CD-TOC EXIT

Click on Item Below:

Abbott Standard Interface RS-232 Manual

List Number 9A43-50

Abbott Laboratories
Abbott Park, IL 60064
69-0638/R2

Foreword

The LCx System represents the latest advancements in immunoassay testing and laboratory instrumentation. We are proud of this product and of the team of scientists, engineers, and manufacturing professionals who produced it.

The system's high rate of production and its advanced user interface incorporate many technological innovations. As you will learn in years to come, we have achieved these advances without sacrificing precision, safety, durability or dependability.

For detailed information on the function and operation of the LCx System, refer to the Abbott LCx System Operations Manual (List. No. 9A43-02). In addition, information regarding the Abbott LCx assays are provided in the Abbott LCx assay-specific package inserts.

The LCx System is manufactured by Abbott Laboratories, Abbott Park IL 60064, USA.

The Abbott Standard Interface RS-232 Manual, LCx Edition Revision 1.00 only applies to LCx System Software Revision 2.0 or higher.

Customer Support

United States:	1-800-527-1869
Canada:	1-800-387-8378
International:	Call your local Customer Support Representative.

Proprietary Statement

The software and manuals were developed solely for use with Abbott Laboratories equipment, for *in vitro* diagnostic applications as specified in the operating instructions.

Pictorial Disclaimer

The sample printouts/screens contained in this manual are for information and illustration purposes only. Abbott Laboratories makes no representation or warranties about the accuracy and reliability of the data on the screens. The data represented is not to be used for clinical or maintenance evaluation.

Warranty

Abbott makes no warranties for the interface, Interface Data Disk, and Host/Instrument Interface Simulator beyond those set forth in the operations manual for the Abbott system/instrument and disclaims all other warranties, express or implied, including but not limited to, the implied warranties of merchantability and fitness for a particular purpose.

In no event shall Abbott be liable for the incidental or consequential damages arising from the use of the interface, Interface Data Disk, and Host/Instrument Interface Simulator.

NOTES

How to Use This Manual

Overview

In this section:

- Overview of the Manual
- Alternative Reference Material

Overview of the Manual

The Abbott Standard Interface RS-232 Manual - LCx Edition provides the necessary information for interfacing the LCx System to hospital or laboratory information systems across the serial RS-232 communications port.

All Abbott Standard Interface RS-232 Manuals are designed to provide clear and concise information on the communications capabilities of Abbott Diagnostic Instruments and Systems that support the Abbott Standard Interface (ASI). This interface is based on the following industry supported standards:

- ASTM E1381-91 “Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems”
- ASTM E1394-91 “Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems”

The manuals provide specific information on the communications capabilities of Abbott ASI instruments and systems as well as general information on the Abbott implementation of the ASTM E1381-91 and E1394-91 communication protocols. Different editions exist for different instruments and systems, however they are all organized as follows:

- How to Use This Manual: Discusses the purpose of the manual and provides a good overview of the information contained within.
- Section 1: Discusses the Abbott implementation of the ASTM E1381-91 and E1394-91 standards. This section is common to all Abbott Standard Interface Manuals.

- Section 2 – Section 6: Discusses specific information about the instrument or system covered by that particular Edition. It covers topics such as instrument overview, communications setup, content of communications messages and instrument communication diagnostics. These sections are unique for each instrument. Sections 2 – 6 of this edition describe the LCx System and its specific interface implementation.
- Section 7: Discusses the use of the Abbott Host/Instrument Interface Simulator, provided on the Interface diskette. This section is common to all Abbott Standard Interface Manuals.

This manual assumes the reader is familiar with programming techniques and is capable of programming using a high level language. This manual also assumes the reader has a good working knowledge of serial communications as they relate to the computer system that will be interfacing with the Abbott instrument or system.

For readers not familiar with the ASTM E1381-91 and E1394-91 communications standards, we highly recommend that these two standards be obtained by calling or writing ASTM using the information provided in "Alternative Reference Materials": All readers should carefully study the "Overview of the Abbott Standard Interface" section and all subsequent sections to understand how Abbott instruments implement the ASTM standards. The reader should then be able to develop and program the logic required to effectively communicate with the LCx System as well as setup and diagnose communications.

Included with this manual is also an Interface Data Disk, containing the Abbott Host/Instrument Interface Simulator (HiiSim version 1.0) program and data transmission files captured from the LCx System. Once the interface program is written on the host computer, the reader may use the Abbott Host/Instrument Interface Simulator (HiiSim) program to initiate communications and transfer instrument data (found on the interface disk) to the host computer.

The Interface Data Disks are provided with the understanding that modifying originals or copies of the data files invalidates the data files. Invalid data files may not be used to represent instrument output.

Abbott provides this software as a tool to assist the development of interface software to Abbott Instruments and Systems. Once the interface software is developed, HiiSim may be used to communicate the available LCx data transmission files to the host system, in ASTM compatible formats, and test the workings of the interface. Developers should not rely solely on the use of this product for verification and validation of their interface software.

The HiiSim software is provided with the understanding that Abbott does not guarantee its support or future availability.

Alternative Reference Materials

Bibliography of Standards and references.

ASTM Standards referenced within this document may be purchased by contacting:

American Society of Testing and Materials (ASTM)
1916 Race Street
Philadelphia, PA 19103-1187
Phone Orders: (215) 299-5585

NOTES

Master Table of Contents

Section 1. Abbott Standard Interface

Section 2. Overview of the LCx System

Section 3. Communication Setup

Section 4. LCx Specific Outgoing Messages

Section 5. LCx Specific Incoming Messages

Section 6. Troubleshooting

Section 7. Abbott Host/Instrument Interface Simulator

NOTES

List of Figures

Section 1. Abbott Standard Interface

Section 4. LCx Specific Outgoing Messages

Section 5. LCx Specific Incoming Messages

Section 7. Abbott Host/Instrument Interface Simulator

List of Tables

Section 1. Abbott Standard Interface

Section 2. Overview of the LCx System

Section 4. LCx Specific Outgoing Messages

Section 5. LCx Specific Incoming Messages

Section 7. Abbott Host/Instrument Interface Simulator

Abbott Standard Interface

Section Overview

This section explains the Abbott implementation of the ASTM E1381-91 and E1394-91 communications standards.

In This Section:

- Overview of the Abbott Standard Interface
- Layered Protocols
- Physical Layer – Electrical, Mechanical, and Signaling Characteristics
- Data Link Layer – Establishment, Transfer, and Termination
- ASTM E1381-91 State Diagram
- Presentation Layer – Message Content
- Applications Layer

Overview of the Abbott Standard Interface (ASI)

Abbott instruments and data management systems provide communications to external host computers via a serial connection conforming to the specifications and requirements set forth in the ASTM E1381-91 and ASTM E1394-91 standards. At the most basic level these standards allow host systems to download (i.e., send) worklist messages to the Abbott instruments/systems. The Abbott instruments can then process the worklist, act on the tests that have been requested, and return the results associated with the worklist. The host computer can then process the results, generate reports, and store the information.

Although these standards form the basis of the type of information exchanged between clinical instruments and the manner that the information is transferred, they allow the instrument and system manufacturers considerable latitude in selecting field use and field substructure. This often causes incompatibilities and increased software development in order to accommodate the variations of all the different instruments.

In order to minimize these variations between Abbott instruments, systems, and external hosts, Abbott has taken the initiative to define the **Abbott Standard Interface (ASI)**. ASI consists of a series of interpretations and definitions of the ASTM standards that provide a strict but consistent compliance to the standards, while providing the needed flexibility to handle the unique data requirements of Abbott's multiple instruments and systems.

By minimizing where instruments can vary and by defining the fields that are instrument specific, developers should benefit by structuring their software to be configurable to the highest possible extent, thus minimizing development time and costs.

Table 1.1: Terms and Definitions

Term	Definition
ASI	Abbott Standard Interface: Abbott's implementation of the American Society for Testing and Materials (ASTM) Standard. E1394-91, A Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems. E1381-91, Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems.
Allowed Data Formats	All data is represented in ASCII format within the range 0 – 255. Values 0 – 127 are defined by ANSI X3.4-1986 Standard. Values 128 – 255 are defined as needed by specific instruments. Values 0 – 31 cannot be used, with the exception of 13 (<CR>). The value 13 is reserved as a record terminator. Values 32 – 255 can be used, with the exception of 127 and 255. Within a data text field, only the ASCII characters 32 – 126 and 128 – 254 are permitted as usable characters. Characters used as delimiters in the transmission are excluded from the above permitted range. The sender is responsible for checking that a data text field does not contain any delimiters. The record identifier fields (H,P, O, R, L, C, M, and Q) are always uppercase when output from the Abbott instrument. On input, both upper- and lowercase record identifiers are accepted. Fields and records are variable in length with no restriction placed on the maximum length of a field or record. The high-level protocol depends on the receiver's buffering capability and the low-level communication ability to divide the information into workable lengths for transmission and processing purposes. All Abbott Standard Interface RS-232 manuals provide the maximum allowable length of each field transmitted and received.
E1394-91 Message	A block of data that is transmitted in a format consistent with the ASTM E1394-91 Standard. Data is transmitted in a series of records starting with a Header Record (H) and ending with a Terminator Record (L). When a transmission is lost, the Abbott instrument retransmits or accepts only complete messages.
E1394-91 Record	An E1394 Record is a string of characters starting with a capital ASCII alphabet character and ending with a carriage return (ASCII 13), as defined by the ASTM E1394-91 Standard.

Table 1.1: Terms and Definitions (Continued)

Term	Definition
Reserved Characters	The following characters have special uses and should not be used for data: Vertical Bar (|) Backslash (\) Ampersand (&) Carriage Return (<CR>) Caret (^)
E1381-91 Message	A block of data that is transmitted in a format consistent with the ASTM E1381-91 Standard. Abbott ASI instruments use an E1394-91 Record as the E1381-91 Message. Thus, an E1381-91 Message may be transmitted using multiple (one or more) frames, based on the length of the message.
E1381-91 Frame	A frame is a subdivision of a message and allows transmission of up to 247 characters (240 data characters and 7 control characters). The Abbott instrument transmits one record per frame. Messages more than 247 characters long can be divided into multiple frames, as long as each frame contains only information from one record at a time.

Layered Protocols

The Abbott Standard Interface (ASI) is based on a four-layer protocol implementation, consistent with the terminology and definitions of the Organization for International Standards (ISO) reference model for Open Systems Interconnection (OSI). The OSI model is concerned with the interconnections between different systems and not with the internal functions that are performed by a given system. The OSI model provides a generalized view of a layered architecture. Using this approach, functions and services required to allow two systems to communicate are grouped in various functional layers. A given layer is responsible for performing a specific set of functions and for providing a specific set of services.

A communications architecture can then be defined in terms of the services provided by each layer and the interface between layers. Protocols define the services offered across a layer interface and the rules that are followed in the processing performed as part of a service. Data formats for the data exchanged across an interface are also defined as part of the architecture.

Two types of interfaces exist in a communications architecture. One set of interfaces exists between the layers in a given system. The second set of interfaces exists between comparable layers of different systems. ASI provides information on the second set of interfaces that allow similar layers of different systems to communicate.

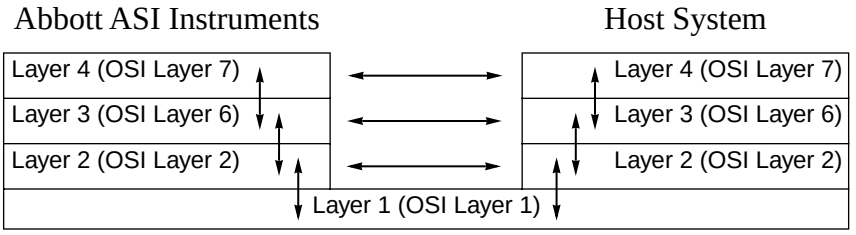


Figure 1.1: Layered Protocol Architecture

The OSI layer designators are used as reference and do not imply compliance with actual ISO/OSI Standards.

Based on this architecture, ASI defines the following layers for implementation of communications software:

- Physical Layer (Layer 1) – Directs transmission of serial binary data bits between the Abbott instruments and systems and external host computers across a mechanical and electrical connection, as defined by this document and ASTM E1381-91 section 5.
- Data Link Layer (Layer 2) – Provides services for establishing a link connection, transferring data, and releasing the connection. Also provides services for delimiting, synchronism, sequence control, error detecting and recovering of the link, as defined by this document and ASTM E1381-91 section 6.
- Presentation Layer (Layer 3) – Provides services for building message content into a standard and interpretable form, as defined by this document and ASTM E1394-91.
- Application Layer (Layer 4) – Provides services for processing test requests, running assays, reporting results, etc., as defined by this document and the instrument specific operations manual.

The following figure depicts the general implementation of these layers on new Abbott instruments and systems that support the ASTM Standards.

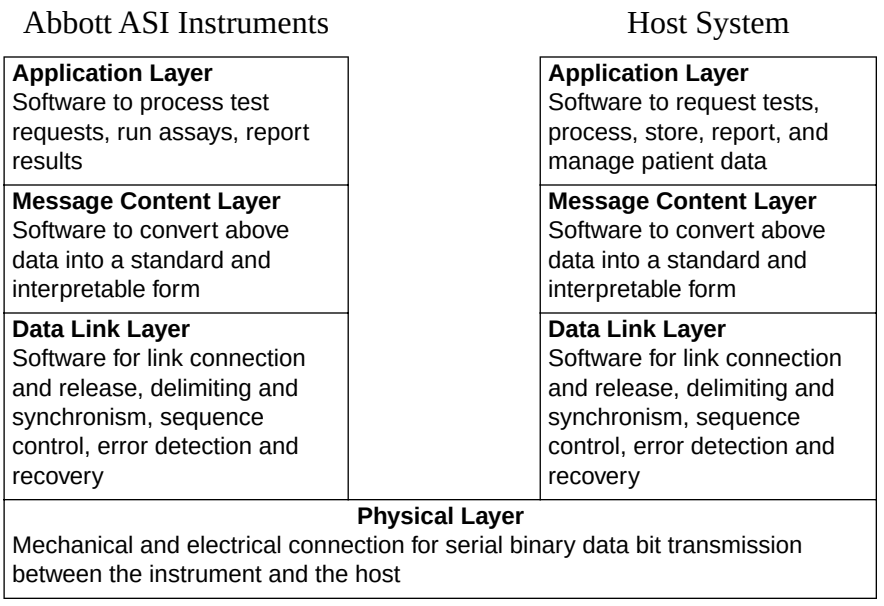


Figure 1.2: ASI Implementations

Physical Layer – Electrical, Mechanical, and Signaling Characteristics

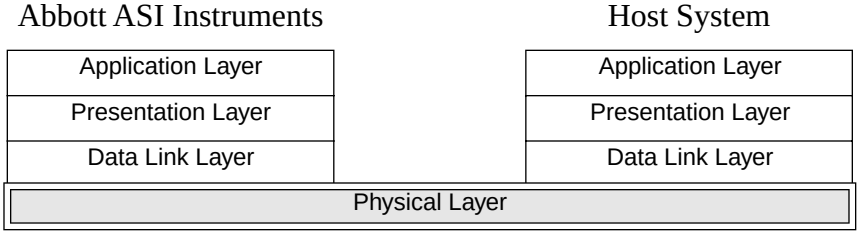


Figure 1.3: Physical Layer

Abbott instruments and systems supporting the Abbott Standard Interface (ASI) implement the physical layer of the interface as specified by the ASTM E1381-91 standard. This interface is based on the EIA RS-232D -1986 standards, for the mechanical and electrical characteristics and the ANSI X3.15-1976 and ANSI X3.16-1976 for the signaling characteristics, such as the structure of the characters being transmitted.

Electrical Characteristics

Abbott instruments use a voltage more negative than minus three volts (with respect to signal ground) to indicate a marking condition (binary one). A voltage more positive than plus three volts (with respect to signal ground) indicates a spacing condition (binary zero). The relevant voltage and impedance levels of the signal generator and the signal receiver circuits of ASI instruments meet the requirements set forth in the RS-232D -1986 standard.

Mechanical Characteristics

ASI instruments use a 25-pin connector to facilitate connection to an external computer system. The ***Communications Setup*** section of each Abbott Standard Interface RS-232 manual covers the specifics for that instrument.

Because Abbott data management systems are sometimes used as hosts for other Abbott instruments, and other times used as "instruments" communicating to LIS Host systems, Abbott includes the appropriate adapters to allow these systems to be connected as needed if the same port is used for both purposes. If required, a male to female adapter that converts the signals from DTE (instrument) to DCE (Host) is provided to facilitate this connection. The requirements of these systems are clearly defined in the ***Communications Setup*** section of this manual.

The cabling and pin-out requirements of Abbott instruments and systems conform to the specifications defined in the ASTM E1381-91 standard. Only pins 1, 2, 3, and 7 of the connector are used. Refer to the following table and figure for pin assignment information. The ASTM E1381-91 standard requires that the external Host computer be configured as a DCE device.

Table 1.2: Pin Assignments for the 25-Pin Connector

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

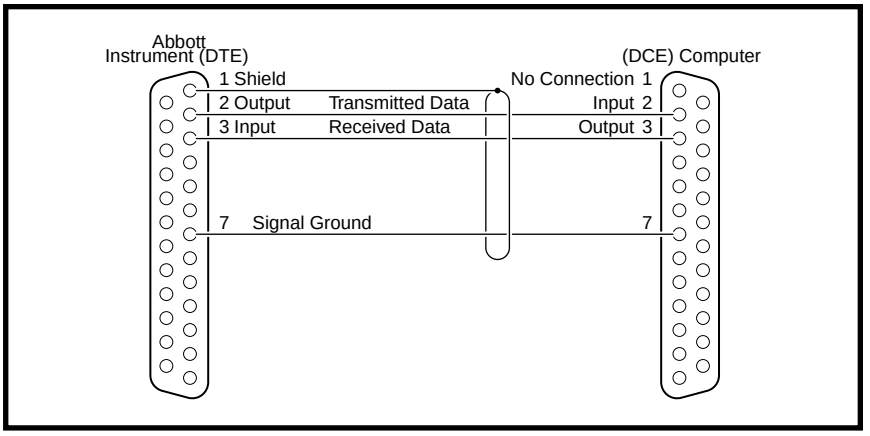


Figure 1.4: Pin-to-Pin Connections (Wiring Diagram)

NOTE: If a computer is configured as a DTE Device (i.e., pin 2 is the output and pin 3 is the input), then the cable connecting the ASI instrument to the computer must have lines 2 and 3 crossed.

For Host computer systems that do not conform to the ASTM standard for the physical connection, other cabling schemes may be required as shown below. Many personal computers may have a 9-pin connector instead of the 25-pin required by the ASTM specifications.

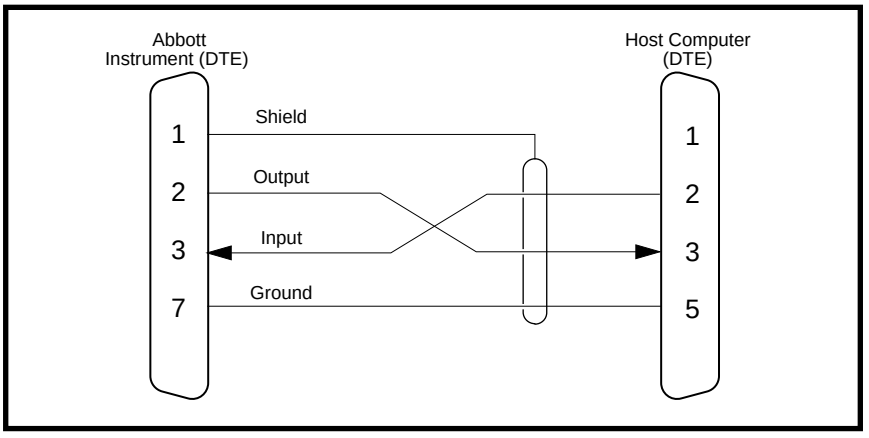


Figure 1.5: Host computer (PC with 9-pin connector) with Non-ASTM compliant connector.

NOTE: Pin 1 is the shield connection and connects to the instrument's (DTE) frame. Leave the shield connection open at the computer (DCE) to avoid ground loops.

If the same computer used a 25-pin connector configured as a DTE, the cabling requirements would be as follows:

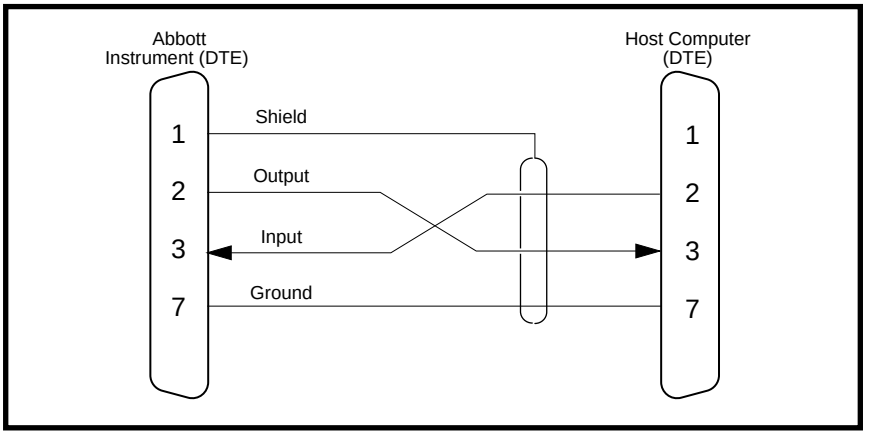


Figure 1.6: Host computer (PC with 25-pin connector) with Non-ASTM compliant connector.

ASI instruments and systems may optionally provide fixed length cables for connecting to external systems. When cable lengths greater than 50 feet are required, then "Low Capacitance" shielded cables are recommended. Local Building Fire Code standards may require the use of "Plenum" rated cables for connecting systems. Please check with your building personnel for specific requirements that apply to wiring and cabling in your specific environment.

Signaling Characteristics

Character Structure

Character bit patterns and bit rates determine how Abbott instruments communicate with computer systems.

The character bit sequencing, structure, and parity sense definitions conform to ANSI standards X3.15-1976 and X3.16-1976. The default structure for Abbott instruments character bit sequencing is:

1. A start bit with a value of zero.
2. The start bit is followed by eight bits that represent character data.
3. A stop bit with a value of one ends the character structure.

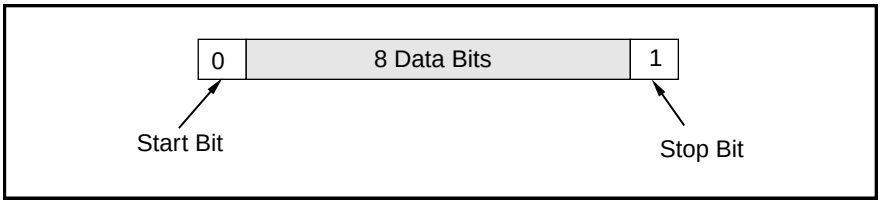


Figure 1.7: Default Abbott Instruments Character Structure. ***The start and stop bits separate ASCII characters which are eight bits long.***

All ASI instruments support the ASTM required combinations of:

- Start bits
- Data bits
- Parity bits
- Stop bits

Speed

Abbott instruments that implement ASI provide multiple baud rates for transmitting data to external systems. As a minimum, all ASI instruments support the ASTM preferred communications speed of 9600 baud, and may also support one or more of the following [1200, 2400, 4800, 19200]. The default setting of all ASI instruments for host communications is 9600 baud. See the ***Communications Setup*** section of the Abbott Standard Interface RS-232 manual for the exact baud rates supported by each instrument.

Abbott data management systems that are used as hosts support all four of the ASTM E1381-91 required baud rates [1200, 2400, 4800, 9600]. Optionally, they may also support other baud rates [e.g., 19200, etc.] as required.

Data Link Layer—Establishment, Transfer, and Termination

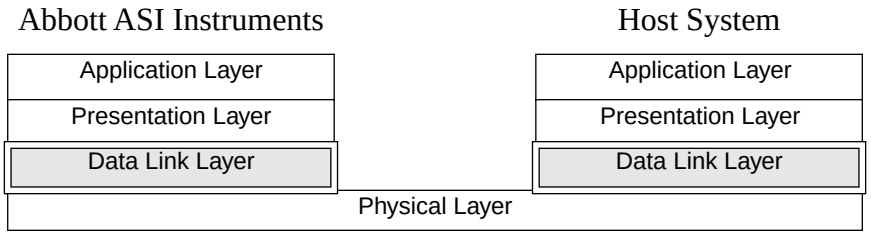


Figure 1.8: Data Link Layer

The data link layer covers methods for the following:

- Establishing communication connections with an external system
- Providing error detection and error recovery of communications
- Delimiting and synchronism
- Sequence control
- Sending and receiving messages
- Terminating the communications connections

In addition, the data link layer performs the following inter-layer functions:

- Interacts with higher layers in transferring data
- Handles requests for establishing and terminating connections
- Reports the data link layer status

The data link layer uses a character-oriented protocol to send messages between two systems that are directly connected. One system transmits while the other system monitors the communications link. Thus, information flows in only one direction at a time. Replies occur after information is sent, never at the same time.

Abbott instruments implement the data link layer as specified in the ASTM E1381-91 standard. This standard defines conditions that apply to a device if the device is an instrument, and other conditions if the device is a host computer system. Because Abbott Data Management systems are sometimes used as hosts for other Abbott instruments and other times as "instruments" communicating to Laboratory Information Systems (LIS Hosts), these systems implement both the "host" and the "instrument" logic of the data link protocol. The configuration of these systems allows them to communicate appropriately based on the role that they are serving.

The data link layer consists of the three following communications phases:

- Establishment phase
- Transfer phase
- Termination phase

Each phase is discussed in detail.

Establishment Phase

The establishment phase determines the direction of information flow and prepares the receiver to accept information. The system with data available for transmission initiates the establishment phase.

When Abbott ASI instruments and systems have data to send, they go into the establishment phase by transmitting the [ENQ] character. If a valid reply is not received within the 15 second time period specified by ASTM E1381-91, the Abbott instruments and systems enter the termination phase. The instrument returns to the establishment phase after waiting a certain amount of time (e.g., 30 seconds, 60 seconds, etc.) specific to that instrument.

If after a certain number of attempts the instrument is unable to establish communications with the external system, the operator is informed via a dialog box (or error message) and an error message is posted to the error log file. The instrument continues trying to establish communications as described above.

Sending an [ENQ] and Receiving an [ACK]

After determining that the data link is in a neutral state, the sender transmits an Enquiry [ENQ] transmission control character to the receiver, notifying the receiver that it has information to send. The receiver must send a Message Acknowledged [ACK] transmission character back to the sender before the information is sent. If the receiver is not ready to receive, it sends a Message Not Acknowledged [NAK] transmission character. All other characters are ignored by the sender and receiver. The only valid characters during the Establishment Phase are [ENQ], [ACK], and [NAK].

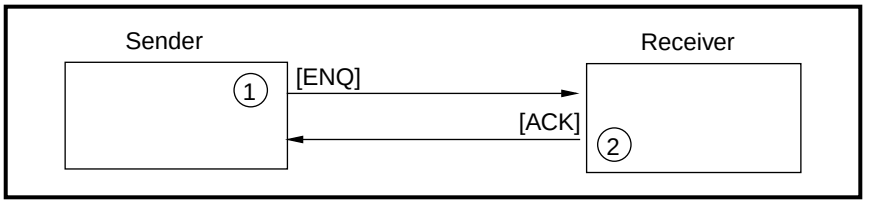


Figure 1.9: Sender Initiating Establishment Phase. ***The receiver returns a signal to the sender acknowledging that it is ready to receive.***

Sending an [ENQ] and Receiving an [NAK]

If the receiver is not ready to receive information, it sends an [NAK] in response to an [ENQ]. The sender must wait ten seconds before sending another [ENQ].

