

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

Part 90101: Analytical instruments — Point-of-care test

ICS 35.240.80

National foreword

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The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its secretary.

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 29 February 2008

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ISBN 978 0 580 53679 3

Amendments/corrigenda issued since publication

Date	Comments

INTERNATIONAL ISO STANDARD 11073-90101

First edition
2008-01-15

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

Part 90101:

Analytical instruments — Point-of-care test

*Informatique de santé — Communication entre dispositifs médicaux sur
le site des soins —*

Partie 90101: Instruments analytiques — Essai sur le site des soins



Reference number
ISO 11073-90101:2008(E)

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Foreword

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Point-of-Care Connectivity; Approved Standard—Second Edition

This document provides the framework for engineers to design devices, work stations, and interfaces that allow multiple types and brands of point-of-care devices to communicate bidirectionally with access points, data managers, and laboratory information systems from a variety of vendors.

A standard for global application developed through the Clinical and Laboratory Standards Institute consensus process.



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Point-of-Care Connectivity; Approved Standard—Second Edition

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Abstract

Clinical and Laboratory Standards Institute document POCT1-A2, *Point-of-Care Connectivity; Approved Standard—Second Edition* was developed for those engaged in the manufacture of point-of-care diagnostic devices, as well as the hardware and software used to connect the devices to various information systems in healthcare facilities. This document incorporates the work product of the Connectivity Industry Consortium, an organization that developed specifications for point-of-care device and information system communication interoperability. It provides the basis for multivendor, seamless interoperability between point-of-care devices, data managers, and clinical results management systems.

Clinical and Laboratory Standards Institute (CLSI). *Point-of-Care Connectivity; Approved Standard—Second Edition*. CLSI document POCT1-A2 (ISBN 1-56238-616-6). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2006.

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Suggested Citation

(Clinical and Laboratory Standards Institute. *Point-of-Care Connectivity; Approved Standard—Second Edition*. CLSI document POCT1-A2 [ISBN 1-56238-616-6]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2006.)

Proposed Standard

May 2001

Approved Standard

December 2001

Approved Standard—Second Edition

July 2006

ISBN 1-56238-616-6

ISSN 0273-3099

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Acknowledgement

CLSI gratefully acknowledges the contributions of the late Dr. Louis J. Dunka, Jr., LifeScan, Inc, who served as the Chairholder of the Area Committee on Point-of-Care Testing and was an active participant on the Working Group on Point-of-Care Connectivity during the revision of this document.

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Foreword

Over the last decade, advances in microfluidic and other miniaturization technologies have enabled a new class of diagnostic device. This new device class—point-of-care diagnostic—supports a wide diversity of diagnostic testing directly at the *point of care*. Tests that had been previously limited to the domain of central laboratory analyzers are now available in a variety of care settings. Sophisticated tests are possible at the hospital bedside, during patient encounters in primary- and secondary-care clinics, and even in the home. This new point-of-care diagnostic device class offers the advantages of fast turnaround time for test results and quite possibly cost reduction for some types of tests.

In general, from a regulatory perspective, a diagnostic test is not differentiated based on where the test is performed. Someone in the institution must be able to show that the test was performed in compliance with the policies of an overall diagnostic testing quality system for the institution. It is thus incumbent upon point-of-care diagnostic device vendors to offer mechanisms by which their devices may be integrated into an institution's diagnostic information management system. It is this requirement for integration that drives the need for standardization.

To date, point-of-care diagnostic vendors and partners have faced this integration problem individually and have derived unique solutions. Any institution embarking on incorporating multivendor point-of-care diagnostic devices into their diagnostic testing facilities has had to face the equipment and management costs of multiple integration solutions. In fact, the cost and disjointedness of multivendor point-of-care diagnostic integration is seen as a significant barrier to the adoption of this new and exciting class of diagnostic device.

For the purposes of this specification, point-of-care testing is defined as all testing conducted near the site of patient care. This encompasses many different environments, including hospital-based testing, near-patient testing, physician's-office testing, and patient self-testing. A point-of-care connectivity specification must be applicable to all of these settings.

In February 2000, 49 healthcare institutions, point-of-care diagnostic vendors, diagnostic test system vendors, and system integrators formed the Connectivity Industry Consortium (CIC) to address this point-of-care diagnostic integration problem. The CIC Board of Directors created the following statement to guide the CIC work teams:

"The vision of the CIC is to expeditiously develop, pilot, and transfer the foundation for a set of seamless 'plug-and-play' POC communication standards ensuring fulfillment of the critical user requirements of bidirectionality, device connection commonality, commercial software interoperability, security, and QC / regulatory compliance."

The result is a set of standards that will become the foundation for POC connectivity across the healthcare continuum. To meet this vision, the resulting standards are self-sustaining and utilize practical, cost-effective, user-focused solutions. The desired outcome of this vision is broad-based vendor and provider adoption of the CIC standards.^a

Sections 1 through 4 of this document introduce and explain the technical aspects of point-of-care connectivity specifications. Appendixes A through C are the specifications for constructing a connectivity system; Appendixes D and E describe the basic concepts CIC employed to develop this standard.

^a The governing principles, guidelines, timeline, and other information about the CIC can be found at the CIC's website: www.poct.fraunhofer.de/about/index.html. The CIC development process emulated the standards-development processes of ANSI-approved standards organizations.

Foreword (Continued)

Note that the following trade names are included in this document: Palm™, Pocket PC™, and Bluetooth™. It is CLSI policy to avoid using trade names unless the products identified are the only ones available; they serve as an example of the point illustrated in the consensus document; and there is no generic description of the design and functional features of the products. Inclusion of these trade names in no way constitutes endorsement by CLSI. Please include in your comments any information that relates to our adherence to this trade name policy.

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Foreword (Continued)

The CIC worked within a “fast-track” model and developed the point-of-care diagnostic integration specification within its planned 12- to 15-month lifetime. The CIC organization then handed the specification to CLSI (www.CLSI.org), Health Level 7 (www.hl7.org), and IEEE (www.ieee.org) organizations for subsequent maintenance and extension.

This document, then, represents the work product of the Connectivity Industry Consortium (CIC).

Since the initial publishing of the CLSI POCT1-A standard, communication technologies have evolved, including in the area of radio frequency (RF) networking. The current POCT1 standard makes numerous references to both Bluetooth (802.15.1) and WiFi (802.11) transport interfaces; however, at that time it wasn't clear whether one technology should be chosen in favor of another. As a result, though RF wireless networking is mentioned in the document, there is no clear direction other than that the standard should be easily extended to include one or more of these transport technologies as long as they provide reliable connection-oriented communications.

This document replaces the first approved edition, POCT1-A, which was published in 2001. Several changes have been made in this edition; chief among them is the addition of a new section related to RF Wireless Networking Technologies (see Section 12 in Appendix A). Another significant change in this document is the conversion of each message prefix from “NCCLS” to “CLSI.” This change has been made to reflect the organizational name change that has occurred since the original publication of this standard. In the case of manufacturers with existing or distributed implementations that used the “NCCLS” prefix, the “NCCLS” prefix is a deprecated but valid string, in addition to the preferred “CLSI.”

CLSI also gratefully acknowledges the approval of POCT1 by the Scientific Division of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). The joint efforts of the AACC Point-of-Care Testing Division, CIC, HL7, IEEE, IFCC, and CLSI, along with the many committee participants and experts involved in the development of POCT1, have served to strengthen the value of this standard and its usefulness worldwide.

Acknowledgements

Many individuals contributed a tremendous amount of time and effort to the CIC toward developing, describing, and reviewing these point-of-care connectivity specifications.

