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CLINICAL AND LABORATORY STANDARDS INSTITUTE®

April 2008

LIS01-A2

Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems; Approved Standard—Second Edition

This document describes the electronic transmission of digital information between clinical laboratory instruments and computer systems.

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

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Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems; Approved Standard—Second Edition

Volume 28 Number 13

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Abstract

CLSI document LIS01-A2—*Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems; Approved Standard—Second Edition* describes the electronic transmission of digital information between clinical laboratory instruments (those that measure one or more parameters from one or multiple samples) and computer systems (those that are configured to accept instrument results for further processing, storage, reporting, or manipulation).

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Foreword

In 2001, ASTM Committee E31 decided to restructure its operations, with the intent of focusing on standards-development issues such as security, privacy, and the electronic health record. Part of the reorganization plan was to transfer responsibility for E31.13 standards to CLSI, then known as NCCLS.

Following this transfer, nine standards (formerly ASTM E792; E1029; E1238; E1246; E1381; E1394; E1466; E1639; and E2118) were redesignated as CLSI/NCCLS standards LIS1 through LIS9.[1-8] This collection of standards provides a wide variety of information relating to clinical laboratory computer systems. Some included documents are of general interest as reference sources; others represent specifications of primary importance to instrument manufacturers. LIS2 is a revision of the former ASTM E1381-02.

The Area Committee on Automation and Informatics has assumed responsibility for maintaining the documents and will revise or update each document in accord with the CLSI Administrative Procedures. The area committee prioritized LIS1-A as the second standard from this collection to be updated, incorporated into the CLSI document template, and advanced through the CLSI consensus process. The area committee will revise other documents in the series in a similar manner.

With the transfer of the former ASTM standards, the Area Committee on Automation and Informatics has expanded its mission statement to include laboratory information systems. In the future, the area committee will develop additional standards addressing informatics issues, as well as issues related to the integration of patient clinical data.

This document replaces the first edition of the approved guideline, LIS1-A, which was published in 2003. Several changes were made in this edition; among them, TCP/IP communication is now included (Sections 4.4 and 4.5) and the state diagram was replaced (see Appendix A) so it is consistent with the text of the document.

The revisions in this edition of the LIS01 standard are also intended to delineate this document from its former ASTM edition. The title and text have been revised throughout to indicate that this standard applies to clinical laboratory instruments. The term *computer* has been replaced with the term *information* to better reflect the current terminology (ie, LIS) and the headings of Sections 6 and 8 have been changed to make them more specific.

Key Words

data link layer, physical layer, serial binary data exchange, TCP/IP data exchange

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Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems; Approved Standard—Second Edition

1 Scope

This specification describes the electronic transmission of digital information between clinical laboratory instruments and computer systems.

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 CLSI/NCCLS document LIS2.[1]

2 Introduction

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).

The terminology of the International Organization for Standardization (ISO) Reference Model for Open Systems Interconnection (OSI) is generally followed in describing the communications protocol and services.[9] The electrical and mechanical connection between instrument and computer is described in the Physical Layer sections (see Sections 5 and 7). The methods for establishing communication, error detection, error recovery, and sending and receiving of messages are described in the Data Link Layer sections (see Sections 6 and 8). The data link layer interacts with higher layers in terms of sending and receiving "messages," handles data link connection and release requests, and reports the data link status.

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; **NOTE:** When used with CLSI/NCCLS document LIS2,[1] this term means a record as defined by CLSI/NCCLS document LIS2.[1]

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

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4 Significance and Use

4.1 Nearly all recent major clinical instruments have provisions 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 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.

4.3 This standard specification does not define the transmission of character encodings that require greater than eight bits; however, character encodings greater than eight bits can be transmitted through the use of appropriate algorithmic transformations. Examples include using Shift JIS for the transmission of Japanese characters defined by the Japanese Industrial Standards JIS X 0207 (single-byte characters) and JIS X 0208 (double-byte characters), as well as the transmission of the Unicode/UCS-2 character set with a UTF-8 encoding. These techniques do not violate the character-oriented protocol and associated character restrictions described by the data link layer of this standard. There are no provisions in the standard to identify if a specific transmission approach is being used; therefore, the character encoding and transmission approach must be agreed upon outside of the context of this standard.

4.4 This standard specification was originally intended for serial communication between clinical laboratory instruments and computer systems. In order to address bandwidth concerns with serial communication and to address a shift toward the use of networked solution, this standard was updated to include TCP/IP communication as well as frame sizes of 64 000 characters.

4.4.1 It is recommended that the use of large frame sizes be restricted to TCP/IP communication, where the frames will be broken down into smaller packets for transmission. This will ensure proper error detection and recovery for the transmissions.

4.4.2 When the TCP/IP data exchange is used, additional overhead is encountered, because TCP/IP is itself a low-level protocol; and LIS01-A2 protocol activities such as error checking and error recovery are also performed as part of the TCP/IP protocol. In addition, this standard specification is often used in combination with CLSI/NCCLS document LIS2,[1] which defines specific message formats. It may be more appropriate to use CLSI/NCCLS document LIS2[1] directly over TCP/IP, the Health Level Seven Protocol for electronic exchange, or the CLSI/NCCLS standard AUTO3[10] for communication with automated clinical laboratory systems, instruments, devices, and information systems when using the TCP/IP communication protocol to exchange information.

4.5 Although this specification addresses serial communication using a 25-pin connector and TCP/IP communication, it can be adapted to other standard communication approaches such as a 9-pin

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serial connector, wireless, high speed USB, and firewire. The physical layer specifications for other approaches must be agreed upon outside the context of this standard. Adaptation to 9-pin, USB, etc. is standard, and can be accomplished in a manner transparent to the specification.

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.[11]

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.[11]

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; and
(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 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.

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5.2.2.6 The character bit sequencing, structure, and parity sense definitions conform to ANSI standards X3.15-1976 and X3.16-1976.[12,13]

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 Figures 1 and 2.) Within the domain of either device, any appropriate connection system may be used, preferably with suitable cable locking hardware.