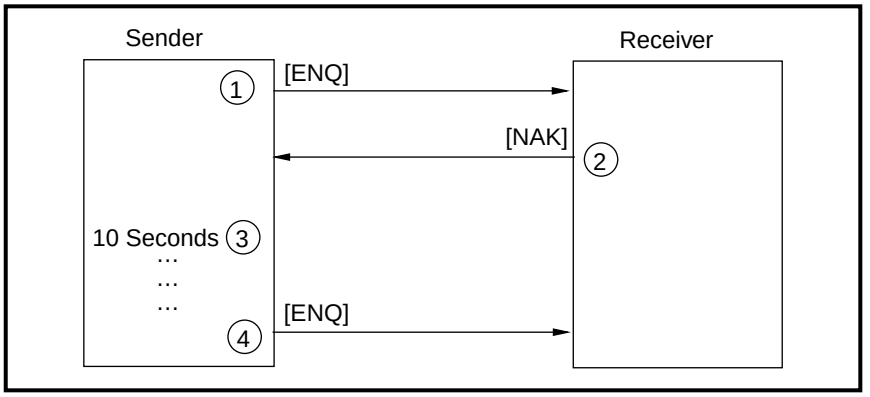


Figure 1.10: Sender Receives an [NAK] Signal. ***If the sender receives an [NAK], the sender waits ten seconds before re-initiating the establishment phase.***

Sending an [ENQ] and Receiving an [ENQ]

When both systems simultaneously send an [ENQ], they are in contention. In that case, the Abbott instrument has first priority to transmit information. For example, the following figure shows a computer and an Abbott instrument simultaneously sending an [ENQ]. The computer must immediately stop trying to transmit and prepare to receive. When the next [ENQ] is received by the computer, the computer replies with an [ACK], or an [NAK], depending on its readiness to receive.

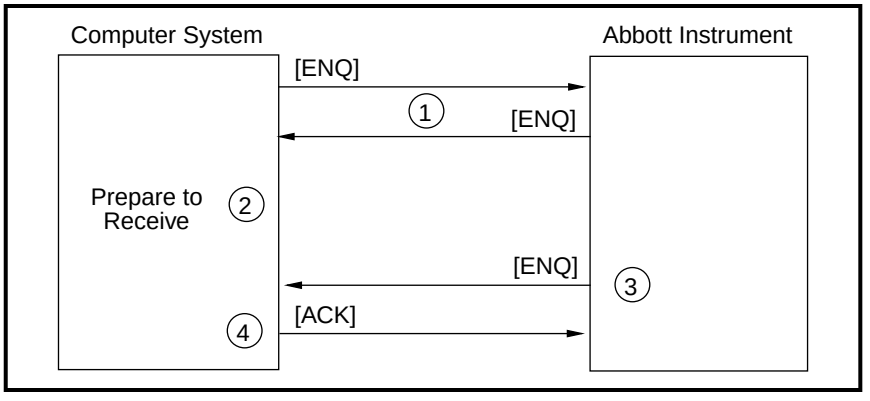


Figure 1.11: Sender Receives an [ENQ] after Sending an [ENQ]. ***The sender prepares to receive.***

In the example shown in the following figure, the instrument sends an [ENQ] and receives an [ENQ]. The instrument waits at least one second before re-sending another [ENQ]. The computer system must wait at least twenty seconds before trying to initiate the communications by sending another [ENQ].

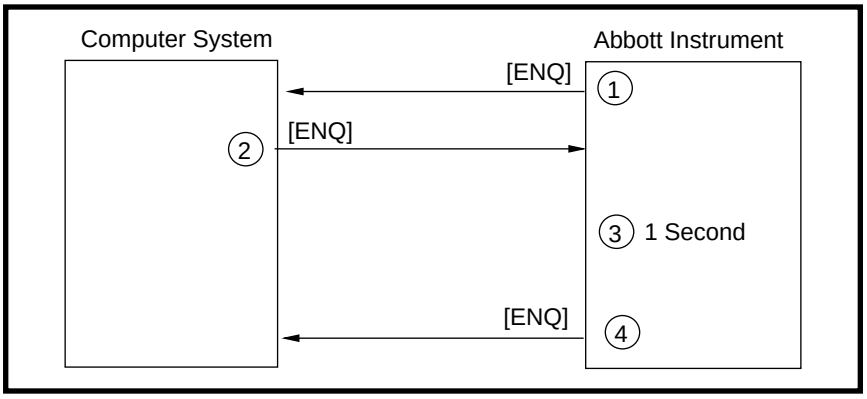


Figure 1.12: Instrument Receives an [ENQ] after Sending an [ENQ]. ***The instrument waits one second before re-sending another [ENQ].***

Transfer Phase

During the transfer phase, the sender transmits messages to the receiver until all messages are sent. Messages are sent in frames which contain a maximum of 247 characters.

Special control characters identify the frame type, the beginning and end of a frame, and provide for error detection. The following table lists the special control characters.

Table 1.3: Special Control Characters

Symbol	Character	Description
[STX]	Start of Text transmission control character	First character transmitted at the beginning of a frame.
F#	Frame Number	The frame number is an ASCII digit from 0 to 7. Its purpose is to permit the receiver to distinguish between new and re-transmitted frames. This single digit is sent immediately after the STX character. The frame number begins with 1 when the transfer phase is initialized and increments by 1 each time a new frame is transmitted and acknowledged. After 7, the frame number returns to 0 and repeats the above sequence.

Table 1.3: Special Control Characters (Continued)

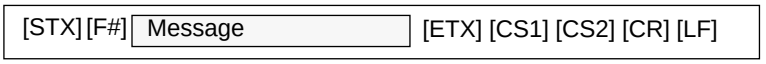
Symbol	Character	Description
[ETB]	End of Transmission Block transmission control character	Character used to indicate end of an intermediate frame.
[ETX]	End of Text transmission control character	Character used to indicate the end of an end frame.
CS1	Most significant character of checksum 0 – 9 and A – F	The checksum determines if a frame is defective. The checksum is encoded as two characters and is sent after the ETB or ETX character. The checksum is computed by adding the binary values of the characters (modulo 256), keeping the least significant 8 bits of the result. The 8 bits can be considered as two groups of 4 bits which are converted to ASCII and represented in hexadecimal format. The two ASCII characters are transmitted as the checksum with the most significant character first. The STX character initializes the checksum to zero. The first character used in computing the checksum is the frame number. The last character used is the ETB or ETX. The STX, CR, or LF are not included. Using the following Frame as an example, the checksum for this frame is calculated. <STX> 1 ABCDEFGHI <ETX> A1 <CR> <LF> <STX> 002 Not included in calculation 1 049 1st character for calculation A 065 2nd B 066 etc. C 067 etc. D 068 etc. E 069 etc. F 070 etc. G 071 etc. H 072 etc. I 073 etc. <ETX> 003 Last character for calculation Total= 673 Total sum value Then 673 (decimal) = 2A1 (HEX) The most significant byte (2) is discarded and the remainder is then transmitted as two characters, “A” (ASCII 55) and “1” (ASCII 49) to form the checksum.
CS2	Least significant character of checksum 0 – 9 and A – F	
[CR]	ASCII character for carriage return	Character used to end an E1394-91 record (i.e., E1381-91 message) and the second to last character transmitted in a frame.
[LF]	ASCII character for line feed	The LF character is used as the last character of a frame. The LF character may not appear in the message text.

Frames

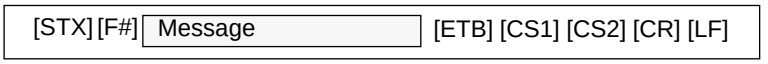
Abbott instruments and systems supporting ASI handle an ASTM E1394-91 record as an ASTM E1381-91 message. If the E1394-91 record is longer than 240 characters, the message is transmitted in multiple frames consisting of end frames and intermediate frames. If the message (i.e., E1394-91 record) is less than or equal to 240 characters, the single frame transmitted is an end frame.

Each new message begins in a new frame. A frame never contains more than one message or parts of more than one message. Two types of frames are used:

- End frames. A message with 240 characters or less is sent in a single end frame.



- Intermediate frames. Messages that are longer than 240 characters are broken into pieces that are 240 characters or less in length and sent in multiple or intermediate frames with the last part of the message sent in an end frame



The following figure shows how a message with more than 240 characters is sent.

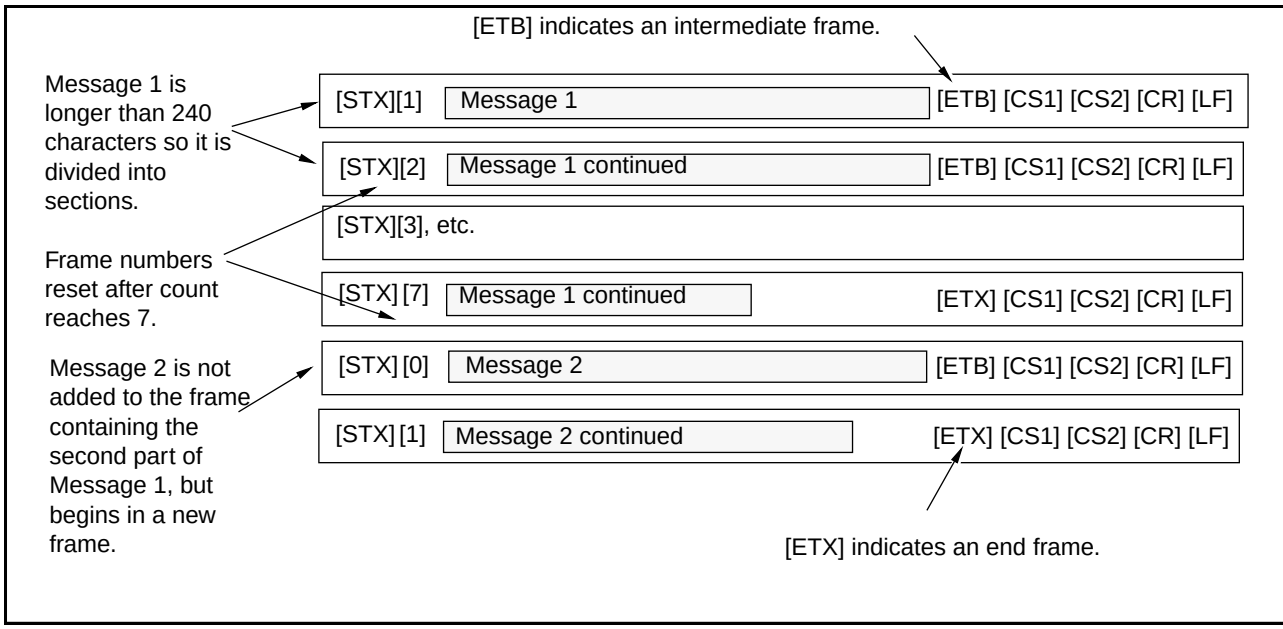


Figure 1.13: Intermediate and End Frames. ***Multiple frame messages start with intermediate frames and end with end frames containing only the end of one message.***

After a frame is sent, the sender stops transmitting and waits for an acknowledgment [ACK] from the receiver. The receiver responds to every frame and when it is ready to receive another frame, it sends one of the following replies:

- Message Acknowledged [ACK]
- Message Not Acknowledged [NAK]
- End of Transmission [EOT]

Each of the replies is discussed below.

A reply of [ACK] acknowledges that the last frame was received successfully and that the receiver is ready for another frame. The sender must increment the frame number and transmit another frame or terminate the message transfer.

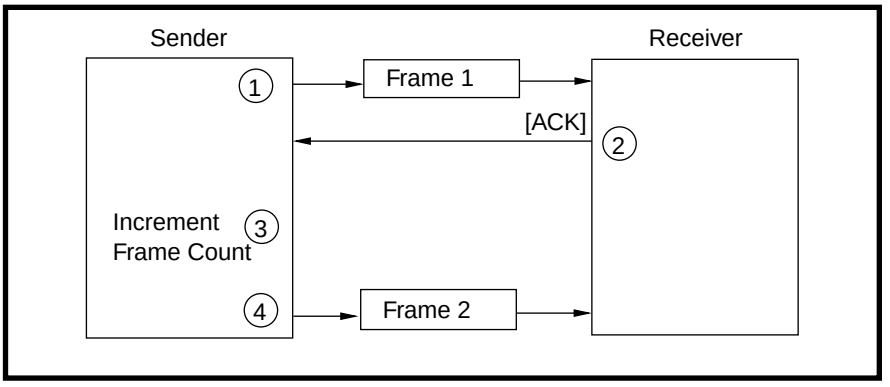


Figure 1.14: Sender Transmitting After Receiving [ACK]. ***The sender sends another frame after successfully transferring a frame.***

A reply of [NAK] means that the last frame was not received successfully and that the receiver is ready to receive the frame again. The sender may re-transmit the frame or proceed to the termination phase.

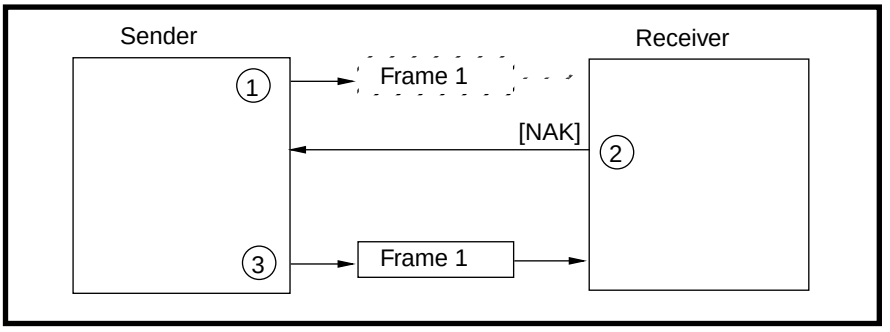


Figure 1.15: Sender Retransmitting a Frame After Transmission Failure. ***The receiver indicates transmission failure with [NAK].***

Abbott ASI instruments and systems [NAK] a frame for the following reasons:

- Improperly framed transmission received after [STX]. Certain situations cause a time-out condition to occur if insufficient information is received to properly process the frame. Under these conditions, ASI instruments return to idle state without transmitting an [NAK] or any other characters.
- Invalid frame number or frame number out of sequence.
- Restricted character received in message text.
- Invalid checksum received.

Characters received before [STX] are ignored. Once [STX] is received, the ASI instrument expects a complete frame.

A reply of [EOT] acknowledges that the last frame was received successfully and that the receiver is ready for another frame, but the receiver is requesting that the sender stop transmitting. The sender must send a reply within the time-out period.

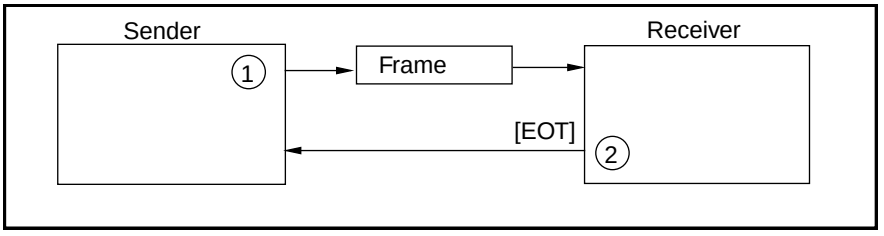


Figure 1.16: End of Transmission. ***The receiver indicates successful receipt of the complete message with an [EOT], but requires an interrupt.***

The sender can ignore the request and continue transmitting. In this case, the receiver must re-request the interrupt for the request to remain valid. Abbott ASI instruments and systems (acting as senders) do not honor the interrupt requests originating from the receiver. Receiving the [EOT] character in place of an [ACK] character is treated equivalent to receiving the [ACK] character. Abbott ASI instruments transmit all available data before entering the termination phase and relinquishing control of the data link (return to neutral state).

Error Handling

When errors in the data transmission occur, both the receiver and sender must have orderly recovery procedures.

The receiver checks every frame for defects. The receiver sends an [NAK] reply if it receives a defective frame. When the sender receives an [NAK], it re-transmits the last frame using the same frame number.

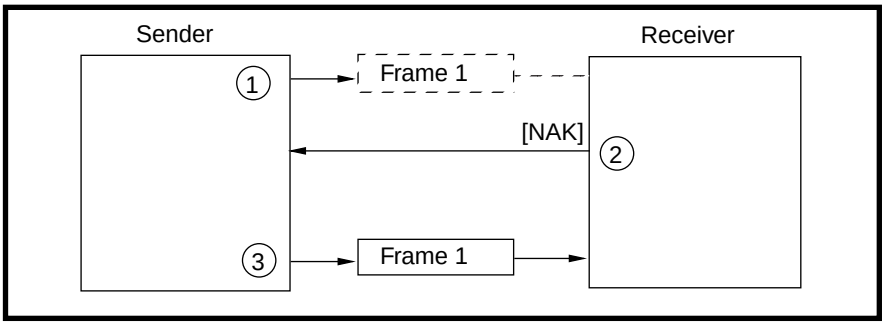


Figure 1.17: Re-sending a Frame After a Transmission Failure. ***The receiver indicates a transmission failure with an [NAK].***

ASI instrument communication software depends on properly framed transmissions being received. If an [STX] is received, it is an indication that a frame is being transmitted. If all of the components of a frame are not received in proper relationship to one another, the frame is rejected.

A frame can be rejected by the receiver for several reasons, including:

- Character structure errors are detected in parity, baud rate, etc., or transmission is improperly framed.
- The frame checksum from the sender does not match the checksum on the receiving end.
- The frame number is incorrect. The number must be the same as the last one rejected or one number higher than the last one accepted by the receiver.

When the sender receives anything other than an [ACK] or an [EOT], it updates a re-transmit counter by one and re-sends the frame. A frame can be re-transmitted a maximum of six times. After that, the sender must abort the message and proceed to the termination phase.

If an [EOT] is encountered by the ASI instruments during the processing of a frame, the instruments return to idle state assuming that the sender terminated transmission prematurely. The sender must re-establish the connection in order to continue.

NOTE: If the [ACK] is corrupted during transmission, the sender of data retransmits the last frame, since any character received other than an [EOT] or [ACK] is treated as a [NAK]. However, since the [ACK] was already transmitted for that frame, the receiver will [NAK] duplicate frames to avoid any possibility of infinite loops. This will lead to Termination Phase after six attempts.

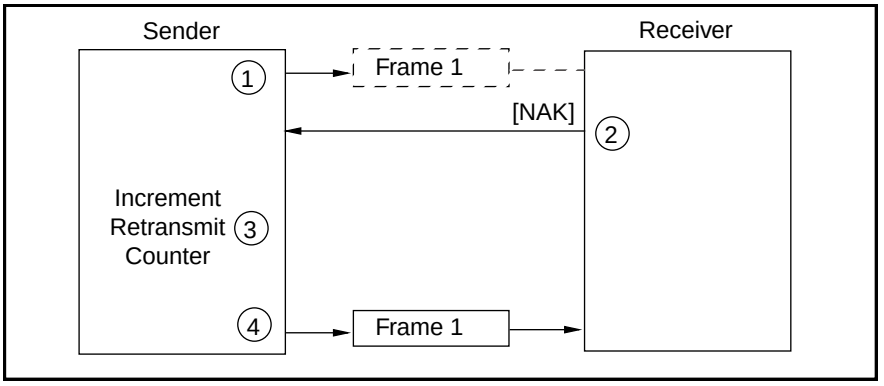


Figure 1.18: Incrementing the Frame Counter. ***The sender keeps track of retransmissions with a frame counter.***

Time-outs

The sender and receiver have timers to control the coordination between them and to allow a recovery method in the event a communication line fails to respond.

- During the establishment phase, the sender sets a timer when sending an [ENQ]. If a reply is not received within 15 seconds, a time-out occurs and the sender proceeds to the termination phase. If the host computer, acting as the receiver, detects contention, it sets a timer. If an [ENQ] is not received from the instrument within 20 seconds, a time-out occurs and the receiver regards the link as being in a neutral state.

- 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 time-out occurs and the sender proceeds to the termination phase. The receiver sets a timer when first entering the transfer phase or when replying to a frame. If no reply is received within 30 seconds, a time-out occurs and the receiver regards the link as being in a neutral state. A time out also occurs if an incomplete frame is received and the timer expires. For example, if ASI instruments do not receive the [CR] [LF] characters at the end of a frame, a time out may occur while the instrument is waiting for the last characters, before processing the frame.

Termination Phase

During the termination phase, the sender transmits the [EOT] transmission control character, notifying the receiver that all of the information has been sent. The sender regards the link to be in a neutral state. After receiving the [EOT], the receiver regards the link to be in a neutral state.

Restricted Message Characters

Certain characters cannot be used in messages. The following table lists characters not allowed in message text.

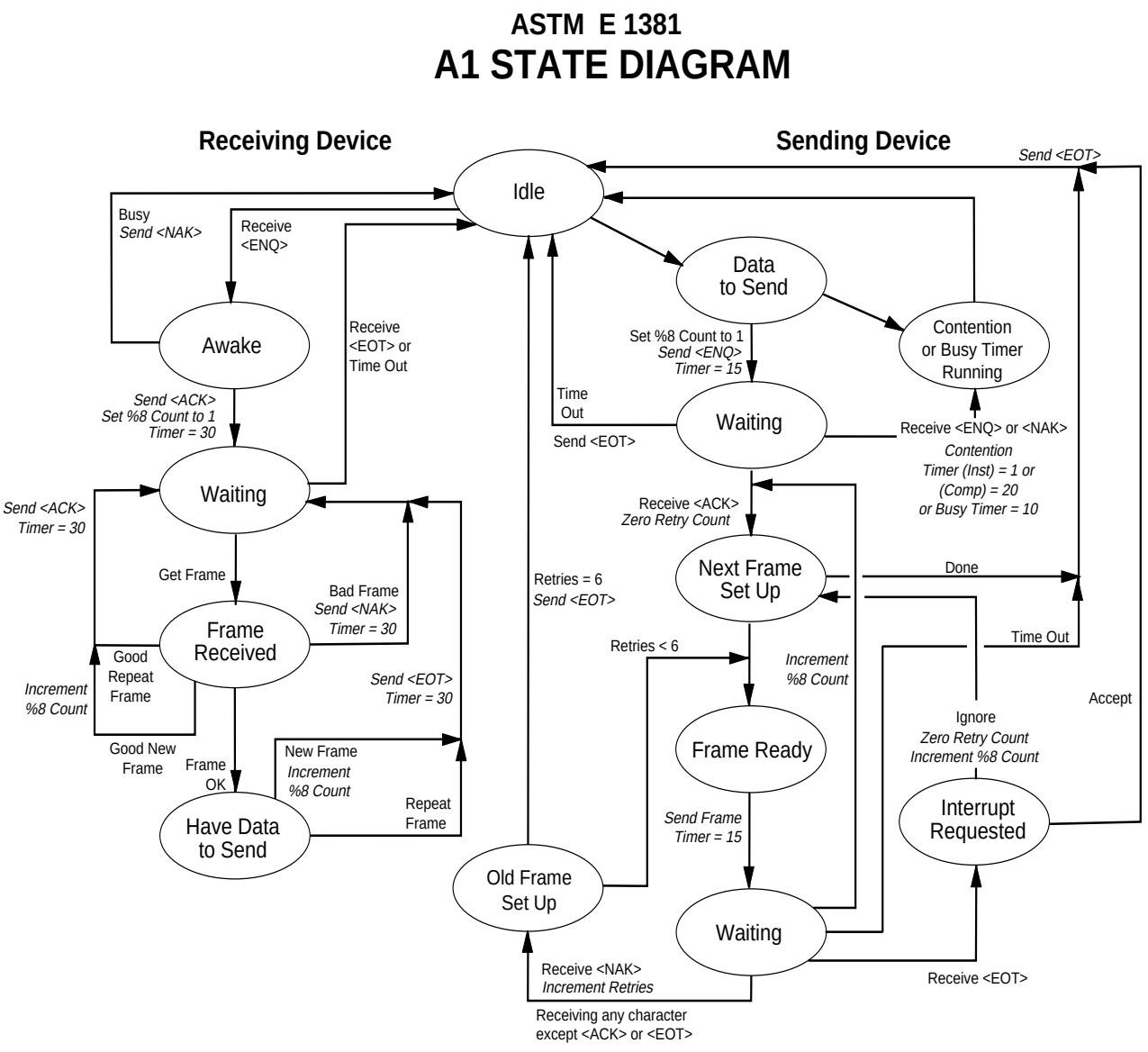
Table 1.4: Restricted Message Characters

Character Symbol	Definition
[SOH]	Start of Header
[STX]	Start of Text Transmission
[ETX]	End of Text Transmission
[EOT]	End of Transmission
[ENQ]	Enquiry
[ACK]	Acknowledge
[DLE]	Data Link Escape
[NAK]	No Acknowledge
[SYN]	Synchronous Idle
[ETB]	End of Transmission Block

Table 1.4: Restricted Message Characters

Character Symbol	Definition
[LF]	Line Feed
[DC1]	Device Control Character 1
[DC2]	Device Control Character 2
[DC3]	Device Control Character 3
[DC4]	Device Control Character 4

ASTM E1381-91 Sender/ Receiver 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.
NOTE 3 – Arrow associated normal text denotes a condition; arrow associated italicized text denotes action taken.

Figure 1.19: Sender/Receiver State Diagram

Table 1.5: ASTM E1381-91 Communication States (for Instrument)

Initial State	Condition	Action	Final State
idle	Have data to send (periodic check) ContentTimer <=0 BusyTimer <=0	send ENQ transTimer = 15	transENQ
	Received ENQ Have Data to Send ContentTimer <=0 BusyTimer <=0	send NAK	Idle
	Received ENQ ContentTimer <=0 BusyTimer <=0	send ACK	rcvWait
	Received ENQ ContentTimer > 0 or BusyTimer > 0	Protocol error	Idle
transENQ	Received ENQ (from Host)	ContentTimer = 1	Idle
	Received NAK	BusyTimer = 10	Idle
	Received ACK	Send Frame numNAK = 0 transTimer = 15	transWait
	Received other characters	Ignore	transENQ
	Received EOT	Ignore	transENQ
	transTimer <=0	Send EOT	Idle
transWait	Received ACK	Send next Frame numNAK = 0 transTimer = 15	transWait
	Received NAK	Send old frame numNAK = numNAK + 1	transWait
	Received EOT	Send next Frame numNAK = 0 transTimer = 15	transWait
	transTimer <=0	Send EOT	Idle
	numNAK = 6	Send EOT	Idle

Table 1.5: ASTM E1381-91 Communication States (for Instrument) (Continued)

Initial State	Condition	Action	Final State
rcvWait	Received Good Frame	send ACK rcvTimer = 30 increment frame #	rcvWait
	Received Bad Frame	send NAK rcvTimer = 30	rcvWait
	Received EOT	discard last incomplete message	idle
	rcvTimer <= 0	discard last incomplete message	idle

Presentation Layer – Message Content

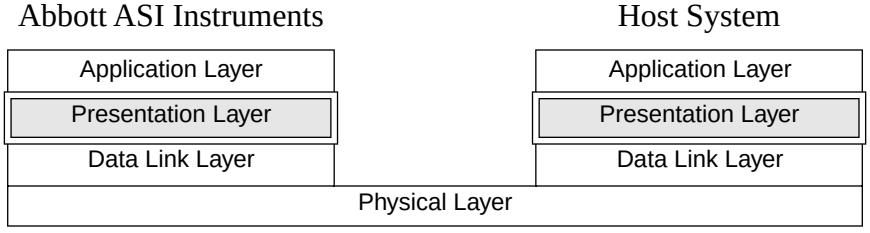


Figure 1.20: Presentation Layer

The Abbott Standard Interface (ASI) uses the protocol defined by ASTM E1394-91 standard as the basis for the message content layer of instrument communications software. This layer specifies the conventions used in structuring information (messages) for transmission to external host systems and for receiving information from these host systems.

Messages

The Presentation Layer requires that transmission and reception of all data must be performed using messages. A message consists of complete study files on one or more patients. Each message is a string of records which in turn are made up of fields. The following figure shows the basic structure of a message.

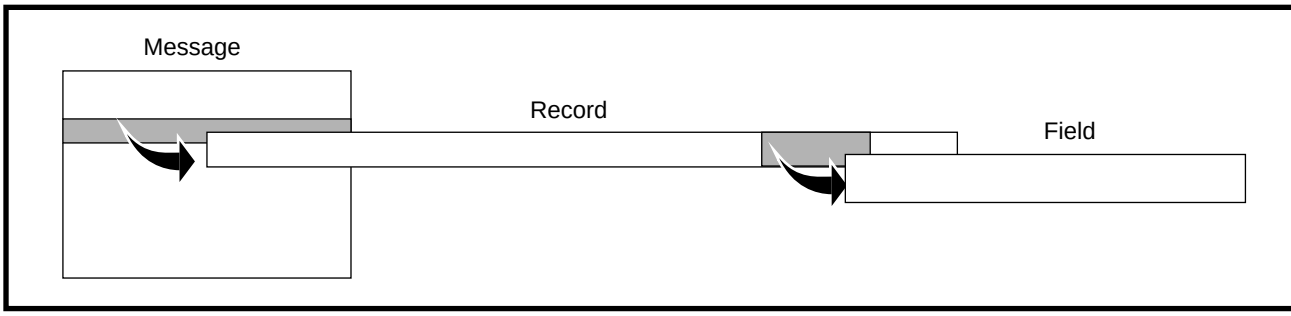


Figure 1.21: Message Logical Structure. ***Messages are subdivided into records which are made up of fields.***

The high-level protocol follows two general conventions:

- A hierarchical convention is implemented where records higher in the hierarchy contain information that is common to all records lower in the hierarchy.
- A positional convention is used to define the structure of the records.