The following individuals served technical organizational roles within the consortium:

Chief Technical Officer:	Jeff Perry, Walker Informatics
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The following individuals are recognized for their significant contributions to the development, authoring, and review of the original CIC Specification:

- Bryan Allen, Bayer Diagnostics
- Bob Anders, HealthWyse
- Nils Graversen, Radiometer Medical
- Alan Greenburg, Roche Diagnostics
- Jack Harrington, Philips Medical Systems
- Rodney Kugizaki, LifeScan
- David Ma, Clarinet Systems
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Key Words

Access point, connectivity, device interfaces, diagnostics, diagnostic devices, HL7, IrDA, IEEE 1073, ISO 11073, medical information bus, MIB, CLSI, point-of-care, POC, point-of-care testing, POCT

Point-of-Care Connectivity; Approved Standard—Second Edition

1 Scope

This standard establishes a set of specifications to allow seamless multivendor interoperability and communication between point-of-care devices, data concentrators, and clinical information systems. CLSI document POCT1 provides the framework for engineers to design devices, workstations, and interfaces that allow multiple types and brands of point-of-care devices to communicate bidirectionally with access points, data concentrators, and laboratory information systems from a variety of vendors.

As an *interface* standard, this document specifies the common communication interfaces and protocols between systems and devices. It facilitates the transfer of data to support the creation of point-of-care applications, services, and institutional policies. This document does not directly address specific point-of-care application and service level functions, such as device lockout and operator list management. This document specifies protocol, not policy. The interfaces specified support the communication required for engineers to build such application-level functionality. Specifying, building, and providing the applications to support these services are left to customers, device and information system vendors.

The only relationship of this point-of-care standard to the laboratory automation domain is through the use of the HL7 standard. In version 2.4,¹ the HL7 standard was expanded to provide elements essential to laboratory automation, which also improved the HL7 standard for the entire laboratory-testing domain. These additions to HL7, along with four proposed new HL7 message triggers (see Section 4.1 in Appendix C of this CLSI standard), enable the point-of-care community to use HL7 as its electronic data interchange (EDI).

This specification also leverages several communication standards. It specifies the use of a single device transport protocol (IrDA TinyTP) running over two possible physical layers: *IrDA-infrared*, as specified by the Infrared Data Association (IrDA) and ISO/IEEE 11073-30300²; and *cable-connected*, as specified by the IEEE 1073 lower-layers standard.³ This specification also utilizes local area networking standards such as IEEE 802.3⁴ and protocols such as TCP/IP in cases where network connectivity is required.

2 Introduction

This document on point-of-care connectivity has been developed by the CLSI Subcommittee on Point-of-Care Connectivity. The core of the standard is a group of three specifications developed by the Connectivity Industry Consortium (CIC). The specifications describe the attributes of an access point; the communication protocols between the device and the access point; and communications between a data manager and clinical information systems. The collaborative effort among providers and manufacturers has produced a set of specifications acceptable to both. The constitution of the subcommittee is a balance among providers; representatives of CLSI, HL7, and IEEE; the professions (CAP); and the government (FDA). The specifications will become standards in IEEE, HL7, and CLSI in parallel.

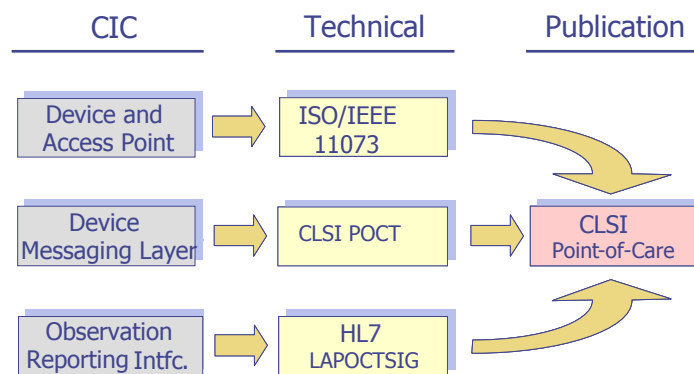


Figure 1. Cooperative Evolution of Point-of-Care Standards

3 Definitions

Access Point (AP) – a subsystem that consolidates data from one or more point-of-care devices (POCD) onto another communication link; **NOTE:** Examples of access points include a multiport concentrator or a dedicated single-port access point, typically connected to a local area network (LAN), or an access point that is part of a multifunctional device such as a patient monitor or personal computer.

ANSI – American National Standards Institute (www.ansi.org).

Clinical Information System (CIS) – any healthcare information system (HIS) responsible for housing clinical information; **NOTE:** Examples include laboratory information systems (LIS), clinical data repository (CDR), and electronic medical records (EMR).

Connectivity – the ability to reliably transfer test information between a point-of-care testing device and an information system.

Data Manager (DM) – typically, a network server that provides the services of an Observation Reviewer (e.g., POC data storage and forwarding, QA/QC, and other POC instrument and data management functions); **NOTE 1:** In addition to these services, Data Managers usually provide other applications or services tailored to particular devices or POC user needs (such as regulatory reporting and operator management applications); **NOTE 2:** Data Manager systems are specific instances of Observation Reviewer services.

Device and Access Point interface (DAP) – specifies the interface between a device and an Access Point or concentrator.

Device Messaging Layer (DML) – the DML describes a complete messaging protocol (message types and message flow) to exchange results and quality information (quality assurance and quality control) between a Device and an Observation Reviewer; **NOTE:** This protocol may sit on top of any robust, reliable transport, such as the one described by the POCT1 Device and Access Point specification.

Docking Station – a mechanical and electrical interface that supports the use of a POC Device, typically employing legacy mechanical interfaces, connectors, protocols, and power delivery methods.

Electronic Data Interchange (EDI) – a term used in many industries to describe protocols to exchange data between enterprise-class information systems; **NOTE 1:** The acronym is general (applying to all such exchange protocols and languages); however, in some industries it has come to refer to specific implementations; **NOTE 2:** In the point-of-care domain, this term is occasionally used to refer to the

specific interface found between point-of-care data management systems, laboratory information systems, clinical information systems, and other systems that serve as the final repository of POC results.

Extensible Markup Language (XML) – a meta-language widely used on the Web and for business-to-business data exchange; **NOTE:** XML is to data and information as HTML is to documents and presentations.

Health Level 7 (HL7) – the Health Level 7 organization (www.hl7.org), an ANSI-accredited standards development organization focused on messaging to support the exchange of clinical and administrative healthcare data; **NOTE:** The HL7 standard specifies a transport-independent messaging framework and structure that enables disparate healthcare information systems to exchange data.

The Institute of Electrical and Electronics Engineers (IEEE) – an international, ANSI-accredited standards development organization dedicated to the advancement of electrical and information technologies; **NOTE:** Among its many roles, the IEEE sets standards for the electronics industry such as IEEE Standard 1073 for Medical Device Communications and IEEE Standard 802.3, which forms much of the lower-layers foundation for the Internet (www.ieee.org).

IEEE 1073 – a family of standards for medical device communications that are optimized for the acute care setting; **NOTE 1:** Devices include patient monitors, ventilators, infusions pumps, pulse oximeters, etc.; standards include IEEE Standard 1073 and lower-layers IEEE Standard 1073.3.2; also referred to as “MIB” (see **Medical Information Bus**); **NOTE 2:** These are internationally harmonized as the ISO/IEEE 11073 set of standards.

Infrared (IR) – the physical layer typically used by infrared data association (IrDA) devices.

Infrared Data Association (IrDA) – an organization that creates and promotes interoperable, low-cost infrared data interconnection standards (www.irda.org); **NOTE:** ‘IrDA’ also refers to the protocol stack authored by that group.

ISO/IEEE 11073 – a family of standards for medical device communications that are optimized for the acute care setting; **NOTE:** When they are harmonized with IEEE 1073 standards, the designation is ISO/IEEE 11073 (see **IEEE 1073**).

Medical Information Bus (MIB) – a common name used for the IEEE 1073 family of standards for medical device communications (see **IEEE 1073**); **NOTE:** Not to be confused with Management Information Base used in SNMP.

Observation Recipient – the Observation Recipient provides services to manage point-of-care test results and ordering information within a healthcare institution; **NOTE:** In current point-of-care information management solutions, this function is often performed by laboratory information systems, clinical information systems, and other systems that serve as the final repository of POC results.

Observation Reporting Interface (ORI) – the ORI specifies messages sent between Observation Reviewers and Observation Recipients; **NOTE:** The messages contain information regarding observation results and associated orders.

