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

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

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Foreword

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 11073-90101 was prepared by the Clinical and Laboratory Standards Institute (as POCT1-A2) and was adopted, under a special “fast-track procedure”, by Technical Committee ISO/TC 215, *Health informatics*, in parallel with its approval by the ISO member bodies.

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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.

CLINICAL AND LABORATORY STANDARDS INSTITUTE ™
(Formerly NCCLS)

ifcc International Federation of Clinical Chemistry and Laboratory Medicine

Connectivity Industry Consortium

Clinical and Laboratory Standards Institute

Advancing Quality in Healthcare Testing

The Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) is an international, interdisciplinary, nonprofit, standards-developing, and educational organization that promotes the development and use of voluntary consensus standards and guidelines within the healthcare community. It is recognized worldwide for the application of its unique consensus process in the development of standards and guidelines for patient testing and related healthcare issues. Our process is based on the principle that consensus is an effective and cost-effective way to improve patient testing and healthcare services.

In addition to developing and promoting the use of voluntary consensus standards and guidelines, we provide an open and unbiased forum to address critical issues affecting the quality of patient testing and health care.

PUBLICATIONS

A document is published as a standard, guideline, or committee report.

Standard A document developed through the consensus process that clearly identifies specific, essential requirements for materials, methods, or practices for use in an unmodified form. A standard may, in addition, contain discretionary elements, which are clearly identified.

Guideline A document developed through the consensus process describing criteria for a general operating practice, procedure, or material for voluntary use. A guideline may be used as written or modified by the user to fit specific needs.

Report A document that has not been subjected to consensus review and is released by the Board of Directors.

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The CLSI voluntary consensus process is a protocol establishing formal criteria for:

- the authorization of a project
- the development and open review of documents
- the revision of documents in response to comments by users
- the acceptance of a document as a consensus standard or guideline.

Most documents are subject to two levels of consensus—“proposed” and “approved.” Depending on the need for field evaluation or data collection, documents may also be made available for review at an intermediate consensus level.

Proposed A consensus document undergoes the first stage of review by the healthcare community as a proposed standard or guideline. The document should receive a wide and thorough technical review, including an overall review of its scope, approach, and utility, and a line-by-line review of its technical and editorial content.

Approved An approved standard or guideline has achieved consensus within the healthcare community. It should be reviewed to assess the utility of the final document, to ensure attainment of consensus (i.e., that comments on earlier versions have been satisfactorily addressed), and to identify the need for additional consensus documents.

Our standards and guidelines represent a consensus opinion on good practices and reflect the substantial agreement by materially affected, competent, and interested parties obtained by following CLSI’s established consensus procedures. Provisions in CLSI standards and guidelines may be more or less stringent than applicable regulations. Consequently, conformance to this voluntary consensus document does not relieve the user of responsibility for compliance with applicable regulations.

COMMENTS

The comments of users are essential to the consensus process. Anyone may submit a comment, and all comments are addressed, according to the consensus process, by the committee that wrote the document. All comments, including those that result in a change to the document when published at the next consensus level and those that do not result in a change, are responded to by the committee in an appendix to the document. Readers are strongly encouraged to comment in any form and at any time on any document. Address comments to the Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

VOLUNTEER PARTICIPATION

Healthcare professionals in all specialties are urged to volunteer for participation in CLSI projects. Please contact us at customerservice@clsi.org or +610.688.0100 for additional information on committee participation.

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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.

The Clinical and Laboratory Standards Institute consensus process, which is the mechanism for moving a document through two or more levels of review by the healthcare community, is an ongoing process. Users should expect revised editions of any given document. Because rapid changes in technology may affect the procedures, methods, and protocols in a standard or guideline, users should replace outdated editions with the current editions of CLSI/NCCLS documents. Current editions are listed in the CLSI catalog, which is distributed to member organizations, and to nonmembers on request. If your organization is not a member and would like to become one, and to request a copy of the catalog, contact us at: Telephone: 610.688.0100; Fax: 610.688.0700; E-Mail: customerservice@clsi.org; Website: www.clsi.org

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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.