These conventions allow the fields, and thus the records, to vary in length. The ASTM E1394-91 standard allows manufacturers the flexibility to:

- Create new record types through the use of the Manufacturer Record.
- Define the structure of certain existing fields.
- Define the structure of new manufacturer records.

This manual describes how Abbott instruments use this flexibility.

Records

Records are collections of related information within a message. For example, one record may contain information about the system sending the message and the system receiving the message while another record may contain personal information about a patient who is to undergo tests. Records begin with an ASCII alphabetical character, called a *record identifier*, and end with a carriage return. In the following example, the record identifier is “H”, which is used to identify the Header Record.

H	[CR]

Abbott ASI instruments use uppercase letters for all record identifiers transmitted. Abbott ASI instruments can receive upper or lowercase letters for record identifiers. The following table describes the records that Abbott instruments use and their associated record identifier fields.

Table 1.6: Record Types

Record Type	Record ID Field	Level	Description	For Field Contents Refer to ASTM E1394-91, Section
Header	H	0	Identifies the message. Contains information about the sender and receiver of the message, such as location and type of equipment used to send and receive the message.	7
Patient Information	P	1	Contains information about a patient.	8
Request Information (Query)	Q	1	Used to request information on a range of test results or test orders from another system.	12
Test Order	O	2	Contains information defining tests performed or requested.	9
Result	R	3	Contains information about test results.	10
Comment	C	1 - 4	Contains comment text on the preceding record.	11
Manufacturer Information	M	1 - 4	Provided for custom use by the instrument or computer system manufacturer.	15
Scientific	S	N/A	Not used.	14
Message Terminator	L	0	Terminates the message.	13

The records within a message are arranged in a hierarchy of levels. The records higher in the hierarchy contain information that is common to all records that are lower in the hierarchy. The lowest number is the highest in the hierarchy. For example a Level 2 record is higher than a Level 3 record.

- Level 0 records contain information about the sender and receiver of the message. Level 0 records always begin and end the message. Level 0 records include:
  - Header Records (H)
  - Message Terminator Records (L)
- Level 1 records contain information about individual patients or information requests. Level 1 records include:
  - Patient Information Records (P)
  - Request Information/Query Records (Q)
- Level 2 records contain information about test order requests and specimens. Test Order Records (O) are Level 2 records.
- Level 3 records contain information about test results. Result Records (R) are Level 3 records.

Manufacturer's Records and Comment Records may be used within any level except Level 0.

Each level, other than Level 0, must be preceded by a higher level. The following record types can be inserted at any level in the hierarchy and are considered to be one level below the preceding record.

- Comment Records (C) contain comments that refer to the record above it.
- Manufacturer Information Records (M) are used for custom manufacturer information by the manufacturer of the sending and receiving equipment and computer systems.

For example, a Comment Record below a Patient Record at Level 1 is considered a Level 2 record and contains comments about the patient in the Patient Record. A Comment Record below a Test Order Record (O) is considered a Level 3 record and contains comments about tests described in the Test Order Record.

The figure below shows how the Comment and Manufacturer Records fit into a message hierarchy.

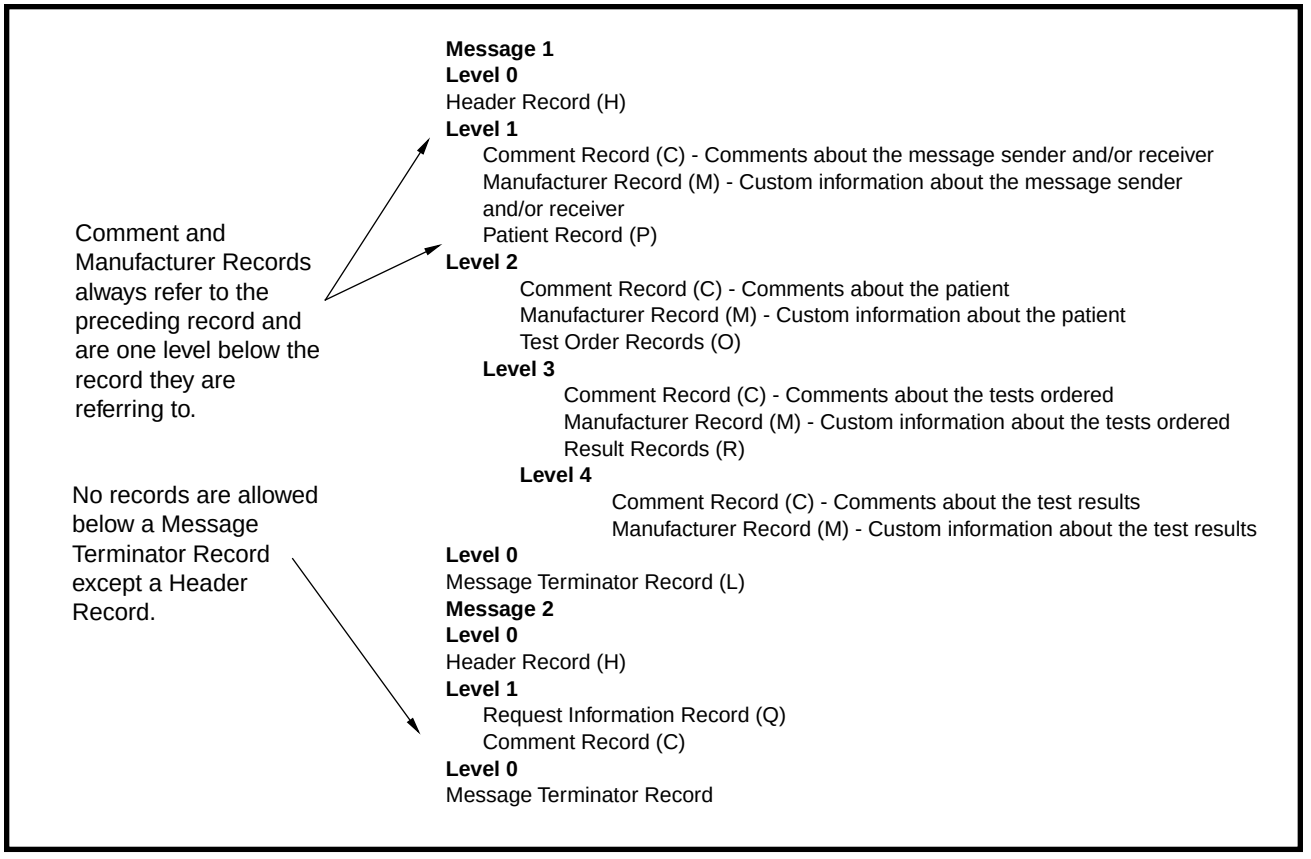


Figure 1.22: Comment and Manufacturer Records. ***These records can be placed anywhere in a message between the Header and Message Terminator Record.***

Abbott ASI instruments may optionally support the use of the Request Information Record (Q). Refer to the instrument specific section of each Abbott Standard Interface RS-232 manual for details on that instrument's support of the Request Information Record.

Abbott ASI instruments do not accept the Request Information Record as part of a message containing Patient (P) and Order (O) Records. Also, ASI instruments do not transmit the Request Information Record as part of a message containing Patient (P), Order (O), and Result (R) Records. When used, the message only includes the following:

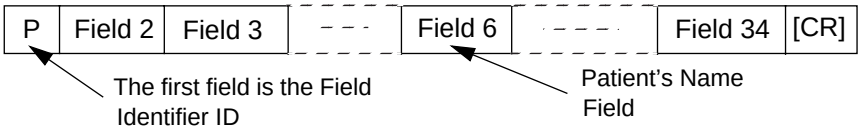
Header Record (H)
Request Information Record (Q)
Terminator Record (L)

Manufacturer and Comment records may be used in conjunction with the Request Information Records, as needed by specific instruments.

ASI instruments and systems may be batch as well as real time. Batch instruments and systems communicate results of a run all at one time, usually at the end of that run. The results message consists of information on multiple samples. Real time systems; however, communicate the information as it becomes available. These systems normally communicate a shorter results message consisting of information on the results of only one sample test (the one that was just completed).

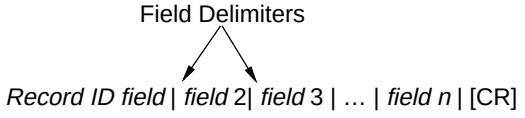
Fields

Fields are groups of characters that define a specific piece of information within a record, such as a patient's name, telephone number, or street address. For example, the patient's name field in the Patient Record is shown below:



Fields are position dependent. That is, fields are identified by their relative position in the record. For example, the field representing a patient's name is always the sixth field in the Patient Record. Fields are all variable length. The Instrument Specific section of the Abbott Standard Interface RS-232 manual provides the maximum allowed length of each field transmitted or received by that instrument.

Delimiters



The ASTM E1394-91 standard allows for the use of special characters to be used to separate:

- Adjacent fields
- Repeating information within a field
- Components of a field

The standard also indicates the use of special characters, such as delimiters, carriage returns, line feeds, etc. imbedded within text fields.

The Abbott Standard Interface defines the delimiters used by Abbott Instruments for transmission to be as follows:

- Field Delimiter..... Vertical Bar (|)
- Repeat Delimiter..... Backslash (\)
- Component Delimiter..... Caret (^)
- Escape Delimiter..... Ampersand (&)

ASI instruments accept any characters defined in the header record and transmitted by the external system as the delimiters for that message. However, ASI instruments ignore the characters received between the escape delimiter defined by the external system. It is the responsibility of the external systems to ensure that the data transmission to Abbott instruments do not include escape characters for the purpose of imbedding delimiters, line feeds, carriage returns, or any other special purpose characters as data.

If a received data field contains a character that conflicts with the ASI defined delimiters (| \ ^ &), ASI instruments and systems will use the Escape Delimiter to return the original data (i.e., conflicting character) back to the external system.

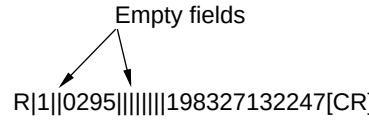
ASI instruments and systems may optionally support the ability to delete contents of specific fields that were previously transmitted by using the ASCII 34 quote character (“) as specified by ASTM E1394-91 standard. Refer to the instrument specific sections to determine if this feature is supported by the instrument or the system.

Field Delimiters

Following is a description of how delimiters work. The record is read one character at a time. When the first field delimiter is read, the instrument knows that it has come to the end of the first field. All characters read after that delimiter are considered to be part of the second field until the second field delimiter is read. When a second field delimiter is read, all characters past that delimiter are considered to be part of the next field until another field delimiter is read. This process continues until the entire record has been read.

Delimiters and Empty Fields

A message can have empty fields. The fields that do not contain information are indicated by two delimiters in a row, as shown below.



If a carriage return is introduced, this indicates that all the remaining fields in the record are empty. A carriage return can also indicate the end of the last field in a record.

Repeat Delimiters

Certain fields may be augmented by the use of repeat delimiters to separate equal elements of the same set. When used, the repeat elements of a field relate to the rest of the record in the same way as if the whole record were replicated, with the only difference being the repeat field.

When only one field is repeating within a record, then the repeat information relates to the rest of the record in a similar fashion as the first.

0|1|Sample#1|^^^Test1\^^^Test2\^^^Test3...[CR]

is equivalent to:

0|1|Sample#1|^^^Test1 . . .

0|2|Sample#1|^^^Test2 . . .

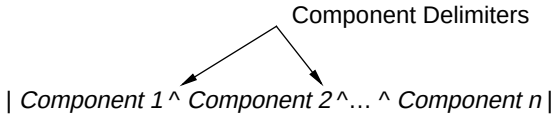
0|3|Sample#1|^^^Test3 . . .

Patient ID fields may never repeat since this would violate the hierarchy of records. Sample ID fields may utilize repeat delimiters to indicate the use of multiple samples required for a test.

ASI instruments do not use repeat delimiters in the primary record fields (i.e., Sample IDs and Universal Test IDs) when returning results. ASI instruments that support repeat delimiters specify the fields that may repeat.

Component Delimiters

Some fields are made of more than one string of characters or components. These strings use carets (^) as delimiters, as shown below:



For example, the Patient Name field uses component delimiters to differentiate between first name, last name, middle name, suffix, and title:

|BLAKE^LINDSEY^ANN^MISS|

The following figure and table summarize the delimiters used by the Abbott instrument.

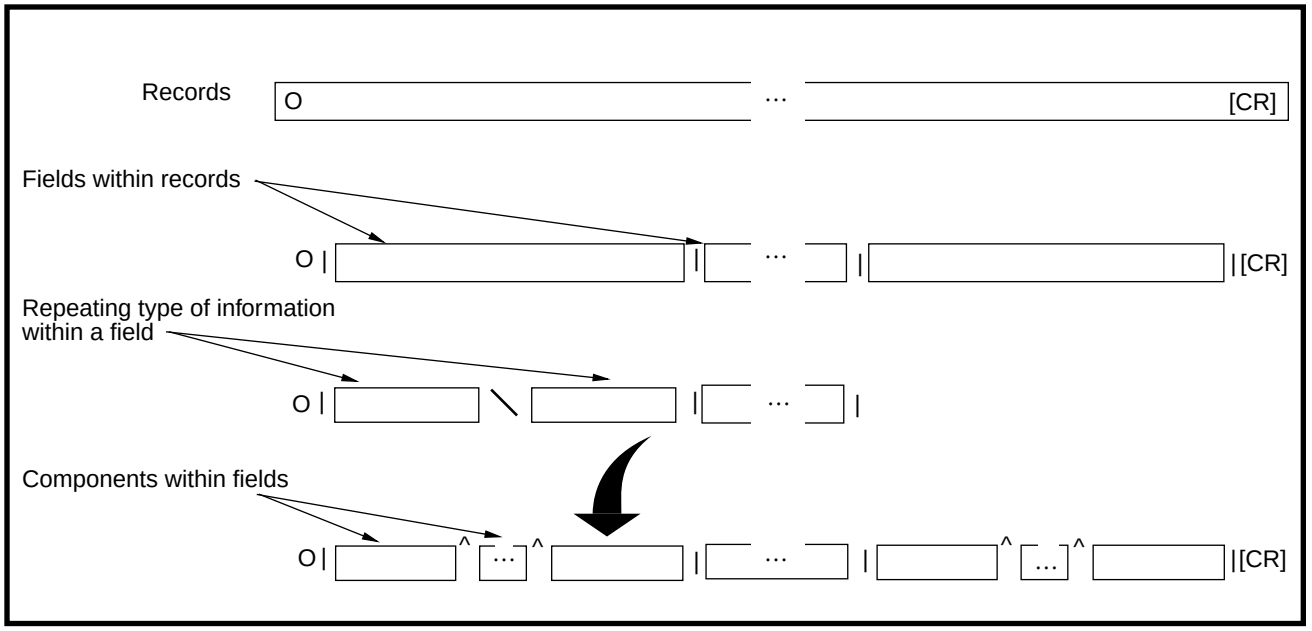


Figure 1.23: **Delimiter Summary.** ***Field delimiters separate fields within records, repeat delimiters separate multiple occurrences of the same type of data within a field, component delimiters separate components within fields.***

Table 1.7: Delimiter Summary

Delimiter Type	Character	Description
Field	|	Separates fields within records.
Repeat	\	Separates multiple occurrences for the same type of information within a field.
Component	^	Separates a field into smaller groups of characters.
Escape	&	Allows imbedding of special characters within the data. Not supported by Abbott ASI instruments.

ASI Defined Fields

The ASTM E1394-91 standard allows each manufacturer the ability to define certain fields based on their needs. The following fields are defined by the Abbott Standard Interface:

- Sender Name or ID (ASTM E1394-91 Field 7.1.5)
- Universal Test ID (ASTM E1394-91 Field 6.6.1)
- Specimen ID (ASTM E1394-91 Field 9.4.3, 9.4.4)
- Patient ID (ASTM E1394-91 Field 8.1.3, 8.1.4, 8.1.5)
- Action Code (ASTM E1394-91 Field 9.4.12)
- Report Type (ASTM E1394-91 Field 9.4.26)
- Date and Time

Sender Name or ID (ASTM E1394-91 Field 7.1.5)

This field is used within the Header Record of the Message to provide a unique identification of the instrument communicating, as well as to provide information on the interface version of the instrument. This field consists of the following four components:

- Instrument/System Name
- Instrument/System Software Version Number
- Instrument/System Serial Number
- Interface Version Control

The Interface Version Control is of the form "XnXn..." (without quotes). The "X" is used to indicate the record types the instrument supports. The "n" is used to indicate the implemented version of that record, and "n" can be any number. The valid characters for "X" are (H, P, O, R, L, C, M, and Q). The S (Scientific) record is not supported by ASI instruments.

Thus, the Interface Version Control string "H1P1O1R1L1" indicates an instrument that supports the header, patient, order, result, and terminator records. Any changes to the interface that would affect a particular record, would increment the version number of that record.

An interface version of "H1P1O2R2Q1L1" would indicate that the interface has changes to the order record, the result record, and the instrument/system is now supporting the query record. This allows host systems to compare the interface version control strings and focus their attention on the records that have changed. The component is optional and may not be supported by all instruments. Refer to the instrument specific section for details.

When all components are supported, this field is transmitted as follows:

|Instrument_name^Software_version^Serial_number^ Interface_version_control|

This field can be used to minimize problems with unplanned field upgrades of interfaced instruments. If host systems support E-mail links to the developers, then this field can be used to inform the interface development team of a potential problem due to a mismatch of interface software between a host and an instrument.

Universal Test ID (ASTM E1394-91 Field 6.6.1)

The Universal Test ID is used as a unique identifier for requesting test orders and for identifying results associated with those orders. This field is used within the following records:

- Test Order Record
- Results Record
- Request Information Record

The Universal Test ID is composed of four major parts. The first three parts are reserved for future ASTM usage and are not used by ASI instruments and systems. As specified by the ASTM Standard E1394-91 (section 6.6.1.4), the fourth part of the Universal Test ID is defined by each manufacturer. ASI instruments use the following components for the manufacturer's code:

- Test or Assay Code
- Test or Assay Name
- Dilution or Neutralization Protocol
- Test Qualifier
- Result Qualifier

When all components of the manufacture's code are used, the Universal Test ID is transmitted as follows:

^^^Test_Code^Test_Name^Dilution^Test_Qualifier^ Result_Qualifier

For downloading orders to instruments or systems, the Test_Code is the only required component of the Universal Test ID. Other components are optional and may be used as needed. The Result_Qualifier component is never downloaded from Host (LIS) systems.

The first three parts are reserved for future use and are not currently used by the Abbott instrument. The valid "Test_Code" and "Test_Name" components for each instrument and system may be obtained by reviewing the Test or Assay Definition files on each instrument. Valid assay protocols such as Dilutions or neutralization protocols are also defined per test or assay code.

Two continuous component delimiters indicate default dilution for that assay. When the Universal Test ID is used in a Result Record, the last component contains a result type code.

Result_Qualifier

The result qualifier is used as the last component of the Universal Test ID field when transmitting results. ASI instruments and systems will use the Result_Qualifier to identify the nature of the result data being communicated. Several codes are defined for use to describe the most common result types returned by Abbott instruments and systems. They are:

Final (F) – Used to identify the calculated values for primary results such as concentrations. The data field contains the actual value of the result. The Units field identifies the units (i.e., type) of the result.

Preliminary (P) – Used to identify the raw instrument readings such as RATES, or POLARIZATIONS, etc. The data field contains the actual value of the result. The units field contains the type of preliminary result.

Interpreted (I) – Used to identify an interpretation such as POSITIVE or NEGATIVE that is based on the ranges defined on the instrument for those interpretations. The data field contains the actual interpretation.

Final Avg. (Favg) – Identifies the average of a set of final results. Returned in cases where multiple repetitions of a test are run for a specific specimen. The data field contains the actual calculated average of the result. The Units field identifies the units of the final result average (e.g., µg/ml, etc.).

Preliminary Avg (Pavg) – Identifies the average of a set of preliminary results. Returned in cases where multiple repetitions of a test are run for a specific specimen. The data field contains the actual calculated average of the preliminary result. The Units field identifies the type of preliminary result average (e.g., RATES, Net Polarization, etc.).

Interpreted Average (Iavg) – Identifies the interpretation associated with the average final result (Favg). The data field contains the actual interpretation such as POSITIVE, NEGATIVE, REACTIVE, etc.

Abbott instruments and systems also communicate other calculated information based on the above result types. For example, it is common for instruments and systems to calculate coefficient of variances, standard deviations, root mean square errors, or curve fit information on final and preliminary results when tests are performed in replicates. In these cases, the result type flag identifies the group of data used (i.e., Final or Preliminary results), the data field contains the actual calculated data, and the units field identifies the type of calculation (i.e., %CV, RMSE, STD, etc.). Refer to instrument specific sections for the complete set of results (i.e., result types) handled by that particular system.

Test_Qualifier

This component may be optionally used to provide a modifier for the test_code. Hematology instruments may use this component to allow an LIS vendor to selectively request only results associated with predefined parameter sets to be returned.

Specimen IDs

ASI instruments and systems use the following definition for specimen ID fields in the Order Record:

- Specimen ID
- Location_ID or Group Number
- Position

The only required component is the Specimen ID. The Location_ID and position are optional components that may be used to:

1. Uniquely identify replicate tests of a sample
2. Match orders and results to previously pipetted samples (specimens)
3. Provide a way to identify specimens processed as a group or batch

When all components are transmitted, the field is as follows:

|specimen ID^location_ID^position|

Patient IDs

The ASTM specification allows for the use of multiple patient IDs that uniquely identify the patient.

The following Patient ID fields are specified for use:

- Practice Patient ID (ASTM E1394-91 Field 8.1.3)
- Laboratory Patient ID (ASTM E1394-91 Field 8.1.4)
- Instrument Patient ID (ASTM E1394-91 Field 8.1.5)

Due to the nature of laboratory instrumentation, it is not possible for all instruments to utilize all three Patient IDs. Therefore, ASI instruments follow these rules for interfacing purposes:

1. The Patient ID communicated by an external host computer must be in the Laboratory Patient ID field (8.1.4). This field will be displayed on the instrument screen as the Patient ID. This ID will be returned unchanged in the same field to the external host computer when the instrument returns results.
2. If the Patient ID is entered at the instrument or changed at the instrument, the new information will be returned to the external host computer in the Instrument Patient ID field (8.1.5). Changes or edits done by an instrument operator to the Patient ID field will not overwrite the previously downloaded Patient ID.
3. Other Patient IDs such as Admission IDs may be communicated in the Practice Patient ID field (8.1.3). These fields may be optionally supported by ASI instruments. Also instruments may optionally allow this ID to be mapped to the Patient ID if no Laboratory Patient ID (8.1.4) is defined.

For example, if an institution uses the social security numbers as patient IDs, but also uses unique admission IDs that are specific to each time the patient receives medical services, then the following would need to be communicated.

```
H|.....<CR>
    P|1|ADMIT1111|SSN123456789||Doe^John|...<CR>
        O|1|SID101||^^^Test1|.....<CR>
        O|2|SID102||^^^Test2|.....<CR>
L|1|N<CR>
```

Figure 1.24: Institution using Laboratory and Practice Patient IDs.

If the instrument supports patient IDs as well as admission IDs then it will assign the following:

Patient ID = SSN123456789 {admission id = ADMIT1111}

Patient name = John Doe

Specimen 1 ID = SID101 Tests Ordered = Test1

Specimen 2 ID = SID102 Tests Ordered = Test2

The admission ID will only be captured if supported by the instrument. If the institution wanted to track laboratory results by the admission ID, the host computer would need to communicate the patient IDs as follows:

```
H|.....<CR>
    P|1||ADMIT1111||Doe^John|...<CR>
        O|1|SID101||^^^Test1|.....<CR>
        O|2|SID102||^^^Test2|.....<CR>
L|1|N<CR>
```

Figure 1.25: Institution using Laboratory Patient ID only.

ASI instruments will then use the following:

Patient ID = ADMIT1111

Patient name = John Doe

Specimen 1 ID = SID101 Tests Ordered = Test1

Specimen 2 ID = SID102 Tests Ordered = Test2

These rules are followed by ASI instruments in order to simplify the interfacing concerns associated with patient IDs.

Action Codes

A test order, for a particular patient, is always identified by the combination of sample ID and test code provided in the order record. The Action Code provides ASI instruments additional information on how to process that test order. Currently the following codes are defined for use:

Cancel (C) – This code is used to cancel a previously transmitted test request (test order). The instrument will search its queue of scheduled test orders and delete the order matching the specimen ID and test code in this order record. The instrument will then return a Test Order Canceled message to the external system with the comment record indicating the reason the order was canceled (i.e., Canceled by Host!) If a match is not found, the instrument ignores this record. If the order is being processed, the instrument ignores this cancel request and returns results upon completion. The instrument may indicate the status by returning the Order record with the flag (I) indicating Instrument Pending.

New (N) – This code is used to indicate a new test order to an instrument. ASI instruments check their queue of scheduled test orders for matching specimen IDs. If no match is found, this order is scheduled for processing. If a match is found, this order is assumed to be a duplicate request and is flagged as an error.

Additional (A) – This code is used to indicate that an additional test of a previously transmitted test order is being requested. ASI instruments check the scheduled test orders for a matching specimen ID. If a match is found, this order is added to the previous order. If a match is not found, this order is created and scheduled for processing.

Quality Control (Q) – This code is used to indicate that this specimen should be treated as a control for the specified test code. The instrument will check the predefined controls of that test code for a matching ID. If a match is found, the order is scheduled for processing. If a match is not found, the order is canceled. A Test Order Canceled message is returned to the Host with the comment record containing the reason for cancellation.

Report Type

The report type flag identifies the purpose of the patient/order or patient/order/result transmission. Refer to the instrument specific section to identify what each instrument supports. The allowed flags and usage of these flags are as follows:

Order (O) – Used to indicate a normal Patient/Order request from a host.

Final Report (F) – Used to indicate a normal report of results (Patient/Order/Results) to a host system.

Query (Q) – Used to indicate that the Patient/Order or Patient/Order/Result transmission is in response to a request for information or Query record. This is the case where an instrument or system had made a request for patient orders or final results.

Canceled (X) – Used to indicate that no results will be forthcoming for this order. This code may be used to indicate that an instrument error occurred while processing that order and the instrument will not be transmitting any results. An ASI instrument or system may return a comment record containing the reason for this condition.

Instrument Pending (I) – Used to indicate that results are not available for the order (specimen/test) identified in this order record. This flag is used to respond to a query for results when the results are not yet available. This flag also indicates that the order (specimen and test) are valid and known to the responding system. It may also be used in response to a test order cancel request.

No Such Test Ordered (Y) – Used in response to a query for results on a specific test for a specimen. If the ASI instrument or system supports the ability to query by specific test for a specimen, that instrument or system uses this flag to indicate that the test has not been ordered.

Date and Time

Dates are represented in the following format, as required by ANSI X3.30:

YYYYMMDD

Where:

- YYYY is the year
- MM is the month
- DD is the day

For example, May 14, 1960, would be represented as 19600514.

Time is represented in the following format, as required by ANSI X3.43.9:

HHMMSS

Where:

- HH is the hour
- MM is the minute
- SS is the second

Date and time together are specified as a fourteen character string:

YYYYMMDDHHMMSS

Abbott ASI instruments do not support time zone designations in the date and time fields. The sender is responsible for insuring that all dates and times transmitted are of the form specified above.

Record Sequence Number

The second field in all record types, other than the Header and Message Terminator Records, contains a Record Sequence Number field.

The field contains a number that indicates how many times the same record type is used at a particular hierarchical level. The number is reset to one under the following conditions:

- Whenever a record of greater hierarchical significance (lower number) is transmitted.
- If the same record is used at a different hierarchical level.

An example of the numbering scheme follows.

