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CLINICAL AND LABORATORY STANDARDS INSTITUTE®

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POCT02-A

Implementation Guide of POCT01 for Health Care Providers; Approved Guideline

This document identifies and describes the particular features that a POCT01-compliant device should ideally have. These features are divided into obligatory and desirable categories. The guideline thus gives the health care provider or end user a practical basis for establishing a list of features or questions to be addressed by the vendor of a compliant device.

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

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For additional information on committee participation or to submit comments, contact CLSI.

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Abstract

Clinical and Laboratory Standards Institute document POCT02-A—*Implementation Guide of POCT01 for Health Care Providers; Approved Guideline* identifies and describes the particular features that a POCT01-compliant device should ideally have. These features are divided into obligatory and desirable categories. Key terms are identified and the most frequent use cases are presented. The guideline thus gives the health care provider or end user a practical basis for establishing a list of features or questions to be addressed by the vendor of a compliant device. Where appropriate, it also indicates options that may be applicable. The guideline, at the same time, tries to be flexible in allowing for adaptation to specific cases and also in considering probable technological advances in the evolution of connectivity solutions. The use of this guideline should thus permit health care providers to acquire the device with a connectivity solution best suited to their needs and also to encourage the development of an acceptable industry-wide standard.

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Foreword

CLSI document POCT01[1] was developed and recently updated to provide the framework for engineers to design devices, workstations, and interfaces that allow multiple types and brands of point-of-care testing (POCT) devices to communicate bidirectionally with access points, data managers, and laboratory information systems (LIS) from a variety of vendors. POCT01 is an excellent document, but is also very technical. This particularly applies to the annexes that comprise the bulk of the document. The document, as the name implies, presents information regarding the development of the interfaces necessary for the universal connectivity of POCT devices. The purpose of this connectivity standard, by reducing manual information entry and transfer, is to permit error-free point-of-care testing and result reporting along with optimal data capture for quality assurance purposes.

Because the document is very technical, there is some lack of understanding, even confusion, as to its practicality. The present guideline addresses this problem and is intended for use by health care providers and end users responsible for point-of-care testing. It presents some background on the rationale behind POCT01, and describes the practical manner in which application of the standard to the POCT device/system should permit the flow of data between the testing system, the data manager, and the LIS/HIS (hospital information system). In other words, it defines the practical features the end user (health care provider) should expect to find and to be able to use for smooth capture and transfer of information between the device and the LIS/HIS. A separate guideline, intended to assist device manufacturers, is currently under development.

The document defines the characteristics and features that should be expected in a connectivity-compliant device. Problems related to the availability or applicability of these features may occur and should be addressed in relation to the particular situation (hardware, environment, institutional information system, specific end use of the test/device, etc.).

Key Words

compliant device, connectivity, interfaces, point-of-care testing, wireless

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1 Scope

This guideline provides the health care provider or end user with clear, concise information on what features to expect in a connectivity-compliant device and practical advice on how to optimally apply these features to their daily operation/practice. It also addresses possible pitfalls, including the question of security, identified by the committee and its advisors. Where necessary or useful, it defines and explains, in nontechnical language, terms used in the POCT01 standard.

This guideline does not address manufacturers' requirements. It is intended that health care providers, by taking into account the information in this document, will be able to develop a list of questions, specific to the particular test and their site, which need to be addressed by potential vendors. This list of questions would be based on the features that a compliant device should have, which are described in this document. Given continuous changes in the area of point-of-care testing (POCT), as well as continuing technological advances, health care providers are encouraged to ask questions or request modifications that reflect these advances.

Some sections in this document provide an overview of desirable features in a compliant device and an example set of questions that may be put to potential vendors.

2 Introduction

Widespread concern among health care providers about the lack of standard, low-cost point-of-care connectivity solutions drove the formation of the Connectivity Industry Consortium (CIC). Prior to the CIC, each vendor developed its own proprietary means of communicating data from POCT devices. The physical connections, the wiring, even the language and communication format or protocol were different between devices and between manufacturers. For point-of-care programs utilizing devices from two or more vendors, transfer of data often required separate computer systems (called "data managers" by some manufacturers), with different functions and applications, separate docking stations, and sometimes even different wiring. Implementation of new POCT devices was expensive and problematic, often requiring expensive institutional renovations that both limited the conversion of hospitals to new technologies and prevented the routine reporting and billing of POCT results. Management of the quality of POCT results and documentation for compliance with regulatory agencies was also complicated, because many hospitals continued with manual logs and reporting systems due to the cost of installing electronic networks that functioned only for a single device.

