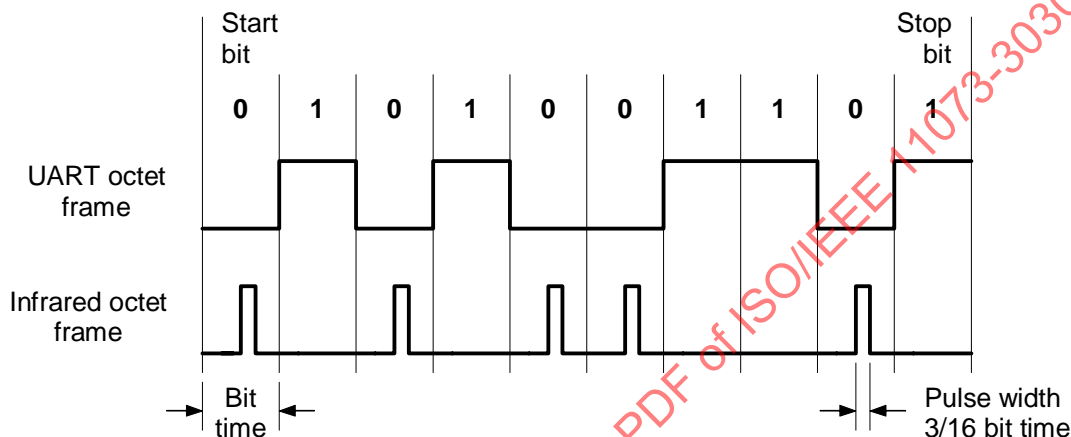

Figure A.2—IrDA SIR 3/16 data encoding

A.3 Background light and electromagnetic compatibility (EMC)

The implementation of ISO/IEEE 11073-30300 shall not interfere with the equipment's ability to comply with applicable EMC standards. The four ambient EMI conditions that can adversely affect an infrared receiver are listed below:

— *Electromagnetic field:* 3 V/m maximum (IEC 61000-4-3 [B3] test level 2)

— *Sunlight:* 10,000 lux maximum at the optical port

— *Incandescent lighting:* 1000 lux maximum

— *Fluorescent lighting:* 1000 lux maximum

Appendix A.1 of the IrDA IrPHY provides normative specifications for the four ambient interference conditions listed above.

A.4 Electrostatic discharge (ESD) immunity

The implementation of ISO/IEEE 11073-30300 shall not interfere with the equipment's ability to comply with applicable ESD standards.

A.5 Eye safety

An implementation of an ISO/IEEE 11073-30300 interface shall be classified according to the power or energy accessible emission level (AEL) class limits and the measurement conditions of IEC 60825-1 and CENELEC EN 60825-1.

The AEL class limits are calculated according to formulas in IEC 60825-1 and CENELEC EN 60825-1, Table 1 through Table 4 and notes to Table 1 through Table 4, under single-fault conditions. A transmitter that meets the AEL Class 1 limit does not require a warning label on the device, but does require the classification to be declared in the product literature. If the transmitter exceeds the Class 1 limit but is less than five times the Class 1 limit, it is classified as Class 3A, and a warning symbol and explanatory label are required on the device, as well as information in the product literature. It is anticipated that no IrDA-compliant sources will produce output above the Class 3A limit.

The AEL classification is based on a number of optical and signaling parameters. Although the majority of IrDA transceivers are designed to minimize eye safety hazards, careful attention needs to be applied to the end-product optical and electronic design. For example, the drive current and duty cycle should be limited during a single-fault condition, especially for a transmitter designed to operate at IrDA standard power levels.

Annex B

(informative)

Overview of ISO/IEEE 11073-30200

ISO/IEEE 11073-30200 specifies a point-to-point cable connection between a DCC and a BCC. The terminology used by ISO/IEEE 11073-30200 and the NCCLS POCT1 is summarized in Figure B.1.
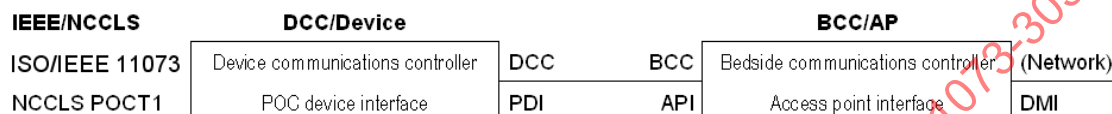
IEEE/NCCLS	DCC/Device			BCC/AP	
ISO/IEEE 11073	Device communications controller	DCC	BCC	Bedside communications controller	(Network)
NCCLS POCT1	POC device interface	PDI	API	Access point interface	DMI

Figure B.1—IEEE and NCCLS terminology

B.1 Key requirements for ISO/IEEE 11073-30200 physical layer

The following text summarizes the key requirements for the physical layer defined in ISO/IEEE 11073-30200:

—   RS-232 signaling levels over unshielded twisted pair (UTP) Category-5 (CAT-5) cable.