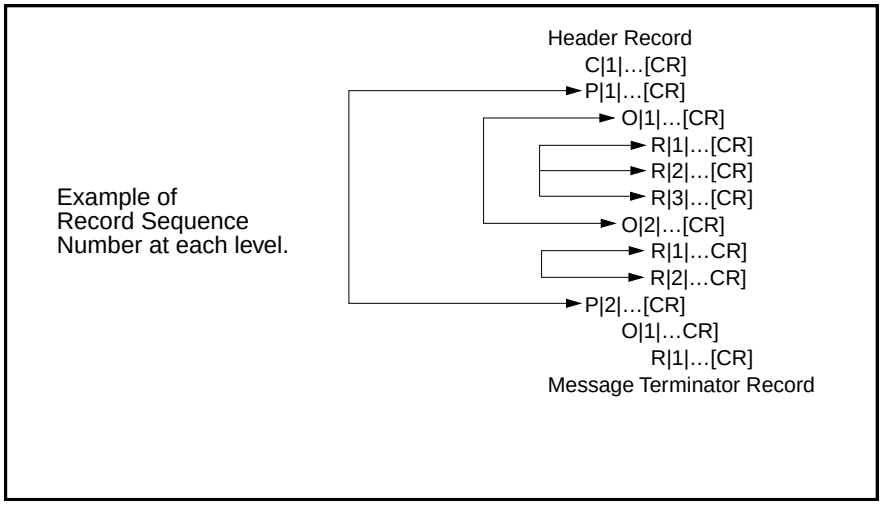


Figure 1.26: Record Sequence Numbers. ***Record Sequence Numbers keep track of the number of records of the same type and at the same hierarchical level.***

NOTE: When the high level messages are parsed, ASI instruments will check for proper sequencing as defined by the ASTM standards. If a record is encountered with an invalid sequence, an error will be logged locally and the remainder of the message will be ignored. Records that were parsed prior to the sequencing error will be accepted and processed further. An error code will not be transmitted to the external system, indicating that the sequencing error occurred.

Records and Fields

The ASI defines the rules of use for fields supported by different instruments and systems. The length of the fields is always assumed to be of variable length. The data type associated with a field is specified by individual instruments and systems. At this time, ASI does not determine the data type for a field (i.e., numeric vs. alphanumeric vs. extended character, etc.). However, as a general rule, fields are assumed to be variable length and character, unless explicitly defined differently by a specific instrument.

Instruments and systems may support a subset of the records and fields defined by ASI. If a defined record or field is communicated to an instrument and that instrument does not support that record or field, the instrument will ignore it. If, however, records not defined by ASI are received by an instrument, that instrument will log an error and not process that message.

Certain key fields are identified as required fields if supported by an instrument. These fields are:

- Patient ID field
- Specimen ID field
- Test Code component of Universal Test ID
- Action Code field

The following tables define the location and contents of each field in a specific type of record. The records and corresponding tables are as follows:

- Table 1.8: *Message Header Record*
- Table 1.9: *Patient Record*
- Table 1.10: *Order Record*
- Table 1.11: *Result Records*
- Table 1.12: *Comment Record*
- Table 1.13: *Request Information Record*
- Table 1.14: *Terminator Record*
- Table 1.15: *Manufacturer's Record*

Table 1.8: Message Header Record

ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
7.1.1	Record Type	H	H	ASI instruments transmit upper case characters, receive upper or lower case.
7.1.2	Delimiters			ASI instruments accept any valid delimiters specified in the header record.
	Field	|		
	Repeat	\	*	
	Component	^		
	Escape	&		Escape delimiter is not supported for use within records.
7.1.3	Message Control ID			Not supported

** Indicates supported field. Refer to instrument sections for size of supported fields.*

Table 1.8: Message Header Record (Continued)

ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
7.1.4	Access Password			Not supported
7.1.5	Sender Name or ID	*	*	This field is made up of the following four (4) components. When transmitting, ASI instruments send their name, software version, and serial number and may also send the interface version control string specified in the fourth component of the field. Upon receiving, ASI instruments and systems treat this field as a single string in this field.
	Name	*		Name of instrument.
	^Software version	*		Version of system software.
	^Serial Number	*		Serial number of instrument or system.
	^Interface version	(XnXn.....)		ASI instruments may use this field to implement an interface version control scheme that indicates the record type and version of the record supported by the instrument. “X” is the record type and “n” is the version number. The possible characters for “X” are (H, P, O, R, L, Q, C, M). See the instrument specific section for handling this field.
7.1.6	Sender Address			Not supported
7.1.7	Reserved			Not supported
7.1.8	Sender Telephone			Not supported
7.1.9	Characteristics of Sender			Not supported
7.1.10	Receiver ID			Not supported for serial (point-to-point) connections.
	Host_Name ^IP_Address	*	*	Network implementations use this field to contain the name and network address (TCP/IP address) of the Host (LIS) system. The structure of this field is Host_ name^IP_ address.
7.1.11	Comment			Not supported

** Indicates supported field. Refer to instrument sections for size of supported fields.*

Table 1.8: Message Header Record (Continued)

ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
7.1.12	Processing ID	P	P	(P)roduction – Treat message as an active message to be completed according to standard processing. If the field is blank, this is the default.
		D	D	(D)ebugging – Message is initiated for the purpose of testing the interface. ASI instruments may use this flag to provide transfer of messages for diagnostic purposes. The diagnostic message consists of at least one record of each type transmitted by the instrument or system. The transmission of this type of message is under operator control and is part of the diagnostics of the instrument/system. Instruments may optionally receive (D)iagnostic messages consisting of header, patient, and order records.
		Q		(Q)uality Control. Message contains only quality control information. See Instrument specific section for information on how this field is handled.
7.1.13	Version Number	1	1	See the instrument specific section for handling this field.
7.1.14	Date and Time	YYYYMMDD HH MMSS	YYYYMMDD HHMMSS	See the instrument specific section for handling this field. This field contains the message transmission time and date.
** Indicates supported field. Refer to instrument sections for size of supported fields.*				

Table 1.9: Patient Record

ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
8.1.1	Record Type	P	P	ASI instruments receive upper or lower case characters.
8.1.2	Sequence Number	*	*	Sequential number starting with one (1) and continuing until the last patient in the message.
8.1.3	Practice PID	*	*	ASI instruments accept the Practice PID if it is transmitted by the Host and return it, if unchanged, to the Host. Otherwise this field is not used.
8.1.4	Laboratory PID	*	*	ASI instruments accept the Laboratory PID transmitted by the Host and return it unchanged to the Host. This field is the recommended field for an LIS to communicate Patient IDs to an instrument.
** Indicates supported field. Refer to instrument sections for size of supported fields.*				

Table 1.9: Patient Record (Continued)

ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
8.1.5	Instrument PID	*	*	ASI instruments may ignore any PID downloaded in this field. This field is used by the instrument or system to communicate a patient ID entered by the Lab operator or read by the instrument, to a Host (LIS).
8.1.6	Patient Name	*	*	ASI instruments may optionally handle this field. When used, this field has the following components: Last_name, First_name, Middle_initial, suffix (Jr.,Sr., etc.), and title (Mr., Mrs., Ms., etc.). See the instrument specific section for handling this field.
8.1.7	Mother's Maiden Name	*	*	ASI instruments may optionally handle this field. See the instrument specific section for handling this field.
8.1.8	Birthdate	*	*	ASI instruments may optionally handle this field. See the instrument specific section for handling this field.
8.1.9	Patient Sex	M F U	M F U	ASI instruments may optionally handle this field. When used, this field has the following flags: (M)ale (F)emale (U)nknown See the instrument specific section for handling this field.
8.1.10	Patient Race – Ethnic Origin	*	*	ASI instruments may optionally handle this field. See the instrument specific section for handling this field.
8.1.11	Patient Address	*	*	ASI instruments may optionally handle this field. See the instrument specific section for handling this field.
8.1.12	Reserved			Not supported
8.1.13	Patient Phone	*	*	ASI instruments may optionally handle this field. See the instrument specific section for handling this field.
8.1.14	Attending Physician	*	*	ASI instruments may optionally handle this field. See the instrument specific section for handling this field.
8.1.15	Special Field 1			Not supported
8.1.16	Special Field 2			Not supported

** Indicates supported field. Refer to instrument sections for size of supported fields.*

Table 1.9: Patient Record (Continued)

ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
8.1.17	Patient Height	*	*	ASI instruments may optionally handle this field. See the instrument specific section for handling this field.
8.1.18	Patient Weight	*	*	ASI instruments may optionally handle this field. See the instrument specific section for handling this field.
8.1.19	Patient Diagnosis			
	Code	*	*	Identifies the ICD-9 code for the diagnosis.
	^Description	*	*	Text description for the code. Both components are optional and are provided as known. Multiple diagnosis may be communicated via the use of repeat delimiters. Refer to instrument specific section for support of this field and support of repeat delimiters within this field.
8.1.20	Patient Medications			
	Name	*	*	Identifies the therapy name or generic drug name (e.g., Aspirin).
	^Level	*	*	Identifies the amount or dosage of drug or therapy as well as the frequency (e.g., 2 tablets every 4 hours).
	^Start_Date	*	*	Refers to the beginning date of the therapy or medication.
	^End_Date	*	*	Refers to the stop date of the therapy or medication. Multiple Medications may be communicated via the use of repeat delimiters. Refer to instrument specific section for support of this field and support of repeat delimiters within this field.
8.1.21	Patient Diet	*	*	ASI instruments may optionally handle this field. See the instrument specific section for handling this field.
8.1.22	Practice Field 1			Not supported
8.1.23	Practice Field 2			Not supported
8.1.24	Admission or Discharge Dates	*	*	ASI instruments may optionally handle this field. See the instrument specific section for handling this field.

** Indicates supported field. Refer to instrument sections for size of supported fields.*

Table 1.9: Patient Record (Continued)

ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
8.1.25	Admission Status	*	*	ASI instruments may optionally handle this field. See the instrument specific section for handling this field.
8.1.26	Location	*	*	ASI instruments may optionally handle this field. See the instrument specific section for handling this field.
8.1.27	Nature of Diagnostic Codes			Not supported
8.1.28	Alternative Diagnostic Codes			Not supported
8.1.29	Patient Religion			Not supported
8.1.30	Marital Status			Not supported
8.1.31	Isolation Status	*	*	ASI instruments may optionally handle this field. See the instrument specific section for handling this field.
8.1.32	Language			Not supported
8.1.33	Hospital Service			Not supported
8.1.34	Hospital Institution	*	*	Name of hospital or lab.
8.1.35	Dosage Category	*	*	Hematology instruments may use this field to communicate Limit Set Information relating to the category the patient/sample should be analyzed against. See instrument specific section for the structure of this field. ASI instruments may optionally handle this field. See the instrument specific section for handling this field.
** Indicates supported field. Refer to instrument sections for size of supported fields.*				

Table 1.10: Order Record

ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
9.4.1	Record Type	O	O	ASI instruments receive upper- or lowercase characters.
9.4.2	Sequence Number	*	*	Sequential number starting with one (1) and continuing until the last patient in the message.
** Indicates supported field. Refer to instrument sections for size of supported fields.*				

Table 1.10: Order Record (Continued)

ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
9.4.3	Specimen ID field			ASI Instruments accept the Specimen ID received in this field and return it unchanged to the Host (LIS) when transmitting.
	Specimen ID	*	*	
	^location ID	*	*	The Location Information (location_ID^position) components may be used to uniquely identify replicates of a single sample. This component is optional when downloading orders to ASI instruments and systems.
	^position	*	*	ASI instruments may optionally accept the location ID and position information. (Recommended for batch systems.)
9.4.4	Instrument SID field			ASI Instruments ignore the contents in this field when receiving information. This field is used by the instrument or system to communicate a specimen ID entered by the lab operator, or read by the instrument to a Host (LIS).
	Specimen_ID	*		
	^location_ID	*		The Location Information (location_ID^position) components may be used to uniquely identify replicates of a single sample.
	^position	*		
9.4.5	Universal Test ID			As defined by ASTM 1394-91 section 6.6.1.4. The manufacturer's local code is made up of five (5) component fields as defined below. ASI instruments handle repeat delimiters in this field.
	^^^Assay_code Assay_name	*	*	The Test Information (Assay_code^Assay_name) is used to uniquely identify the test or tests to be done on the specimen.
	^Assay protocol	*	*	Dilution or neutralization protocols defined per assay code. See the instrument specific section for applicable assay protocols.
	^Test Qualifier	*	*	Optional qualifier for test code. See the instrument specific section for handling this field.
	^Result Qualifier	*	*	Not applicable on Order Records.
9.4.6	Priority	S R	S R	(S)tat (R)outine – default value See the instrument specific section for handling this field.

** Indicates supported field. Refer to instrument sections for size of supported fields.*

Table 1.10: Order Record (Continued)

ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
9.4.7	Requested Date and Time	*	*	See the instrument specific section for handling this field.
9.4.8	Collection Date and Time	*	*	Date and time of sample collection. See the instrument specific section for handling this field.
9.4.9	Collection End Time			Not supported
9.4.10	Collection Volume			Not supported
9.4.11	Collector ID	*	*	See the instrument specific section for handling this field.
9.4.12	Action Code		C	(C)ancel – Used to cancel a previously downloaded Test Order.
			A	(A)dd – Used to add a test to a known specimen.
			N	(N)ew – Used to identify new Test Orders for an unknown specimen. If the specimen is known by the instrument/system, this message is ignored as a duplicate transmission.
		Q	Q	(Q)uality Control Specimen See the instrument specific section for handling this field.
9.4.13	Danger Code	*	*	See the instrument specific section for handling this field.
9.4.14	Relevant Clinical Info	*	*	See the instrument specific section for handling this field.
9.4.15	Date/Time Specimen Received	*	*	Date and Time specimen received in the Lab. See the instrument specific section for handling this field.
9.4.16	Specimen Descriptor Specimen Type ^Specimen Source	* *	* *	See the instrument specific section for handling this field.
9.4.17	Ordering Physician	*	*	See the instrument specific section for handling this field.
9.4.18	Physician's Phone	*	*	See the instrument specific section for handling this field.
9.4.19	User Field No. 1	*	*	See the instrument specific section for handling this field.
9.4.20	User Field No. 2	*	*	See the instrument specific section for handling this field.

** Indicates supported field. Refer to instrument sections for size of supported fields.*

Table 1.10: Order Record (Continued)

ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
9.4.21	Lab Field No. 1			Not supported
9.4.22	Lab Field No. 2			Not supported
9.4.23	Date/Time Reported			Not supported
9.4.24	Instrument Charge			Not supported
9.4.25	Instrument Section	*	*	Abbott Data Management systems use this field to assign test instruments.
9.4.26	Report Type		O	(O)rder – Normal request from Host.
		F		(F)inal Results – Returned with result records.
		X		(X) – Request cannot be done—Canceled. ASI Instruments return a Comment Record containing the specific reason why a request cannot be done.
		I		(I)nstrument Pending (in response to query).
		Y	Y	(Y) – No such order (in response to query).
		Z	Z	(Z) – No such patient and or Specimen (in response to query).
		Q	Q	(Q)uery response – Indicates that this order record and all associated information are being sent in response to a query.
9.4.27	Reserved Field			Not supported
9.4.28	Location or Ward for Collection	*	*	See the instrument specific section for handling this field.
9.4.29	Nosocomial Infection Flag			Not supported
9.4.30	Specimen Service			Not supported
9.4.31	Specimen Institution			Not supported

** Indicates supported field. Refer to instrument sections for size of supported fields.*

Table 1.11: Result Records

ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
10.1.1	Record Type	R		Result records are never accepted from an LIS or Host system. ASI instruments and systems use separate result records for replicates, averages of replicates, intermediate, final, and interpreted results.
10.1.2	Sequence Number	*		Sequential number starting with one.
10.1.3	Universal Test ID			The manufacturer's local code is made up of five (5) component fields as defined below. ASI instruments do not use repeat delimiters in this field.
	^^^Assay_code ^Assay_name	*		The Test Information (Assay_code^Assay_name) component is used to uniquely identify the test or tests done on the specimen.
	^Assay_protocol	*		Dilution or neutralization protocols defined per assay code. See the instrument specific section for applicable assay protocols.
	^Test Qualifier	*		Further qualification of the test or assay code.
	^Result type	F		(F)inal –Indicates final calculated values of concentrations, etc.
		I		(I)nterpreted –Indicates interpretations of final results based on user-defined criteria.
		P		(P)reliminary – Indicates raw instrument readings such as the RATE.
		Favg		Identifies the average of a set of final results.
		Pavg		Identifies the average of a set of preliminary results.
		Iavg		Identifies the interpretation associated with the average final result.
				See the instrument specific section for handling this field.
10.1.4	Data/Measurement	*		See the instrument specific section for handling this field.
10.1.5	Units	*		See the instrument specific section for handling this field.

** Indicates supported field. Refer to instrument sections for size of supported fields.*

Table 1.11: Result Records (Continued)

ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
10.1.6	Reference Ranges			This field is used to communicate the laboratory-defined ranges for this assay. It is composed of two components separated by the component delimiter (^).
	Range	*		Multiple ranges may be communicated using repeat delimiters. The range is of the form, value to value. See the instrument specific section for specific ranges communicated.
	^Description	*		Label assigned by the laboratory to the preceding range. See the instrument specific section for handling this field.
10.1.7	Result Abnormal Flags	L		(L)ess than normal range
		H		(H)igher than normal range
		LL		(LL) – Less than extreme range
		HH		(HH) – Higher than extreme range
		QC		(QC) – Result based on a QC out of range
		>		(>) – Above dynamic range of assay
		<		(<) – Below dynamic range of assay
		EX		(EX) - Result based on expired reagent. Additional abnormal flags may be defined as needed by instruments.
10.1.8	Nature of Abnormality	*		See the instrument specific section for handling this field.
10.1.9	Result Status	F		(F)inal Results – Used to indicate initial transmission of results.
		R		(R)epeat – Used to indicate previously transmitted results.
		X		(X) – Test cannot be completed. Used to indicate error during processing.
10.1.10	Date of Change in Instrument Values	*		This field may be used to indicate the date of the last calibration of an instrument.

** Indicates supported field. Refer to instrument sections for size of supported fields.*

Table 1.11: Result Records (Continued)

ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
10.1.11	Operator IDs			
	operator	*		(operator) – When used, this field contains the ID or name of the operator who performed the test.
	^approver	*		(approver) – When used, this field contains the ID or name of the operator who approved the test results. See the instrument specific section for handling this field.
10.1.12	Date/Time Test Started	*		See the instrument specific section for handling this field.
10.1.13	Date/Time Test Completed	*		See the instrument specific section for handling this field.
10.1.14	Instrument ID	*		Used by Abbott Data Management Systems to indicate the source of results. When used, this field contains the serial number or a unique identifier for each instrument returning results.
		MANUALLY ENTERED		If results are manually entered, this field contains the string MANUALLY ENTERED, and the Operator Id (10.1.11) contains the ID or name of the person entering the results.

** Indicates supported field. Refer to instrument sections for size of supported fields.*

Table 1.12: Comment Record

ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
11.1.1	Record Type	C		Comment records are never accepted from an LIS or Host system.
11.1.2	Sequence Number	*		Sequential number starting with one.
11.1.3	Comment Source	I		(I)nstrument
		D		(D)ata Management Systems
11.1.4	Comment Text	*		As described by each instrument.
11.1.5	Comment Type	G		(G)eneric free form comments entered by the lab operator.
		I		(I)nstrument generated exception string.

** Indicates supported field. Refer to instrument sections for size of supported fields.*

Request Information Record

The Request Information Record allows one system to request specific information from another. Each system may request patient demographics and patient/test orders and results. Instruments and systems may request results that were previously transmitted in order to use the information in their analysis of current samples or tests, or to provide time-based comparisons (or tracking) for test results relating to a patient. The request status code (12.1.13) identifies the purpose of the request.

Refer to the instrument specific sections to identify which type of request of those defined below are supported by that specific instrument and system. The allowed requests for information may be made based on the following types of data:

Patient IDs – Requests can be made based on single patient IDs or a range of patient IDs. The "ALL" qualifier may be used to request information on all the patient IDs known by this system. This qualifier is not recommended for common use since it returns all of the relevant information stored in the receiving systems database. Ranges of patient IDs may be requested by providing the starting patient ID (12.1.3) and the ending patient ID (12.1.4). Repeat delimiters may not be used to indicate multiple patient IDs or ranges.

Specimen IDs – Requests can be made based on specimen IDs or a range of specimen IDs. The "ALL" qualifier may be used to request information on all the specimen IDs known by this system. This qualifier is not recommended for common use since it returns all the relevant information stored in the receiving systems database. Ranges of specimen IDs may be requested by providing the starting specimen ID (12.1.3) and the ending specimen ID (12.1.4). The specimen ID is the second component in these fields. If the request is made based on the specimen ID only, it would be transmitted as "|^specimen_ID|". If the request is made based on patient ID and Specimen ID, it would be transmitted as "|patient_ID^Specimen_ID|". Repeat delimiters may not be used to indicate multiple specimen IDs or ranges.

Test Code – Requests can be made based on the test code.

Date/Time – Requests can also be made based on a specific date and/or time, or a range of date/time. For a single date/time, only field 12.1.7 should be used. If a time is not specified, the entire day is assumed for that date. Field 12.1.6 specifies what type of time and date is being requested.

Ranges – A range may be specified by utilizing the Starting Range (12.1.3) and Ending Range (12.1.4) fields for patient IDs or specimen IDs. The range is interpreted using ASCII byte ordering (numbers before all alphabetic letters and upper case letters before lower case letters) to identify the matched IDs that fall between the starting and ending values. For example, using the following data set:

{Abcd, abcd, ABcd, AB123, aBcd, 12ab, 12bb}

The sort of this data (in ascending order) will generate the following order:

{12ab, 12bb, AB123, ABcd, Abcd, aBcd, abcd}

Therefore, if the range had been specified as **12ab** and **abcd** the data associated with all the IDs above would be returned. Some systems may support only upper case letters (or assign equivalent values to upper and lower case letters). A system that treats upper and lower case as equivalent would treat {ABcd, Abcd, aBcd, abcd} as equivalent IDs.

NOTE: Each condition specified in the Request Information Record narrows the request further. The request will return records with information matching all the conditions specified (logical AND operation).

NOTE: ASI instruments and systems may not honor the request that uses only the “ALL” qualifiers for patient and sample IDs together. ASI instruments and systems will not generate queries using the “ALL” qualifier for patient and sample IDs together (i.e., no queries for information on ALL samples of ALL patients).

Nature of Request Time Limits (12.1.6)

Since an instrument or system may track the date and time of several events, ASI instruments and systems will use this field to identify against which date and time an information request is made. Refer to the instrument specific sections to identify which of the defined flags are supported by each instrument. The currently allowed values for this field are:

Specimen Collection Date/Time (S) – Identifies the date and time a specimen was collected. Relates to field 9.4.9 (Collection End Time) of the Order Record.

Order Request Date/Time (O) – Identifies the date and time the order (specimen/test) was requested for processing. Relates to field 9.4.7 (Request Date/Time) of the Order Record. If no specific information is provided in the Request Date/Time field (field 9.4.7) then the date and time the order message was received is used as the Request Date/Time for this order.

Result Date/Time (R) – Identifies the date and time that a test was completed (i.e., result was generated).

Request Status Codes (12.1.3)

The Request Status Code field is used to identify the nature of the request for information. ASI instruments may support all or a subset of the following types of requests. Refer to the instrument specific section in which requests for information are supported by a specific instrument. The allowable request types are as follows:

Final Report (F) – This indicates a request for results. Based on the information provided in the query record and the ability of the instrument or system, this request will return all results (final, preliminary, interpreted, averages, calculations, etc.) associated with that patient, sample and/or test. This query will return previously transmitted results as well as any new results waiting to be transmitted. This request may be made based on single or ranges of patient(s), specimen(s), date(s)/time(s), and/or test code.

New/Edited Results (N) – This indicates a request for results that have not been previously transmitted or that have been edited. ASI instruments and systems supporting this feature will not return previously transmitted results in response to this query. This request may be made based on single or ranges of patient(s), specimen(s), date(s)/time(s), and/or test code.

Orders/Demographics (O) – This indicates a request for patient and orders. This request returns all patient and order records meeting the request criteria. The request may be made based on single or ranges of patient(s), specimen(s), date(s)/time(s), and/or test code.

Patient Demographics (D) – This indicates a request for patient demographics only. This request returns all patient records meeting the request criteria. This request may be made based on single or ranges of patient(s).

Canceled – Cannot be Done (X) – This indicates that the request previously made cannot be performed with the information provided. ASI instruments and systems may return a Comment record following the Request Information Record (Q) with the reason for not completing the request.

Abort Last Request (A) – This indicates that the requesting system would like to cancel the previously transmitted request.

Table 1.13: Request Information Record

ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
12.1.1	Record Type	Q	Q	Request Information Records may be used to request information on patients, samples, and tests. These requests may be specific to a date and time or may apply to a time period with a start date and time and an end date and time. Patient IDs, Sample IDs, Test IDs, and Date/Times are AND conditions to make the request more specific.
12.1.2	Sequence Number	1	1	Sequence number is always one (1). Only one Request Information Record is sent at any one time.
12.1.3	Starting Range ID			
	Patient ID	* ALL	* ALL	From Host: (ALL) indicates return all information associated with all known Patient IDs and/or Specimen IDs. From Instrument: (ALL) indicates return all requested information associated with known Patient IDs and/or Specimen IDs assigned to this instrument.
	^Specimen ID	* ALL	* ALL	
12.1.4	Ending Range ID Patient ID ^Specimen ID	 * *	 * *	Used when Patient and/or Specimen IDs are sequential. Standard string comparison rules apply to determine if a Patient ID Specimen ID falls within the range provided by fields 12.1.3 and 12.1.4.

** Indicates supported field. Refer to instrument sections for size of supported fields.*

Table 1.13: Request Information Record (Continued)

ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
12.1.5	Universal Test ID	^^^ALL	^^^ALL	Used to request test results for the specified test (assay code) on a specific sample or patient ID. This field becomes an AND condition to the previous fields. (ALL) indicates all test codes and result types.
	^^^Assay_code ^Assay_name	*	*	The Test Information (Assay_code ^ Assay_name) component is used to uniquely identify the test or tests to be done on the specimens.
12.1.6	Request Time Limits	S R	S R	(S) Specimen order dates. (R) Result test dates.
12.1.7	Beginning Request Date and Time	*	*	Instrument's Date and Time. When a time is not specified, the 24-hour range for that date is assumed.
12.1.8	Ending Request Date and Time	*	*	Instrument's Date and Time. When used, the date and time specified is the end of the time range of interest. When a beginning Date and Time is not specified (field 12.1.7), this field is interpreted as known information up to and including this date and time. If a time is not specified, 12:00 p.m. is used as the default.
12.1.9	Requesting Physician Name	*	*	See the instrument specific section for handling this field.
12.1.10	Requesting Physician Phone #			Not supported
12.1.11	User Field No. 1			Not supported
12.1.12	User Field No. 2			Not supported
12.1.13	Request Status Codes	A	A	(A)bort – Cancel last request.
		F	F	(F)inal Report
		N	N	(N)ew or Edited Results
		O	O	(O)rders and Demographics
		D	D	(D)emographics only
		X	X	(X) – Request cannot be done.

** Indicates supported field. Refer to instrument sections for size of supported fields.*

Table 1.14: Terminator Record

ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
13.1.1	Record Type	L		Terminator records indicate the end of a message.
13.1.2	Sequence Number	1	1	Sequential number always equal to one (1).
13.1.3	Termination Code	N	N	(N)ormal termination. If this field is not transmitted, (N) is assumed.
		I	I	(I)nformation not available on last request.
		F	F	(F)inished processing last request.

Table 1.15: Manufacturer's Record

ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
15.1.1	Record Type	M		(M)anufacturer Defined Records Refer to instrument specific sections on support and structure of manufacturer – Instrument record types. These records are used to supplement the information provided in the PATIENT/ORDER/ RESULT records. They are used specifically to provide a mechanism for communicating information that does not fit within the PATIENT/ORDER/RESULT structure.
15.1.2	Sequence Number	*		Any sequential number within a level.
15.1.3	Abbott Record Type			Defines the usage of the Abbott Manufacturer record. It contains two components.
	Record Class	I		Identifies the information content of the record. Valid Classes of manufacturer records are as follows:
	^Instrument_Record_ Type			(I)nstrument Information Records. Examples of instrument information record types are as follows:
		^DM		(DM) – Destination Maps for pippetting information
		^SM		(SM) – Source Maps for pippetting information
		^GR		(GR) – Graphics Record
		^CL		(CL) – Instrument Calibration information
		P		(P)atient class – Contains information relevant to patient demographics.

