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

Part 90101:

**Analytical instruments — Point-of-care
test**

iTeh STANDARD PREVIEW
*Informatique de santé — Communication entre dispositifs médicaux sur
le site des soins —
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Partie 90101. Instruments analytiques — Essai sur le site des soins

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Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
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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

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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

Advancing Quality in Healthcare Testing

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

Lou Dunka, PhD
 Bryan Allen
 Todd Cooper
 Christopher Fetters
 Wayne Mullins
 James Nichols, PhD
 Thomas Norgall
 Paul Schluter, PhD
 Robert Uleski

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.

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Committee Membership

Area Committee on Point-of-Care Testing

Louis J. Dunka, Jr, PhD
Chairholder
LifeScan, Inc.
Milpitas, California

James H. Nichols, PhD, DABCC, FACB
Vice Chairholder
Baystate Medical Center
Springfield, Massachusetts

Diana R. DeHoyos, MS, MT(ASCP)
 The University of Texas Medical
 Branch
 Galveston, Texas

Christopher Fettes
 NOVA Biomedical
 Waltham, Massachusetts

George W. Gaebler, III, MSEd., RRT,
 FAARC
 University Hospital
 Syracuse, New York

Ethan D. Hausman, MD, FAAP,
 FCAP
 FDA Ctr. for Devices/Rad. Health
 Rockville, Maryland

Frank M. LaDuca, PhD
 Bayer HealthCare Diagnostics
 Division
 Tarrytown, New York

Raelene M. Peretto, MBA,
 MT(ASCP)
 Centers for Medicare & Medicaid
 Services
 Baltimore, Maryland

Kathy Scruggs, MT(ASCP)
 Dayton VA Medical Center
 Dayton, Ohio

Patrick J. St. Louis, Ph.D., Dip.CC
 Ste. Justine Hospital
 Montreal, Quebec

Advisors

Jeff Dahlen, PhD
 Biosite Incorporated
 San Diego, California

Sharon S. Ehrmeyer, PhD
 University of Wisconsin
 Madison, Wisconsin

Valerio M. Genta, MD
 Sentara Virginia Beach General
 Hospital
 Virginia Beach, Virginia

Barry H. Ginsberg, MD, PhD
 BD
 Franklin Lakes, New Jersey

Ellis Jacobs, PhD, DABCC, FACB
 New York State Dept. of Health
 Albany, New York

David Klonoff, MD
 Diabetes Technology Society
 Foster City, California

Katsuhiko Kuwa, PhD
 University of Tsukuba
 Tsukuba 305-8575, Japan

Ronald H. Ng, PhD, DABCC, FACB
 Abbott Diabetes Care
 Alameda, California

Carmina Pascual, MT(ASCP),
 CLS(NCA)
 Roche Instrument Center AG
 Rotkreuz, Switzerland

David L. Phillips
 HemoSense, Inc.
 San Jose, California

Paula J. Santrach, MD
 Mayo Clinic
 Rochester, Minnesota

Lou Ann Wyer, MT(ASCP)
 Sentara Healthcare
 Norfolk, Virginia

Working Group on Point-of-Care Connectivity

Louis J. Dunka, Jr, PhD
Chairholder
LifeScan, Inc.
Milpitas, California

Joanna C. Baker, MSPH,
 MT(ASCP)SC, C
 Moncrief Army Community Hospital
 Ft. Jackson, South Carolina

Chris Budgen
 Canterbury Health Laboratories
 Christchurch, New Zealand

James Callaghan
 FDA Center for Devices/Radiological
 Health
 Rockville, Maryland

Todd Cooper
 Breakthrough Solutions, Inc.
 (Representing IEEE)
 Poway, California

Christopher Fettes
 NOVA Biomedical
 Waltham, Massachusetts

Andrzej J. Knafel, PhD
 Roche Instrument Center
 (Representing HL7)
 Rotkreuz, Switzerland

Wayne Mullins
 Medical Automation Systems
 Charlottesville, Virginia

James Nichols, PhD
 Baystate Medical Center
 (Representing CLSI)
 Springfield, Massachusetts

Thomas Norgall
 Institut Integrierte Schaltungen
 Erlangen, Germany

Carmina Pascual, MT(ASCP),
 CLS(NCA)
 Roche Instrument Center AG
 Rotkreuz, Switzerland

Phil Pash
 Roche Diagnostics
 Indianapolis, Indiana

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BD

Working Group (Continued)

Melvin I. Reynolds
AMS Consulting
Ross-on-Wye
Herefordshire, United Kingdom

Christina Rode-Schubert, MBA
BE Consult
Heidelberg, Germany

Paul Schluter, PhD
GE Medical Systems *Information Technologies*
(Representing IEEE)
Milwaukee, Wisconsin

Allan Soerensen
Radiometer Medical Aps
Broenshoej, Denmark

Andrew St. John
ARC Consulting
Mt. Lawley, Washington

Andreas Staubert, PhD
Roche Diagnostics GmbH
Mannheim, Germany

William Thorpe
Bayer
Norwood, Massachusetts

Robert Uleski
Robert Uleski Consulting
Fishers, Indiana

Staff

Clinical and Laboratory Standards
Institute
Wayne, Pennsylvania

John J. Zlockie, MBA
Vice President, Standards

David E. Sterry, MT(ASCP)
Staff Liaison

Donna M. Wilhelm
Editor

Melissa A. Lewis
Assistant Editor

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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.

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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.