Observation Reviewer – the Observation Reviewer provides services to support the management of test results, quality assurance and quality control data, and medical orders; **NOTE:** In current point-of-care information management solutions, this function is often performed by a Data Manager.

Personal Digital Assistant (PDA) – the class of consumer electronic devices that handle functions such as management of calendars, contact lists, and task lists; **NOTE 1:** Examples of PDAs include the Palm™ and Pocket PC™ devices; **NOTE 2:** Please see Disclaimer Statement in the beginning of this standard.

Point-of-Care (POC) – the environment immediately surrounding a patient.

Point-of-Care Coordinator (POCC) – an individual who has overall responsibility for assuring that the operation of all POC devices in the institution is compliant with the institution's POC quality system; **NOTE:** The services provided by the data manager(s) in the system are key tools used by the POC Coordinator to assure compliance.

Point-of-Care Device (POCD) – in the context of this standard, a point-of-care device is an instrument used at the patient's side to measure and/or record a clinical observation; **NOTE:** This definition does not require that the POCD measure the observed value; thus, this definition encompasses devices that perform biochemical analyses, devices that calculate observations from results determined externally, or devices that simply record values determined by other procedures.

Quality assurance (QA) – part of quality management focused on providing confidence that quality requirements will be fulfilled (ISO 9000, 3.2.11⁵).

Quality control (QC) – part of quality management focused on fulfilling quality requirements (ISO 9000 3.2.10⁵).

Tiny Transport Protocol (TinyTP) – IrDA transport protocol that provides multiple, concurrent, reliable, bidirectional communication streams on an IrDA link with robust flow control.

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

4 Specifications

This specification covers two broad areas of point-of-care device behavior:

- *Application Integration*

This specification defines the dialogs in which point-of-care diagnostic devices and participating systems engage. Ultimately, these dialogs manifest as a set of *messages* that pass between participants via well-defined *interfaces* in a system compliant with this specification. This specification has sought to define a sufficient set of dialogs to meet the integration and regulatory requirements imposed on a diagnostic test system that includes point-of-care diagnostic devices. This specification has been careful to not over-specify such dialogs; doing so would leave the specification brittle in response to change and could impede innovative development in the relatively young point-of-care diagnostic industry.

- *Physical Integration*

There are significant costs in multivendor point-of-care diagnostic integration that cannot be reduced unless there is some standardization of the physical and link-level interfaces used by point-of-care diagnostic devices and associated systems. This specification, therefore, also defines a set of physical connections and associated protocols. This specification has sought to prescribe a minimal set of physical definitions to reduce the cost of point-of-care diagnostic integration but not restrict vendors in their delivery of point-of-care diagnostic innovation.

This specification has defined two interfaces — a Device Interface and an Observation Reporting Interface.^b Figure 2 overlays these interfaces on the “boxes and wires” that comprise typical solutions for point-of-care information management.

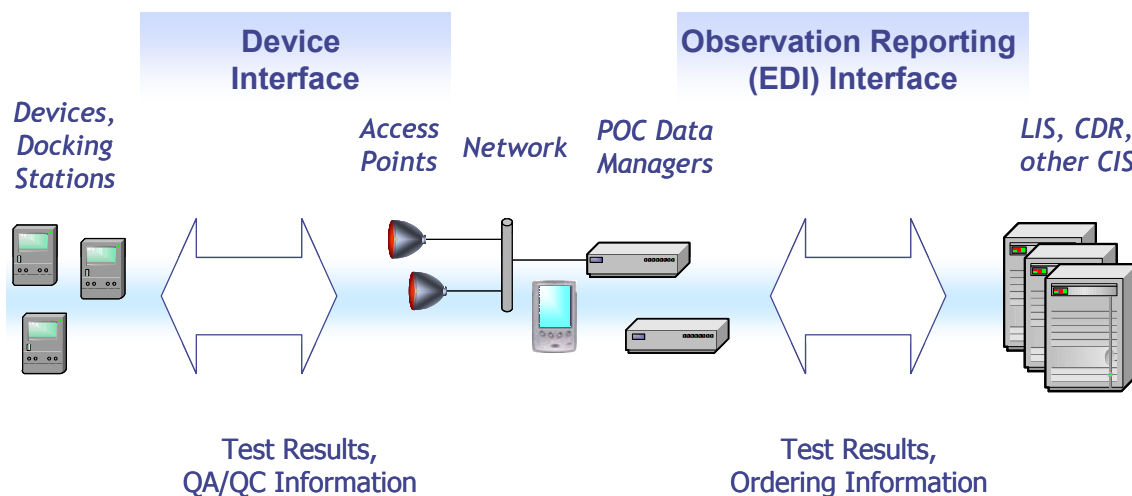


Figure 2. The Two Interfaces

4.1 Description of Connectivity System Components

Perhaps it is best to start by describing the devices and networks typically found in point-of-care testing systems to which this specification applies. It should be easier to understand the abstract parts of the interface specifications with a good image of a physical system in mind. The components and elements of the system may be:



4.1.1 The Point-of-Care Device

The emerging new diagnostic test technologies are packaged in a variety of devices. The devices that are within the scope of this specification are hand-held devices; test modules that are part of other instrumentation (a patient monitor, for example); or small, bench-top analyzers.

The bench-top devices support the concept of a remote or “satellite” laboratory located close to patients in the hospital or in a clinic setting. These modules leverage the electrical power and connectivity infrastructure provided by host instrumentation at the bedside. The hand-held devices are portable. They are used in a variety of settings that range from the hospital room to the home, as well as the clinic.

Although there is considerable diversity in device type and role, this specification attempts to support all point-of-care diagnostic devices. Accommodation is made in this specification to recognize the typically limited computing power and user interface facilities of these devices. In addition, this specification recognizes that hand-held devices are not continuously connected to a network, whereas other analyzers typically are.

^b Also referred to as the “EDI interface.”



4.1.2 Access Points

POC devices will need to communicate with an Observation Reviewer to report results and exchange information. In many hospital settings, one or more networked Access Points can be used to extend the ‘reach’ of the Observation Reviewer to all clinical care areas where POC devices can be used, both inside and outside the hospital or clinic. Standardization of this connectivity component is important, since it provides a common communication infrastructure that can be shared by many devices and services.



4.1.3 The Observation Reviewer (POC Data Manager)

The primary role of an Observation Reviewer is to host one or more services to which point-of-care diagnostic devices connect. These services facilitate the collection of test and quality data from, as well as the management of these devices. In addition, services hosted by an Observation Reviewer may exchange data with existing information systems that already exist in the hospital or laboratory. In particular, Observation Reviewer services may interact with laboratory information systems (LIS), order communication systems, and medical record systems.

In general, products such as POC data managers currently fill the role of the Observation Reviewer; however, it is possible that in the future other systems concerned with observation management and reporting (e.g., LIS) may serve as Observation Reviewers. It may be easier to refer to Observation Reviewers as “data managers”; however, keep in mind that this specification does not require the existence of a stand-alone data manager. Instead, it requires only that some system fill the role and responsibilities of an Observation Reviewer.

Observation Reviewers are usually implemented in conventional information technology (IT) hardware with conventional IT software. Observation Reviewers typically reside within the IT spaces of the institution with fixed connections to the hospital’s network.

There may be more than one Observation Reviewer in a healthcare system. There may be some specialization of services in any given Observation Reviewer. An Observation Reviewer may host vendor-specific services in addition to the services required to support this connectivity standard.



4.1.4 The Observation Recipient (LIS, CDR, or EMR)

Although outside the scope of this specification, Observation Recipient systems play an important role in point-of-care diagnostic systems. In many cases, the final resting place of a point-of-care diagnostic test observation is inside an Observation Recipient system.

Typically, LIS or Clinical Data Repository (CDR) systems fill the role of Observation Recipient.

This specification does not describe Observation Recipient behavior; however, services specified by this specification do facilitate interaction with Observation Recipient systems (e.g., to exchange test results and ordering information).