** Indicates supported field. Refer to instrument sections for size of supported fields.*

Table 1.15: Manufacturer's Record (Continued)

ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
		O		(O)rder Class – Contains information relevant to order information.
		R		(R)esult Class – Contains information relevant to result information.

** Indicates supported field. Refer to instrument sections for size of supported fields.*

Refer to instrument specific sections for information on supported Manufacturer Records. Additional Abbott Record Types may be created by ASI instruments and systems as needed, to communicate information not covered by the ASTM standards and this document.

Example Messages

Below are examples of messages which conform to the requirements defined for instruments implementing the Abbott Standard Interface as described in the preceding section.

Specimen Query from an ASI Instrument

The following example shows a simple request for test information and patient demographics for a range of specimens (SID1000 through SID1008).

```
H|\^&|||ASI^1.0^s/n^H1P1O1R1Q1L1C1|||||My^Host^System||P|1|19930631[CR]
Q|1|^SID1000|^SID1008|^^^ALL|||||||O[CR]
L|1|N[CR]
```

Figure 1.27: Example of Specimen Test Order Query

Test Ordering by an External Host Computer

The following figure shows the partial Test Request message from an external host system to an ASI instrument. It contains patient demographics and test orders associated with each patient. The download of the Test Request message may be initiated by the external system or may be in reply to a query from the ASI instrument as indicated above.

```
H|\^&|||My^Host^Computer|||||ASI^1.0^s/n||P|1|19930631[CR]
P|1||PID1234||Doe^John|Smith|19500522|M|||||Jones^Bob^^^Dr|||||300.0^Anxiety\311.0^Depression|[CR}
O|1|SID1000||^^^10^Test10^protocol1|S|19930631|19930629||||N||||SERUM|Miller^John^^^Dr|||||||||Q|[CR}
O|2|SID1000||^^^22^Test22|S|19930631|19930629||||A||||SERUM|Miller^John^^^Dr|||||||||Q|[CR}
P|2||PID2222||Small^Jane|Smith|19400820|M|||||Jones^John^^^Dr|||||||[CR}
O|1|SID1001||^^^20^Test20^protocol4|R|19930631|19930629||||N||||SERUM|Ahmad^Joe^^^Dr|||||||||Q|[CR}
P|3|.....
.........
L|1|F [CR]
```

Figure 1.28: Example of Test Ordering

NOTE: The Report Type field of the Order record as well as the Terminator record (L|1|F [CR]) indicate that the Test Request message was in response to a query (Report Type = Q, Termination Code = F). Also, the two test orders for patient John Doe (PID1234, SID1000) could be communicated in one order record with the use of the repeat delimiters in the Universal Test ID field. The Test Request message would have been transmitted as follows:

```
H|\^&|||My^Host^Computer|||||ASI^1.0^s/n||P|1|19930631[CR]
P|1||PID1234||Doe^John|Smith|19500522|M|||||Jones^Bob^^^Dr|||||300.0^Anxiety\311.0^Depression|[CR}
O|1|SID1000||^^^10^Test10^protocol1\^^^22^Test22|S|19930631|19930629||||N||||SERUM|Miller^John^^^Dr|||||||||O|[CR}
P|2||PID2222||Small^Jane|Smith|19400820|M|||||Jones^John^^^Dr|||||||[CR}
O|1|SID1001||^^^20^Test20^protocol4|R|19930631|19930629||||N||||SERUM|Ahmad^Joe^^^Dr|||||||||O|[CR}
P|3|.....
.........
L|1|N [CR]
```

Figure 1.29: Example of Test Ordering with Repeat Delimiters

NOTE: The above message was not a response to a query (Report Type = O, Termination Code = N).

Results from an ASI Instrument to a Computer System

The following figure shows a partial Test Results message from an ASI instrument to an external host computer. This message may contain the results for multiple patients and tests if they have been completed and approved. One or more result records associated with a test will follow each order record. All result records for that test (per specimen) are communicated together.

```
H|\^&|||ASI^1.0^s/n^H1P1O1R1Q1L1C1|||||My^Host^System||P|1|19930631[CR]
P|1||PID1234||Doe^John|Smith|19500522|M|||||Jones^Bob^^^Dr|||||300.0^Anxiety\311.0^Depression|[CR}
O|1|SID1000||^^^10^Test10^protocol1|S|19930631|19930629|||||||SERUM|Miller^John^^^Dr|||||||||O|[CR}
R|1|^^^10^Test10^protocol1^^P|500.56|RATE|||F||OPERATOR12^SUPER12|| 199306310930|MANUALLY ENTERED[CR}
C|1|I|Accidently deleted result and had to reenter|G [CR]
R|2|^^^10^Test10^protocol1^^F|56.33|ng/ml|25 to 60^normal||F||OPERATOR12 ^SUPER12|| 199306310930|[CR}
O|2|SID1000||^^^22^Test22|S|19930631|19930629|||||||SERUM|Miller^John^^^Dr|||||||||O|[CR}
R|1|^^^22^Test22^^^I|REACTIVE||||F||OPERATOR#5^SUPER12||199306310930|[CR}
P|2|.....
.....
.....
L|1|N [CR]
```

Figure 1.30: Example of Test Results from an ASI Instrument

Query for Final Results

The following example shows a simple request for final results associated with previously run samples and tests for a patient (PID1234). This query may be used to provide a lab operator with a temporary view of patient history to facilitate approval of current results.

```
H|\^&|||ASI^1.0^s/n^H1P1O1R1Q1L1C1|||||My^Host^System||P|1|19930631[CR]
Q|1|PID1234^ALL||^^^ALL|||||||F[CR]
L|1|N[CR]
```

Figure 1.31: Example of ASI Instrument Query for Test Results

Application Layer

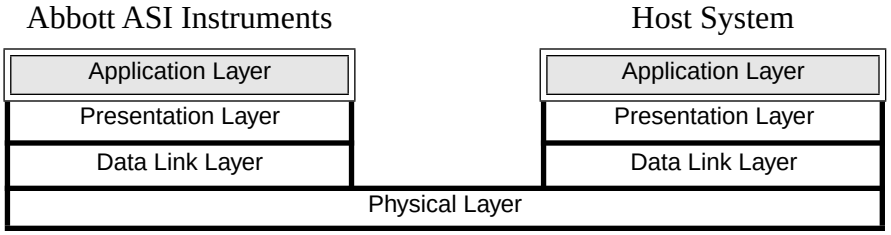


Figure 1.32: Application Layer

Generally, the Application Layer of ASI instruments and systems provides services for user interaction, instrument operation, maintenance, communication, etc. These services vary considerably from instrument to instrument and system to system, based on instrument capability, target market, and other design considerations.

In terms of communications, the Application Layer of each ASI instrument and system defines the type of messages that an instrument or system can support. In order to clarify this point, ASI instruments are grouped in the following four categories.

All ASI instruments and systems, regardless of the category, implement the Data Link layer in a similar fashion. Also, ASI instruments and systems, regardless of category, assay implement Comment and Manufacturer records as part of their supported messages in order to pass back information that does not fit within the ASTM defined records.

Category I:

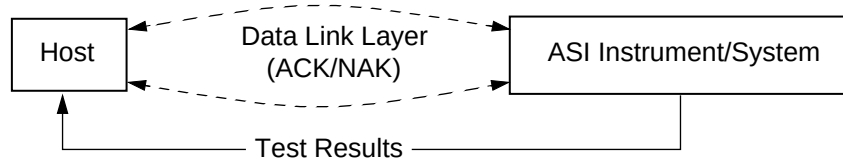


Figure 1.33: Category I Instruments and Systems

Category I instruments and systems have the ability to return test result messages to a host system in accordance with ASTM E1394-91 standard and as described in this document. The Test Result messages consist of Header, Patient, Order, Result, and Terminator Records. Because of the minimal data management capabilities of these instruments and systems, Patient Demographics is unlikely to be supported (with the possible exception of patient IDs).

Category II:

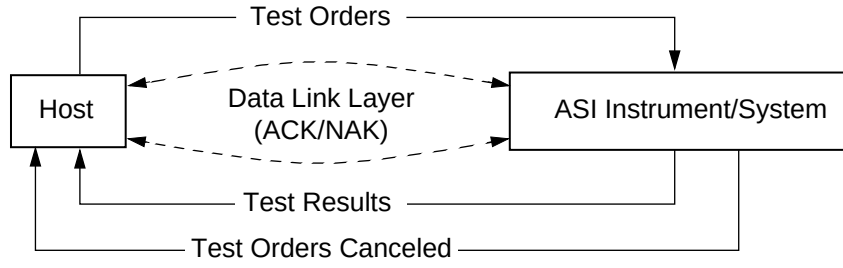


Figure 1.34: Category II Instruments and Systems

Category II instruments and systems have the ability to accept Test Order messages from an external host and return Test Result messages to that host system in accordance with ASTM E1394-91 standard and as described in this document. In addition, these instruments and systems also return Test Order Canceled messages if an invalid order is received.

Test Order messages minimally consist of Header, Patient, Order, and Terminator records.

Test Result messages minimally consist of Header, Patient, Order, Result, and Terminator records.

Test Orders Canceled messages consist of Header, Patient, Order, and Terminator records. The Report Type field of the Order record contains an "X" (without quotes). The Test Order Canceled message may also contain a Comment record with the specific reason why the test was canceled.

The extent that patient demographics are supported (with the exception of patient IDs) by these instruments and systems varies based on their data management capabilities.

Category III:

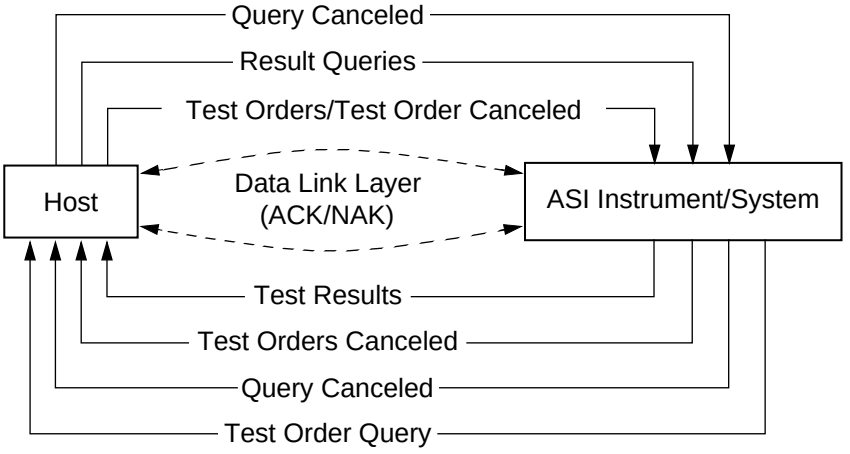


Figure 1.35: Category III Instruments and Systems

In addition to the capabilities described for Category II instruments and systems, Category III instruments accept the Result Query message and return a Query Canceled message whenever they are unable to perform the requested query. Also, they may submit a Test order Query message requesting test orders assigned to this instrument. Instruments also accept the Query canceled message if the Host is unable to satisfy the request.

Result Query messages consist of Header, Request Information, and Terminator records. The Request Status Code field in the Request Information record contains an F to indicate final results or an N to indicate new or updated results from a certain start date. The Test Order Query message is similar. The Request Status code field contains an O.

Query Canceled messages consist of Header, Request Information, and Terminator records. The Request Information record contains an X in the Request Status Code field to indicate that the request cannot be done. A variation of the Query canceled message is used to abort a previously made Query.

The extent that patient demographics are supported (with the exception of patient IDs) by these instruments and systems varies based on their data management capabilities. A variation of the Test Order canceled message is used to abort a previously made Test Order.

Category IV:

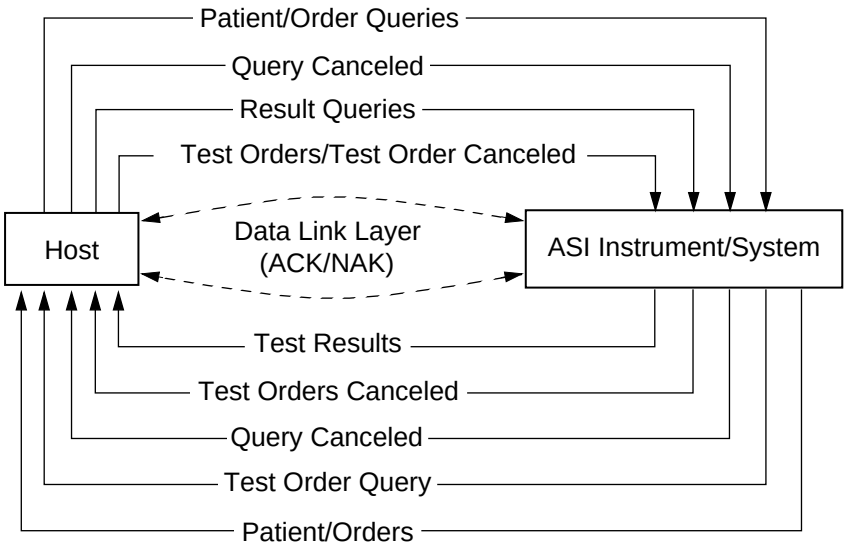


Figure 1.36: Category IV Instruments and Systems

In addition to the abilities described for Category III instruments and systems, Category IV instruments and systems can accept Patient Demographics Query and Test Order Query messages from an external host and return Patient and Order messages to that host system, in accordance with ASTM E1394-91 standard and as described in this document. In addition, these systems may generate Patient Demographics Queries and Test Order queries.

The Patient Demographics Query messages and the Test Order Query messages consist of Header, Request Information, and Terminator records. When requesting Patient Demographics only, the Request Status Code field in the Request Information record contains a D. When requesting Orders also, the field contains an O.

The Patient messages minimally consist of Header, Patient, and Terminator records while the Test Order messages consist of Header, Patient, Order, and Terminator records.

All instruments and systems in Category IV support complete demographic and order information as described in the ASTM E1394-91 standard and this document. The instruments and systems provide the most flexibility for a lab environment. They allow the generation and input of Patient Demographics and Test Orders on any interconnected system. Through the use of the Query messages, the systems are able to synchronize the data bases on all relevant patients and orders without requiring redundant manual input of information that has already been entered once.

NOTES

Overview of the LCx System

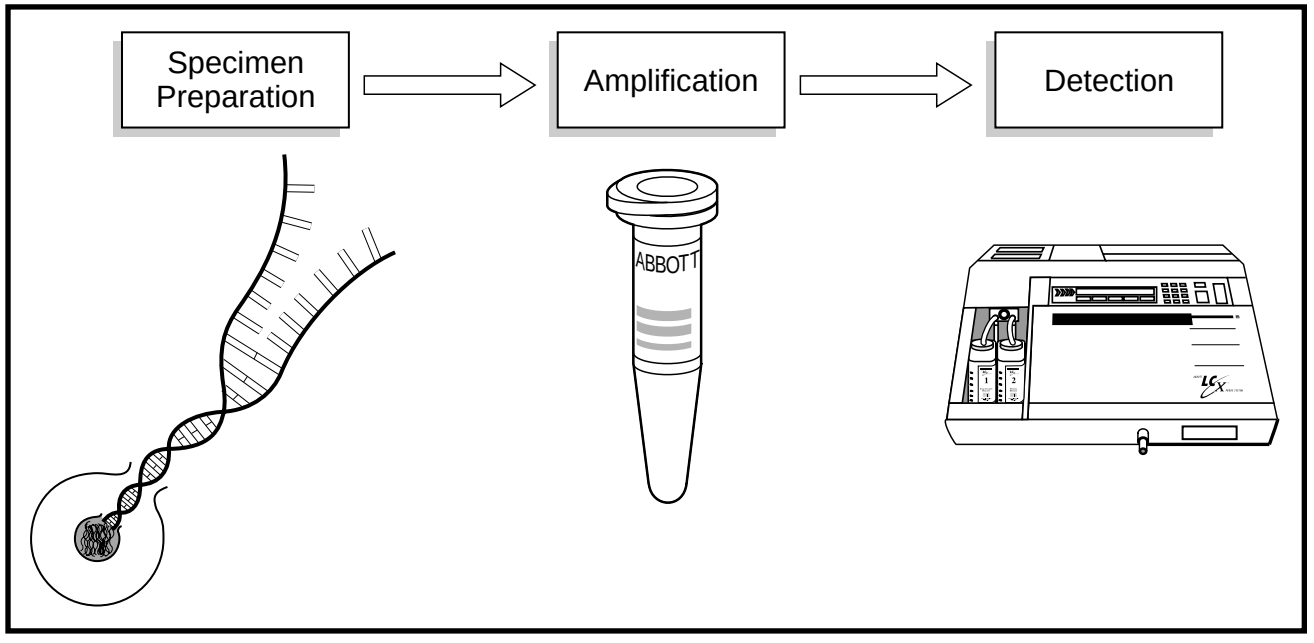
Overview

The Abbott LCx Probe System is an integrated system designed to use amplified nucleic acid probe technology to detect specific nucleic acid sequences in human specimens.

The Abbott LCx Probe System combines all the benefits of an amplified nucleic acid probe assay with fully-automated detection and ready-to-use amplification reagents.

The Abbott LCx Probe System integrates three distinct processes:

- **Specimen Preparation** releases the nucleic acid from its native biological source.
- **Nucleic Acid Amplification** exponentially generates copies of the specific nucleic acid sequence of interest.
- Automated **Amplified Nucleic Acid Detection** utilizes an immunoassay technique to detect the nucleic acid amplification products.



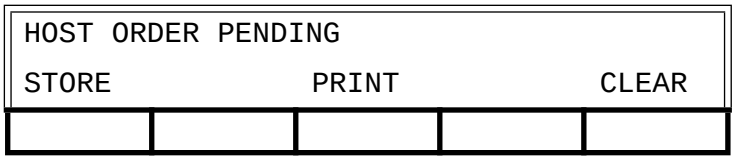
General Description

Specific Interface Information

The following is specific communication information for the LCx System:

Host Order Pending Screen

When an order is successfully down loaded, the user is notified with the following message when entering Sample Management to create a new loadlist or starting an assay run:



During Sample Management:

Key Press	Instrument Action	Next Instrument Action
STORE	Copies Sample IDs to assay loadlist. Downloaded IDs are also saved so that they can be sent to the spooler when the assay run is completed.	Sample Management Menu
PRINT	Prints the Sample IDs downloaded from the Host System.	No change (Host Order Pending display)
CLEAR	Clears downloaded ASTM order. Exits out of Sample Management.	Assay Menu

During Assay Run:

Key Press	Instrument Action	Next Instrument Action
STORE	Copies Sample IDs to assay loadlist. Downloaded IDs are also saved so that they can be sent to the spooler when the assay run is completed. Assay Run continues.	Perform Spooler Capacity Test
PRINT	Prints the Sample IDs downloaded from the Host System.	No change (Host Order Pending display)
CLEAR	Clears downloaded ASTM order. Assay Run continues.	Perform Spooler Capacity Test

The test for a pending order is made after the reagent pack barcode is read when entering Sample Management or at the beginning of an Assay Run. After the barcode is read, the downloaded order is validated against assay information derived from reading the barcode including the assay number and capacity to accommodate the run. If any of these tests fail, the HOST ORDER PENDING screen will not appear and the error will be logged to the ASTM LOG - Sample Management or Assay Run will continue.

NOTE:

1. When downloading an order, Sample Management must be clear of any existing loadlist.
2. Printing the downloaded loadlist from the HOST ORDER PENDING screen displays the instrument-assigned Control and Calibrator IDs and Sample IDs sent by the host system. If the loadlist is stored and is printed from Sample Management, the loadlist will display Control and Calibrator IDs assigned by the instrument along with the downloaded patient sample IDs.

Allowed ASCII Characters

Valid ASCII characters recognized by the LCx ASTM parser are 0DH and 20H - 7EH.

Delimiters

Delimiters are utilized in the separation of adjacent fields, repeat information within a field, and components of a field. The actual delimiters employed in a given transmission are defined in the Header Record. The following delimiter examples will be used in this specification:

Field Delimiters: **|**

The LCx ASTM parser will read in a record one character at a time. When a field delimiter is encountered, the parser will treat all characters read up to the delimiter to be part of the field. The parser will continue to read in fields until a carriage return [CR] is encountered indicating that the entire record has been read. Consecutive field delimiters without characters between the delimiters are treated as empty fields. A carriage return [CR] indicates that all remaining fields in the record are empty.

```
Record ID field|field 2|field 3|||||field n[CR]
```

Repeat Delimiters: ****

The LCx ASTM interface does not support the use of repeat delimiters.

Component Delimiters: **^**

The LCx ASTM parser will treat component delimiters as data element separators within fields. An example of this is the use of component delimiters to separate a patient's last name, first name, middle name, suffix, and title:

```
|Tesla^Nikola^^Mr|
```

Consecutive component delimiters indicate an empty subgroup within a field.

Escape Delimiters: **&**

The LCx ASTM interface does not support the use of escape delimiters.

Table 2.1: Delimiter Summary

Delimiter Type	Character	Description
Field	|	Separates fields within records.
Repeat	\	Not Supported
Component	^	Separates a field into smaller groups of characters.
Escape	&	Not Supported

Message Information

Spooler

The LCx will incorporate a spooler buffer that will hold up to four sets of results. When an assay run is completed, it is queued into a buffer. Note that a run can be spooled for output even if the host did not order it. The spooler will attempt to dump its contents when the host system is available. If the host is not available, the runs are held in the spooler buffer until it is possible to dump to the host system.

Capacity

When the ASTM Spooler buffer capacity is reached, the operator is notified at the start of an assay run. At this point, the operator may cancel the run and establish contact with the host LIS system so that the spooler contents may be transferred or proceed with the run. In the last case, the oldest record in the spooler buffer will be overwritten with the new assay results upon completion.

The spooler capacity value is set in System Parameter 1.20 SPOOLER WARN. The value in the parameter denotes the remaining number of runs the spooler can accommodate before it is full.

The allowed values are:

1. Spooler can accommodate 1 more run before reaching capacity.
2. Spooler can accommodate 2 more runs before reaching capacity.

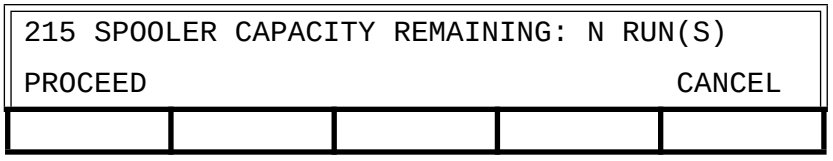
3. Spooler can accommodate 3 more runs before reaching capacity.

The default value is 1.

The spooler capacity is checked after the reagent pack is read at the start of an assay run. If the remaining capacity matches the value in System Parameter 1.20, the user will be notified with the warning message. At this point, the user may continue the run or cancel the run and establish contact with the host system to dump the spooler contents. The notification will have no influence over the run being executed—should the operator ignore the message, the current run results will be stored in the next available spooler buffer slot if available or the oldest record will be overwritten if no slots are available.

The spooler incorporates a checksum that is updated when results are saved and released. On instrument powerup, this checksum is verified. If the checksum test fails, the error "252 ASTM SPOOLER INIT" will be logged in the ASTM error log.

The following message will appear on the LCx screen when the spooler capacity is reached:



N indicates remaining number of runs spooler can accommodate.

Key Press	Instrument Action	Next Instrument Action
PROCEED	Instrument will continue the assay prologue. If spooler buffer is at partial capacity, results will be written into next available buffer slot. If spooler buffer is full, oldest record in buffer will be overwritten with the results of the current run.	Checking carousel type
CANCEL	Cancel the current assay run.	Returns to Ready Menu after exiting the 245 message.

The error message: ”SPOOLER RUN CAPACITY” will be logged to the system log file.

Assay Lockout

Certain assays will be locked out of the ASTM parser. If an order for a locked out assay is sent to the parser, the parser will not generate a loadlist and an ASSAY LOCKOUT error will be logged. All assays whether they have been ordered by a host system or created from the front panel are routed to the spooler on completion of a run with the exception of assays that are not to be spooled. The lockout selection is determined by the value in assay file parameter 1. A value of ‘0’ indicates lockout. A value of ‘1’ indicates not locked out.

Cancellation of a Run in Progress

If an Assay Run is canceled while in Multitask, the loadlist with the downloaded IDs are cleared. If an Assay Run is canceled while in Prologue, the IDs are maintained intact so that the run can be started again or the IDs cleared from Sample Management.

Order Lockout

The ASTM parser will accept one downloaded order from the host system. If the downloaded order is successfully parsed, the interface will lockout any further attempts to download an order. The interface is unlocked if the downloaded order is not accepted (refer to section: Host Order Pending), if a downloaded loadlist is cleared from Sample Management, or if the run goes to completion. Disabling the ASTM interface will also unlock the interface. Refer to section: Interface Activation/Deactivation.

Changing/Clearing a Loadlist

If the operator makes changes to the loadlist in Sample Management or during Multitask (i.e. changing the Patient Sample ID), these changes will be reflected in the returned Order Record along with the original information sent by the host system. Note: If the operator clears the loadlist from Sample Management before the run is started, the ASTM order will be deleted. There will not be any message back to the host indicating that the order loadlist was cleared. At this point, the operator can manually create a new loadlist or send a new order battery from the host system.

> NOTE: If the instrument has an existing loadlist and an order is to be downloaded, the existing loadlist must be cleared from Sample Management before downloading a new order. If an ASTM order is accepted at the start of an assay run and there is an existing loadlist, then the existing loadlist will be overwritten. Return to the READY menu when downloading the order.

Operator Interface

The ASTM operation will be transparent to the operator. During normal operation, there will be no change to the operator interface. Low level Communications and ASTM Format/Processing errors are silently logged to an ASTM error file which can be accessed from the front panel for diagnostic purposes. The one exception to this is when the ASTM Spooler buffer capacity is reached, the operator is notified at the start of an assay run. At this point, the operator may cancel the run and establish contact with the host LIS system so that the spooler contents may be transferred or proceed with the run. In this case, the oldest record in the spooler buffer will be overwritten with the new assay results upon completion

Order Queueing

Because the LCx is a batch type instrument, a complete carousel battery of orders must be sent by the host system - i.e. a Header record followed by all the Patient records/Order records and concluded with a Terminator record. Only one loadlist is handled at a time. When an order is successfully downloaded, the interface will be locked to new downloads. The interface is unlocked by clearing the order from Sample Management or allowing an order to run to completion. Once loaded, the orders will be translated into a loadlist that is available to the operator from the front panel via Sample Management. If the operator clears the loadlist, then the orders must be resent by the host system. If the LCx is power cycled with a downloaded loadlist in the instrument, the loadlist will be lost and must be resent.

Carousel Mapping

The downloaded order sequence must reflect the location of the test in the carousel. The Patient Samples will be assigned carousel locations following the carousel locations used for Controls and Calibrators. Also, orders sent by the host system must identify Patient Samples with an Action Code of 'A' in Order Field 9.4.12.

> NOTE: The downloaded Patient Orders plus the carousel spaces required for Calibrators and Controls must not exceed 24.

Example:

Location	Sample Type	Action Code in Field 9.4.12
1	NEG CNTL	N/A - Assigned by instrument
2	NEG CNTL	N/A - Assigned by instrument
3	CAL	N/A - Assigned by instrument
4	CAL	N/A - Assigned by instrument
5	Patient Sample	A
6	Patient Sample	A

Sample Download Example

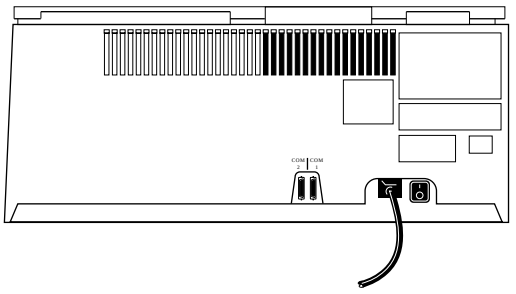
The following is an example of an assay download that can be sent by HIISIM (Host/Instrument Interface Simulator - Refer to Section 7). In this case, there are twenty orders for Assay 10 Chlamydia. Given two negative controls and two calibrators, this will yield a full carousel.