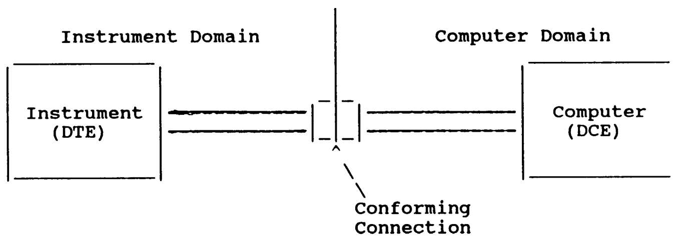

Figure 1. Connector Strategy for Instrument Computer Connection—Cable Mounted

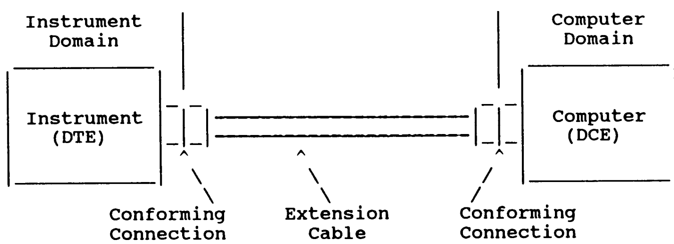

Figure 2. Connector Strategy for Instrument Computer Connections—Chassis Mounted

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.[11]

Table 1. Connector Contact Assignments for RS 232 D Serial Binary Data Exchange

Contact No.	EIA Circuit	Description	Direction	
			Instrument	Computer
1	...	Shield	...	No Connection
2	BA	Transmitted Data	Output	Input
3	BB	Received Data	Input	Output
7	AB	Signal Ground	...	...

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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.[11]

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 Figure 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 Figure 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 for Serial Binary Data Exchange

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 B for the coding of the ASCII characters.[14]) Some restrictions are placed on the characters that can appear in the message content.

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6.1.3 The data link mode of operation is one-way transfer of information with alternate supervision. Information flows in one direction at a time. Replies occur after information is sent, never at the same time. It is a simplex stop-and-wait protocol.

6.1.4 At times, the two systems are actively operating to transfer information. The remainder of the time the data link is in a neutral state. See the state diagram in Appendix A.

6.1.5 There are three distinct phases in transferring information between instrument and computer system. In each phase, one system directs the operation and is responsible for continuity of the communication. The three phases ensure the actions of the sender and receiver are coordinated. The three phases are establishment, transfer, and termination.

6.2 Establishment Phase (Link Connection)

6.2.1 The establishment phase determines the direction of information flow and prepares the receiver to accept information.

6.2.2 The sender notifies the receiver that information is available. The receiver responds that it is prepared to receive before information is transmitted.

6.2.3 A system that does not have information to send normally monitors the data link to detect the establishment phase. It acts as a receiver, waiting for the other system.

6.2.4 The system with information available initiates the establishment phase. After the sender determines the data link is in a neutral state, it transmits the **<ENQ>** transmission control character to the intended receiver. The sender will ignore all responses other than **<ACK>, <NAK>,** or **<ENQ>**.

6.2.5 Upon receiving the **<ENQ>**, the receiver prepares to receive information. All other characters are ignored. It replies with the **<ACK>** transmission control character signifying it is ready. With this sequence of events, the establishment phase ends and the transfer phase begins.

6.2.6 A receiver that cannot immediately receive information replies with the **<NAK>** transmission control character. Upon receiving **<NAK>**, the sender must wait at least ten seconds before transmitting another **<ENQ>**.

6.2.7 Systems not having the ability to receive information always respond to an **<ENQ>** by replying with a **<NAK>**. Systems not having the ability to send information never transmit an **<ENQ>**.

6.2.7.1 Contention

Should both systems simultaneously transmit an **<ENQ>**, the data link is in contention. The instrument system has priority to transmit information when contention occurs. Contention is resolved as follows:

(1) Upon receiving a reply of **<ENQ>** to its transmitted **<ENQ>**, the computer system must stop trying to transmit; it must prepare to receive. When the next **<ENQ>** is received, it replies with an **<ACK>** or **<NAK>,** depending on its readiness to receive.

(2) Upon receiving a reply of **<ENQ>** to its transmitted **<ENQ>**, the instrument must wait at least one second before sending another **<ENQ>**.

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6.3 Transfer Phase

During the transfer phase, the sender transmits messages to the receiver. The transfer phase continues until all messages are sent.

6.3.1 Frames

Messages are sent in frames; each frame contains a maximum of 64 000 characters (including frame overhead). Messages longer than 64 000 characters are divided between two or more frames.

6.3.1.1 Multiple messages are never combined in a single frame. Every message must begin in a new frame.

6.3.1.2 A frame is one of two types: an intermediate frame or an end frame. Intermediate frames terminate with the characters **<ETB>**, checksum, **<CR>,** and **<LF>**. End frames terminate with the characters **<ETX>**, checksum, **<CR>,** and **<LF>**. A message containing 64 000 characters or less is sent in a single end frame. Longer messages are sent in intermediate frames, with the last part of the message sent in an end frame. The frame structure is illustrated as follows:

<STX> FN text **<ETB>** C1 C2 **<CR>** **<LF>** ← intermediate frame
<STX> FN text **<ETX>** C1 C2 **<CR>** **<LF>** ← end frame

where:

<STX>	=	Start of Text transmission control character
FN	=	single digit Frame Number **0** to **7**
text	=	Data Content of Message
<ETB>	=	End of Transmission Block transmission control character
<ETX>	=	End of Text transmission control character
C1	=	most significant character of checksum **0** to **9** and **A** to **F**
C2	=	least significant character of checksum **0** to **9** and **A** to **F**
<CR>	=	Carriage Return ASCII character
<LF>	=	Line Feed ASCII character

6.3.2 Frame Number

The frame number permits the receiver to distinguish between new and retransmitted frames. It is a single digit sent immediately after the **<STX>** character.

6.3.2.1 The frame number is an ASCII digit ranging from **0** to **7**. The frame number begins at **1** with the first frame of the transfer phase. The frame number is incremented by one for every new frame transmitted. After **7**, the frame number rolls over to **0** and continues in this fashion.

6.3.3 Checksum

The checksum permits the receiver to detect a defective frame. The checksum is encoded as two characters, which are sent after the **<ETB>** or **<ETX>** character. The checksum is computed by adding the binary values of the characters, keeping the least significant eight bits of the result.