4.2 The Interfaces

One of the goals of this specification is to support a wide variety of POC information management implementations, including existing systems, as well as all reasonably conceivable future developments and topologies.

Two interfaces comprise the heart of this specification (Figure 2). In general, the *Device Interface* governs the flow of information between devices and Observation Reviewers, and the *Observation Reporting Interface* (sometimes referred to as the *EDI interface*) describes messaging between Observation Reviewers and Observation Recipients.

The character, nature, and attributes of the Device Messaging Layer and Access Point specifications are described in more detail in the following subsections.

4.2.1 The Device Interface

In general, Devices and Observation Reviewers are very tightly coupled systems. Devices with limited user-interface capabilities must rely on configuration and management services provided by Observation Reviewers. In turn, Observation Reviewers need strict control of devices to fulfill their responsibility to manage the quality and reporting of POC test results. The fact that this tight coupling must be deployed and maintained across large geographic areas and over a variety of telecommunication infrastructures (LAN, phone, Internet, wireless) presents additional complexity to the design of this interface.

The Device Interface addresses these requirements and challenges with a two-part specification. The Device Messaging Layer (DML) specification describes the structure, content, and flows of messages between a device and an Observation Reviewer. The Device and Access Point (DAP) specification defines a low-cost, flexible means to reliably communicate these messages.

Figure 3 illustrates how these two specifications are layered on top of one another.

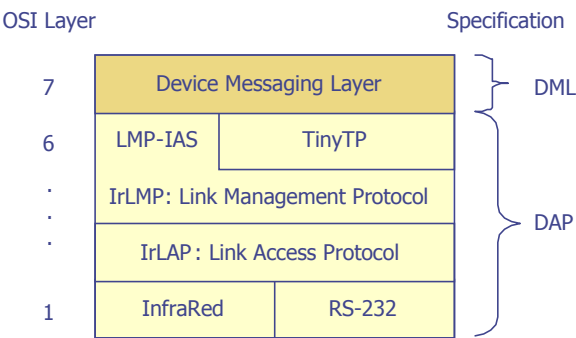


Figure 3. Device Interface Layers

Separating the specifications for messaging and for network access allows great flexibility for the future evolution of this interface. For example, one needs only to update the messaging layer to add support for additional application-level services (such as point-of-care ordering or result review). Similarly, the DAP can support other applications and devices, such as Medical Information Bus (MIB) and personal digital assistants (PDAs). The DAP can also support existing or vendor-specific protocols.

Likewise, while the DAP specification defines a transport optimized for current technology and market economics today (IrDA infrared and cable-connected), it is important to allow the future use of other lower-level transport and physical layers (e.g., Bluetooth™ or IEEE 802.11⁶ wireless networking).

Figure 4 illustrates how other robust, reliable transports could be utilized in the future to carry device messages.

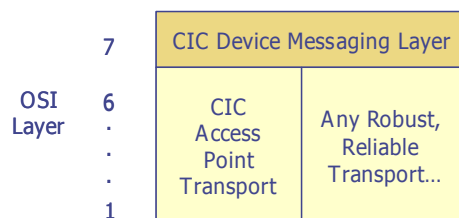


Figure 4. Lower-Layer Networking Evolution

Device Messaging Layer (DML) Specification (For the complete specification, see Appendix B.)

The Device Messaging Layer (DML) specification describes the dialog between a device and an Observation Reviewer. This protocol is a pure application-layer messaging scheme, requiring the existence of a robust, reliable lower-level transport.^c

The DML allows for bidirectional data exchange on the following topics:

- 1 Device Status
- 2 Observations
 - 2.1 Patient Tests
 - 2.2 Calibration Tests
 - 2.3 Quality Tests
 - 2.3.1 Liquid QC
 - 2.3.2 Electronic QC
 - 2.3.3 Calibration Verification
 - 2.3.4 Proficiency Test
- 3 Device Events
 - 3.1 Test Denied
 - 3.2 Uncertified Operator
 - 3.3 Vendor-specific
- 4 Update Lists
 - 4.1 Operator List
 - 4.2 Patient List
- 5 Directives
 - 5.1 Set Time
 - 5.2 Lockout (with explanation)
 - 5.3 Remove Lockout
 - 5.4 Vendor-specific
- 6 Vendor-specific Data Exchange

Figure 5. Device Messaging Layer Data Topics

Point-of-care devices on the market today encompass a wide range of capabilities and complexity. For example, “simple” devices like some hand-held glucose meters only need to (and only are able to) report

^c The terms “robust” and “reliable” have formal meanings. In short, a transport with these attributes guarantees messages will not be corrupted in transit and that senders will always be informed if a message can’t be delivered.

their status and stored observations. Other more complex hand-held devices may be able to handle the entire range of topics listed in Figure 5.

In addition, devices connect differently to download data. Most hand-held devices require a user to periodically “dock” the device to initiate the data exchange. In some cases, this docking involves placing the device in a special cradle. In other cases, it involves pointing the device’s infrared port at a fixed transceiver. No matter what the mechanism, the following general observations apply to these “docking” systems:

- user-initiated establishment of a physical connection;
- user-initiated start of a “data download” sequence; and
- periodic interruption of the physical connection (when the device is “undocked”).

In contrast to this *intermittent* connection model, some devices have built-in network connectivity, and can remain *continuously* connected to network-located Observation Reviewer services.^d Consequently, there is no need for users to initiate download sequences. Typically, these devices automatically report new status, configuration, or observation information whenever it becomes available.

This variability presents several challenges for the messaging layer. In order to address these issues, the Device Messaging Layer allows some flexibility in how devices implement data exchange. Key aspects of this approach are as follows:

- (1) Minimum Topic Requirements—All devices are required to support at least the status and observation topics. An exchange covering only these topics would be sufficient to support test result reporting processes.
- (2) Scalable Conversation Topics—Beyond the minimum topic requirement, devices may support any number or combination of the additional topics listed in Figure 5. The Device Messaging Layer specification outlines a means by which a device informs an Observation Reviewer of the topics it supports.
- (3) Dialogs Tailored to Device Capabilities—The Observation Reviewer bears the responsibility to tailor the conversation to only those subjects that are relevant to the device.
- (4) Support for Intermittently and Continuously Connected Devices—The characteristics of the device connection determine the nature of the Device and Observation Reviewer message exchange. *Intermittently* connected devices use a message flow that is designed to rapidly exchange all data required to synchronize the Device and Observation Reviewer. *Continuously* connected devices maintain a long-term message flow, reporting new information as it becomes available.

Consider the following example of a dialog between an intermittently connected Device and an Observation Reviewer, described in terms of a dialog between two actors. The following “script” outlines how this dialog proceeds between a Device (DEV) and an Observation Reviewer (OR):

^d Usually the connection is Ethernet running over twisted-pair cabling, but in some cases it is RS-232.

DEV: Hello Observation Reviewer, I'm device 'xyz'. I'm on-line.
OR: Hello 'xyz'. You are a registered device. Please proceed.
DEV: Here is my device status. What else would you like me to do?
OR: Device 'xyz', please report your observations.
DEV: Here are my observations. What else would you like me to do?
OR: Device 'xyz', please report your device events.
DEV: Here are my device events. What else would you like me to do?
OR: Device 'xyz', please accept this Directive: 'xxx'.
DEV: I can perform directive 'xxx'. What else would you like me to do?
OR: Device 'xyz', please accept this vendor-specific communication: 'yyy'.
DEV: I have received vendor-specific communication 'yyy'. What else would you like me to do?
OR: Device 'xyz', please terminate this conversation.
DEV: Goodbye, Observation Reviewer.

Figure 6. Device Messaging Layer 'Script'

The individual messages in this conversation are encoded in XML. The XML-based approach best meets the requirements of flexibility, robustness, simplicity, and widespread, cross-industry support.

Rather than developing a completely new language in XML, the Device Messaging Layer leverages existing work done by HL7. Principally, this specification leverages the rules for encoding data types^e and elements of the information model defined for Version 3 of the HL7 standard.⁷

^e Defined in the HL7 *Version 3 Data Types – Ballot Draft II (revision 1.3)* document.

