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Abbott Standard Interface RS-232 Manual

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Abbott Park, IL 60064
66-6837/R3

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Foreword

The AxSYM 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 AxSYM System, refer to the Abbott AxSYM System Operation Manual, Volume 1 and Volume 2 (List. No. 09A26-02). In addition, information regarding the Abbott AxSYM assays are provided in the Abbott AxSYM Assay Manual.

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

The Abbott Standard Interface RS-232 Manual, AxSYM Edition Revision 2 only refers to System Software Version 2.0 of the AxSYM System.

Version 3.0 System Software Updates

The following is a brief description of the major functional changes in Version 3.0 of the Abbott Standard Interface - AxSYM Edition.

Transmission of Multiple Flags

This new General Configuration option allows the user to transmit to the Host computer all applicable result flags generated for a result during a run. If configured ON the AxSYM will report all applicable result flags according to the following hierarchy: EX, QC, < or >, HH or LL, H or L. If configured OFF the AxSYM will report only the highest priority result flag (the same as in Version 2.X System Software).

Reflex Testing

Patient sample orders that use operator defined ranges to automatically run a different assay than the one used with the original order. These operator defined ranges work in much the same way as retest rules. For example, if a TSH result falls within a certain concentration range it may be desirable to automatically run a FT4 assay. This result will look exactly the same as any other result.

Customer Support

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

Proprietary Statement

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.

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Section 2. Overview of the AxSYM System

Section 3. Communication Setup

How to Use This Manual

Overview

In this section:

Overview of the Manual

The Abbott Standard Interface RS-232 Manual - AxSYM Edition provides the necessary information for interfacing the AxSYM 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: Discuss specific information about the instrument or system covered by that particular Edition. They cover 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 AxSYM 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 AxSYM 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 2.0) program and data transmission files captured from the AxSYM 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 AxSYM 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

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Abbott Standard Interface

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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 Sender/Receiver State Diagram
- Presentation Layer – Message Content
- Application 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.

In order to ensure compatibility 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 ensuring compatibility 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.

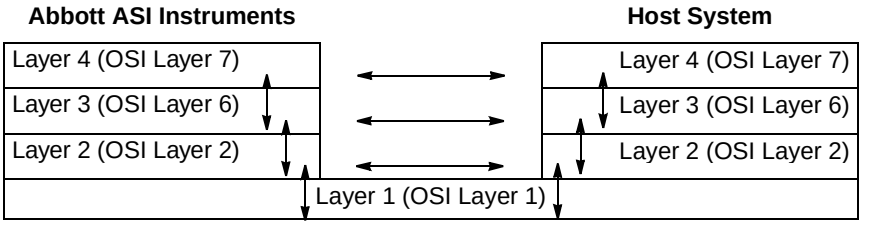


Figure 1-1. Layered Protocol Architecture

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.

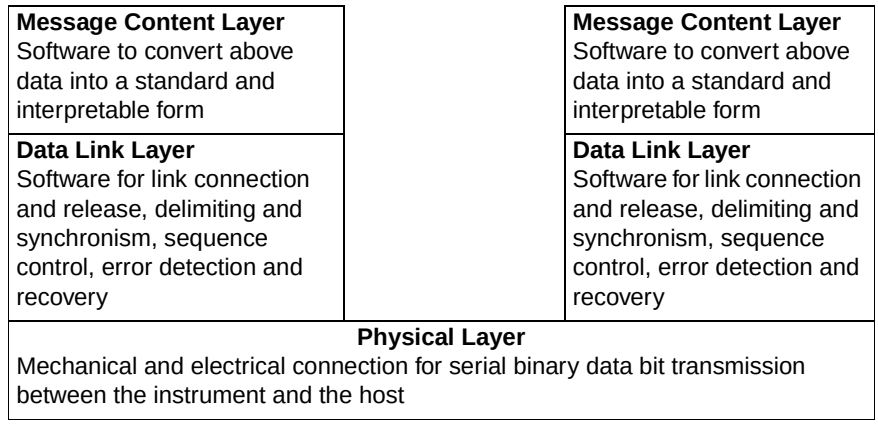


Figure 1-2. ASI Implementations

Physical Layer

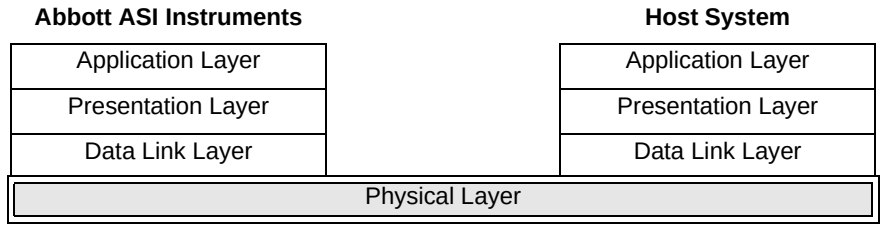


Figure 1-3. Physical Layer

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 connector is a DB-25P (i.e., male) connector conforming to the requirements of the EIA RS-232D standard. If the instrument or system hardware has a non-conforming connector, Abbott provides an adapter with adequate mounting hardware to convert the non-conforming connector to the DB-25P connector required by the ASTM standard. This adapter may be included with the instrument accessories kit. The ***Communication 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 a link 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 ***Communication 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	–	–