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6.3.3.1 The checksum is initialized to zero with the **<STX>** character. The first character used in computing the checksum is the frame number. Each character in the message text is added to the checksum (modulo 256). The computation for the checksum does not include **<STX>**, the checksum characters, or the trailing **<CR>** and **<LF>**.

6.3.3.2 The checksum is an integer represented by eight bits; it can be considered as two groups of four bits. The groups of four bits are converted to the ASCII characters of the hexadecimal representation. The two ASCII characters are transmitted as the checksum, with the most significant character first.

6.3.3.3 For example, a checksum of 122 can be represented as 01111010 in binary or **7A** in hexadecimal. The checksum is transmitted as the ASCII character **7** followed by the character **A**.

6.3.4 Acknowledgments

After a frame is sent, the sender stops transmitting until a reply is received.

6.3.4.1 The receiver replies to each frame. When it is ready to receive the next frame, it transmits one of three replies to acknowledge the last frame. This reply must be transmitted within the timeout period specified in Section 6.5.2.

6.3.4.2 A reply of **<ACK>** signifies the last frame was received successfully, and the receiver is prepared to receive another frame. The sender must increment the frame number and either send a new frame or terminate.

6.3.4.3 A reply of **<NAK>** signifies the last frame was not successfully received, and the receiver is prepared to receive the frame again.

6.3.4.4 A reply of **<EOT>** signifies the last frame was received successfully; the receiver is prepared to receive another frame but requests that the sender stop transmitting. (See the following section on receiver interrupts.)

6.3.5 Receiver Interrupts

The receiver interrupt is a means for the receiver to request the sender to stop transmitting messages as soon as possible.

6.3.5.1 During the transfer phase, if the receiver responds to a frame with an **<EOT>** in place of the usual **<ACK>**, the sender must interpret this reply as a receiver interrupt request. The **<EOT>** is a positive acknowledgment of the end frame, signifies the receiver is prepared to receive next frame, and is a request to the sender to stop transmitting.

6.3.5.2 The sender does not have to stop transmitting after receiving the receiver interrupt request. If the sender chooses to ignore the **<EOT>**, the receiver must re-request the interrupt for the request to remain valid.

6.3.5.3 If the sender chooses to honor the receiver interrupt request, it must first enter the termination phase to return the data link to the neutral state. This gives the receiver an opportunity to enter the establishment phase and become the sender. The original sender must not enter the establishment phase for at least 15 seconds or until the receiver has sent a message and returned the data link to the neutral state.

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6.4 Termination Phase (Link Release)

The termination phase returns the data link to the clear or neutral state. The sender notifies the receiver that all messages have been sent.

6.4.1 The sender transmits the **<EOT>** transmission control character and then regards the data link to be in a neutral state. Upon receiving **<EOT>**, the receiver also regards the data link to be in the neutral state.

6.5 Error Recovery

Methods are described that enable both sender and receiver to recover, in an orderly way, from errors in data transmission.

6.5.1 Defective Frames

A receiver checks every frame to guarantee it is valid. A reply of **<NAK>** is transmitted for invalid frames. Upon receiving the **<NAK>**, the sender retransmits the last frame with the same frame number. In this way, transmission errors are detected and automatically corrected.

6.5.1.1 Any characters occurring before the **<STX>** or **<EOT>** or after the end of the block character (the **<ETB>** or **<ETX>**) are ignored by the receiver when checking the frame. A frame should be rejected because:

(1) Any character errors are detected (parity error, framing error, etc.);
(2) The frame checksum does not match the checksum computed on the received frame; or
(3) The frame number is not the same as the last accepted frame or one number higher (modulo 8).

6.5.1.2 Upon receiving a **<NAK>** or any character except an **<ACK>** or **<EOT>** (a **<NAK>** condition), the sender increments a retransmit counter and retransmits the frame. If this counter shows a single frame was sent and not accepted six times, the sender must abort this message by proceeding to the termination phase. An abort should be extremely rare, but it provides a mechanism to escape from a condition where the transfer phase cannot continue.

6.5.2 Timeouts

The sender and receiver both use timers to detect loss of coordination between them. The timers provide a method for recovery if the communication line or the other device fails to respond.

6.5.2.1 During the establishment phase, the sender sets a timer when transmitting the **<ENQ>**. If a reply of an **<ACK>**, **<NAK>**, or **<ENQ>** is not received within 15 seconds, a timeout occurs. After a timeout, the sender enters the termination phase.

6.5.2.2 During the establishment phase, if the computer (as receiver) detects contention, it sets a timer. If an **<ENQ>** is not received within 20 seconds, a timeout occurs. After a timeout, the receiver regards the line to be in the neutral state.

6.5.2.3 During the transfer phase, the sender sets a timer when transmitting the last character of a frame. If a reply is not received within 15 seconds, a timeout occurs. After a timeout, the sender aborts the message transfer by proceeding to the termination phase. As with excessive retransmissions of defective frames, the message must be remembered so it can be completely repeated.

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6.5.2.4 During the transfer phase, the receiver sets a timer when first entering the transfer phase or when replying to a frame. If a frame or **<EOT>** is not received within 30 seconds, a timeout occurs. After a timeout, the receiver discards the last incomplete message and regards the line to be in the neutral state.

6.5.2.5 A receiver must reply to a frame within 15 seconds or the sender will timeout. A receiver can delay its reply for up to 15 seconds to process the frame or to otherwise go into "busy" mode. Longer delays cause the sender to abort the message.

6.5.2.6 Receivers that cannot process messages fast enough to keep up with a sender may cause message buffer overflows in the sender. A sender can normally store at least one complete message. Storage space for more than one outgoing message is desirable but optional.

6.6 Restricted Message Characters

The data link protocol is designed for sending character-based message text. Restrictions are placed on which characters may appear in the message text. The restrictions make it simpler for senders and receivers to recognize replies and frame delimiters. Additional characters are restricted to avoid interfering with software controls for devices such as multiplexers.

6.6.1 A **<LF>** character is not permitted to appear in the message text; it can appear only as the last character of a frame.

6.6.2 None of the ten transmission control characters, the **<LF>** format effector control character, or four device control characters may appear in message text. The restricted characters are: **<SOH>**, **<STX>**, **<ETX>**, **<EOT>**, **<ENQ>**, **<ACK>**, **<DLE>**, **<NAK>**, **<SYN>**, **<ETB>**, **<LF>**, **<DC1>**, **<DC2>**, **<DC3>**, and **<DC4>**.