The following figure shows an example of the observation message used to report a glucose test result.

	<pre> <?xml version="1.0" encoding="UTF-8"?> <!DOCTYPE OBS.R01 SYSTEM "OBS.R01.dtd"> <OBS.R01> <HDR> <HDR.control_id V="10003"/> <HDR.version_id V="POCT1"/> <HDR.creation_dttm V="2001-11-01T16:30:06-08:00"/> </HDR> <SVC> <SVC.role_cd V="OBS"/> <SVC.observation_dttm V="2001-11-01T16:29:54-08:00"/> <SVC.status_cd V="NRM"/> <SVC.reason_cd V="NEW"/> <SVC.sequence_nbr V="2524"/> <PT> <PT.patient_id V="PT222-55-7777"/> <PT.location V="ICU-4"/> <PT.name V="Jan Patient"> <GIV V="Janet"/> <FAM V="Patient"/> </PT.name> <PT.birth_date V="1960-08-29"/> <PT.gender_cd V="F"/> <PT.weight V="110" U="lbs"/> <PT.height V="66" U="inches"/> <OBS> <OBS.observation_id V="1517-2" SN="LN" DN="Glucose"/> <OBS.value V="85" U="mg/dL"/> <OBS.method_cd V="M"/> <OBS.status_cd V="A"/> <OBS.interpretation_cd V="N"/> <OBS.normal_lo_hi_limit V="[80;120]" U="mg/dL"/> <OBS> <OBS.critical_lo_hi_limit V="[30;160]" U="mg/dL"/> <NTE> <NTE.text V="Temp warning"/> </NTE> </OBS> </PT> <OPR> <OPR.operator_id V="OP777-88-9999"/> <OPR.name V="Pat Operator"> <GIV V="Patrick"/> <FAM V="Operator"/> </OPR.name> </OPR> <SPC> <SPC.specimen_dttm V="2001-11-01T16:27:00-08:00"/> </SPC> <RGT> <RGT.name V="GlucoseControl"/> <RGT.lot_number V="123456" SN="BCHMX" SV="1.0"/> <RGT.expiration_date V="2002-05-31"/> </RGT> <NTE> <NTE.text V="New strip"/> </NTE> <NTE> <NTE.text V="Repeat test"/> </NTE> </SVC> </OBS.R01> </pre>
--	---

Figure 7. Example Glucose Test Results Message

4.2.1.1 Device and Access Point (DAP) Specification (For the complete specification, see Appendix A.)

The Device and Access Point (DAP) specification describes a low-cost, flexible, reliable means to connect devices to Observation Reviewers located on a network. This standard describes low-level

communication protocols and physical interfaces used to connect to point-of-care devices. It specifies the use of a single transport protocol running over either of two physical layers—*IrDA infrared*^f or *cable-connected*.^g

To keep the implementation cost low (less than a dollar per device), this specification leverages widely adopted, commercially available existing standards. The infrared connection is based on the IrDA technology that is found in more than 100 million laptops, cell phones, and personal digital assistants.^h

This standard also specifies how a *network access point* acts as a relay between the TinyTP connection to the device and a TCP/IP connection to a data manager on the network, and how the services of one or more POC data managers can be *registered* at an access point. This solution places most of the burden of finding, binding, and communicating with the appropriate network services on the access point rather than the device. Figure 8 illustrates how an Access Point can be used to provide an infrared or cable-connected device access to an Observation Reviewer located on a network.

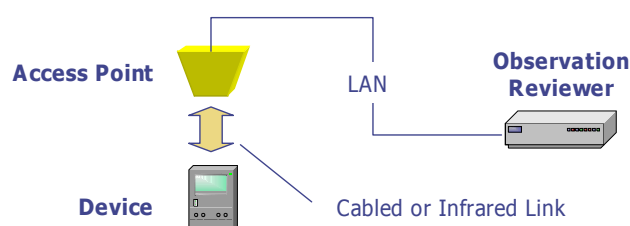


Figure 8. Example Access Point Deployment Scenario

Although not formally required by this standard, a key objective of this proposal is that it should be possible to build a *common access point* that can support point-of-care devices, MIBⁱ and PDA^j devices, regardless of differences between their upper-layer protocols and applications. The availability of a common access point infrastructure that could support POC, MIB, and hand-held PDA devices in all patient care areas would be a major benefit to clinicians and will accelerate the adoption of this standard.

Consistent with the need to support a variety of telecommunication and networking infrastructures, the Device and Access Point specification also provides recommendations regarding remote modem access. Commercially available IrDA-modem adapters provide one possible solution for remote modem access.

4.2.2 The Observation Reporting Interface

The Observation Reporting Interface facilitates the communication of test results and order information between Observation Reviewers and Observation Recipients.^k The interface provides bidirectional information flow between these services.

^f As specified by the Infrared Data Association (IrDA).

^g As specified by the ISO/IEEE 11073 lower-layers IrDA-based transport standard (ISO/IEEE 11073-30200³).

^h The IrDA port is the small, semitransparent, red window on one of these devices.

ⁱ “Medical Information Bus” – an informal name for the IEEE 1073 family of standards for medical device communications, typically concerned with acute care devices such as infusion pumps, ventilators, and vital signs monitors to bedside patient monitors, internationally harmonized as ISO/IEEE 11073 standards.

^j “Personal Digital Assistants” – consumer-oriented, hand-held computers.

^k Again, it may help to think of Observation Reviewers as POC data managers and Observation Recipients as LIS systems. It’s important to keep in mind, though, that these alternate names describe one possible deployment configuration. For example, it’s quite possible that instead of an LIS, a clinical data repository (CDR) or other electronic medical record (EMR) system will serve the role of Observation Recipient.

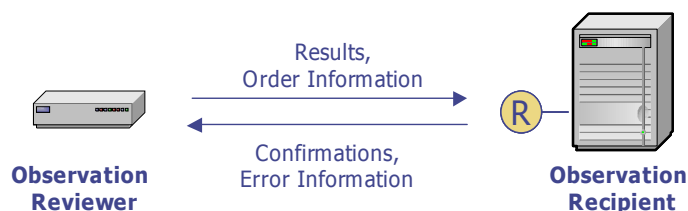


Figure 9. Observation Reporting Interface

Observation Reviewers use this interface to report test results with associated order information. Observation Recipients use this interface either to inform the Observation Reviewer when results have been successfully reported, or to communicate error information when a result or order can't be stored.

The clinical workflow surrounding point-of-care measurement and ordering processes is quite complex, dynamic, and flexible. The Observation Reviewer and Observation Recipient bear the major responsibility for making and managing the connection between orders and results. Thus, the Observation Reporting Interface is designed to handle the three most common result-and-ordering use cases:

- **Unordered Observation, Place an Order** – A test is performed without an order where the Observation Recipient should place an order.

One example of this use case occurs when a doctor verbally instructs a nurse to perform a test. From an information management perspective, it would be best if the nurse electronically enters an order before performing the test. However, in the real world, there usually isn't time for order entry in these situations. In fact, it is highly desirable for the point-of-care measurement process to become automated so that the only action a user needs to take is to make a measurement on the POC device, with all other processes for generating an order, and tying it in to the observation handled by the "machines."

- **New Observation, Search for an Order** – A test is performed which may or may not have an order previously placed.

In this case, the Observation Reviewer does not know if an order has been placed. It instructs the Observation Recipient to search for an existing order for the associated results. The institution's business rules will determine what the Observation Recipient does if it can't find a matching order. Possibilities include automatically placing an order (as in use case 1, above), or logging an exception rather than recording the result.

- **Preordered Observation** – A test is performed that was previously ordered.

From a traditional central laboratory perspective, this use case is probably the predominant (if not exclusive) one. However, in the point-of-care environment, it is actually uncommon to have an order already generated when a test is performed.