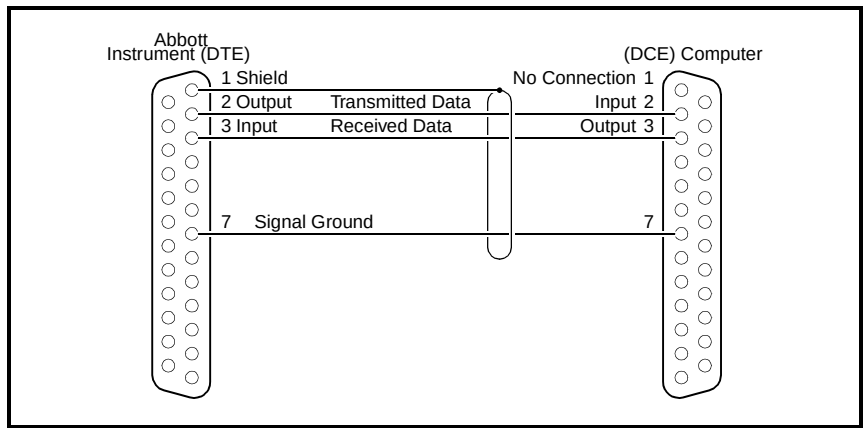


Figure 1-4. Pin-to-Pin Connections (Wiring Diagram)

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.

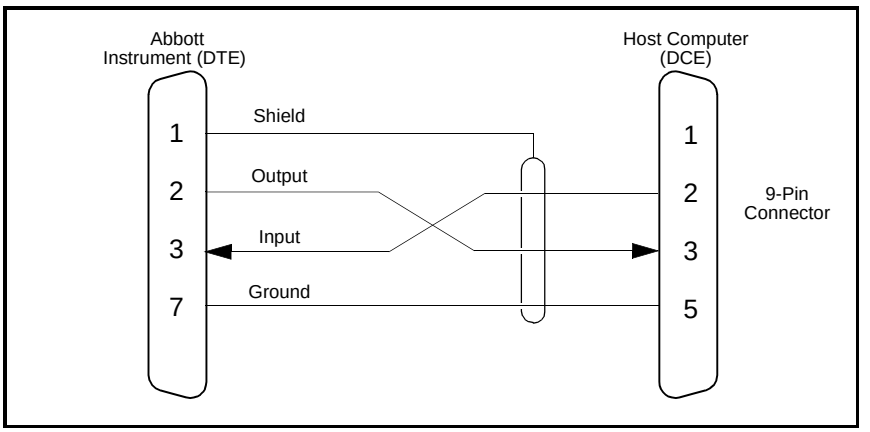


Figure 1-5. Host computer (PC with 9-pin connector) with Non-ASTM compliant connector.

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.

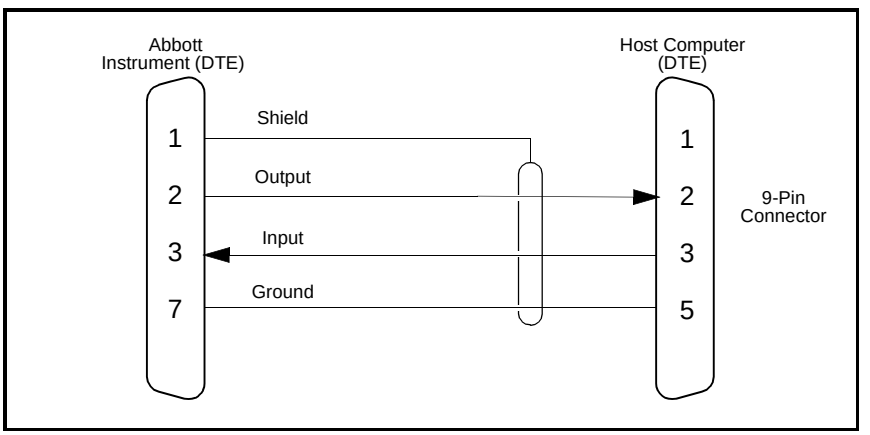


Figure 1-6. Host Computer with 9-Pin PC-AT style connector.