7 Physical Layer for TCP/IP Data Exchange

7.1 Overview

The mechanical and electrical connection for TCP/IP data transmission between instrument and computer system is described in this section. The topology is not a point-to-point, direct connection between two devices, but utilizes a central hub for device connection.

7.2 Electrical Characteristics

The voltage and impedance levels for the generator and receiver circuits are as specified in the IEEE 802.3 standard.[15]

7.2.1 Signal Levels

7.2.1.1 The signal levels conform to the IEEE 802.3 standard.[15]

7.2.2 Character Structure

7.2.2.1 The method of data transmission is TCP/IP. 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; and
(4) Stop bit(s), corresponding to a binary 1.

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7.2.2.2 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.

7.2.2.3 Even parity corresponds to a parity bit chosen in 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.

7.2.2.4 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.

7.2.2.5 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.

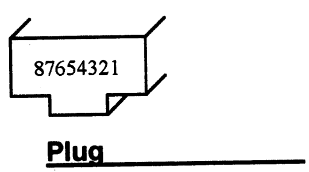
7.2.2.6 The character bit sequencing, structure, and parity sense definitions conform to ANSI standards X3.15-1976 and X3.16-1976.[12,13]

7.2.3 Speed

7.2.3.1 The data transmission rate for instruments shall conform to IEEE 802.3[15] and operate at least 10 MB/second. A computer system using TCP/IP must have the capability to conform to a minimum speed of 10 MB/second.

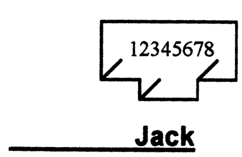
7.2.4 Interface Connections

7.2.4.1 The conforming connection specified here defines the point of interconnection between the domain of the instrument and domain of the computer system. (See Figures 3 and 4.) Within the domain of the devices, an RJ45 connection system is used.



NOTE: Looking at connector end with cable running away from you.

Figure 3. Plug



NOTE: Looking at cavity in the wall.

Figure 4. Jack

7.2.4.2 The conforming connection utilizes an eight-line connector. The connector contact assignments are listed in Table 2. The connector contact assignments conform to the ANSI EIA/TIA 568B standard[16] (also called the AT&T specification).

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Table 2. Connector Contact Assignments

Pin	Color
1	white/orange
2	orange
3	white/green
4	blue
5	white/blue
6	green
7	white/brown
8	brown

7.3 Mechanical Characteristics

7.3.1 Connector

7.3.1.1 The conforming connector associated with the instrument is a commercial type RJ-45F style connector. The conforming connector associated with the computer is a commercial type RJ-45F style connector. The connector dimensions must correspond to those given in the ANSI EIA/TIA 568B standard.[16]

7.3.2 Cable

Category 5 cable as defined by ANSI EIA/TIA 568B[16] is preferred for all connections. In general, no extension cables should be required to connect the instrument to the computer network. Detailed requirements of an interconnecting cable are undefined, but good engineering practice should be followed in selecting the cable and connectors. Low-capacitance cable and shielded connectors may be necessary to suppress electromagnetic interface (EMI). Appropriate connector-locking hardware should be used at the conforming connectors.

8 Data Link Layer for TCP/IP Data Exchange

8.1 Overview

The data link layer has procedures for link connection and release; delimiting and synchronism; sequential control; error detection; and error recovery.

8.1.1 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 messages or returning the link to a neutral state from otherwise unrecoverable errors.

8.1.2 The data link layer uses a character-oriented protocol to send messages between directly connected systems. (See ANSI X3.4-1986. Also, see Appendix B for the coding of the ASCII characters.[14]) Some restrictions are placed on the characters that can appear in the message content.

8.1.3 The data link mode of operation is one-way transfer of information with alternate supervision. Information flows in one direction at a time. Replies occur after information is sent, never at the same time. It is a simplex stop-and-wait protocol.

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8.1.4 At times, the two systems are actively operating to transfer information. The remainder of the time the data link is in a neutral state. See the state diagram in Appendix A.

8.1.5 There are three distinct phases in transferring information between instrument and computer systems. In each phase, one system directs the operation and is responsible for continuity of the communication. The three phases ensure the actions of the sender and receiver are coordinated. The three phases are establishment, transfer, and termination.

8.2 Establishment Phase (Link Connection)

8.2.1 The establishment phase determines the direction of information flow and prepares the receiver to accept information.

8.2.1.1 The standard framework for TCP/IP network implementation is generally referred to as a "socket" implementation. The normal implementation of a socket-based communication protocol is asymmetric. One end is considered a "server" providing service to the other end, which is considered a "client." Under this client/server paradigm, the "computer system" is defined as the "server," and the "instrument" is defined as the "client." Both ends must initially create sockets and bind their local Internet address to their socket. The computer system, as the server, offers a socket for connection. The instrument (client) must be independently configurable for both socket and IP address (to facilitate use of server-defined socket number and IP address), so it can request a connection to the offered socket.

8.2.2 The sender notifies the receiver that information is available. The receiver responds that it is prepared to receive before information is transmitted.

8.2.3 A system that does not have information to send normally monitors the data link to detect the establishment phase. It acts as a receiver, waiting for the other system.

8.2.4 The system with information available initiates the establishment phase. After the sender determines the data link is in a neutral state, it transmits the **<ENQ>** transmission control character to the intended receiver. The sender will ignore all responses other than **<ACK>**, **<NAK>**, or **<ENQ>**.

8.2.5 Upon receiving the **<ENQ>**, the receiver prepares to receive information. All other characters are ignored. It replies with the **<ACK>** transmission control character signifying it is ready. With this sequence of events, the establishment phase ends and the transfer phase begins.

8.2.6 A receiver that cannot immediately receive information replies with the **<NAK>** transmission control character. Upon receiving **<NAK>**, the sender must wait at least ten seconds before transmitting another **<ENQ>**.

8.2.7 Systems not having the ability to receive information always respond to an **<ENQ>** by replying with a **<NAK>**. Systems not having the ability to send information never transmit an **<ENQ>**.