4.2.2.1 Observation Reporting Interface (ORI) Specification (For the complete specification, see Appendix C.)

The Observation Reporting Interface (ORI) specification heavily leverages the messages defined for laboratory instrument communication defined in Chapters 4, 7, and 13 of HL7's Version 2.4¹ specification. In fact, the specification is an implementation guide for using HL7 v2.4¹ messages to

support POC testing. As such, this specification does not define any new messages, segments or fields.¹ Instead, it simply provides a strict set of rules defining which messages are used and how each message is constructed. These rules increase the likelihood that separate implementations of this interface will easily interoperate.

For illustration purposes, Figure 10 shows a hypothetical message from an Observation Reviewer reporting a new result from a glucose meter (120 mg/dL) that is associated with a previously placed order (“OrdIDA24680”).

```
<VT>
MSH|^~\&|CICDMS|OBSREV|CICLIS|OBSRCPT|20000610010355||ORU^R30|20000610010355:023|P|2.4|||AL|AL<CR>
PID|||MR12345678^^^1|||||||||||||ActID135792468^^^1<CR>
ORC|RE<CR>
OBR||OrdIDA24680||1234-5^GLU^LN|||||O||||5555^Smith^John^J^Dr<CR>
OBX||ST|1234-5^GLU^LN||120|mg/dl||||F||||User9876||CICDEV-111^SINGRES|20000609102135<CR>
NTE|||Stat~Physician Notified<CR>
<FS><CR>
```

Figure 10. Sample Observation Reporting Interface Message

¹ The Observation Reporting Interface specification introduces four new HL7 message triggers that were not in the original v2.4 specification. HL7 has issued an “authoritative use statement” to formally authorize the use of these four new triggers in advance of being balloted by HL7 for a future version of their standard.

References

- ¹ HL7. *Health Level Seven – An Application Protocol for Electronic Exchange in Healthcare Environments*, Version 2.4. Ann Arbor, MI: Health Level Seven; 2000.
- ² ISO/IEEE 11073-30300 *Health Informatics - Standard for point-of-care medical device communication – Part 30300: Transport profile – Infrared wireless*. Piscataway, NJ: Institute of Electrical and Electronics Engineers, Inc.; 2001.
- ³ ISO/IEEE 11073-30200. *Health Informatics – Point-of-care device communication – Transport file – Cable connected*. Piscataway, NJ: Institute of Electrical and Electronics Engineers, Inc.; Geneva, Switzerland: International Organization for Standardization; 2004.
- ⁴ IEEE 802.3. *Information Technology – LAN/MAN – Carrier Sense Multiple Access with Collision Detection (CSMA/CD) Access Method and Physical Layer Specifications*. Piscataway, NJ: Institute of Electrical and Electronics Engineers, Inc.; 2000.
- ⁵ ISO. ISO 9000:2000. *Quality management systems—Fundamentals and vocabulary*. Milwaukee, WI: American Society for Quality; 2000.
- ⁶ IEEE 802.11. *Information Technology – Telecommunications and Information Exchange Between Systems – LAN/MAN – Specific Requirements – Wireless LAN Medium Access Control (MAC) and Physical Layer (PHY) Specifications*. Piscataway, NJ: Institute of Electrical and Electronics Engineers, Inc.; 1999.
- ⁷ HL7. Health Level Seven. Version 3. Ann Arbor, MI: Health Level Seven; 2005.

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POINT-OF-CARE CONNECTIVITY SPECIFICATION

A standard for global application developed through the Clinical and Laboratory Standards Institute consensus process.



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APPENDIX A. DEVICE AND ACCESS POINT (DAP) INTERFACE SPECIFICATION

Transport and Physical Layer Specification

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A standard for global application developed through the Clinical and Laboratory Standards Institute consensus process.



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POINT-OF-CARE CONNECTIVITY SPECIFICATION

1 Scope and Introduction

This standard specifies the lower-layer communication protocols and physical interfaces for ‘point-of-care’ (POC) *Devices* and *Access Points*. The following figure illustrates this specification’s role relative to the other POCT1 specifications.

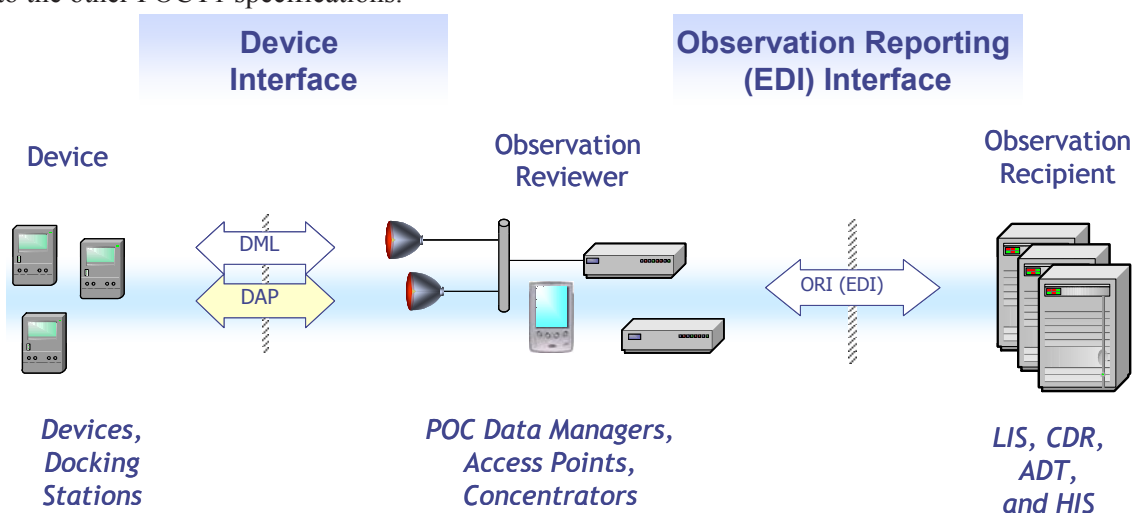


Figure 11. Device and Access Point Scope

This standard specifies the use of a single-transport protocol (IrDA TinyTP) running over either of two physical layers: 1) *IrDA-infrared*, as specified by the Infrared Data Association (IrDA); and 2) *cable-connected*, as specified by the IEEE Medical Information Bus (MIB) lower-layers standard ISO/IEEE 11073-30200.

This standard also specifies how a *network access point* acts as a relay between the TinyTP connection to the Device and a TCP/IP connection to a Data Manager on the network, and how the services of one or more POC Data Managers can be *registered* at a network access point. This solution places most of the burden of finding, binding, and communicating with the appropriate network services on the access point rather than the Device.

Although not formally required by this standard, a key objective is that it should be possible to build a *Common Access Point* that can support POC, MIB, and hand-held PDA devices, regardless of differences between their upper-layer protocols and applications. The availability of a Common Access Point infrastructure that could support POC, MIB, and hand-held PDA devices in all patient care areas would be a major benefit to clinicians and would accelerate the adoption of this standard.

Recommendations regarding remote modem access are also provided, based on the IrDA infrastructure and protocols defined by this document.

2 Definitions

Access Point (AP) – a subsystem that consolidates data from one or more point-of-care devices (POCD) onto another communication link; **NOTE:** Examples of access points include a multiport concentrator or a dedicated single-port access point, typically connected to a local area network (LAN), or an access point that is part of a multifunctional device such as a patient monitor or personal computer.

Access Point Interface (API) – specifies the interface (principally input) to an Access Point or concentrator; **NOTE:** This definition is equivalent to IEEE ‘BCC.’

Bedside Communication Controller (BCC) – specifies the interface (principally input) to an Access Point or concentrator; **NOTE:** This is an IEEE definition, equivalent to ‘API.’

Common Access Point (CAP) – an Access Point that can service MIB, POC, and hand-held PDA devices.

Connectivity Industry Consortium (CIC) – a group of more than 50 healthcare institutions, point-of-care diagnostic vendors, diagnostic test system vendors, and system integrators who formed a consortium in 2000 to address standards for point-of-care connectivity; **NOTE 1:** The CIC developed a standardization specification within its planned one-year lifetime, and then handed this specification over to CLSI (www.clsi.org), Health Level 7 (www.hl7.org), and IEEE (www.ieee.org) organizations for subsequent maintenance and extension; **NOTE 2:** The CIC specification forms the basis for the CLSI POCT1 standard.

