CLINICAL AND LABORATORY STANDARDS INSTITUTE®

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POCT01-A2

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 POCT01-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.

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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.

Connectivity Industry Consortium Membership

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Pharmacia & Upjohn	
SMS/Siemens	
TELCOR Inc	

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 POCT01 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 POCT01 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 POCT01, have served to strengthen the value of this standard and its usefulness worldwide.

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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:

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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 POCT01 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 11073-30300[2]; and *cable-connected*, as specified by the IEEE 1073 lower-layers standard.[3] This specification also utilizes local area networking standards such as IEEE 802.3[4] 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.