Designation: E 1381 – 02

An American National Standard

Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems[1]

This standard is issued under the fixed designation E 1381; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification describes the electronic transmission of digital information between clinical laboratory instruments and computer systems. The clinical laboratory instruments under consideration are those that measure one or more parameters from one or more patient samples. Often they will be automated instruments that measure many parameters from many patient samples. The computer systems considered here are those that are configured to accept instrument results for further processing, storage, reporting, or manipulation. This instrument output may include patient results, quality control results, and other related information. Typically, the computer system will be a Clinical Laboratory Information Management System (CLIMS).

1.2 The terminology of the Organization for International Standards (ISO) Reference Model for Open Systems Interconnection (OSI) is generally followed in describing the communications protocol and services. The electrical and mechanical connection between instrument and computer is described in the Physical Layer section. The methods for establishing communication, error detection, error recovery, and sending and receiving of messages are described in the Data Link Layer section. The data link layer interacts with higher layers in terms of sends and receives "messages," handles data link connection and release requests, and reports the data link status.

1.3 This specification addresses the low level protocol used for both serial binary data exchange and TCP/IP data exchange. For message content in the interface between clinical instruments and computer systems, reference Specification E 1394. Topics are found in the following sections:

2. Referenced Documents

2.1 *ASTM Standards:*

E 1394 Specification for Transferring Information Between Clinical Instruments and Computer Systems[2]

[1] This specification is under the jurisdiction of ASTM Committee E31 on Healthcare Informatics and is the direct responsibility of Subcommittee E31.13 on Clinical Laboratory Instrument Interface.

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[2] *Annual Book of ASTM Standards*, Vol 14.01.

2.2 *ANSI Standards:*[3]

X3.4-1986 American National Standard Code for Information Systems—Coded Character Sets—7-Bit American National Standard Code for Information Interchange (7-Bit ASCII)

X3.15-1976 American National Standard for Bit Sequencing of the American National Standard Code for Information Interchange in Serial-by-Bit Data Transmission

X3.16-1976 American National Standard Character Structure and Character Parity Sense for Serial-by-Bit Data Communication in the American National Standard Code for Information Interchange

2.3 *ISO Standard:*[3]

International Standard ISO 7498-1984(E), Information Processing Systems—Open Systems Interconnection—Basic Reference Model, International Organization for Standardization

2.4 *Other Documents:*[4]

EIA-232-D-1986 Interface Between Data Terminal Equipment and Data Circuit-Terminating Equipment Employing Serial Binary Data Interchange

IEEE-802.3, 2000 Edition, Information Technology—Telecommunications and Information Exchange Between Systems—Local and Metropolitan Area Networks—Specific Requirements—Part 3: Carrier Sense Multiple Access With Collision Detection (CSMA/CD) Access Method and Physical Layer Specifications 2000

ANSI EIA/TIA 568A

ANSI EIA/TIA 568B

3. Terminology

3.1 *receiver*—the device that responds to the sender and accepts the message.

3.2 *sender*—the device that has a message to send and initiates the transmission process.

3.3 The parts of a communication between instrument and computer are identified by the following terms. The parts are hierarchical and are listed in order of most encompassing first.

3.3.1 *session*—a total unit of communication activity, used in this standard to indicate the events starting with the establishment phase and ending with the termination phase, as described in subsequent sections.

3.3.2 *message*—a collection of related information on a single topic, used here to mean all the identity, tests, and comments sent at one time. When used with Specification E 1394, this term means a record as defined by Specification E 1394.

3.3.3 *frame*—a subdivision of a message, used to allow periodic communication housekeeping such as error checks and acknowledgments.

4. Significance and Use

4.1 Nearly all recent major clinical instruments have provision for connection to a computer system, and in nearly all laboratories that have implemented a CLIMS, there is a need to connect the laboratory's high volume automated instruments to the CLIMS so that results can be transferred automatically. To accomplish this connection, both the instrument and the computer must have compatible circuits and appropriate software, and there must be a proper cable to connect the two systems.

4.1.1 Without this standard specification, the interface between each different instrument and each different computer system is likely to be a different product. This increases the cost, the chances for compatibility problems, and the difficulty of specifying and designing a proper system. In addition, interfaces for every instrument-computer combination may not be available, forcing expensive and time-consuming custom development projects.

4.2 This standard specification defines the electrical parameters, cabling, data codes, transmission protocol, and error recovery for the information that passes between the instrument and the laboratory computer. It is expected that future products from instrument manufacturers and computer system developers, released after the publication of this specification, will conform to this specification, and that will lead to plug-together compatibility of clinical instruments and computer systems.

5. Physical Layer for Serial Binary Data Exchange

5.1 *Overview*—The mechanical and electrical connection for serial binary data bit transmission between instrument and computer system is described in the physical layer. The topology is point-to-point, a direct connection between two devices.

5.2 *Electrical Characteristics*—The voltage and impedance levels for the generator and receiver circuits are as specified in the EIA-232-D-1986 standard.

5.2.1 *Signal Levels*:

5.2.1.1 For the data interchange circuits, a marking condition corresponds to a voltage more negative than minus three volts with respect to signal ground at the interface point. A spacing condition corresponds to a voltage more positive than plus three volts with respect to signal ground at the interface point.

5.2.1.2 Binary state ONE (1) corresponds to the marking condition; binary state ZERO (0) corresponds to the spacing condition.