—   RS-232 signaling speeds: 9600 Bd and optional negotiated speeds of 19.2 kBd, 38.4 kBd, 57.6 kBd, and 115.2 kBd.

—   Octet encoding: 1 start bit, 8 data bits, no parity bit, 1 stop bit.

—   An 8-pin registered jack (RJ)-45 modular connector at the BCC/AP using the pin assignments shown in Table B.1. The DCC/device or docking station may use

  —   An RJ-45 connector with the pinout shown in Table B.1,

  —   Any other connector or pinout appropriate to the clinical use of the device, or

  —   A permanently attached cable.

Table B.1—ISO/IEEE 11073-30200 pinout and functionality

BCC/AP	Pin and signal direction	Function	DCC/Device
*b*RD+	1 ⇐	*DPWR/10/100BASE-T*	*d*DPWR/*d*TD+
*b*RD–	2 ⇐	*BCC sense/10/100BASE-T*	*d*CS–/*d*TD–
*b*CS+/*b*TD+	3 ⇒	*DCC sense/10/100BASE-T*	*d*RD+
*b*GND	4 ⇔	*Signal ground*	*d*GND
*b*RxD	5 ⇐	*RS-232*	*d*TxD
*b*CS–/*b*TD–	6 ⇒	*DCC sense/10/100BASE-T*	*d*RD–

Table B.1—ISO/IEEE 11073-30200 pinout and functionality *(continued)*

BCC/AP	Pin and signal direction	Function	DCC/Device
*b*TxD	7 ⇒	*RS-232*	*d*RxD
*b*BPWR	8 ⇒	*BPWR*	*d*BPWR

Pinout Notes

1—The receive data (RxD), transmit data (TxD), and ground (GND) signals support the RS-232 serial data interface. BCC power (BPWR) and DCC power (DPWR) provide power for a line accessory or a DCC. Connection sense (CS) and DPWR provide connection sensing.

2—This standard is compatible with a 10/100BASE-T interface, supported by the receive data (RD±) and transmit data (TD±) signals (pins 1-2 and 3-6). A BCC port may be designed to support the ability to detect an ISO/IEEE 11073-30200 (RS-232) connection or a 10/100BASE-T connection and to communicate with either device. [However, 10/100BASE-T functions for BCCs and DCCs are currently out of the scope of the ISO/IEEE 11073-30200.]

3—A BCC can sense the connection of a DCC by testing the resistance across its *b*CS+ and *b*CS– pins. The alternative names *b*TD+ and *b*TD– indicate the 10/100BASE-T transmit data function.

4—A DCC may provide power on its *d*DPWR line to a line-extender or communications adapter. A DCC can sense its connection to a BCC by testing the resistance between its *d*DPWR and *d*CS– pins. The alternative names *d*TD+ and *d*TD– indicate the 10/100BASE-T transmit data function.

B.2 Optional capabilities for ISO/IEEE 11073-30200 physical layer

The following text summarizes the optional capabilities for the ISO/IEEE 11073-30200 cable-connected physical layer:

— ISO/IEEE 11073-30200 specifies three dc power delivery options as shown in Table B.2.

Table B.2—ISO/IEEE 11073-30200 dc power delivery options

Zero power	The BCC or DCC does not provide power.
Low power	The BCC or DCC offers power levels that are typically provided by the parallel connection of request to send (RTS) || data terminal ready (DTR) or a single RTS or DTR pin of a standard RS-232 communications port. This power level can be used to power line isolators and extenders.
High power	The BCC or DCC offers dc power of + 5.0 V ± 5% @ 100 mA. This can be used for powering a wide range of devices that have modest power requirements.

ISO/IEEE 11073-30200 provides a detailed discussion of the three dc power options. Although complete interoperability would require a single dc power delivery option (e.g., high power), the ability to communicate with a standard serial port using a passive adapter was also considered an essential requirement by the ISO/IEEE 11073-30200 subcommittee, and hence the zero-power and low-power options were created. In order to promote the highest degree of cable-connected device interoperability, it is recommended that the high-power option be implemented at the BCC/AP.