8.2.7.1 Contention

Should both systems simultaneously transmit an **<ENQ>**, the data link is in contention. The instrument system has priority to transmit information when contention occurs. Contention is resolved as follows:

(1) Upon receiving a reply of **<ENQ>** to its transmitted **<ENQ>**, the computer system must stop trying to transmit; it must prepare to receive. When the next **<ENQ>** is received, it replies with an **<ACK>** or **<NAK>,** depending on its readiness to receive.

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(2) Upon receiving a reply of **<ENQ>** to its transmitted **<ENQ>**, the instrument must wait at least one second before sending another **<ENQ>**.

8.3 Transfer Phase

During the transfer phase, the sender transmits messages to the receiver. The transfer phase continues until all messages are sent.

8.3.1 Frames

Messages are sent in frames; each frame contains a maximum of 64 000 characters (including frame overhead). Messages longer than 63 993 characters are divided between two or more frames.

8.3.1.1 Multiple messages are never combined in a single frame. Every message must begin in a new frame.

8.3.1.2 A frame is one of two types: an intermediate frame or an end frame. Intermediate frames terminate with the characters **<ETB>**, checksum, **<CR>,** and **<LF>**. End frames terminate with the characters **<ETX>**, checksum, **<CR>,** and **<LF>**. A message containing 63 993 characters or less is sent in a single end frame. Longer messages are sent in intermediate frames, with the last part of the message sent in an end frame. The frame structure is illustrated as follows:

<STX> FN text **<ETB>** C1 C2 **<CR>** **<LF>** ← intermediate frame
<STX> FN text **<ETX>** C1 C2 **<CR>** **<LF>** ← end frame

where:

<STX>	=	Start of Text transmission control character
FN	=	single digit Frame Number **0** to **7**
text	=	Data Content of Message
<ETB>	=	End of Transmission Block transmission control character
<ETX>	=	End of Text transmission control character
C1	=	most significant character of checksum **0** to **9** and **A** to **F**
C2	=	least significant character of checksum **0** to **9** and **A** to **F**
<CR>	=	Carriage Return ASCII character
<LF>	=	Line Feed ASCII character

8.3.2 Frame Number

The frame number permits the receiver to distinguish between new and retransmitted frames. It is a single digit sent immediately after the **<STX>** character.

8.3.2.1 The frame number is an ASCII digit ranging from **0** to **7**. The frame number begins at **1** with the first frame of the transfer phase. The frame number is incremented by one for every new frame transmitted. After **7**, the frame number rolls over to **0** and continues in this fashion.

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8.3.3 Checksum

The checksum permits the receiver to detect a defective frame. The checksum is encoded as two characters, which are sent after the **<ETB>** or **<ETX>** character. The checksum is computed by adding the binary values of the characters, keeping the least significant eight bits of the result.

8.3.3.1 The checksum is initialized to zero with the **<STX>** character. The first character used in computing the checksum is the frame number. Each character in the message text is added to the checksum (modulo 256). The computation for the checksum does not include **<STX>**, the checksum characters, or the trailing **<CR>** and **<LF>**.

8.3.3.2 The checksum is an integer represented by eight bits; it can be considered as two groups of four bits. The groups of four bits are converted to the ASCII characters of the hexadecimal representation. The two ASCII characters are transmitted as the checksum, with the most significant character first.

8.3.3.3 For example, a checksum of 122 can be represented as 01111010 in binary or **7A** in hexadecimal. The checksum is transmitted as the ASCII character **7** followed by the character **A**.

8.3.4 Acknowledgments

After a frame is sent, the sender stops transmitting until a reply is received.

8.3.4.1 The receiver replies to each frame. When it is ready to receive the next frame, it transmits one of three replies to acknowledge the last frame. This reply must be transmitted within the timeout period specified in Section 8.5.2.

8.3.4.2 A reply of **<ACK>** signifies the last frame was received successfully and the receiver is prepared to receive another frame. The sender must increment the frame number and either send a new frame or terminate.

8.3.4.3 A reply of **<NAK>** signifies the last frame was not successfully received and the receiver is prepared to receive the frame again.

8.3.4.4 A reply of **<EOT>** signifies the last frame was received successfully, the receiver is prepared to receive another frame, but requests that the sender stop transmitting. (See the following section on receiver interrupts.)

8.3.5 Receiver Interrupts

The receiver interrupt is a means for the receiver to request the sender to stop transmitting messages as soon as possible.

8.3.5.1 During the transfer phase, if the receiver responds to a frame with an **<EOT>** in place of the usual **<ACK>**, the sender must interpret this reply as a receiver-interrupt request. The **<EOT>** is a positive acknowledgment of the end frame, signifies the receiver is prepared to receive next frame, and is a request to the sender to stop transmitting.

8.3.5.2 The sender does not have to stop transmitting after receiving the receiver-interrupt request. If the sender chooses to ignore the **<EOT>**, the receiver must re-request the interrupt for the request to remain valid.

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8.3.5.3 If the sender chooses to honor the receiver-interrupt request, it must first enter the termination phase to return the data link to the neutral state. This gives the receiver an opportunity to enter the establishment phase and become the sender. The original sender must not enter the establishment phase for at least 15 seconds or until the receiver has sent a message and returned the data link to the neutral state.

8.4 Termination Phase (Link Release)

The termination phase returns the data link to the clear or neutral state. The sender notifies the receiver that all messages have been sent.

8.4.1 The sender transmits the **<EOT>** transmission control character and then regards the data link to be in a neutral state. Upon receiving **<EOT>**, the receiver also regards the data link to be in the neutral state.

8.5 Error Recovery

Methods are described that enable both sender and receiver to recover, in an orderly way, from errors in data transmission.

8.5.1 Defective Frames

A receiver checks every frame to guarantee it is valid. A reply of **<NAK>** is transmitted for invalid frames. Upon receiving the **<NAK>**, the sender retransmits the last frame with the same frame number. In this way, transmission errors are detected and automatically corrected.

8.5.1.1 Any characters occurring before the **<STX>** or **<EOT>** or after the end of the block character (the **<ETB>** or **<ETX>**) are ignored by the receiver when checking the frame. A frame should be rejected because:

(1) Any character errors are detected (parity error, framing error, etc.);
(2) The frame checksum does not match the checksum computed on the received frame; or
(3) The frame number is not the same as the last accepted frame or one number higher (modulo 8).