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

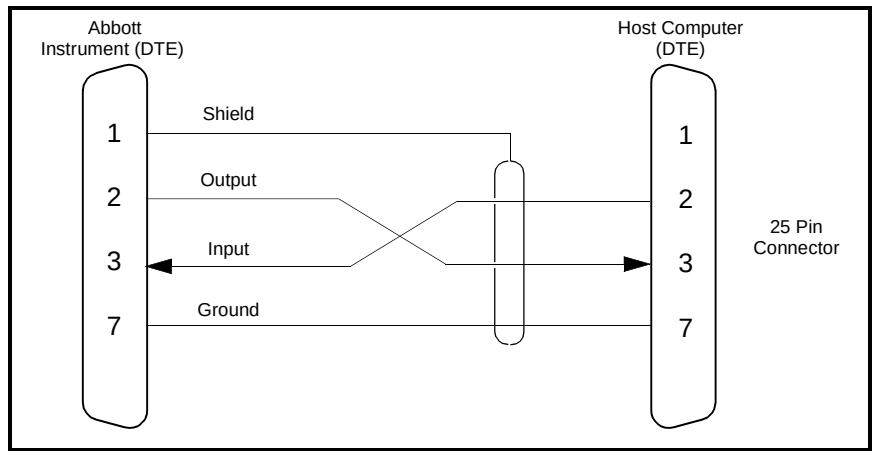


Figure 1-7. Host computer (PC with 25-pin connector) with Non-ASTM compliant connector.

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.

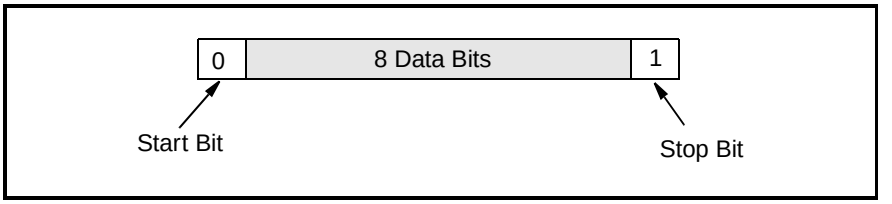


Figure 1-8. Default Abbott Instruments Character Structure. *The start and stop bits separate ASCII characters which are eight bits long.*

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. For information on the exact baud rates supported by each instrument, refer to **Section 3: *Communication Setup***.

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

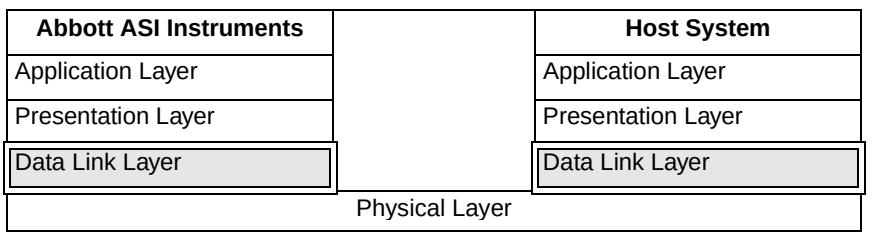


Figure 1-9. Data Link Layer

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
- Controlling sequence
- 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 a link communicating to Laboratory Information Systems (LIS Hosts), these systems implement both the ASTM 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].

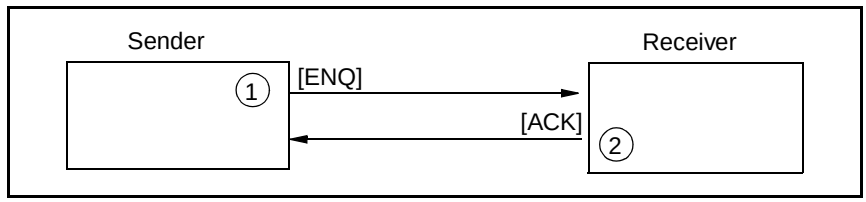


Figure 1-10. **Sender Initiating Establishment Phase.** *The receiver returns a signal to the sender acknowledging that it is ready to receive.*

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].