— ISO/IEEE 11073-30200 also defines additional optional physical layer capabilities, such as the ability of a BCC to sense the connection of a DCC and the ability of a DCC to sense its connection to an BCC, without requiring the sensed entity to be powered. This capability can be used to provide informative messages to the user such as "please turn on the device" or "communication error." Implementation of the terminating impedance (or short) in the DCC and BCC is mandatory, but implementation of the detection circuitry is optional.

— ISO/IEEE 11073-30200 is compatible with the RJ-45 pinout for 10BASE-T as defined in Clause 14 of ISO/IEC 8802-3 and IEEE Std 802.3, and 100BASE-TX for UTP cable as defined in Clause 25 of IEEE Std 802.3. The two standards, 10BASE-T and 100BASE-TX, are collectively referred to as *10/100BASE-T* in this document.[25] Implementation of either of these physical layers is not required, nor has a complete set of ISO/IEEE 11073 protocol(s) been defined for them at the present time.

— The maximum recommended ISO/IEEE 11073-30200 cable length is 20 m, based on the electrical properties of the cable and connectors and use of the high-power dc power delivery option.

— ISO/IEEE 11073-30200 provides guidelines for physical media marking and color (yellow).

Although a nonisolated connection between the DCC and BCC is permitted by ISO/IEEE 11073-30200, it is highly recommended that at least one component (either the DCC, BCC, or a cable adapter) provide electrical isolation if direct connection to the patient could occur or in situations where ground loops would compromise communications reliability.

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[25]ISO/IEEE 11073-30200 did not include 100BASE-TX when it was approved. 100BASE-TX and 10BASE-T use the same pinout, and automatic and transparent negotiation of signaling rate is possible.

Annex C

(informative)

ISO/IEEE 11073-30200 cable-to-infrared adapter

This annex describes an IrDA-infrared adapter that directly connects to an ISO/IEEE 11073-30200 cable-connected BCC port. Such an adapter would enable a multiport BCC to support infrared communication, if it was not already built in.

A block diagram of an ISO/IEEE 11073-30200 IrDA-infrared adapter is shown in Figure C.1, and a packaging design example is shown in Figure D.4 in Annex D.
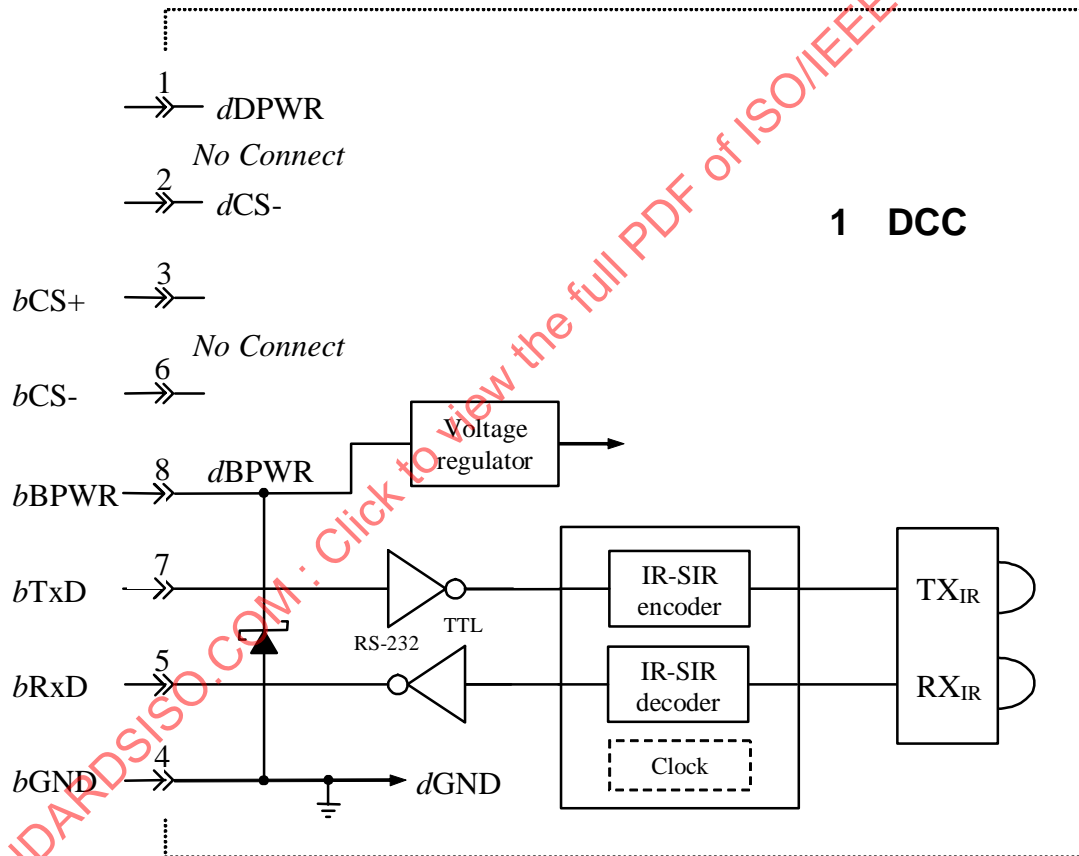
Figure C.1—Block diagram for an ISO/IEEE 11073-30200 IrDA-infrared adapter