5.2.1.3 The signal levels conform to the EIA-232-D-1986 standard.

5.2.2 *Character Structure*:

5.2.2.1 The method of data transmission is serial-by-bit start/stop. The order of the bits in a character is:

(1) One start bit, corresponding to a binary 0,

(2) The data bits of the character, least significant bit transmitted first,

(3) Parity bit,

(4) Stop bit(s), corresponding to a binary 1.

5.2.2.2 The time between the stop bit of one character and the start bit of the next character may be of any duration. The data interchange circuit is in the marking condition between characters.

5.2.2.3 Even parity corresponds to a parity bit chosen in

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

[4] Available from Electronics Industries Association, 2001 I Street, N.W., Washington, DC 20006.

such a way that there are an even number of ONE bits in the sequence of data bits and parity bit. Odd parity corresponds to an odd number of ONE bits when formed in the same way.

5.2.2.4 All devices must be capable of sending and receiving characters consisting of one start bit, eight data bits, no parity bit, and one stop bit.

5.2.2.5 The default character structure consists of one start bit, eight data bits, no parity bit, and one stop bit. Eight data bit character sets are allowed but not specified by this standard. Other character structures can be used for specialized applications, for example, seven data bits, odd, even, mark or space parity, or two stop bits.

5.2.2.6 The character bit sequencing, structure, and parity sense definitions conform to ANSI standards X3.15-1976 and X3.16-1976.

5.2.3 *Speed*:

5.2.3.1 The data transmission rate for instruments shall be at least one of these baud rates: 1200, 2400, 4800, or 9600 baud. The preferred rate is 9600 baud and should be the default setting of the instrument when more than one baud rate is available. The computer system must have the capability for all four baud rates.

5.2.3.2 Devices may optionally have the capability for other baud rates such as 300, 19 200, and 38 400 baud for use in specialized applications.

5.2.4 *Interface Connections*:

5.2.4.1 The conforming connection specified here defines the point of interconnection between the domain of the instrument and domain of the computer system. (See Fig. 1 and Fig. 2.) Within the domain of either device, any appropriate connection system may be used, preferably with suitable cable locking hardware.

5.2.4.2 The conforming connection utilizes a 25-position connector. The connector contact assignments are listed in Table 1. Connector contacts not listed are unused. The connector contact assignments conform to the EIA-232-D-1986 standard for the circuits that are used.

5.2.4.3 Contact 1 is the shield connection, it connects to the instrument's (the DTE) frame. The shield connection is left open at the computer (the DCE) to avoid ground loops. There will be no connections on any other pins. All other pins will be open circuits.

5.3 *Mechanical Characteristics*

5.3.1 *Connector*:

5.3.1.1 The conforming connector associated with the instrument is a commercial type DB-25P (subminiature D male) style connector. The conforming connector associated with the computer is a commercial type DB-25S (subminiature D female) style connector. The connector dimensions must correspond to those given in the EIA-232-D-1986 standard.

5.3.1.2 When the conforming connector of the instrument is cable mounted, it shall be configured with a locking device such as No. 4-40 or M-3 thread female screw locking hardware. When the conforming connector of the computer is cable mounted, it shall be configured with a locking device such as No. 4-40 or M-3 thread male screw locking hardware. (See Fig. 1.)

5.3.1.3 When the conforming connector of either device is chassis mounted, it shall be configured with devices such as No. 4-40 or M-3 thread female screw locking hardware. The mating cable connector shall use devices such as No. 4-40 or M-3 thread male screw locking hardware. (See Fig. 2.)

5.3.1.4 When the conforming connector of the instrument is cable mounted and the conforming connector of the computer is chassis mounted, then a change in the cable mounted locking hardware is necessary.

5.3.2 *Cable*—Any extension cables to connect the instrument to the computer require a female connector on one end to mate with the instrument and a male connector on the other end to mate with the computer. Detailed requirements of an interconnecting cable are undefined but good engineering practice should be followed in selecting the cable and connectors. Shielded cable and connectors may be necessary to suppress electromagnetic interface (EMI). Low capacitance cable may be necessary for long cable lengths or the higher data rates. Appropriate connector locking hardware should be used at the conforming connectors.

6. Data Link Layer

6.1 *Overview*—The data link layer has procedures for link connection and release, delimiting and synchronism, sequential control, error detection, and error recovery.

6.1.1 Link connection and release establish which system sends and which system receives information. Delimiting and synchronism provide for framing of the data and recognition of frames. Sequence control maintains the sequential order of information across the connection. Error detection senses transmission or format errors. Error recovery attempts to recover from detected errors by retransmitting defective frames or returning the link to a neutral state from otherwise unrecoverable errors.

6.1.2 The data link layer uses a character-oriented protocol to send messages between directly connected systems. (See ANSI X3.4-1986. Also, see Appendix X1 for the coding of the ASCI characters.) Some restrictions are placed on the characters which can appear in the message content.

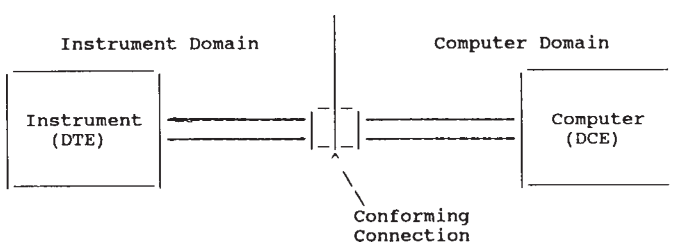

FIG. 1 Connector Strategy for Instrument Computer Connection—Cable Mounted