INTERNATIONAL STANDARD **ISO 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)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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.

POCT1-A2
Vol. 26 No. 28
Replaces POCT1-A
Vol. 21 No. 24

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.

CONSENSUS PROCESS

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.

POCT1-A2
ISBN 1-56238-616-6
Volume 26 Number 28
ISSN 0273-3099

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.

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.

CLINICAL AND LABORATORY STANDARDS INSTITUTE ™

(Formerly NCCLS)

ifcc International Federation of Clinical Chemistry and Laboratory Medicine

Connectivity Industry Consortium

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

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 Fetters
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. Perfetto, 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, Wisconsins

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 Fetters
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

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

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.

Contents

Abstract i

Committee Membership iii

Foreword ix

1 Scope 1

2 Introduction 1

3 Definitions 2

4 Specifications 4

4.1 Description of Connectivity System Components 5
4.2 The Interfaces 6

References 15

Figures

Figure 1. Cooperative Evolution of Point-of-Care Standards 2
Figure 2. The Two Interfaces 5
Figure 3. Device Interface Layers 7
Figure 4. Lower-Layer Networking Evolution 8
Figure 5. Device Messaging Layer Data Topics 8
Figure 6. Device Messaging Layer ‘Script’ 10
Figure 7. Example Glucose Test Results Message 11
Figure 8. Example Access Point Deployment Scenario 12
Figure 9. Observation Reporting Interface 13
Figure 10. Sample Observation Reporting Interface Message 14

Contents—Appendixes

Appendix A. Device and Access Point (DAP) Interface Specification

1 Scope and Introduction 25
2 Definitions 25
3 Abbreviations 27
4 Overview of POC Device Networking (Informative) 28
5 Overview of IrDA and ISO/IEEE 11073-30200 (Informative) 30
6 Requirements for a 'POCT1-compatible' Device (Normative) 36
7 Requirements for a 'POCT1-compatible' Access Point (Normative) 38
8 Networked Access Points (Normative if Implemented) 41
9 Remote Modem Access (Informative) 47
10 POC Devices With Direct Network Connections (Informative) 48
11 Data Security (Informative) 49
12 RF Wireless Networking Technologies (Informative) 50
13 References 53

Appendix B. Device Messaging Layer (DML) Specification

1 Scope and Introduction 63
2 Bidirectional Communication 66
3 General Messaging Issues 71
4 Messaging Profile 76
5 Information Model 91
6 Messaging Model 110
7 Extending the Device Messaging Layer 126
8 Annex A. Device Messaging Layer Data Types (Normative) 128
9 Annex B. Asynchronous Observation Acknowledgements (Normative) 138
10 Annex C. 'SET-TIME' Time Stamp and Time Zone Information 139
11 Annex D. Example Messages (Informative) 144

Contents—Appendixes (Continued)

12 Annex E. POCT1 Messaging DTDs (Normative) 171

Appendix C. Observation Reporting Interface (ORI) Specification

1 Scope and Introduction 203

2 Use Case Descriptions 203

3 Message Profile 205

4 HL7 Message Definition 208

5 Sample Messages 223

Appendix D. Point-of-Care Requirements

1 Requirements 257

Appendix E. Connectivity Architecture

1 Architecture 275

2 Principles 275

3 Approach 277

4 Model 278

Appendix F. Vendor Codes

1 Vendor Codes 283

Summary of Comments and Subcommittee Responses 285

The Quality System Approach 288

Related CLSI/NCCLS Publications 289

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

CORE VENDORS	CORE PROVIDERS
Abbott Laboratories	Banner Health System
Agilent Technologies	Bradford Royal Infirmary
Bayer Diagnostics	Geisinger Healthcare System
BD	John Hopkins Medical Institutions
Instrumentation Laboratory	Kaiser Permanente
Lifescan/J&J	Mayo Clinic
Medical Automation Systems	Profil GmbH
Radiometer Medical	St. Vincent Mercy Medical Center
Roche Diagnostics	The Mount Sinai Hospital
Sunquest Information Systems	University of Iowa Healthcare

SUPPORTING VENDORS	INDIVIDUAL PROVIDERS
Abaxis	Maurice Green, PhD
Avocet Medical	Neil Halpern, MD
Cerner	Georg Hoffmann
Clarinet Systems	Colonel Forrest Kneisel
Comtrol Corporation	Gerald Kost, MD, PhD
First Medical/Sigma Diagnostics	Petrie Rainey, MD PhD
GE Medical Systems *Information Technologies*	
HemoCue	**LIAISONS**
HemoSense	AACC
InterComponentWare	COLA
i-STAT Corporation	IFCC Scientific Division
International Technidyne Corporation (ITC)	Medical Devices Agency
Lantronix	
Medtronic	
Motorola	
Orasure Technologies, Inc.	
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 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
Architecture Team:	Jack Harrington, Philips Medical Systems
Device Team Co-Chairs:	Alan Greenburg, Roche Diagnostics Bob Uleski, FluorRx
EDI Team Co-Chairs:	Rodney Kugizaki, LifeScan Wayne Mullins, Medical Automation Systems
Point-of-Care Workflow:	Marcy Anderson, Medical Automation Systems
Requirements Team:	Teresa Prego, Bayer Diagnostics

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
- Mark Maund, i-STAT Corporation
- Chris Melo, Philips Medical Systems
- Wayne Mullins, Medical Automation Systems
- Dan Nowicki, GE Medical Systems *Information Technologies*
- Joe Rogers, i-STAT Corporation
- Paul Schluter, GE Medical Systems *Information Technologies*
- Allan Soerensen, Radiometer Medical
- Dan Trainor, Philips Medical Systems
- Imre Trefil, LifeScan
- Bob Uleski, FluorRx

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 11073-30300[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.