A significant design issue is that the IrDA 3/16 encoder/decoder must be aware of the signaling speed to correctly encode and decode the SIR-encoded infrared data. When transmitting, the encoder must sample the bit positions after the start bit. When receiving, the incoming infrared pulses must be converted back to a traditional UART bit stream. If signaling rates other than 9600 Bd are supported, the encoder/decoder must be able to support the additional signaling rates on a frame-by-frame basis.

The majority of commercially available IrDA transceivers use additional signal lines to configure the 3/16 encoder/decoder. Some designs use a 16X baud-rate clock or use additional lines (e.g., RTS and DTR on a serial communication port or dedicated lines on an IrDA motherboard connector) to configure the speed and other operational modes of the infrared transceiver.

None of these signals are present on an ISO/IEEE 11073-30200 port; however, only TxD and RxD are available.

The simplest approach would be to configure the encoder/decoder[26] to operate at 9600 Bd only. This satisfies the minimum IrDA and ISO/IEEE 11073-30200 and ISO/IEEE 11073-30300 requirements for negotiating IrDA communication parameters and communication and would suffice for many clinical applications.

Adaptive speed selection, perhaps based on the timing of XBOFs at the beginning of an IrDA SIR frame, is also possible, but may impose additional timing constraints on the IrDA communication stack that are outside the scope of ISO/IEEE 11073-30200 and this standard.

It should be noted that the bCS+ and bCS– lines are not shorted since the use of the infrared adapter does not imply that a physical connection has been made to a medical device.

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[26]For example, an Agilent HSDL-7001 or Infineon Technologies IRM7001 IrDA SIR encoder/decoder.

Annex D

(informative)

Marking guidelines

This annex describes marking guidelines for an infrared port.

D.1 Labeling for infrared ports

ISO/IEEE 11073-30300 infrared ports and adapters should be labeled as shown in Figure D.1 and Figure D.2. The shaded areas of these figures represent the color yellow.

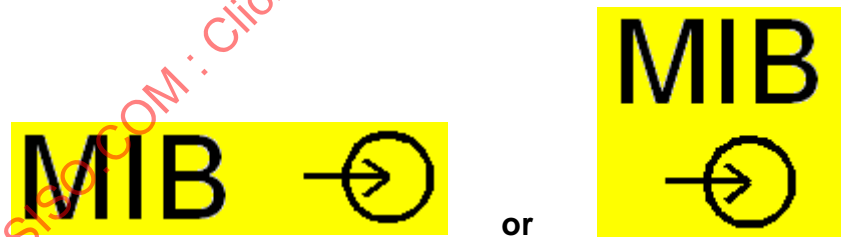**Figure D.1—MIB labeling on a DCC port**

Figure D.2—MIB labeling on a BCC port

The acronym MIB should be treated as part of the symbol; it should not be translated. It should appear in a sans serif typeface.

The color yellow should be used in addition to the symbol where feasible, e.g., as background for labels with the symbols or as the color of the cable, connectors, or adapters. The foreground (symbol, including text) color is black.

The alternate color scheme is a yellow symbol on a dark background.

The input symbol used with the BCC port is symbol number 5034, from IEC 60417-1. The output symbol used with the DCC port is symbol number 5035.

NOTE—Labeling should not involve a variant of these guidelines. Variations are reserved for future ISO/IEEE 11073 standards.