Data Manager (DM) – typically, a network server that provides the services of an Observation Reviewer (e.g., POC data storage and forwarding, QA/QC, and other POC instrument and data management functions); **NOTE 1:** In addition to these services, Data Managers usually provide other applications or services tailored to particular devices or POC user needs (such as regulatory reporting and operator management applications); **NOTE 2:** Data Manager systems are specific instances of Observation Reviewer services.

Data Manager Interface (DMI) – specifies the TCP/IP network interface and protocol between a Data Manager and one or more Access Points.

Device Communication Controller (DCC) – specifies the interface (principally output) of a POC Device or its Docking Station to an Access Point; **NOTE:** This is an IEEE definition, equivalent to ‘PDI.’

Docking Station (DS) – a mechanical and electrical interface that supports the use of a POC Device, typically employing legacy mechanical interfaces, connectors, protocols, and power delivery methods.

Electronic Data Interchange (EDI) – electronic Data Interchange is a term used in many industries to describe protocols to exchange data between enterprise-class information systems; **NOTE 1:** The acronym is general (applying to all such exchange protocols and languages); however, in some industries it has come to refer to specific implementations; **NOTE 2:** In the point-of-care domain, this term is occasionally used to refer to the specific interface found between point-of-care data management systems, laboratory information systems, clinical information systems, and other systems that serve as the final repository of POC results.

Information Access Service (IAS) – advertises capabilities of IrDA Devices; **NOTE:** Also termed IrLMP-IAS.

Infrared (IR) – the physical layer typically used by infrared data association (IrDA) devices.

Infrared Data Association (IrDA) – an organization that creates and promotes interoperable, low-cost infrared data interconnection standards (www.irda.org); **NOTE:** ‘IrDA’ also refers to the protocol stack authored by that group.

The Institute of Electrical and Electronics Engineers (IEEE) – an international, ANSI-accredited standard development organization dedicated to the advancement of electrical and information technologies; **NOTE:** Among its many roles, the IEEE sets standards for the electronics industry such as

IEEE Standard 1073 for Medical Device Communications and IEEE Standard 802.3, which forms much of the lower-layers foundation for the Internet (www.ieee.org).

ISO/IEEE 11073 – a family of standards for medical device communications that are optimized for the acute care setting; **NOTE:** When they are harmonized with IEEE 1073 standards, the designation is ISO/IEEE 11073 (see **IEEE 1073**).

Link Service Access Point (LSAP) – see **Service Access Point**.

Medical Data Device Language (MDDL) – used as the upper-layer protocol for ISO/IEEE 11073 devices.

Network Time Protocol (NTP) – principal time synchronization and distribution protocol used on the Internet (RFC-1305); **NOTE:** NTP provides robust, reliable, and highly accurate time synchronization using algorithms and protocols that utilize a hierarchical network of time servers and clients that are ultimately tied to one or more primary time servers connected to external times sources, such as a GPS radio clock or ACTS telephone modem time service.

Point of Care (POC) – the environment immediately surrounding a patient.

Point-of-Care Device (POCD) – in the context of this standard, a point-of-care device is an instrument used at the patient's side to measure and/or record a clinical observation; **NOTE:** This definition does not require that the POCD measure the observed value; thus, this definition encompasses devices that perform biochemical analyses, devices that calculate observations from results determined externally, or devices that simply record values determined by other procedures.

POC Device Interface (PDI) – specifies the interface (principally output) of a POC Device or its Docking Station to an Access Point; **NOTE:** This definition is equivalent to IEEE 'DCC.'

Point-to-Point Protocol (PPP) – a protocol for framing IP datagrams over a serial line.

Service Access Point (SAP) – an IrDA connection service endpoint provided by the IrLMP-IAS Information Access Service directory; **NOTE:** Also termed **Link Service Access Point (LSAP)**.

Simple Network Time Protocol (SNTP) – a simplified version of NTP that can be used by small, lightweight clients (RFC-2030).

Tiny Transport Protocol (TinyTP) – IrDA transport protocol that provides multiple, concurrent, reliable, bidirectional communication streams on an IrDA link with robust flow control.

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

Unshielded Twisted Pair (UTP) – the type of CAT-5 cabling used in this standard.

3 Abbreviations

DHCP Dynamic Host Configuration Protocol [RFC-2131]

FIR IrDA 'Fast Infrared' at the negotiated speed of 4 MBd

MIB	Medical Information Bus — ISO/IEEE standards, including the lower-layers standards ISO/IEEE 11073-30200 and 11073-30300
MIB	Management Information Base [RFC-1213 ‘MIB-II’ and related RFCs]
MIR	IrDA ‘Medium Infrared’ at the negotiated speeds of 576 or 1152 kBd
SIR	IrDA ‘Serial Infrared’ at the slower speeds of 9600 Bd to 115.2 kBd
SNMP	Simple Network Management Protocol [RFC-1157 for SNMPv1; SNMPv3 is the latest version]
SNTP	Simple Network Time Protocol [RFC-2030] — A simplified version of SNTP suitable for ‘leaf’ Devices on a network
VFIR	IrDA ‘Very Fast Infrared’ at the negotiated speed of 16 MBd

4 Overview of POC Device Networking (Informative)

A ‘POC System’ is defined as a collection of one or more Devices and subsystems that can perform a POC measurement in the patient care area and report the results using an ‘Electronic Data Interchange’ (EDI) interface to a hospital ‘Laboratory Information System’ (LIS), ‘Hospital Information System’ (HIS), or other system that is the final repository for the POC measurement results. In most installations, the EDI interface uses the HL7 upper-layer protocol running over a network TCP/IP connection.

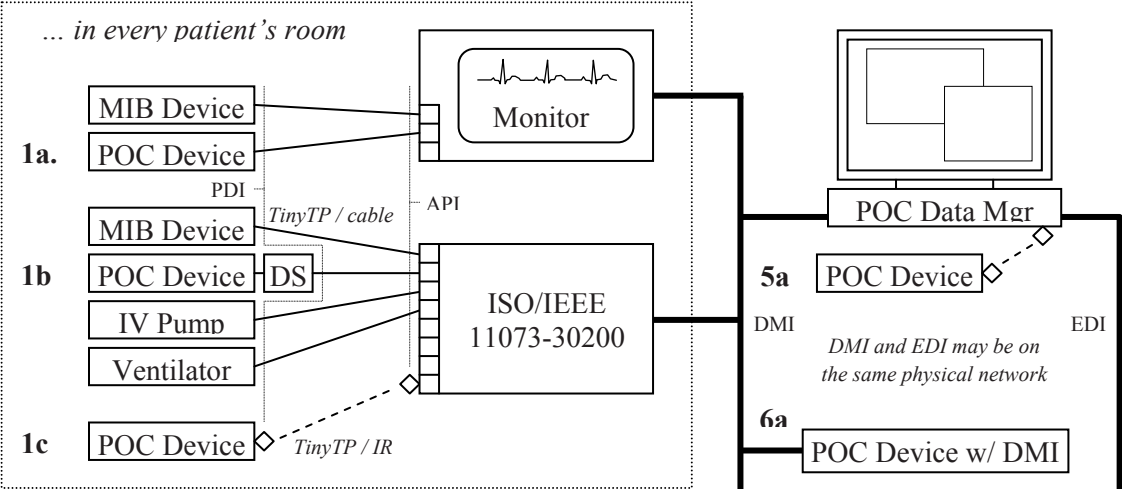
Devices, subsystems, and principal interfaces (highlighted in gray) that comprise a POC System are defined below in the order of data flow from a POC Device to a Laboratory Information System (LIS).