The first clear expression of the lack of POCT-compliant devices/systems came from a 1998 survey conducted by the American Association of Clinical Chemistry (AACC) Point-of-Care Testing Division. In this survey, point-of-care customers highlighted the lack of acceptable connectivity and information management solutions as the most significant problem with point-of-care product offerings. In July 1999, at a day-long focus group, clinicians and clinical laboratorians from leading health care institutions developed and prioritized a list of connectivity requirements. Over the lifetime of CIC, the Provider Review Committee (PRC) refined and elaborated on these requirements in order to help guide the technical development efforts of the POCT01 standard. The end result of this process is that the objectives and design of POCT01 have been driven by requirements provided by leading users of point-of-care products.

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3   Definitions

access point (**AP) –** a piece of equipment that connects and merges data from one or more point-of-care testing devices into an interface or communication link to a network; **NOTE:** Examples of access points include single- or multiple-port connection equipment, typically connected to a network (a local area network [LAN]); or an access point can be part of more complex equipment, such as bedside patient monitors or personal desktop computers.

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

bidirectional – bidirectional systems or devices can both send (results, QC, etc.) from the devices to the observation reviewer and receive data (like operator lists) from the observation reviewer to the device, as opposed to devices that can only send results (unidirectional*)*; **NOTE:** See also Section 4.6.3.

clinical information system (CIS) – any information system or computer system database responsible for housing clinical patient information; **NOTE:** Examples include hospital information systems (HIS), laboratory information systems (LIS), clinical data repository (CDR), and electronic medical records (EMR).

connectivity – the ability to reliably transfer data between a point-of-care testing device and a computer system database.

data manager (DM) – typically, a manufacturer-specific network server or more general computer system that acts as an observation reviewer to provide collection of POC data and storage of data, and communication of data, QA/QC, and other POC instrument and data management functions; **NOTE:** In addition to these functions, data managers usually provide other applications or services tailored to specific devices or POC user needs (such as management of operators, reagent lot numbers/expiration dates, and reports for regulatory compliance).

device and access point interface (**DAP)** – specifies the interface or communication connection between a device and an access point.

docking station – equipment designed to physically connect and interface a POCT device, including all of the wiring, cables, ports, connections, power supply, and communication formats and protocols.

electronic data interchange (**EDI)** – the interface protocols and message formats required to exchange data between information systems or computers; **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 among point-of-care data management systems, laboratory information systems, clinical information systems, and other systems that serve as the final repository of POC results.

electronic medical record (EMR) – a computerized patient medical history; **NOTE:** Hospitals are converting older paper copies of records with handwritten physician and nursing notes to computerized records that can store and transfer data in a standardized fashion.

extensible markup language (**XML)** – a language widely used for data exchange in electronic communications; **NOTE:** XML is to data and information as HyperText Markup Language (HTML) is to documents and presentations (HTML is another widely utilized Internet language format).

failure mode and effects analysis (FMEA) – analysis technique for system reliability, based on assumptions of possible failure states of each component of a device or system.[2]

The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents. The approach is based on the model presented in the most current edition of CLSI/NCCLS document HS01—*A Quality Management System Model for Health Care.* The quality management system approach applies a core set of "quality system essentials" (QSEs), basic to any organization, to all operations in any health care service's path of workflow (ie, operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager's guide. The QSEs are:

Documents & Records	Equipment	Information Management	Process Improvement
Organization	Purchasing & Inventory	Occurrence Management	Customer Service
Personnel	Process Control	Assessments—External & Internal	Facilities & Safety

POCT02-A addresses the QSEs indicated by an "X." For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Documents & Records	Organization	Personnel	Equipment	Purchasing & Inventory	Process Control	Information Management	Occurrence Management	Assessments —External & Internal	Process Improvement	Customer Service	Facilities & Safety
			X		X	POCT01					

Adapted from CLSI/NCCLS document HS01—*A Quality Management System Model for Health Care*.

Path of Workflow

A path of workflow is the description of the necessary steps to deliver the particular product or service that the organization or entity provides. For example, CLSI/NCCLS document GP26—*Application of a Quality Management System Model for Laboratory Services* defines a clinical laboratory path of workflow, which consists of three sequential processes: preexamination, examination, and postexamination. All clinical laboratories follow these processes to deliver the laboratory's services, namely quality laboratory information.

POCT02-A addresses the clinical laboratory path of workflow steps indicated by an "X." For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Preexamination				Examination			Postexamination	
Examination ordering	Sample collection	Sample transport	Sample receipt/processing	Examination	Results review and follow-up	Interpretation	Results reporting and archiving	Sample management
							X POCT01	

Adapted from CLSI/NCCLS document HS01—*A Quality Management System Model for Health Care*.

Related CLSI Reference Materials*

POCT01-A2   **Point-of-Care Connectivity; Approved Standard—Second Edition (2006).** 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.

SAMPLE

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* Proposed-level documents are being advanced through the Clinical and Laboratory Standards Institute consensus process; therefore, readers should refer to the most current editions.

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