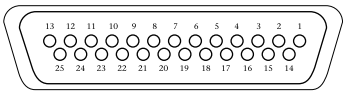
```
H|\^&||||||||||P|1<CR>
P|1<CR>
O|1|ASTMSID1||^^^10|||||||A||||||||||||O<CR>
P|2<CR>
O|1|ASTMSID2||^^^10|||||||A||||||||||||O<CR>
P|3<CR>
O|1|ASTMSID3||^^^10|||||||A||||||||||||O<CR>
P|4<CR>
O|1|ASTMSID4||^^^10|||||||A||||||||||||O<CR>
P|5<CR>
O|1|ASTMSID5||^^^10|||||||A||||||||||||O<CR>
P|6<CR>
O|1|ASTMSID6||^^^10|||||||A||||||||||||O<CR>
P|7<CR>
O|1|ASTMSID7||^^^10|||||||A||||||||||||O<CR>
P|8<CR>
O|1|ASTMSID8||^^^10|||||||A||||||||||||O<CR>
P|9<CR>
O|1|ASTMSID9||^^^10|||||||A||||||||||||O<CR>
P|10<CR>
O|1|ASTMSID10||^^^10|||||||A||||||||||||O<CR>
P|11<CR>
O|1|ASTMSID11||^^^10|||||||A||||||||||||O<CR>
P|12<CR>
O|1|ASTMSID12||^^^10|||||||A||||||||||||O<CR>
P|13<CR>
O|1|ASTMSID13||^^^10|||||||A||||||||||||O<CR>
P|14<CR>
O|1|ASTMSID14||^^^10|||||||A||||||||||||O<CR>
P|15<CR>
O|1|ASTMSID15||^^^10|||||||A||||||||||||O<CR>
P|16<CR>
O|1|ASTMSID16||^^^10|||||||A||||||||||||O<CR>
P|17<CR>
O|1|ASTMSID17||^^^10|||||||A||||||||||||O<CR>
P|18<CR>
O|1|ASTMSID18||^^^10|||||||A||||||||||||O<CR>
P|19<CR>
O|1|ASTMSID19||^^^10|||||||A||||||||||||O<CR>
P|20<CR>
O|1|ASTMSID20||^^^10|||||||A||||||||||||O<CR>
L|1<CR>
```

Communication Setup

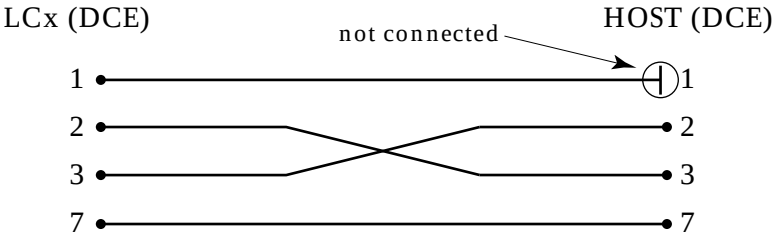
Interface Connection

The LCx interfaces to a host computer via an EIA RS232C serial port designated as COM2, as shown in the picture below. COM2 is a female DB25 connector.





According to the ASTM specification, the instrument (LCx) should be configured as a data terminal equipment (DTE) and the host computer as a data communication equipment (DCE). The following cabling must be used to make the LCx appear as a DTE, since by default it is configured as a DCE.



DCE	DTE	PIN	SIGNAL	FUNCTION
N/A	N/A	1	– – –	PROTECTIVE GROUND
INPUT	OUTPUT	2	TxD	TRANSMITTED DATA
OUTPUT	INPUT	3	RxD	RECEIVED DATA
N/A	N/A	7	SG	SIGNAL COMMON

These four pins are required by the ASTM specification.

NOTE: Hardware handshaking and XON/XOFF must NOT be used. Pin 4 (RTS) must be connected to pin 5 (CTS), similarly for pin 6 (DSR) and pin 20 (DTR) on COM2. Other unused pins must be disconnected.

Interface Activation

Setting System File parameter 1.18 to a value of 7598 activates the interface. Once activated, the instrument is available to communicate with the host system via the COM2 RS232 port. When the instrument is powered off, the activation password will be retained in the System Parameters. Thus, when the instrument is powered up again, the interface is still available. The user must set System File parameter 1.18 to any value 0 to 9999 other than 7598 to deactivate the interface.

Deactivating/Activating the interface will set the interface to an initialized state.

The default communication parameters are as follows:

- DCE
- 9600 baud
- No parity
- 8 data bits and 1 stop bit

Refer to the LCx Operations Manual to change the above default configuration.

LCx Specific Outgoing Messages

Overview

The following two sections outline the ASTM records and field contents needed to establish bidirectional communication between the LCx System and a host computer.

Communication: LCx to Host

Transmission of Patient Results and Quality Control Results utilizes the high level ASTM records and fields described in this section. Unused fields are not listed.

Successfully completed test results are transmitted from the LCx System to the host according to the following logical record hierarchy:

Message Header Record
Patient Information Record
Test Order Record
Result Record Rate
Result Record S/CO (Samples Only)
or concentration
Result Record Note
Comment Record (optional)
Message Terminator Record

The LCx System transmits each individual test result framed by the Header Record and the Terminator Record. If two results are being transmitted the Message Header and all records are repeated as shown below:

Message Header Record
Patient Information Record
Test Order Record
Result Record Rate
Result Record S/CO (Samples Only)
or concentration
Result Record Note
Comment Record (optional)
Patient Information Record
Test Order Record
Result Record Rate
Result Record S/CO (Samples Only)
or concentration
Result Record Note
Comment Record (optional)
Message Terminator Record

Results are queued to a buffer when an assay run is completed. The spooler will hold up to 4 sets of results. The spooler will attempt to send its results to the host when the host is available. If the host is not available, the results will be held in the spooler.

> NOTE: See section 2 for more information concerning the spooler.

Format Detail

The following sections detail the exact formats for these ASTM records:

- Message Header Record
- Patient Information Record
- Test Order Record
- Result Record
- Comment Record
- Message Terminator Record

ASTM records that are not used:

- Request Information Record
- Scientific Record
- Manufacturer Information Record

Message Header Record

Table 4.1: Message Header: LCx to Host

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
7.1.1	Record Type ID	1	H	Header
7.1.2	Delimiter Definition	4	| \ ^ &	Field delimiter, vertical bar Repeat delimiter, backslash Component delimiter, caret Escape delimiter, ampersand
7.1.5	Sender Name or ID ^Software Version ^Serial Number ^Interface Version	3 4 7 12	LCx ^Version Number (Numeric) ^Serial Number (Numeric) ^Interface Version (Alphanumeric)	Instrument Name System Version Number in the format 1.23. Instrument Serial Number Record types the LCx System supports.
7.1.12	Processing ID	1	P	Patient results
7.1.13	Version No.	1	1	Mandatory Field
7.1.14	Date and Time	14	YYYYMMDDHHMMSS	Date and time of transmission in ASTM format.

```
H|\^&|||LCx^2.00^1234567^H1P1O1R1C1L1|||||||P|1|19950224121212[CR]
```

Figure 4.1: Example of Message Header Record: LCx to Host

Patient Information Record

Table 4.2: Patient Information Record: LCx to Host

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
8.1.1	Record Type ID	1	P	Patient
8.1.2	Sequence Number	5	1 to n	n represents any number.

```
P|1[CR]
```

Figure 4.2: Example of Patient Information Record: LCx to Host

Test Order Record

Table 4.3: Test Order Record: LCx to Host

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
9.4.1	Record Type ID	1	O	Order
9.4.2	Sequence Number	5	1 to n	n represents any number.
9.4.3	Specimen ID	9	Specimen (Alphanumeric)	Sample ID downloaded from Host, returned unchanged to Host.
9.4.4	Instrument specimen ID ^location_ID ^position	9 3 2	Specimen(Alphanumeric) ^Carousel ID (Numeric) ^Carousel position (Numeric)	Instrument Sample ID, Carousel ID, and position are returned for all specimens tested, although Instrument Sample ID may be different than Sample ID in 9.4.3 if changed by operator.
9.4.5	Universal Test ID Code	3	^^^ Assay Number (Numeric)	Specific number that identifies the test.
9.4.12	Action Code	1	Q	Empty for Patient Result Q for Quality Control/Cals
9.4.26	Report Types	1	F	Final Result

O|1|BR549|DSR58^999^6|^^^111||||||||||||||||||||F[CR]

Figure 4.3: Example of Test Order Record: LCx to Host

Result Record

Multiple Result Records may be sent for a single test result. Separate Result Records are sent for each of the following:

- Adjusted rate - Preliminary
- Final result – SCO/Concentration
- Interpreted NOTE

The Universal Test ID field of the Result Record identifies the type of result.

Table 4.4: Result Record: LCx to Host

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
10.1.1	Record Type ID	1	R	Result
10.1.2	Sequence Number	5	1 to n	n represents any number
10.1.3	Universal Test ID Code	3	^^^Assay Number (Numeric)	Specific number that identified the test
	^Name	14	^Assay Name (Alphanumeric)	Test name
	^^^Result Type	1	^^^F (S/CO) or concentration P (Adj Rate) I (Note)	Final Result ratio percentage/ concentration Preliminary instrument result Interpreted result note examples: POS - Positive INV - Invalid EQV - Equivocal NEG - Negative
10.1.4	Data Value	8 5 5	Float Numeric Float Numeric Interpretation String	For Result Type F For Result Type P For Result Type I
10.1.5	Units	7	Concentration Empty Empty	Result Type F Result Type P Result Type I
10.1.9	Result Status	1	F X	(F)inal Results (X) Test can not be completed.
10.1.11	Operator Identification	9	Alphanumeric	Tech ID
10.1.13	Date/Time Test	14	YYYYMMDDHHMMSS	Date/time from results printout.

Quantitative

R|1|^^^999^RHUBARB^^^F|3.1415|Km/ml||||F||123456789||19950224121212[CR]

Qualitative

R|1|^^^11^CHLAMYDIA^^^I|POS|||||F||123456789||19950224121212[CR]

Figure 4.4: Example of Result Record: LCx to Host

Comment Record

A Comment Record follows a Result Record if:

- an error occurred during an assay run.

Table 4.5: Comment Record: LCx to Host

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
11.1.1	Record Type ID	1	C	Comment
11.1.2	Sequence Number	5	1 to n	n represents any number
11.1.3	Comment Source	1	I	Instrument
11.1.4	Comment Text	40	Result Comment or Exception String	
11.1.5	Comment Type	1	G I	Result Comment Exception String

C|1|I|Comment Goes Here|G[CR]

Figure 4.5: Example of Comment Record: LCx to Host

Request Information Record

The LCx System does not generate a Request Information Record nor does it recognize Request Information Records received from the host.

Message Terminator Record

The Message Terminator Record is the last record of a result transmission.

Table 4.6: Message Terminator Record

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
13.1.1	Record Type ID	1	L	Last
13.1.2	Sequence Number	1	1	Will always contain 1

L|1[CR]

Figure 4.6: Example of Terminator Record: LCx to Host

NOTES

LCx Specific Incoming Messages

Communication: Host to the LCx System

Transmission of Patient ID, Sample ID, and Test Orders utilizes the high level ASTM records and fields described in this section. Unlisted fields are ignored by the LCx System.

Transmission to the LCx System from the host takes place according to the following logical record hierarchy:

Message Header Record
Patient Information Record
Test Order Record

Patient Information Record
Test Order Record

Patient Information Record
Test Order Record
Message Terminator Record

Format Detail

The LCx System recognizes fields when parsing for the following records:

- Message Header Record
- Patient Information Record
- Test Order Record
- Message Terminator Record

All other *fields* are ignored regardless of content.

The following *records* are ignored by the LCx System:

- Comment Record
- Request Information Record
- Scientific Record
- Manufacturer Information Record

Message Header Record

Table 5.1: Message Header: Host to LCx

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
7.1.1	Record Type ID	1	H or h	Header
7.1.2	Delimiter Definition			Characters 2 and 6 of the record must be the same.
7.1.12	Processing ID	1	P or p	Processing ID
7.1.13	Version Number	1	1	Must be 1

```
H|\^&||||||||||P|1[CR]
```

Figure 5.1: Example of Message Header Record: Host to LCx

Processing ID must be P or an ILLEGAL PROCESS ID error will be generated. The Version Number must be 1 otherwise a HEADER VERSION error will be generated.

ASTM Fields 7.1.1, 7.1.2, 7.1.12, and 7.1.13 of the Message Header Record are all required by the LCx System.

Patient Information Record

Table 5.2: Patient Information Record: Host to LCx

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
8.1.1	Record Type ID	1	P or p	Patient
8.1.2	Sequence Number	5	1 to 65535	Must be consistent with sequence number rules.

```
P|1[CR]
```

Figure 5.2: Example of Patient Information Record: Host to LCx

ASTM Fields 8.1.1 and 8.1.2 of the Patient Information Record are required by the LCx System.

Test Order Record

Table 5.3: Test Order Record: Host to LCx

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
9.4.1	Record Type ID	1	O or o	Order
9.4.2	Sequence Number	5	1 to 65535	Must be consistent with sequence number rules.
9.4.3	Specimen ID	9	Specimen (Alphanumeric)	Sample ID downloaded from Host, returned unchanged to Host.
9.4.5	Universal Test ID Code	3	^^^Assay Number	Specific number that identifies the test.
9.4.12	Action Code	1	A	(A)dd a new Patient Order
9.4.26	Report Types	1	O	(O)rder This should always be an order. Query is not supported.

O|1|BR549||^^^111|||||||A|||||||||||||O[CR]

Figure 5.3: Example of Test Order Record: Host to LCx

ASTM Fields 9.4.1, 9.4.2, 9.4.3, 9.4.5, 9.4.12, and 9.4.26 of the Test Order Record are required by the LCx System.

Field 9.4.3 must include the Specimen ID.

Request Information Record

The LCx System does not generate a Request Information Record nor does it recognize Request Information Records received from the host.

Message Terminator Record

Table 5.4: Message Terminator Record: Host to LCx

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
13.1.1	Record Type ID	1	L	Last
13.1.2	Sequence Number	1	1	Will always contain 1

L|1[CR]

Figure 5.4: Example of Message Terminator Record: Host to LCx

ASTM Fields 13.1.1 and 13.1.2 of the Message Terminator Record are required by the LCx System.

Troubleshooting

Introduction

Error messages are grouped into three (3) basic categories.

- 213 Format Errors

  These errors occur when the ASTM parser detects a format error in the messages sent by the Host System to the LCx. Note: This error will only occur when the host interface is activated.

- 214 Process Errors

  These errors can occur while processing the ASTM orders after the complete message has been received. Note: This error will only occur when the host interface is activated.

- 216 – 253 Low Level Communication Errors

  These errors can occur during the low level communications phase between the instrument and the Host system. Note: This error will only occur when the host is activated.

LCx Customer Support Center

Corrective action for each error regarding the Host Interface should initially include resending the test request. If the error repeats, proceed with the additional corrective actions listed. If the corrective actions do not solve the problem, call the LCx Customer Support Center.

Error Codes

213 ASTM Format Error with the following error description subtitles

HEADER DELIMITER	1st Field Delimiter does not match Host defined Field Delimiter.
HEADER VERSION	Incorrect version number in Header Record.
HEADER FLUSH	There have been 6 attempts to decode a Header Record without success.
DUPLICATE HEADER	A second Header Record was encountered after a Header Record has been successfully decoded.
ILLEGAL DELIMITER	Parser encountered an illegal delimiter
RECORD FORMAT	Record terminated before all required fields have been parsed.
RECORD LEVEL	Message Records did not follow ASTM message hierarchy.
RECORD SEQUENCE	Record Sequence numbers are incorrect.
FIELD TRUNCATION	Field contents exceeded allocated space resulting in a truncation of the field.
FIELD FORMAT	Field terminated before all required components have been parsed.
TOO MANY FIELDS	Excess number of fields encountered for a particular record.
ILLEGAL RECORD	Illegal Record identifier character encountered.
ILLEGAL PROCESS ID	Process id in header record was not ‘P’.
ILLEGAL CHARACTER	Illegal character encountered during parsing.

214 ASTM Process Error with the following error description subtitles

SID REQUIRED	Sample ID's omitted from Order Record.
ILLEGAL ACTION CODE	Illegal Action Code in Order Record.
MISSING ACTION CODE	Action Code missing in Order Record.
ILLEGAL REPORT	Illegal Report Option in Order Record.
MISSING REPORT	Report Code missing in Order Record.
INVALID ASSAY NUMBER	Assay Number in Order Record is not on assay module.
MISSING ASSAY NUMBER	Assay Number missing in Order Record
CAPACITY EXCEEDED	Load capacity (Cal/CNTL/Sample) for an LCx carousel exceeded.
ASSAY LOCKOUT	Order battery Test ID (Assay Number) is locked out from the ASTM parser.
LOADLIST NOT AVAILABLE	Order battery sent to instrument after an Assay run is initiated or Sample Management Loadlist is being edited.
ASSAY NUMBER MISMATCH	Different assay numbers encountered in the order battery or Assay number read off reagent pack does not match the downloaded Assay number
ORDER CLEARED	Downloaded order cleared by operator.

216 ASTM COMM TIMEOUT

Timeout occurs during ASTM communication

247 ASTM COMM BAD MESSAGE LENGTH

Message length in a frame exceeds 240 characters.

248 ASTM COMM INVALID FRAME TYPE

Frame is not an end type.

249 ASTM COMM NUM RETRIES EXCEEDED

Instrument is unable to send a frame to the host after 6 retries.

250 ASTM COMM INVALID RESPONSE

Response sent by host is incorrect.

251 ASTM COMM INVALID FRAME

Frame checksum or format is incorrect.

252 ASTM SPOOLER INIT

Spooler checksum test failed.

253 ASTM COMM BAD FRAME NUM

The frame number is incorrect.

LCx ERROR LOGGING

Instances when errors take place during link establishment or during communication between the instrument and host as well as during processing of an order will be logged to an ASTM error log file. Spooler buffer full errors will be sent to the system log file. The error log can be printed on the LCx printer. This will allow limited low level analysis of the communications link for diagnostic purposes.

Print Log of ASTM errors

A printed log of ASTM errors can be generated from the UTILITY\OTHER\OTHER\SERVICE\OTHER\OTHER ASTM_LOG menu.

Errors are displayed in the following fashion:

Low Level Communication Errors

```
MM/DD/YYYY HH:MM:SS      nnn
ASTM COMM zzzzzzzzzzzzzzzzzzzzzzzzzzzzzz
```

where:

nnn = error code number
zzz... = error description message.

Format Errors

```
MM/DD/YYYY HH:MM:SS     213  xxxx   yyyy
ASTM FORM zzzzzzzzzzzzzzzzzzzzzzzzzzzzz
```

where:

xxxx = index of record being parsed where the error took place.
yyyy = character index within record where the error took place.
zzz... = error description message.

Process Errors

```
MM/DD/YYYY HH:MM:SS     214
ASTM PROC zzzzzzzzzzzzzzzzzzzzzzzzzzzzz
```

where:

zzz... = error description message.

Print Log of ASTM Spooler Buffer Capacity error

Spooler Buffer Capacity errors are sent to the System Error Log. The error is displayed in the following fashion:

```
MM/DD/YYYY HH:MM:SS     215
SPOOLER RUN CAPACITY
```

NOTES

Abbott Host/Instrument Interface Simulator

Section Overview

This section provides information about the Interface Data Disk included with this manual. It describes how to use the Abbott Host/Instrument Interface Simulator (HIISIM) to communicate data files found on the disk for the purpose of testing the interface to the instrument or system.

The Interface Data Disk includes the following:

- A Host/Instrument Interface Simulator program
- Actual Data files captured from the instrument or system
- A "README.TXT" file describing the contents of the different data files

The Host/Instrument Interface Simulator program is provided to assist customers and LIS Vendors with the development of interface software to Abbott instruments and systems supporting the ASTM communication protocols.

In This Section:

- Simulator Use and Function
- Simulator Requirements and Installation
- Principle of Operation
- HIISIM Operating Instructions

Simulator Use or Function

Abbott customers and LIS vendors can use HIISIM to simulate new Abbott instruments and systems by communicating previously captured data files to their new interfaces. This allows testing of the communications interface to Abbott instruments, and reduces the amount of testing required in a "live" lab environment.

Extensive logging capabilities provide software developers with an audit trail of communication activity for easy troubleshooting and diagnostics. Erroneous transactions can be created which can be used to test the interfaced instruments' or systems' response to error conditions.

Simulator Requirements and Installation

System Requirements

The Host/Instrument Interface Simulator software runs on an IBM compatible personal computer using DOS 3.3 or higher. A minimum of 640 K of memory is required on the system to properly run the DOS environment and the Host/Instrument Interface Simulator.

The simulator uses a single serial port, which can be either COM1 or COM2. Either a standard RS-232 25-pin connector or a 9-pin connector may be used; the only pins used by the software are the TRANSMIT, RECEIVE, and SIGNAL_GROUND (i.e., 2, 3, and 7 pins). If the systems being connected are configured similarly (i.e., DTE/DTE or DCE/DCE), then the cable needs to be a null modem cable (i.e., pins 2 and 3 crossed).

Making a Back-up of the Data Disk

Prior to using this software, it is a good idea to make a backup copy of the master disk. Place this disk in the A: drive. At the DOS prompt type:

DISKCOPY A: A: (and press ENTER)

When asked for the SOURCE diskette, put the master disk into drive A:.

When asked for the TARGET diskette, remove the master disk and put a new diskette into drive A:. (You do not need to format the TARGET diskette, DOS does this during DISKCOPY.)

> NOTE: The master diskette may be “write-protected.” You will be unable to run the program from a “write-protected” disk, since it writes parameter files, log files, etc., to disk.

At completion, store the master diskette in a safe place and label and use the TARGET diskette. Should you have problems, you can always go back and use the master diskette. We will call this diskette the HIISIM diskette throughout the rest of the manual.

Installation on Hard Disk Systems

In order to install the program on a system with a hard disk, you must ensure that all files from the Interface Data Disk are copied to the hard drive. In order to simplify use of the simulator and the data files included on the Interface Data Disk, you should create a separate directory for this instrument interface data and simulator.

To start, place the Interface Data Disk in the A: drive. From the DOS prompt, type the following commands (followed by ENTER):

**CD **	Returns to the root C:\ directory assuming the hard disk is drive C:
MD HIISIM	Creates the directory HIISIM
CD HIISIM	Changes the default directory to be HIISIM
COPY A: *.*	Copies all files from the A: drive to the directory HIISIM
**CD **	Changes the default directory to C:\

Installing on Floppy Disk Systems

This software does not require that it be installed on a system with a hard disk. It may be run directly from the floppy disk. Simply use the Interface Data Disk in your 3.5" floppy drive and execute the program directly from the Interface Data Disk.

> NOTE: Be sure to follow the DISKCOPY directions above, save the master diskette in a safe place, and check that the disk being used is not “write protected”. HIISIM writes its default parameter file and message file to disk upon start-up.

Place the Interface Data Disk in the 3.5" floppy drive and type the following commands (followed by ENTER) at the DOS prompt:

A:	Changes the default drive and directory to A:\ assuming the 3.5" floppy is drive A:
HIISIM	Starts the program. You are ready to proceed.

Principle of Operation

After thorough review of the RS-232 interface specification defined within this manual and the appropriate ASTM communications standards (i.e., E1394-91 and E1381-91), customers and LIS vendors have sufficient information to develop an interface to this instrument or system.

Once the interface software has been written, the Host/Instrument Interface Simulator provided may be used to test the interface and to communicate data files available on the data disk that represent the output of the instrument or system.

> NOTE: Although Abbott provides this tool in order to assist with the development of interface software to our instruments and systems, Abbott does not recommend using this tool as the only means of testing and validating the interface. Final validation and verification (V&V) of the interface should only be done through an approved development, testing, and V&V process and through testing with a live instrument in the environment that it is being used.

The Host/Instrument Interface Simulator provides a developer or user several valuable functions to simplify the troubleshooting and testing of interface software. The functions supported are:

- Ability to modify communication parameters
- Ability to capture transmitted data to a file
- Ability to transmit previously captured data from a file
- Ability to simulate communications/protocol errors while sending

- Ability to simulate communications/protocol errors while receiving
- Ability to interactively support bidirectional communications while sending or receiving, using function keys to transmit protocol characters
- Ability to edit data files and create framed data files for transmission

Central to all the functions listed above (except modifying communications parameters and editing data files) is the simulator's ability to log communications activity and provide insight (through diagnostic messages) into error conditions that have occurred.

HIISIM Operating Instructions

To start the simulator program, change the drive/directory (CD) to the one containing the HIISIM.EXE program and type **HIISIM** at the DOS prompt.

Upon start-up, the HIISIM program writes two files to disk that contain its default settings.

1. HIISIM.PRM

   File used to store the default communication parameters. The defaults are:

   – Port: COM1
   – Baud Rate: 9600
   – Parity: N (None)
   – Data Bits: 8
   – Stop Bits 1
   – Simulate Instrument

2. HIISIM.MSG

   File used to store menu text and other user prompts. This file may be edited by the user to customize the menus; however, this is not recommended.

The user should be aware that both of these files have specific record formats and any distortion to that format could make the program unable to run. If the file is edited and becomes corrupted, the user may recover by deleting both files from the drive/directory. The simulator (HIISIM) automatically regenerates the default files if they are not found.

Once HIISIM is running, the copyright screen is displayed. This screen is displayed for a short period of time and is then replaced with the main menu.

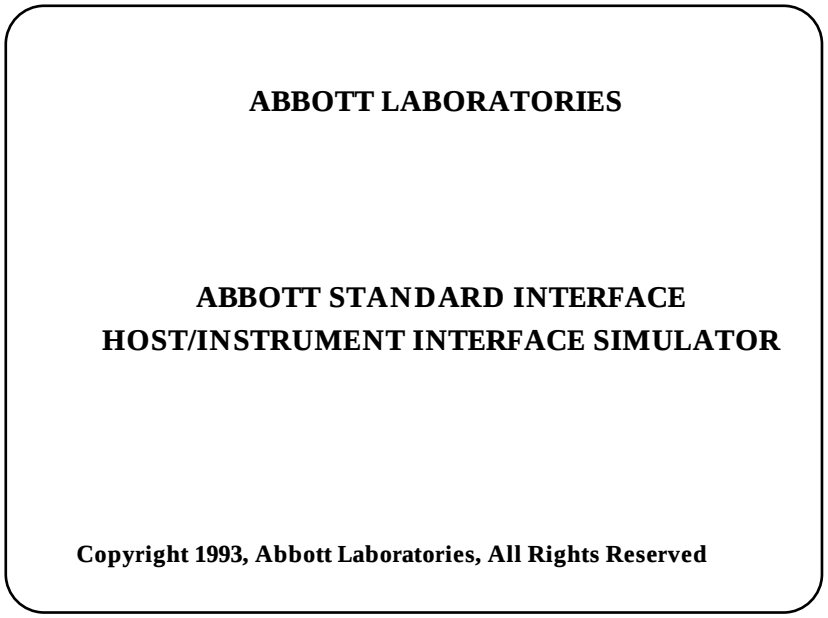


Figure 7.1: HIISIM Copyright Screen

You can speed up the process by pressing any key to advance immediately to the Main Menu

The Main Menu provides access to all functions supported by the HIISIM program. To start the execution of any of the functions identified on the screen, simply press the number corresponding to that function. Upon completion, each function returns to the Main Menu. The program is designed to allow a user to cancel execution of any function or exit by pressing the EXIT key (normally F10). The ESC key is also used in several places (discussed later) to cancel execution of a function without saving or modifying opened files.

To exit the program completely, press 8 (8. Exit this program) at the Main Menu. The computer returns to the DOS prompt.

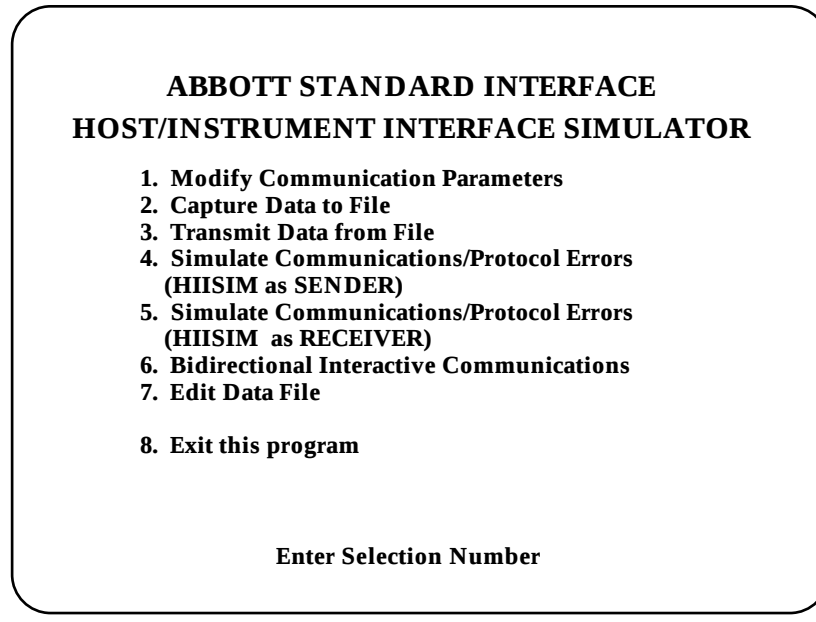


Figure 7.2: HIISIM Main Menu Screen

The following subsections describe the purpose and operation of each of the HIISIM supported functions.