8.5.1.2 Upon receiving a **<NAK>** or any character except an **<ACK>** or **<EOT>** (a **<NAK>** condition), the sender increments a retransmit counter and retransmits the frame. If this counter shows a single frame was sent and not accepted six times, the sender must abort this message by proceeding to the termination phase. An abort should be extremely rare, but it provides a mechanism to escape from a condition where the transfer phase cannot continue.

8.5.2 Timeout

The sender and receiver both use timers to detect loss of coordination between them. The timers provide a method for recovery if the communication line or the other device fails to respond.

8.5.2.1 During the establishment phase, the sender sets a timer when transmitting the **<ENQ>**. If a reply of an **<ACK>**, **<NAK>**, or **<ENQ>** is not received within 15 seconds, a timeout occurs. After a timeout, the sender enters the termination phase.

8.5.2.2 During the establishment phase, if the computer (as receiver) detects contention, it sets a timer. If an **<ENQ>** is not received within 20 seconds, a timeout occurs. After a timeout, the receiver regards the line to be in the neutral state.

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8.5.2.3 During the transfer phase, the sender sets a timer when transmitting the last character of a frame. If a reply is not received within 15 seconds, a timeout occurs. After a timeout, the sender aborts the message transfer by proceeding to the termination phase. As with excessive retransmissions of defective frames, the message must be remembered so it can be completely repeated.

8.5.2.4 During the transfer phase, the receiver sets a timer when first entering the transfer phase or when replying to a frame. If a frame or **<EOT>** is not received within 30 seconds, a timeout occurs. After a timeout, the receiver discards the last incomplete message and regards the line to be in the neutral state.

8.5.2.5 A receiver must reply to a frame within 15 seconds or the sender will timeout. A receiver can delay its reply for up to 15 seconds to process the frame or to otherwise go into "busy" mode. Longer delays cause the sender to abort the message.

8.5.2.6 Receivers that cannot process messages fast enough to keep up with a sender may cause message buffer overflows in the sender. A sender can normally store at least one complete message. Storage space for more than one outgoing message is desirable but optional.

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8.6.2 None of the ten transmission control characters, the **<LF>** format effector control character, or four device control characters may appear in message text. The restricted characters are: **<SOH>**, **<STX>**, **<ETX>**, **<EOT>**, **<ENQ>**, **<ACK>**, **<DLE>**, **<NAK>**, **<SYN>**, **<ETB>**, **<LF>**, **<DC1>**, **<DC2>**, **<DC3>**, and **<DC4>**.

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INCITS. *Information Technology – ISO 7-bit coded Character Set for Information Interchange [L2]*. INCITS/ISO/IEC 646:1991[R2004]. Washington, DC: InterNational Committee for Information Technology Standards; 2004.

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Appendix A. Mandatory Information

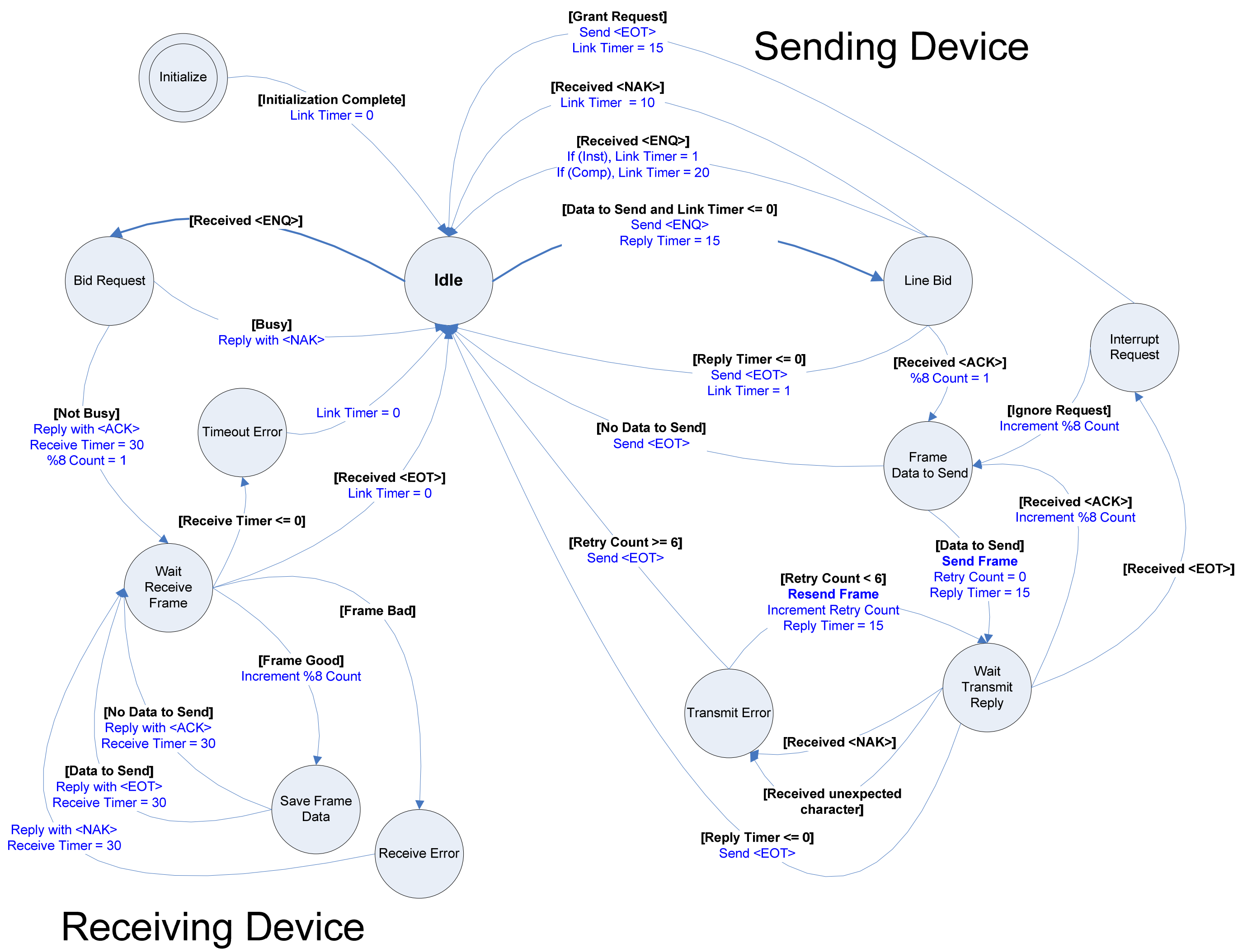

Figure A1. State Diagram

NOTE 1: “%8” represents modulo 8.
NOTE 2: “ = ” represents assignment of a value. “Timer: = 15” resets the timer to 15 s as used here.