POCD	A ‘POC Device’ performs the blood chemistry and other measurement(s) in the patient care area.
DS	A ‘Docking Station’ may be used to provide a mechanical and electrical interface that supports the POC Device. The docking station may use a legacy mechanical interface, a connector, a protocol and a power delivery method. <i>The docking station is optional.</i>
PDI	The POC Device or its Docking Station uses its ‘POC Device Interface’ to communicate its data (principally output) to an Access Point Interface.
API	The ‘Access Point Interface’ specifies the interface (principally input) to an Access Point or Concentrator.
AP	The ‘Access Point’ or ‘Concentrator’ consolidates the data from one or more Devices onto another communication link, possibly using a different physical layer and transport protocol. <i>This subsystem is optional.</i> Examples of an Access Point are listed below, and other implementations are permitted: (a) a multiport concentrator, typically connected to a local area network (LAN); (b) a dedicated single-port access point, typically connected to a LAN; and (c) an access point that is part of a multifunctional Device such as a personal computer.
DMI	The ‘Data Manager Interface’ specifies the TCP/IP network interface to a Data Manager.
DM	A ‘Data Manager’ performs such functions as (1) Device data storage and forwarding, (2) QA/QC, and (3) other vendor-specific functionality.
EDI	The ‘EDI Interface’ , typically provided by the Data Manager, is used to report the results to a hospital ‘Laboratory Information System’ (LIS), ‘Hospital Information System’ (HIS), or other system that is the final repository for the POC measurement results. The EDI interface typically uses HL7 over a network TCP/IP connection.

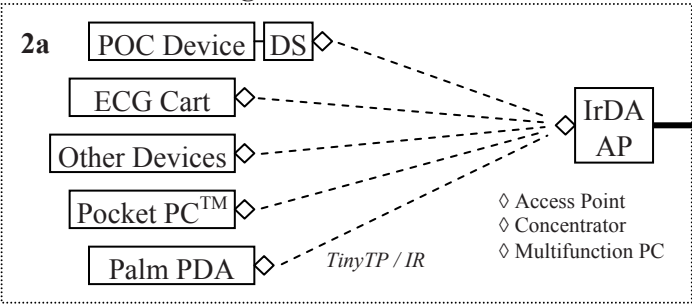
Boxes 1a - 7a of Figure 12 on the following page illustrate how POC Devices, subsystems, and their principal interfaces can be used in a typical hospital environment, including remote-access configurations that employ modems and analog phone lines. This figure depicts many of the common scenarios that the CIC has identified for possible standardization, but is not meant to preclude other configurations, such as connecting a Device in a home through a personal computer.

Although not shown on the diagram, multiple vendor-specific Data Managers can coexist on the network, and this standard allows a Device to communicate with a *vendor-specific* or *generic* Data Manager.

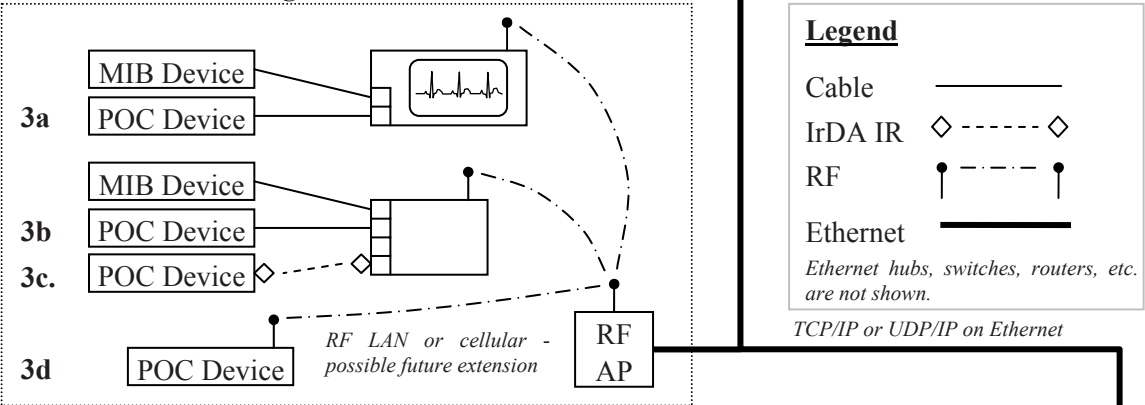
1. Acute care settings (ICU, CCU, OR ...)



2. IrDA devices in general clinical care areas



3. Mobile devices using RF LAN or cellular



4. Remote POC device using modem access

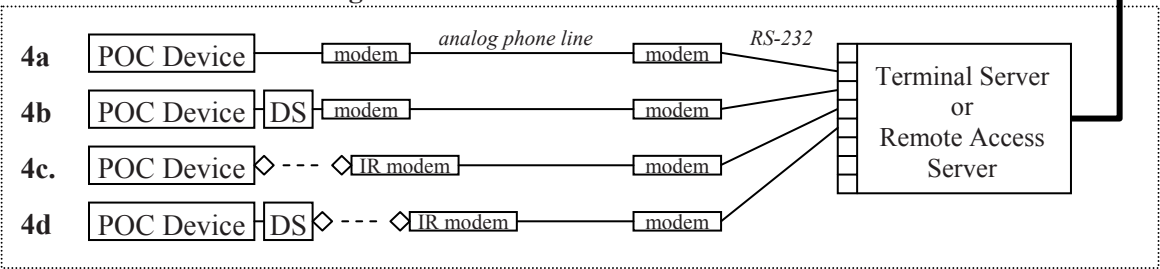


Figure 12. Boxes 1a-7a. Local and Remote Access Examples for POC Devices

5 Overview of IrDA and ISO/IEEE 11073-30200 (Informative)

This section provides an overview of the Infrared Data Association (IrDA) and ISO/IEEE 11073-30200 on which most of this standard is based. References to these standards are listed in Section 13.

5.1 IrDA Protocol Stack Summary

Communication protocol layering is consistent with IrDA-Data standards, as shown below.

Related OSI Layer		IrDA and ISO/IEEE 11073-30200 Layers	
Service Access Points		IrLMP IAS	<i>CLSI:POCT1:MGR</i> Service Access Point <i>Other Service Access Points (SAPs)</i>
	Transport	4	TinyTP: Tiny Transport
Network	3	IrLMP: Link Management Protocol	
Data Link	2	IrLAP: Link Access Protocol	
Physical Link	1	<i>Cable-connected</i>	<i>Infrared</i>
		ISO/IEEE 11073-30200	IrDA SIR, MIR, FIR, VFIR

Figure 13. IrDA and IEEE OSI Stack Components

The components of the stack are briefly as follows:

Physical layer – defines a standard connector and electrical characteristics.

ISO/IEEE 11073-30200: cable-connected, RS-232; default: 9600 Bd, negotiated: 19.2, 38.4, 57.6, 115.2 kBd.

IrDA ‘Serial Infrared’ (SIR): default: 9600 Bd, negotiated: 19.2, 38.4, 57.6, 115.2 kBd.

IrDA ‘Medium Infrared’ (MIR): default: 9600 Bd, negotiated: 576 or 1152 kBd (optional).

IrDA ‘Fast Infrared’ (FIR): default: 9600 Bd, negotiated: 4 MBd (optional).

IrDA ‘Very Fast Infrared’ (VFIR): default: 9600 Bd, negotiated: 16 MBd (optional).

This standard, as well as ISO/IEEE 11073-30200, specifies signaling speeds consistent with IrDA SIR [default 9600 Bd and optional negotiated signaling speeds of 19.2, 38.4, 57.6, and 115.2 kBd]. An infrared access point or device may also support the optional IrDA ‘MIR’ speeds [576, 1152 kBd], ‘FIR’ speed [4 MBd] and/or ‘VFIR’ speed [16 MBd]. It should be recognized, however, that the majority of point-of-care devices will use the slower SIR signaling rates, and that the availability of multiple SIR rates should not be sacrificed in order to support the faster MIR, FIR, and VFIR rates. Like many other IrDA communication parameters, the signaling rate is negotiated and the fastest common rate is used by both entities, and communication at 9600 Bd is always possible.

IrLAP – provides a Device-to-host connection for the reliable, ordered transfer of data, including Device discovery procedures.