D.2 Labeling examples

Figure D.3, Figure D.4, and Figure D.5 show examples of labeling for infrared adapters and ports.
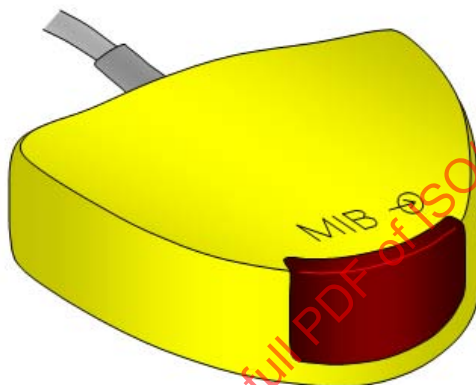

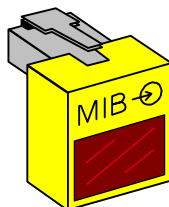**Figure D.3—Desktop infrared port for a BCC/AP**

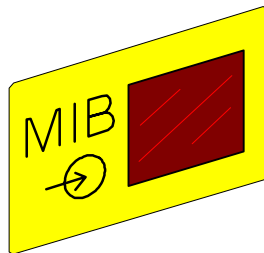**Figure D.4—Infrared adapter for an ISO/IEEE 11073-30200 BCC port**

Figure D.5—Infrared BCC port

Annex E

(normative)

IrDA conformance requirements

This annex is adapted from the Implementation Guide for IrDA Standards [B5]. It is intended to include specifications pertaining to the ISO/IEEE 11073-30200 IrDA profile and to be used as a statement of conformance for ISO/IEEE 11073-30300 implementers.

The status of each IrDA feature is M for mandatory, R for recommended, C for conditional, and O for optional.

E.1 IrLAP implementation

Document results by circling the appropriate response(s) in Table E.1.

Specification version: _____

Table E.1—IrLAP conformance requirements

Function	BCC	DCC	Supported
Secondary station	C[a]	C	Yes/No
Primary station	M	C	Yes/No
9600 Bd supported	M	M	Yes/No
Other SIR signaling speeds supported	R	R	19.2, 38.4, 57.6, 115.2 kBd
Other signaling speeds supported	O	O	576.0, 1115.2 kBd; 4, 16 MBd
500 ms maximum turnaround supported	M	M	Yes/No
Other maximum turnaround supported	O	O	250, 100, 50 ms
64 octets data size supported	M	M	Yes/No
Other data sizes supported	O	O	128, 256, 512, 1024, 2048 octets
1 transmit frame window supported	M	M	Yes/No
Other transmit window sizes supported	O	O	2, 3, 4, 5, 6, 7 frames
1 receive frame window supported	M	M	Yes/No
Other receive window sizes supported	O	O	2, 3, 4, 5, 6, 7 frames
Number of BOF required @ 115 kBd	Specify		48, 24, 12, 5, 3, 2, 1, 0
Minimum turnaround time	Specify		0, 0.01, 0.05, 0.1, 0.5, 1, 5, 10 ms
3 s link disconnect time supported	R	R	Yes/No

[a]Operation as an IrDA secondary station is required in a BCC or AP that supports the NCCLS POCT1 or infrared-enabled PDA devices.

E.2 IrLMP implementation

Document results by circling the appropriate response(s) in Table E.2.

Specification version: _____

Table E.2—IrLMP conformance requirements

Function	BCC	DCC	Supported
Link management multiplexer	M	M	Yes/No
Device nickname	M[a]	M[a]	Yes/No (specify name)
Hint bit 12	M[a]	M[a]	Yes/No
IAS objects and attributes:			
Device			
DeviceName	M	M	Yes/No
IrLMPSupport	M	M	Yes/No
IEEE:1073:3:3			
GlobalID	M[b]	M[b]	Yes/No
NodeType	M	M	Yes/No
PortNumber	M	M	Yes/No
PollInterval	O[c]	O[c]	Yes/No
IEEE:1073:3:3:SNTP			
LsapSel	R	N/A	Yes/No
IEEE:1073:3:3:MDDL			
LsapSel	N/A	M[d]	Yes/No
IAS services			
GetValue	R	R	Yes/No
GetValueByClass	M	M	Yes/No

[a]At a minimum, a valid device nickname or hint bit 12 shall be set (both preferred).
[b]The 5-octet extension identifier may be 0 for devices that cannot be individually serialized.
[c]Optional capability for a BCC or DCC that can participate as an IrDA secondary station.
[d]Mandatory if the DCC is an ISO/IEEE 11073 MIB device that supports MDDL.

E.3 IrDA TinyTP implementation

Document results by circling the appropriate response(s) in Table E.3.

Specification version: _____