Appendix B. Nonmandatory Information

B1. Seven-Bit ASCII Code Charts

| dec CHR |

ASCII Character

Decimal Character Code

000	NUL	016	DLE	032	SP	048	0	064	@	080	P	096	`	112	p
001	SOH	017	DC1	033	!	049	1	065	A	081	Q	097	a	113	q
002	STX	018	DC2	034	"	050	2	066	B	082	R	098	b	114	r
003	ETX	019	DC3	035	#	051	3	067	C	083	S	099	c	115	s
004	EOT	020	DC4	036	$	052	4	068	D	084	T	100	d	116	t
005	ENQ	021	NAK	037	%	053	5	069	E	085	U	101	e	117	u
006	ACK	022	SYN	038	&	054	6	070	F	086	V	102	f	118	v
007	BEL	023	ETB	039	'	055	7	071	G	087	W	103	g	119	w
008	BS	024	CAN	040	(	056	8	072	H	088	X	104	h	120	x
009	HT	025	EM	041	)	057	9	073	I	089	Y	105	i	121	y
010	LF	026	SUB	042	*	058	:	074	J	090	Z	106	j	122	z
011	VT	027	ESC	043	+	059	;	075	K	091	[	107	k	123	{
012	FF	028	FS	044	,	060	<	076	L	092	\	108	l	124	|
013	CR	029	GS	045	-	061	=	077	M	093	]	109	m	125	}
014	SO	030	RS	046	.	062	>	078	N	094	^	110	n	126	~
015	SI	031	US	047	/	063	?	079	O	095	_	111	o	127	DEL

Figure B1. Decimal Character Code

| hex CHR |

ASCII Character

Hexadecimal Character Code

00	NUL	10	DLE	20	SP	30	0	40	@	50	P	60	`	70	p
01	SOH	11	DC1	21	!	31	1	41	A	51	Q	61	a	71	q
02	STX	12	DC2	22	"	32	2	42	B	52	R	62	b	72	r
03	ETX	13	DC3	23	#	33	3	43	C	53	S	63	c	73	s
04	EOT	14	DC4	24	$	34	4	44	D	54	T	64	d	74	t
05	ENQ	15	NAK	25	%	35	5	45	E	55	U	65	e	75	u
06	ACK	16	SYN	26	&	36	6	46	F	56	V	66	f	76	v
07	BEL	17	ETB	27	'	37	7	47	G	57	W	67	g	77	w
08	BS	18	CAN	28	(	38	8	48	H	58	X	68	h	78	x
09	HT	19	EM	29	)	39	9	49	I	59	Y	69	i	79	y
0A	LF	1A	SUB	2A	*	3A	:	4A	J	5A	Z	6A	j	7A	z
0B	VT	1B	ESC	2B	+	3B	;	4B	K	5B	[	6B	k	7B	{
0C	FF	1C	FS	2C	,	3C	<	4C	L	5C	\	6C	l	7C	|
0D	CR	1D	GS	2D	-	3D	=	4D	M	5D	]	6D	m	7D	}
0E	SO	1E	RS	2E	.	3E	>	4E	N	5E	^	6E	n	7E	~
0F	SI	1F	US	2F	/	3F	?	4F	O	5F	_	6F	0	7F	DEL

Figure B2. Hexadecimal Character Code

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Summary of Delegate Comments and Area Committee Responses

LIS01-A2: *Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems; Approved Standard—Second Edition*

General

1. This is a review document of the RS-232 interface, which is rarely used now. Most laboratory equipment comes as an integrated system with simple interfacing software.

- **There are still IVD, middleware, and LIS vendors that make use of this specification for interfaces to legacy and new IVD instruments. There are current IVD vendors that still support RS-232 connectivity to their instruments. Often, this native RS-232 interface may be connected by a very short cable to a device server, either single or multiple ports, but the native instrument datastream is RS-232. The specification still supports these devices.**

2. The College of American Pathologists recommends that the document drafters might want to consider adding commentary about wireless communications possibilities, as the document assumes wired connections.

- **See the response to comment 7 below.**

3. The document describes Ethernet with TCP/IP as an alternative choice for serial communication. The CLIMS shall be TCP/IP-server, the analyzer TCP/IP-client. There are analyzers out in the field that offer ASTM-communication by TCP/IP, but can only play the TCP/IP-server. There is a need for the CLSI standard to permit analyzers as TCP/IP-servers. This behavior is not wrong because analyzers are servers for diagnostic measurements, too. It is also reasonable for the CLIMS to reorganize the analyzer connection after reboot or network shutdown.

- **There are advantages to having the CLIMS assigned the server role. Logically a client-server approach implies one server and many clients, which is true for the case of one CLIMS and multiple instruments. Assigning the instrument the role of client puts control of the initiation and maintenance of the TCP/IP session in the hands of what is presumably the less powerful system. Also, the configuration of the network environment can be simpler if only one server must be identified on the network (the CLIMS), rather than multiple servers if each analyzer were a server. In addition, having the analyzer assigned as the client provides a level of protection for the analyzer, as it must initiate communication rather than receive an unsolicited connection. Finally, if the analyzer is protected by a component such as a firewall, the component would need to be configured to allow the inbound traffic if the analyzer is the server. Configuration is not necessary if the analyzer initiates the communication as a client. This is addressed in Section 8.2.1.1.**

4. Most of the document describes the connectivity hardware. In fact, this hardware is described in other standards very well. If LIS01-A2 would refer to these hardware standards without reproducing, then it is updated automatically after hardware improvements. For example, there is described a 25-pin DB-25 S/P connector, but all modern analyzers are fitted with the newer 9-pin connectors. There is a need for 9-pin connectors to be permitted by the standard.