Modify Communication Parameters

This function allows the user to set the communication parameters of HIISIM to match that of the attached instrument or host system. You can also specify HIISIM to simulate an instrument or host system for the purpose of resolving line contention and using appropriate time-out conditions.

Press 1 (1. Modify Communication Parameters) at the HIISIM main menu to execute this function. The program advances to the Modify Communication Parameters menu.

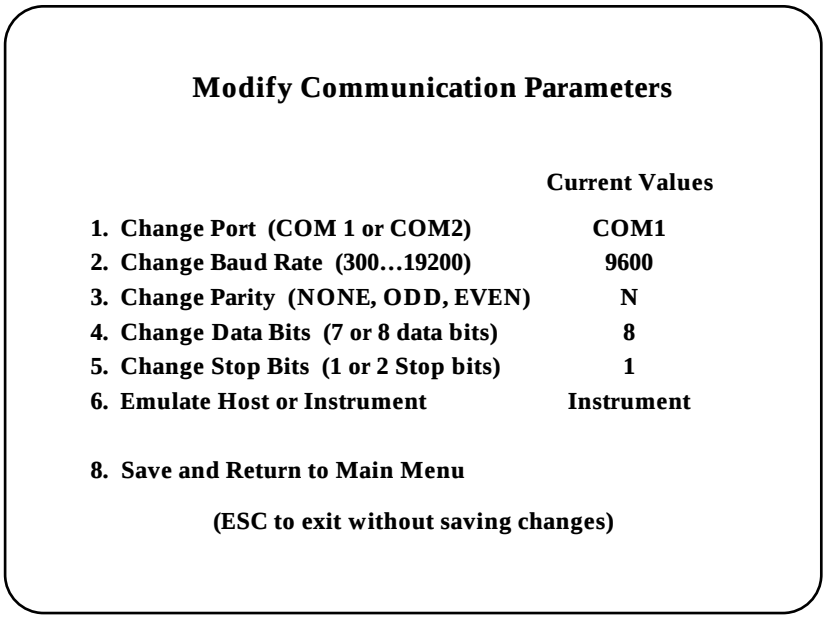


Figure 7.3: HIISIM Modify Communication Parameters Screen

The screen shows the current values for each communication parameter. When you start the system, each parameter is set to its default value which in most cases will not need to be changed. To change the value of any parameter, simply press the number corresponding to that parameter (displayed on the left). By repeatedly pressing the selection number, the value for that parameter scrolls through the list of options.

For example, if the baud rate is set to 9600 (the default), then pressing the number 2 advances the value for the baud rate to 19200. Pressing 2 again advances the value to 300. And pressing 2 again advances it to 600, and so on through the list of supported baud rates.

This menu works the same way for all communication parameters available. For instance, pressing 6 advances the value for what is being simulated from Instrument (the default) to Host. Pressing 6 again advances it back to Instrument since these are the only two options for the parameter.

The Host or Instrument setting is important for the simulator to apply the appropriate time-out conditions, as required by the ASTM E1381-91 standard. Also, if the simulator is set to act as a HOST in Transmit mode and line contention is encountered (receiving an <ENQ> to a transmitted <ENQ>), the simulator automatically switches to receive mode to capture an instrument's output. No data file is saved, but all communications are captured to a log file.

When you have all selections as you need them, press 8 to return to the main menu and save your changes. These selections remain in effect until they are changed or default back to their original values (by deleting HIISIM.PRM file).

In order to exit this menu and return to the main menu without saving your changes, press the ESC key.

> NOTE: Until the communication parameters are set properly, no communications will occur. You must have these settings correct before proceeding to any other HIISIM function. Look in the instrument or host system documentation under Communications or RS-232 to determine what that system expects for these settings. You should not have to change the instrument or host, you should let HIISIM be the flexible one; make the changes of baud rate, etc., on the HIISIM program.

Capture Data to File

This function allows the user to capture a transmitted file from the attached instrument or host system and save it to disk. It provides full support of the ASTM E1381-91 protocol as a receiver during the establishment phase, the transfer phase, and the termination phase.

Press 2 (2. Capture Data to File) at the HIISIM main menu to execute this function.

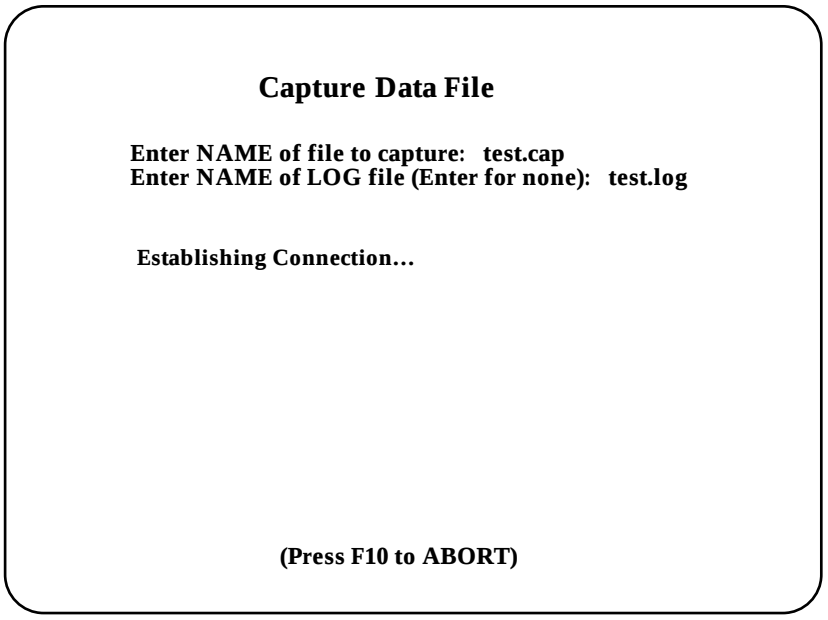


Figure 7.4: Capture Data File Screen

The program displays:

Enter NAME of file to capture:

Type a filename, which may include a drive and path that receives the data transmitted from the attached instrument or host. The name entered must meet all of the file naming conventions required by DOS 3.3 and above. You might consider using ".CAP" as the extension to the file name to distinguish these files from others. If you press ENTER with no filename, then HIISIM will receive the file but not store it to disk. This might be done if you are simply testing the communications and don't care to save the file.

After you have pressed ENTER to complete your response, HIISIM displays:

Enter NAME of LOG file (Enter for none):

Type a valid filename with drive and path, if you like. This file contains a log of all characters received and sent. Also, various diagnostic messages are written to this file, such as reasons HIISIM rejected a message (bad checksum, etc.).

If you press ENTER to this prompt with no filename, then there is no logging. It is suggested that you use ".LOG" as the extension for log files. This convention simplifies things when you need to find and print the log files.

> NOTE: If you specify a file that already exists, either for capture or logging, that file's contents are erased before new records are written.

Once you have answered the two filename prompts, HIISIM begins to establish the communications session. The program displays:

Establishing Connection.....

According to ASTM standards, a receiver waits in idle state to enter the establishment phase. The HIISIM program continues checking the communication ports, waiting for the <ENQ> character. A dot (.) is written to the screen every second as an indication to the user that the program is running.

The user may abort at any time by pressing F10 to abort the communication session and return to the main menu.

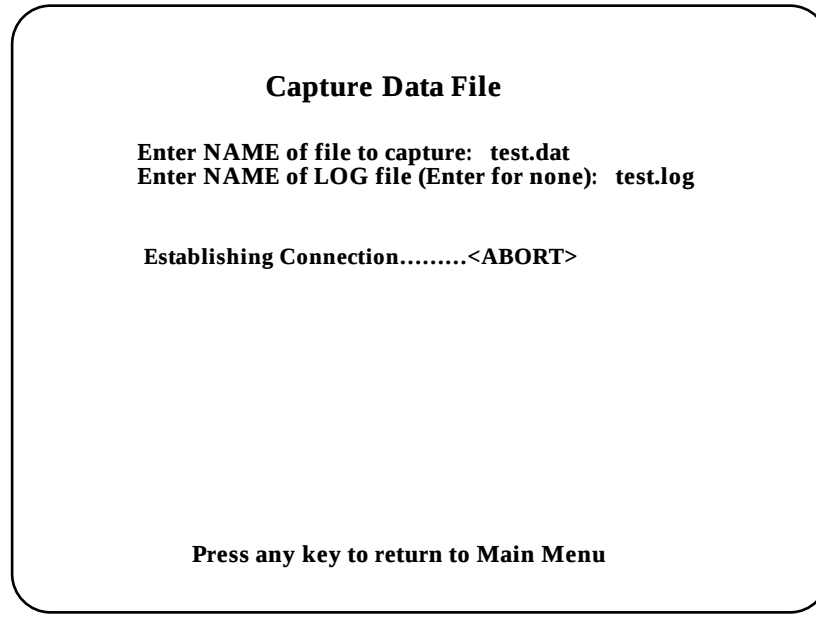


Figure 7.5: Abort Capture Mode

Once the <ENQ> character is received, HIISIM continues a communication session until the sender terminates the connection by sending the <EOT> message. The program then returns to the main menu.

As characters are sent and received, they are displayed on the screen. If logging is on, they are also written to the log file.

Capture Data File

Enter NAME of file to capture: test.dat
Enter NAME of LOG file (Enter for none): test.log

S:<ACK>
R:<STX>4P|4<CR><ETX>44<CR><LF>
S:<ACK>
R:<STX>5-0|1|3341\3092\3993\3664\3545||^^^TO1|||||N||||||||O<CR>
<ETX>D2<CR><LF>
S:<ACK>
R:<STX>6L|1<CR><ETX>3F<CR><LF>
S:<ACK>
R:<STX>7<CR><ETX>47<CR><LF>
S:<ACK>
R:<EOT>

Press any key to return to Main Menu

Figure 7.6: Capture Data Communications Session

The program displays all characters transmitted (S:) and received (R:) by this function. Protocol characters are encoded using <> nomenclature. For example, <STX> indicates receiving the “Start of Text” character.

Only the message content is written to the captured data file. At the beginning of each record in this file is a time stamp, which is seconds and hundredths of seconds since the last message was received. This time stamp is used in retransmission of the data.

When HIISIM receives an <EOT>, End Of Transmission character, the files are closed and the system returns to the main menu. At any time you may press F10 to abort and return to the main menu. If you press F10, the files are properly closed and saved.

Transmit Data from File

This function allows the user to send a file containing data in the format described by the ASTM E1394-91 standard to the attached instrument or host system. It fully supports the requirements, as specified in ASTM E1381-91 for the sender.

Press 3 (3. Transmit Data From File) at the HIISIM main menu to execute this function.

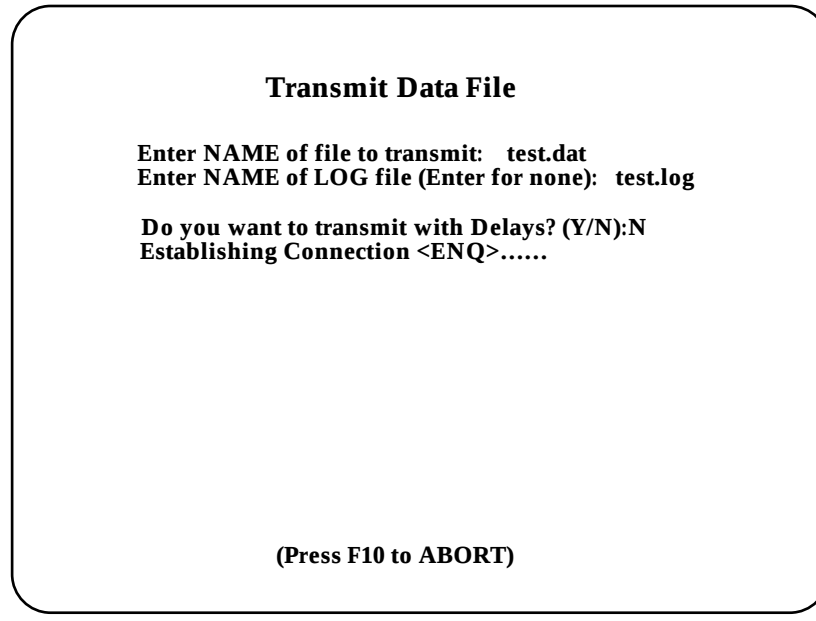


Figure 7.7: Transmit Data File

The program displays:

Enter NAME of file to transmit:

Type a filename, which may include a drive and path, that is transmitted to the attached instrument or host. A valid filename must be entered. If the file does not exist, a message is displayed and the program returns to the main menu.

The program looks at the current drive and directory if none is specified. After you have pressed ENTER to complete your response, HIISIM displays:

Enter NAME of LOG file (Enter for none):

Type a valid filename with the drive and path. This file contains a log of all characters received and sent. Various diagnostic messages are written to this file, such as reasons HIISIM rejected a message (bad checksum).

If you press ENTER to this prompt with no filename, then there is no logging. It is suggested that you use ".LOG" as the extension for log files. This convention simplifies things when you need to find and print the log files. Once you have answered the two filename prompts, HIISIM opens the data file to check the format. If the format of the file indicates that the file contains time stamps, the program displays:

Do you want to transmit with delays? (Y/N):

This prompt is not displayed if the file does not contain any time stamps at the beginning of each record. The function proceeds to the establishment phase by transmitting the <ENQ> character.

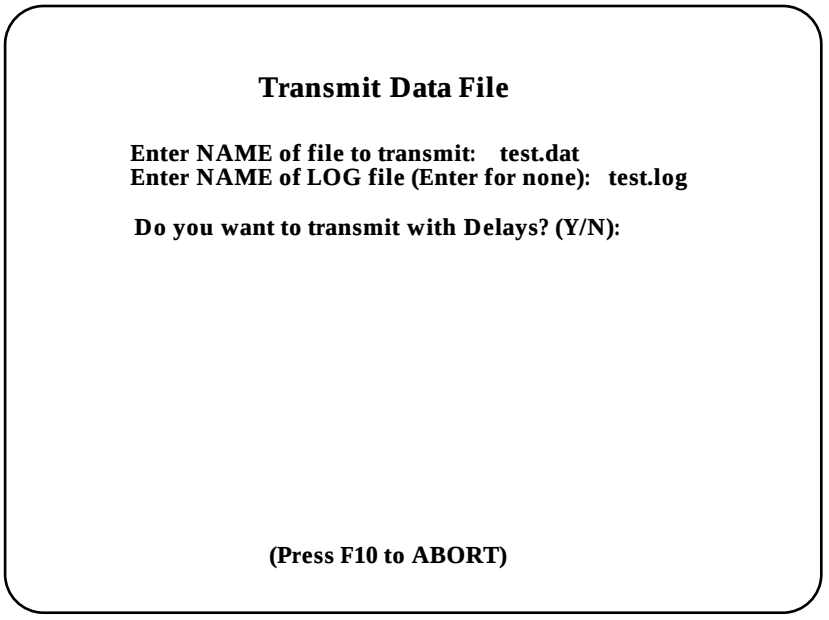


Figure 7.8: Transmit Data File With Time Delays Screen

Enter "Y" (without quotes) to delay transmission of each frame with the time stamp that is in the first six positions of each line of the file.

Enter "N" (without quotes) to ignore the time stamps in the first six positions of each line of the file.

HIISIM then proceeds to establish the communications session. HIISIM sends an <ENQ> character and waits for a reply from the attached system for a specified amount of time.

The user may abort the communications activity at any time by pressing F10 and then F10 again to return to the main menu. If you press F10, the files are properly closed and the log file saved.

Since the transmit function only attempts to establish a connection for a short amount of time (15 seconds as specified by ASTM E1381-91 standard), it is recommended that the receiving system be started first, and then start the system that will transmit.

A dot (.) is written once every second while waiting for the receiver's response.

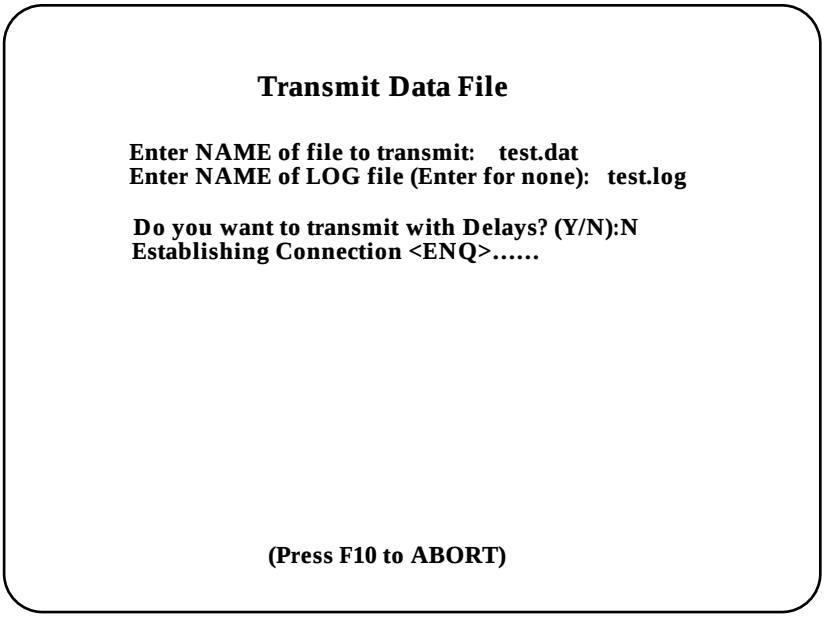


Figure 7.9: Transmit Data File Screen

As characters are sent and received, they are displayed on the screen. Logging on these characters is also written to the log file. Characters that are sent by the transmit function appear on the lines starting with “S:”. Characters that are received by this function appear on the lines starting with “R:”.

Protocol control characters are converted to their mnemonic equivalent for readability, as shown on the screen.

When HIISIM reads the end of file, it sends an <EOT>, End Of Transmission, and the system returns to the main menu. Also, if a time-out occurs during the establishment phase (i.e., after sending the <ENQ>), HIISIM sends an <EOT> to terminate the transmit session.

Simulate Communications/Protocol Errors (as Sender)

This function is used in testing the ASTM compliance of the attached system while that system is acting as the receiver. The user is able to choose from a list of possible errors that may occur while the other system is in the receiver mode.

Press 4 (4. Simulate Communications/Protocol Errors [HIISIM as Sender]) at the HIISIM main menu.

The program responds by displaying the Simulate Communications/Protocol Errors (HIISIM as SENDER) screen.

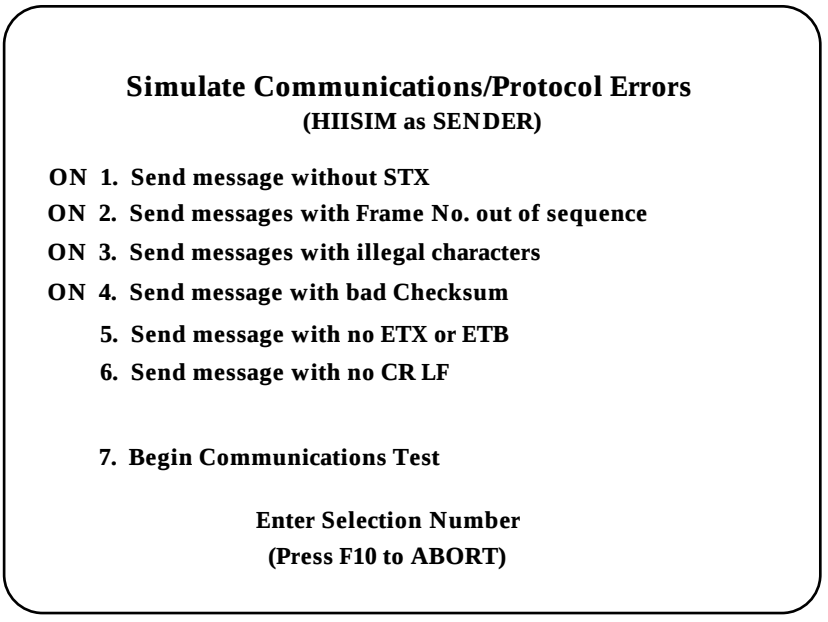


Figure 7.10: Simulate Communications/Protocol Errors Screen

To select a test (or error condition), press the corresponding selection number and the state of each error condition toggles between ON and OFF (default). When the selections are as you desire, press 7 (7. Begin Communications Test) to continue.

The program prompts the user for the name of the file to be transmitted, the name of the file to log the communications activity, if the file contains time delays, and if the delay should be used.

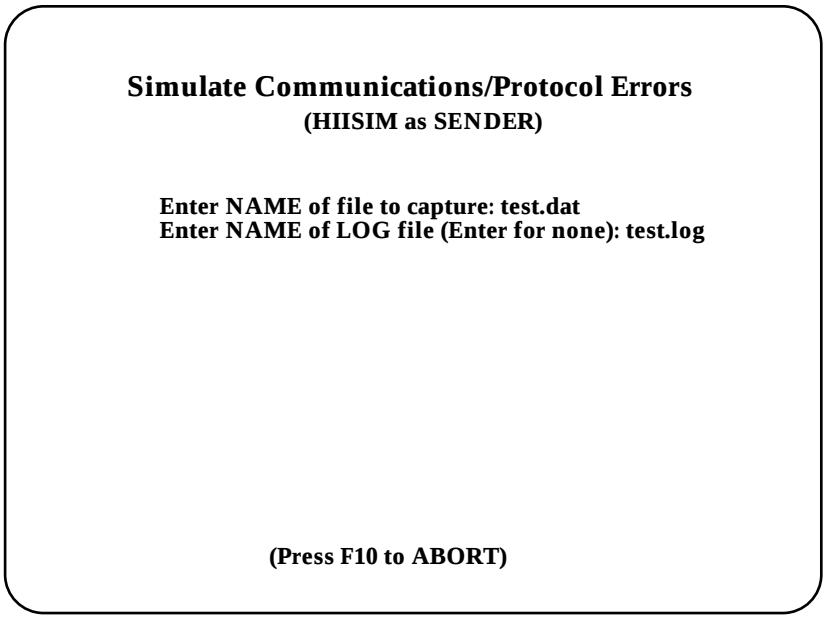


Figure 7.11: Simulate Communications/Protocol Errors

During this session, these selected error conditions are generated and logged. The log file also contains diagnostic messages indicating what should be expected by the receiving system. Examination of the log file proves or disproves that the attached system properly handled the error condition.

Certain error conditions terminate the communication session, and subsequent errors are not tested. You may have to use this function several times with various error selections to do a thorough job of testing for ASTM compliance and correct error handling by the attached system.

It is suggested that each function be performed individually first before doing combinations of errors.

There are messages written to the log file that describe the test being performed and also the expected response from the attached system. These messages have the "T" ID at the start of the line to indicate a test message.

Simulate Communications/Protocol Errors (HIISIM as RECEIVER)

This function is used in testing the ASTM compliance of the attached system while that system is acting as the sender. The user is able to choose from a list of possible errors that may occur while the other system is in the transmit (Sender) mode.

This function first displays a menu of various error conditions that you may turn ON and OFF. After making your selections, you initiate the communication session.

Press 5 (5. Simulate Communications/Protocol Errors [HIISIM as Receiver]) at the HIISIM main menu.

The program responds by displaying the Simulate Communications/Protocol Errors (HIISIM as RECEIVER) screen.

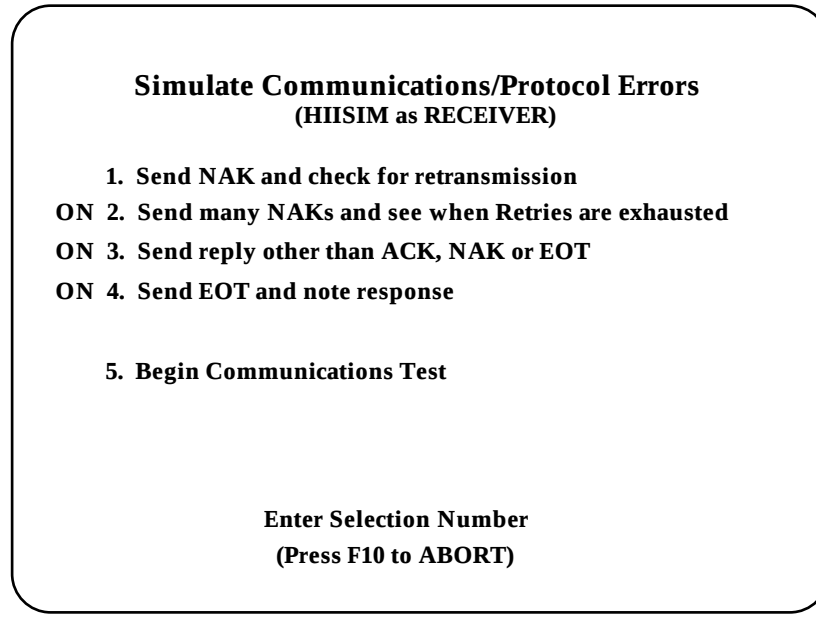


Figure 7.12: Simulate Communications/Protocol Errors Screen

To select a test (or error condition), press the corresponding selection number and the state of each error condition toggles between ON and OFF (default). When the selections are as you desire, press 5 (Begin Communications Test) to continue.

The program prompts the user for the name of the file to capture the data and the name of the file to log the communications activity. If for either data file or log file the user presses ENTER without first entering a filename, the information is displayed to the screen, but not saved, in the corresponding file.

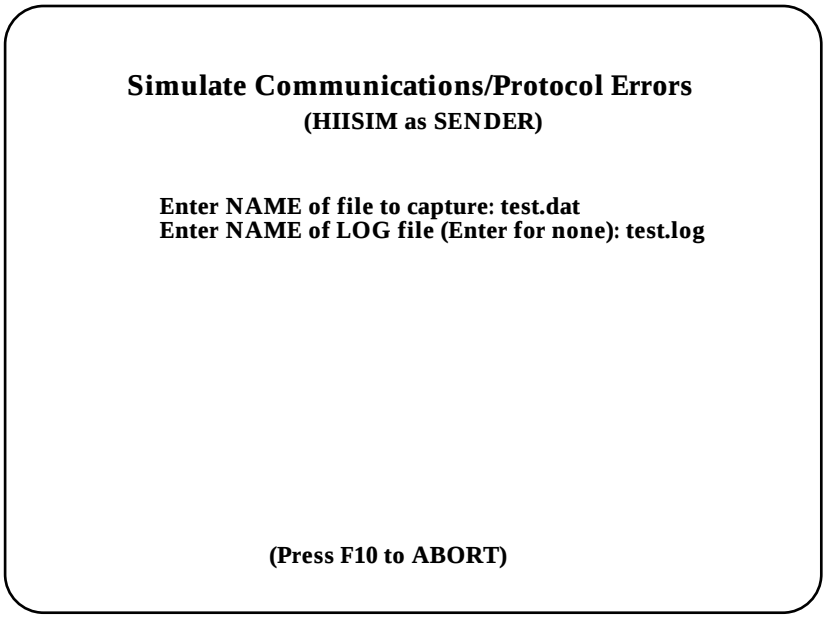


Figure 7.13: Simulate Communications/Protocol Errors

During this session, these selected error conditions are generated and logged.

The log file also contains diagnostic messages indicating what should be expected by the transmitting system. Examination of the log file proves or disproves that the attached system properly handled the error condition.

Certain error conditions terminate the communication session, and subsequent errors are not tested. This means you may have to use this function several times, with various error selections to do a thorough job of testing for ASTM compliance and correct error handling by the attached system.

There are messages written to the log file that describe the test being performed and also the expected response from the attached system. These messages have the “T” ID at the start of the line.

Bidirectional Interactive Communications

This function is used in testing the ASTM compliance of the attached instrument or host system. This function provides a transmit and a receive mode to allow the development of very sophisticated testing scenarios. The combination of function key equivalents of protocol character and the ability to define, build, and transmit a file with framed data, provide an unlimited functionality for testing.