- **The reviewer makes a good point, but one of the goals for this standard was to maintain compatibility with the previous version. See the response to comment 7 below.**

5. The new standard increases the possible frame length from 255 up to 64 000 characters. This is advantageous for the developer because intermediate frames become no longer necessary, but there is a danger. A 2-digit

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checksum cannot hedge 64 000 bytes in case of serial communication. In case of TCP/IP communication, the frame length can be unlimited without danger and even the checksum is obsolete. I think 64 000 is a bad compromise between 256 and infinity, and there is a need for a frame length reduction in case of serial communication.

- **See Sections 4.4 and 4.4.1, which address the reviewer's comments concerning large frame sizes and restricting their use to TCP/IP communication.**

6. In case of TCP/IP communication, frame length limitations and checksums are obsolete; but compatibility with serial communication requires ability of processing checksums and intermediate frames, so the checksum shall be an optional parameter.

- **As noted by the reviewer, the checksum is no longer required for TCP/IP communication. However, the structure of the frame was not modified for TCP/IP communication in order to maintain complete compatibility with legacy RS-232 interfaces. Compatibility and simplification of frame structure argues against allowing for multiple possible frame structures, and support for an optional checksum parameter introduces opportunities for error based on multiple options. Because the calculation of the checksum is required for serial modes, it introduces no new effort and minimal communication overhead to the standard.**

7. Since the document has been updated to include TCP/IP communication, would it also be possible to include a small section on other communication technologies, such as virtual COM ports over USB, high speed USB, and firewire (IEEE 1394)?

- **Because of the nature of the typical laboratory environment, where a central LIS is connected to multiple instruments located at various locations, it is expected the majority of connections will be RS-232 or TCP/IP. The use of virtual COM ports, through the use of devices such as terminal servers, can be implemented in a manner that is transparent to this specification. Likewise, a wireless implementation could be transparent depending on the implementation. This revision was intended to clarify the existing standards, and the implementation of other technologies is beyond the scope of this effort.**

- **For clarification, Section 4.5 has been added: "Although this specification addresses serial communication using a 25-pin connector and TCP/IP communication, it can be adapted to other standard communication approaches such as a 9-pin serial connector, wireless, high speed USB, and firewire. The physical layer specifications for other approaches must be agreed upon outside the context of this standard. Adaptation to 9-pin, USB, etc. is standard, and can be accomplished in a manner transparent to the specification."**

<u>Table of Contents</u>

8. The proposed Table of Contents is less detailed than it was in the first edition. An original construction of the table was more convenient for users. Preserve the original format of the table (from the first edition).

- **Although less detailed, the Table of Contents is consistent with other CLSI documents (such as LIS2-A2). The structure of the Table of Contents should be consistent across all CLSI documents, and questions about the acceptability/usability of that structure should take place at a higher level than this document.**

<u>Section 3, Terminology</u>

9. It would be helpful for users to see additional terms that were frequently used in a text. Add descriptions for the following terms: stop bit, parity bit, neutral stage, checksum, instrument domain, and computer domain.

- **There are other terms that are not specifically defined in the terminology section, such as TCP/IP. The specification does reference other standards that provide definitions for most terms not listed in the terminology section. The terms used are common to the communications industry and could reasonably be expected to be understood by a reader/user of this standard, or can be understood by reviewing the referenced standards.**

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<u>Section 5.2.3.1</u>

10. 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.

    Is it still necessary that when faster baud rates are available (ie, 57 600) that the default setting of the instrument be 9600?

    Is it still true that instruments must support 1200, 2400, 4800, or 9600? And if so, is this meant to ensure compatibility with older computer systems?

    Note: Since the document has been updated to include TCP/IP data exchange, the TCP/IP characteristics specify speed in terms of a "minimum" such as "at least 10MB/sec" vs stating that systems "must support 10MB/sec."

- **The reviewer makes a good point, but legacy compatibility is an important component of the standard. In order to maintain compatibility with existing implementations, it is best to leave the default value at 9600. Note that the wording does not preclude use of faster transmission rates when possible, but rather requires compatibility to slower computer systems to prevent incompatibilities.**

- **"Minimum" was used so as not to exclude other speeds such as 100MB/sec.**

<u>Section 5.2.4.2</u>

11. 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.

    Is it still a requirement that the conforming interface connection on laboratory instruments utilize a 25-position connector? Considering only four pins are used, and the industry focus on making instruments more compact, a 9-pin connection or possibly a USB type connection would be more appropriate depending on the device. In many cases where serial communication is required, more and more users are running serial-to-Ethernet convertors, or serial-to-USB convertors to attach to systems/networks.

- **See the response to comment 7 above.**

<u>Sections 6.3.1.2 and 8.3.1.2</u>

12. These sections include the same table of frame codes. Include ALL frame code in one comprehensive table that should be added to one of appendixes; exclude tables of frame codes from the body of the standard.

- **The frame layout was included in the original ASTM standard body, as well as the previous CLSI version. The frame layout is included where it might be most immediately referenced, making it easier for a reader to reference the frame definition for a specific implementation (RS-232, TCP/IP). Having to go to an appendix and then back to the body of the document detracts from usability.**

<u>Section 8.2.1.1</u>

13. It might be preferred that the instrument is designated as the server and the computer system is identified as the client. The rationale is that if one has to reboot the computer system for some reason, and it is designated as the "server," all instruments that are connected to it will need to reconnect to that computer system. If the instruments are "servers," they are not affected when the computer system is rebooted.

- **See the discussion and response to comment 3 above.**

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

LIS01-A2 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 AUTO3 LIS2	X AUTO3 LIS2					

Adapted from CLSI/NCCLS document HS1—*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.

LIS01-A2 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 AUTO3 LIS2	

Adapted from CLSI/NCCLS document HS1—*A Quality Management System Model for Health Care*.

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Related CLSI Reference Materials*

AUTO3-A **Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard (2000).** This document provides standards to facilitate accurate and timely electronic exchange of data and information between the automated laboratory elements.

LIS2-A2 **Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems; Approved Standard—Second Edition (2004).** This document covers the two-way digital transmission of remote requests and results between clinical laboratory instruments and information systems.

* 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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