By using the Edit Data File function, you may build files that contain frames of data. These frames may be used to provide specific testing of an interface. In this mode, HIISIM transmits records from a file "as is." HIISIM does not add the protocol framing characters. There are function keys which send the various single character replies, <ACK>, <NAK>, and the like.

Press 6 (6. Bidirectional Interactive Communications) at the HIISIM main menu. The program responds by displaying:

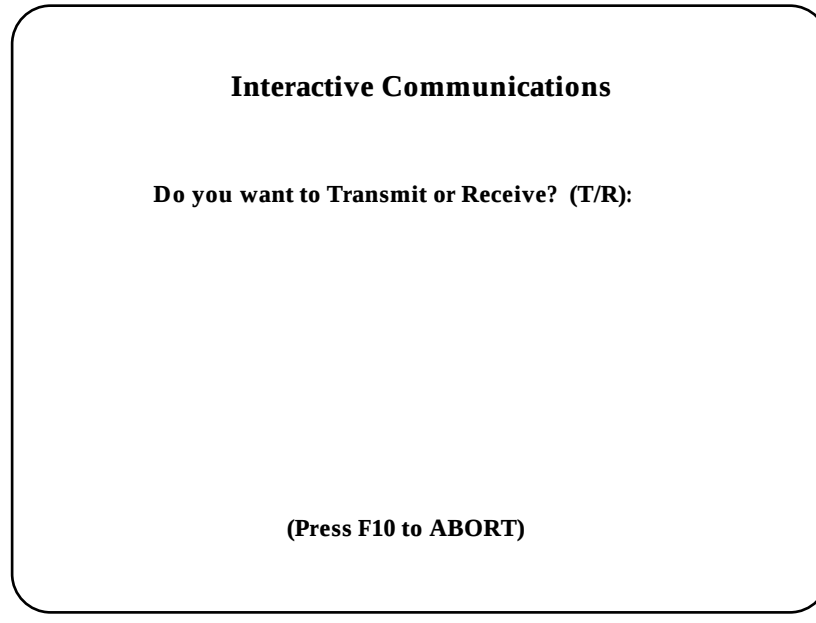


Figure 7.14: Interactive Communications Screen

Press the T or the R for transmit or receive.

Transmit Mode

If this function is used in the Transmit Mode (T), then the program prompts the user for the name of the file to be transmitted and the name of the log file to capture all of the communications activity. The name of the transmit file must be the valid name of an existing file. Pressing ENTER without specifying a log file allows the program to display communication activity without saving it to a file.

The program then displays:

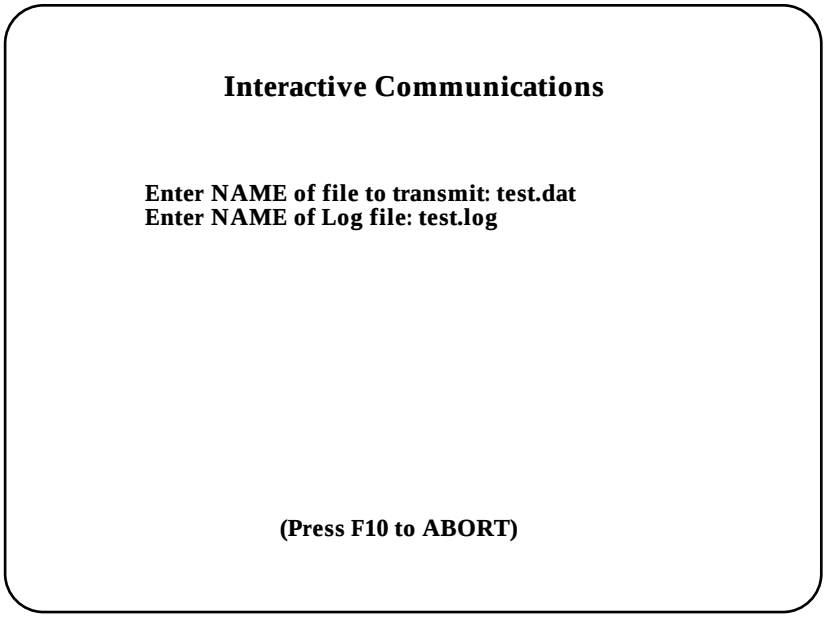


Figure 7.15: Interactive Communications Screen

Receive Mode

If this function is used in Receive Mode, the program prompts for the name of the file to capture the data and then the name of the log file. Pressing ENTER without first entering a file name at any of the prompts causes the program to display that information only, without writing it to a file.

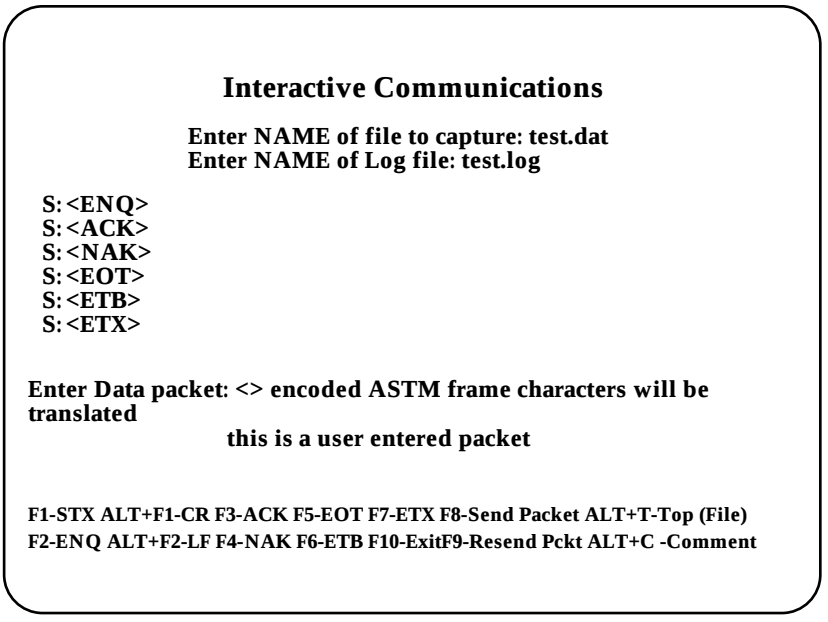


Figure 7.16: Interactive Communications Screen

At the bottom of the screen is displayed the action of various function keys. F10 exits or aborts as it does in the rest of the system.

Pressing a function key causes the corresponding character to be transmitted out of the port. Transmitted characters are logged and tagged with (S:) sent. Characters that are received are identified with an (R:).

The following table shows the keys supported during Interactive Communications.

Table 7.1: Interactive Communications Keys

Key	Description
F1	Send the <STX> character
F2	Send the <ENQ> character
F3	Send the <ACK> character
F4	Send the <NAK> character
F5	Send the <EOT> character
F6	Send the <ETB> character
F7	Send the <ETX> character
F8	Send a packet of characters. While in Transmit mode, the packets are read from the file sequentially. While in Receive mode, the user is prompted for a data packet with the following message: "Enter Data Packet: <> encoded ASTM frame characters will be translated".
F9	Re-send previously transmitted packet
F10	Exit
ALT+F1	Send the <CR> character
ALT+F2	Send the <LF> character
ALT+T	Resume from top of file. While in Transmit mode, the program resets its file pointer so that the next packet read is from the top of the file. While in Receive mode, the user will be asked to confirm that they want the Receive file to be overwritten with the new information.
ALT+C	Enter a user comment for the log file.

Press F10 to exit and return to the main menu at any time.

Edit Data File

This function is used to create or modify files which may be transmitted using either: "Bidirectional Interactive Communications" or "Transmit Data from File." You may create files that simulate protocol errors. This function, used in concert with "Bidirectional", allows the creation of any number of error conditions such as:

Frame number out of sequence
Incorrect check sum
Missing Frame characters

With this function, you can also modify the delay times that are at the beginning of each line of a captured file.

From the main menu press 7 (7. Edit Data File).

The program prompts for the name of the file to edit and the output file. Enter a valid DOS filename, include the drive and path if required. This editor leaves the original file unaltered.

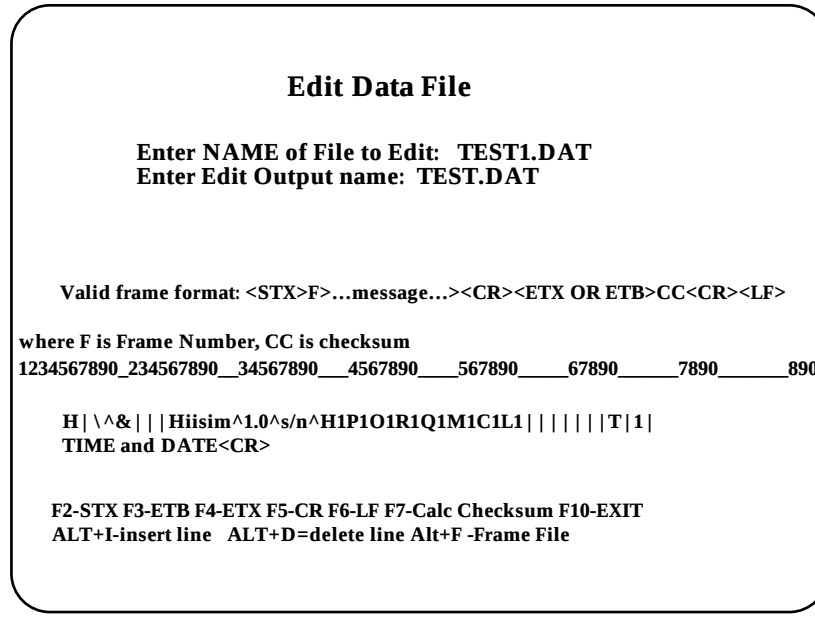


Figure 7.17: Edit Data File Screen

The Edit Data File screen displays a two-line description of the valid format of a frame, a one-line editing ruler to assist in editing the file, a single line displaying the line being edited, and at the bottom of the page is a two-line description showing the protocol control characters. The protocol control characters are mapped to function keys and several other functions to allow easier editing of the file.

The ruler provides an easy way to identify the position of a character within a displayed line. The simple way to interpret the ruler is as follows:

1234567890_234567890_34567890_4567890

- _2 indicates the “2” is the 12th character position
- _3 indicates the “3” is the 23rd character position
- _4 indicates the “4” is the 34th character position, and so on

This editor follows the conventions of most screen editors, and supports the following keys:

Table 7.2: Edit Data File Screen Keys

Key	Function
HOME	Moves cursor to beginning of displayed line
END	Moves cursor to end of displayed line
UP ARROW	Saves current edits on line and displays previous line
DOWN ARROW	Saves current changes on line and displays next line
ENTER	Same as DOWN ARROW
DELETE	Deletes characters to the right of the cursor position
BACKSPACE	Deletes characters to the left of the cursor position
INSERT	Toggles mode from INSERT to OVERWRITE
F2	Inserts the characters <STX> at the cursor position
F3	Inserts the characters <ETB> at the cursor position
F4	Inserts the characters <ETX> at the cursor position
F5	Inserts the characters <CR> at the cursor position
F6	Inserts the characters <LF> at the cursor position
F7	Calculates the checksum for characters between <STX> and <ETB> or <ETX>
F10	Saves the changes to the new file and exits to main menu
ESC	Exits to main menu without saving changes
Alt+I	Inserts a blank line immediately before the line displayed
Alt+D	Deletes the current displayed line
Alt+F	Automatically frames a non-framed file

One line from the file is displayed at a time.

Press <Up Arrow> or <Down Arrow> to display other lines.

After editing a line, you can calculate a correct checksum by pressing F7. This checksum is inserted after the first <ETX> or <ETB>.

When you are done editing, press F10 to save, exit, and return to the main menu. Here, press 6 to enter "Bidirectional Interactive Communications", specifying where you can transmit this file.

HIISIM File Layout and Usage

The Abbott Host/Instrument Interface Simulator (HIISIM) uses several files with unique layouts and information content to effectively and accurately execute the various functions. The user should be familiar with the layout, structure, and information content of all the different file types in order to utilize the simulator effectively.

The simulator allows data files to contain comment lines that are used for documentation purposes and are ignored by all communication functions of the simulator. Comment lines are identified by the label "REM>>>" (without quotes) in the first six positions of each line. These comment lines may be used anywhere within the data file and they will be ignored as part of the communications.

Data File With Time Stamps

This file is created when using the simulator to capture data from an external system (selection 2 (2. Capture Data to File) on the main menu. The file can be transmitted using selection 3 (3. Transmit Data From File) on the main menu. The structure and data content of the file is shown below:

```
REM>>> ************************************************************************
REM>>> Example of host downloaded data file with timestamp information
REM>>> (first seven spaces of each line) as captured by the simulator
REM>>>
REM>>> Note: The timestamps are written by the simulator and not communicated
REM>>>       by instruments.  Timestamps may be used to delay communication of
REM>>>       records to test timeout boundary conditions
REM>>> ************************************************************************
7.00 H|\^&|||Hiisim^1.0^s/n^H1P1O1R1R1Q1M1C1L1||||||T|1|TIMEandDATE<CR>
2.25 P|1<CR>
12.11 O|1|3101^CRSL123^2||^^^T01^testname^dilution^testqualifier|S||||||N|||||||||||||O<CR>
14.50 O|2|356101||^^^T01|||||||N|||||||||||||O<CR>
.25 P|2<CR>
3.75 O|1|3121||^^^T01^testname|||||||N|||||||||||||O<CR>
4.00 O|2|322201||^^^T02^^1:100|||||||N|||||||||||||O<CR>
1.15 P|3<CR>
3.55 O|1|3102^CRSL123^1||^^^T01^^1:1000|||||||N|||||||||||||O<CR>
9.00 O|2|3992||^^^T02^testname|||||||N|||||||||||||O<CR>
1.00 O|3|3102||^^^T04\^^^T05\^^^T06|||||||N|||||||||||||O<CR>
.75 P|4<CR>
9.35 O|1|3341\3092\3993\3664\3545||^^^T99|||||||N|||||||||||||O<CR>
.65 L|1<CR>
```

Figure 7.18: Data File With Time Stamp

When the simulator is capturing data from an external system, it time stamps every frame received during the transfer phase of the communication session. The time stamp is written to the first six (6) positions of each line as shown above. The time stamp indicates the delta time (or time elapsed) between receiving a frame and receiving the next frame.

The time stamp is written in seconds and hundreds of a second. The seventh (7th) position is left blank to separate the time stamp from the actual data received. The remainder of each line contains the text (or message) portion of each frame that was received.

During transmit mode, this file is parsed to identify whether time stamps exist. If the file contains time stamps, the user is prompted to indicate whether the time stamps should be used to delay transmission of each frame.

While in transmit mode, the file is read and framed, as required by the ASTM protocol. Framing characters should not be included in this file since this would create redundant characters during transmission. This file should only contain high level records terminated with a <CR> to indicate the end of the record. Multiple records should not be combined in each line, since ASI instruments expect records as separate frames.

Data File Without Time Stamps

A variation of the above file may also be used during transmit mode. This file does not use time stamps in the first six positions of each line. The simulator correctly recognizes the absence of time stamps and does not prompt the user. Framing characters should not be included in this file. The file should only contain high level records terminated with a <CR> to indicate the end of the record. Multiple records should not be combined in each line, since ASI instruments expect records as separate frames. The file structure is as shown below:

```
REM>>> ************************************************************************
REM>>> Example of host downloaded data file without timestamps
REM>>> This example shows ordering test orders without any patient demographics
REM>>> ************************************************************************
H|\^&|||Hiisim^1.0^s/n^H1P1O1R1R1Q1M1C1L1|||||||T|1|TIMEandDATE<CR>
P|1<CR>
O|1|3101^CRSL123^2||^^^T01^testname^dilution^testqualifier|S||||||N|||||||||||||O<CR>
O|2|356101||^^^T01|||||||N|||||||||||||O<CR>
P|2<CR>
O|1|3121||^^^T01^testname|||||||N|||||||||||||O<CR>
O|2|322201||^^^T02^^1:100|||||||N|||||||||||||O<CR>
P|3<CR>
O|1|3102^CRSL123^1||^^^T01^^1:1000|||||||N|||||||||||||O<CR>
O|2|3992||^^^T02^testname|||||||N|||||||||||||O<CR>
O|3|3102||^^^T04\^^^T05\^^^T06|||||||N|||||||||||||O<CR>
P|4<CR>
O|1|3341\3092\3993\3664\3545||^^^T99|||||||N|||||||||||||O<CR>
L|1<CR>
```

Figure 7.19: Data File Without Time Stamps

Framed Data Files

In addition to the files described above, the simulator is able to utilize a data file that is framed, according to the ASTM E1381-91 standard.

<STX> Frame_Num {message text}{<ETX> or <ETB>}C1 C2 <CR> <LF>

This file may only be used in the transmit mode of the Bi-Directional Interactive Communications function of the simulator. Since this function does not provide automatic framing of data, the data communicated must be framed prior to initiating this function. The structure of the file is shown below:

```
REM>>> ************************************************************************
REM>>> Example of host downloaded data file with all low level communications
REM>>> characters used in framing records displayed in the <xxx> format
REM>>> This example shows ordering test orders without any patient demographics
REM>>>
REM>>> Note: Frame blocking is done on a per record basis (i.e. record blocking)
REM>>> ************************************************************************
<STX>1H|\^&|||Hiisim^1.0^s/n^H1P1O1R1R1Q1M1C1L1||||||T|1|TIMEandDATE<CR><ETX>47<CR><LF>
<STX>2P|1<CR><ETX>3F<CR><LF>
<STX>3O|1|3101^CRSL123^2||^^^T01^testname^dilution^testqualifier|S||||||N|||||||||||||O<CR><ETX>80<CR><LF>
<STX>4O|2|356101||^^^T01|||||||N|||||||||||||O<CR><ETX>7D<CR><LF>
<STX>5P|2<CR><ETX>43<CR><LF>
<STX>6O|1|3121||^^^T01^testname|||||||N|||||||||||||O<CR><ETX>D4<CR><LF>
<STX>7O|2|322201||^^^T02^^1:100|||||||N|||||||||||||O<CR><ETX>33<CR><LF>
<STX>0P|3<CR><ETX>3F<CR><LF>
<STX>1O|1|3102^CRSL123^1||^^^T01^^1:1000|||||||N|||||||||||||O<CR><ETX>AE<CR><LF>
<STX>2O|2|3992||^^^T02^testname|||||||N|||||||||||||O<CR><ETX>E2<CR><LF>
<STX>3O|3|3102||^^^T04\^^^T05\^^^T06|||||||N|||||||||||||O<CR><ETX>75<CR><LF>
<STX>4P|4<CR><ETX>44<CR><LF>
<STX>5O|1|3341\3092\3993\3664\3545||^^^T99|||||||N|||||||||||||O<CR><ETX>E3<CR><LF>
<STX>6L|1<CR><ETX>3F<CR><LF>
```

Figure 7.20: Framed Data Files

The simulator provides an easy way to convert a data file to a framed file by using the ALT+F keys when using the “Edit Data File” function of the simulator.

Log File

During execution of any of the communications functions of the simulator, the user has the option to log all communication activity. The log file contains valuable information about the interaction of the two systems. All lines found in the log file start with a single character (position #1), indicating the source of the information.

The following characters are used:

- **D (Diagnostic)** – Message written by the simulator in the log file to provide added information to the user.

- **T (Test)** – Message written by the simulator providing information on a specific test that is being performed while working with selection 4 and 5 of the main menu. "4. Simulate Communications/Protocol Errors (HIISIM as SENDER)" "5. Simulate Communications/Protocol Errors (HIISIM as RECEIVER)"
- **S (Send)** – Message indicating data transmitted by the simulator
- **R (Received)** – Message indicating data received by the simulator
- **U (User)** – Message indicating comment entered by the user during execution of selection 6 of the main menu "6. Bidirectional Interactive Communications."

The next seven characters of each line of the log file are used to print the time stamp. This time stamp is the same as the one used in the data files described above. It shows the delta time (elapsed time) between transmission activity.

The remainder of the characters of each line are the actual information received or transmitted (in the case of R and S) or the text associated with the informational messages (D, T, U).

The following example shows a complete communication session between the simulator and an external instrument. In this case, the simulator is acting as the SENDER (initiated communication by sending <ENQ> character) while the external system is the RECEIVER.

```
D      0   HIISIM  1.0  Acting as an Instrument
S      0   <ENQ>
R    .28   <ACK>
S   7.08   <STX>1H|\^&|||Hiisim^1.0^s/n^H1P1O1R1R1Q1M1C1L1||||||T|1|TIMEandDATE<CR><ETX>47<CR><LF>
R   1.19   <ACK>
S   2.26   <STX>2P|1<CR><ETX>3F<CR><LF>
R    .37   <ACK>
S  12.19   <STX>3O|1|3101^CRSL123^2||^^^T01^testname^dilution^testqualifier|S|||||N||||||||||||O<CR><ETX>80<CR><LF>
R   1.48   <ACK>
S  14.55   <STX>4O|2|356101||^^^T01|||||||N||||||||||||O<CR><ETX>7D<CR><LF>
R    .87   <ACK>
S    .26   <STX>5P|2<CR><ETX>43<CR><LF>
R    .39   <ACK>
S     3.9  <STX>6O|1|3121||^^^T01^testname|||||||N||||||||||||O<CR><ETX>D4<CR><LF>
R    .98   <ACK>
S   4.12   <STX>7O|2|322201||^^^T02^^1:100|||||||N||||||||||||O<CR><ETX>33<CR><LF>
R    .98   <ACK>
S   1.15   <STX>0P|3<CR><ETX>3F<CR><LF>
R    .37   <ACK>
S   3.62   <STX>1O|1|3102^CRSL123^1||^^^T01^^1:1000|||||||N||||||||||||O<CR><ETX>AE<CR><LF>
R    1.1   <ACK>
S      9   <STX>2O|2|3992||^^^T02^testname|||||||N||||||||||||O<CR><ETX>E2<CR><LF>
R    1.2   <ACK>
S   1.09   <STX>3O|3|3102||^^^T04\^^^T05\^^^T06|||||||N||||||||||||O<CR><ETX>75<CR><LF>
R   1.05   <ACK>
S    .82   <STX>4P|4<CR><ETX>44<CR><LF>
R    .44   <ACK>
S   9.44   <STX>5O|1|3341\3092\3993\3664\3545||^^^T99|||||||N||||||||||||O<CR><ETX>E3<CR><LF>
R   1.08   <ACK>
S    .71   <STX>6L|1<CR><ETX>3F<CR><LF>
R    .37   <ACK>
S      0   <EOT>
```

Figure 7.21: Log File

Bibliography

American National Standards Institute. 1976. *X3.16-1976 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.

American National Standards Institute. 1984. *International Standard ISO 7498-1984(E)*.

American National Standards Institute. *1986. ANSI Standards - X3.4-1986 American National Standard Code for Information Systems*.

American National Standards Institute. 1989. *X3.30 ANSI Information System Codes*.
X3.43 ANSI Information System Codes.

American National Standards Institute. 1993. *ISO 2955-93 Information Processing-Representation of SI and Other Units in Systems with Limited Character Sets*.

American Society of Testing and Materials. 1991. *ASTM Designation: E 1381-91 Specification for Low-level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems*.

ASTM Designation: E 1394-91 Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems.

Electronics Industries Association. 1986. *EIA-232-D-1986 Interface Between Data Terminal Equipment and Data Circuit-Terminating Equipment Employing Serial Binary Data Interchange*.

NOTES

Glossary

Allowed Data Formats

All data is represented in ASCII format within the range 0 - 255.
Values 0 - 127 are defined by ANSI X3.4-196 Standard.
Values 128 - 255 are defined as needed by specific instruments.
Values 0 - 31 cannot be used, with the exception of 13 (<CR>).
The value 13 is reserved as a record terminator.
Values 32 - 255 can be used, with the exception of 127 and 255.
Within a data text field, only the ASCII characters 32 - 126 and 128 - 254 are permitted as usable characters. Characters used as delimiters in the transmission are excluded from the above permitted range. The sender is responsible for checking that a data field does not contain any delimiters. The record identified fields (H, P, O, R, L, M, and Q) are always uppercase when output from the Abbott instrument. On input, both upper- and lowercase record identifiers are accepted. Fields and records are variable in length with no restriction placed on the maximum length of a field or record. The high-level protocol depends on the receiver's buffering capability and the low-level communication ability to divide the information into workable lengths for transmission and processing purposes. All Abbott Standard Interface RS-232 manuals provide the maximum allowable length of each field transmitted and received.

Analyte

Substance being measured or detected by a specific test procedure (assay).

ASI

Abbott Standard Interface: Abbott's implementation of the American Society for Testing and Materials (ASTM) Standard. E1394-91, A Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems. E1381-91, Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems.

Assay

Protocol designed to detect and/or measure a specific substance (analyte).

Assay parameters

File that contains pertinent information specific to that assay, (i.e., Assay Name, Number, Version and Type).

Calibration run

A procedure that standardizes an instrument prior to assaying patient samples for a particular analyte.

Calibrator

Analyte sample provided for use in standardizing an instrument.

Component A subdivision of a field containing one specific piece of information, such as a patient's first name.

Controls Predetermined quantified sample provided for monitoring the performance of a calibrated instrument.

Dilution Procedure used to reduce the amount of analyte in a sample to accurately measure its concentration.

E1381-91 Frame A frame is a subdivision of a message and allows transmission of up to 247 characters (240 data characters and 7 control characters).
The Abbott instrument transmits one record per frame. Messages more than 247 characters long can be divided into multiple frames, as long as each frame contains only information from one record at a time.

E1381--91 Message A block of data that is transmitted in a format consistent with the ASTM E1381-91 Standard. Abbott ASI instruments use an E1394-91 Record as the E1381-91 Message. Thus, an E1381-91 Message may be transmitted using multiple (one or more) frames, based on the length of the message.

E1394-91 Message A block of data that is transmitted in a format consistent with the ASTM E1394-91 Standard. Data is transmitted in a series of records starting with a Header Record (H) and ending with a Terminator Record (L).
When a transmission is lost, the Abbott instrument retransmits or accepts only complete messages.

E1394-91 Record An E1394 Record is a string of characters starting with a capital ASCII alphabet character and ending with a carriage return (ASCII 13), as defined by the ASTM E1394-91 Standard.

Field A subdivision of a record containing one specific piece of information, such as an address.

Frame A subdivision of a message (in low-level protocol context) that allows error checking and acknowledgment to occur at least every 240 characters.

High-level protocol Specifies the conventions used for transferring information between Abbott Clinical Laboratory Instruments and host computer systems. High-level software works at the application level as defined by terminology from the International Organization for Standards (ISO) Reference Model for Open Systems Interconnection (OSI).

Low-level protocol Software that occupies the Physical and Data Link layer as defined by terminology from the International Organization for Standards (ISO) Reference Model for Open Systems Interconnection (OSI).

Matrix Cell A disposable used in the processing of samples which contains a glass fiber matrix used to bind the MEIA immune complexes for detection by the optics.

MEIA A heterogeneous technology used for high molecular weight/ low concentration analytes.

Message A collection of related information such as a complete study file.

Order list The order list is the list of tests requested by the operator, either through the Data Management Center or through the host computer.

Processing Carousel Twenty-four position carousel that holds Reaction Vessels for processing.

Qualitative A type of test which provides a non-numerical result, in the format of “reactive” (positive) or “non-reactive” (negative).

Quantitative A type of test which provides a numerical result in the format of a concentration unit.

Reaction Vessel A multi-well disposable which carries a matrix cell and a LCx unit dose vial.

Reagent Pack Contains the reagents needed to run current MEIA and FPIA assay technologies.

Receiver A device which responds to a sender and accepts information.

Record Related information which forms a subdivision of a complete ASTM message.

Repeat field A single data element which expresses a duplication of the field definition it represents. It is used for demographics, requests, orders and the like, where each element of a repeat field is to be treated as having equal priority to associated repeat fields.

Reserved Characters — The following characters have special uses and should not be used for data:
Vertical Bar (|)
Backslash (\)
Ampersand (&)
Carriage Return (<CR>)
Caret (^)

Sender — A device that initiates the transmission process.

System Control Center — Allows reviewing of test and quality control results and the entering of patient information, test, and calibrator and control requests.

Test — A procedure for examining a specific objective, substance, or set of values to determine a specific result, condition, or value.

Waste and Supply Center — Provides storage for bulk solutions and liquid and solid waste.

Index

R

S

T

U

V

NOTES