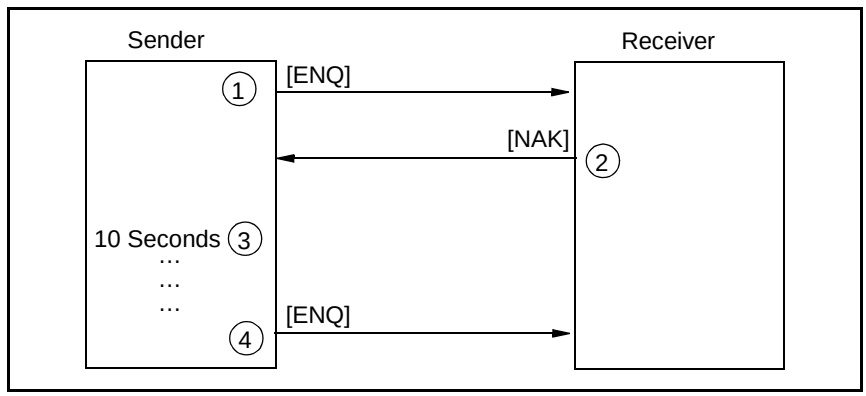


Figure 1-11. **Sender Receives an [NAK] Signal.** *If the sender receives an [NAK], the sender waits ten seconds before re-initiating the establishment phase.*

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.

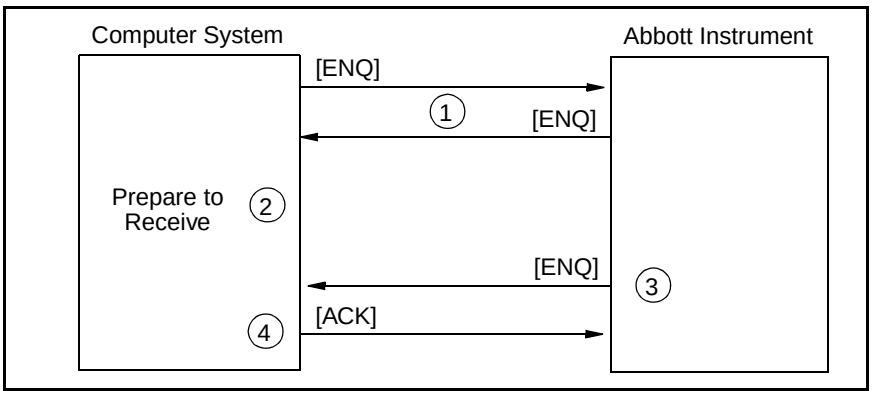


Figure 1-12. Sender Receives an [ENQ] after Sending an [ENQ].
The sender prepares to receive.

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].

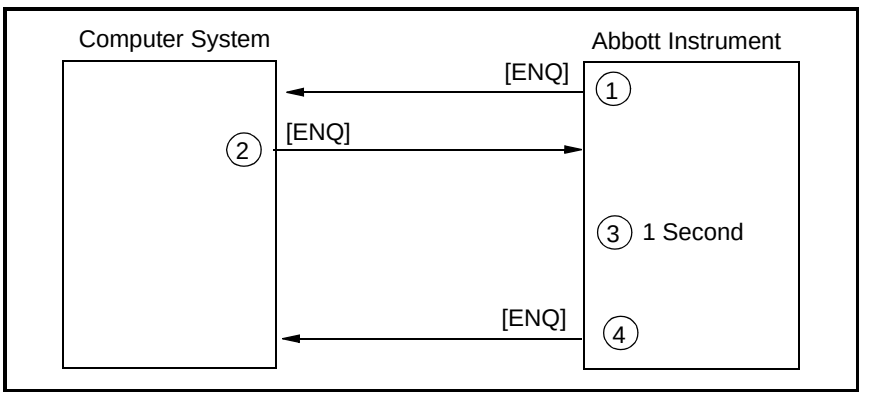


Figure 1-13. Instrument Receives an [ENQ] after Sending an [ENQ].
The instrument waits one second before re-sending another [ENQ].

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.
[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.

Table 1-3: Special Control Characters (Continued)

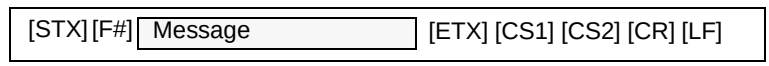
Symbol	Character	Description
CS1	Most significant character of checksum 0 – 9 and A – F	The checksum determines if a frame is defective. The checksum is encoded as two characters and is sent after the ETB or ETX character. The checksum is computed by adding the binary values of the characters (modulo 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

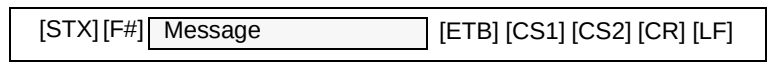
Abbott instruments and systems supporting ASI handle an ASTM E1394-91 record as an ASTM E1381-91 message. If the E1394-91 record is longer than 240 characters, the message is transmitted in multiple frames consisting of end frames and intermediate frames. If the message (i.e., E1394-91 record) is less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

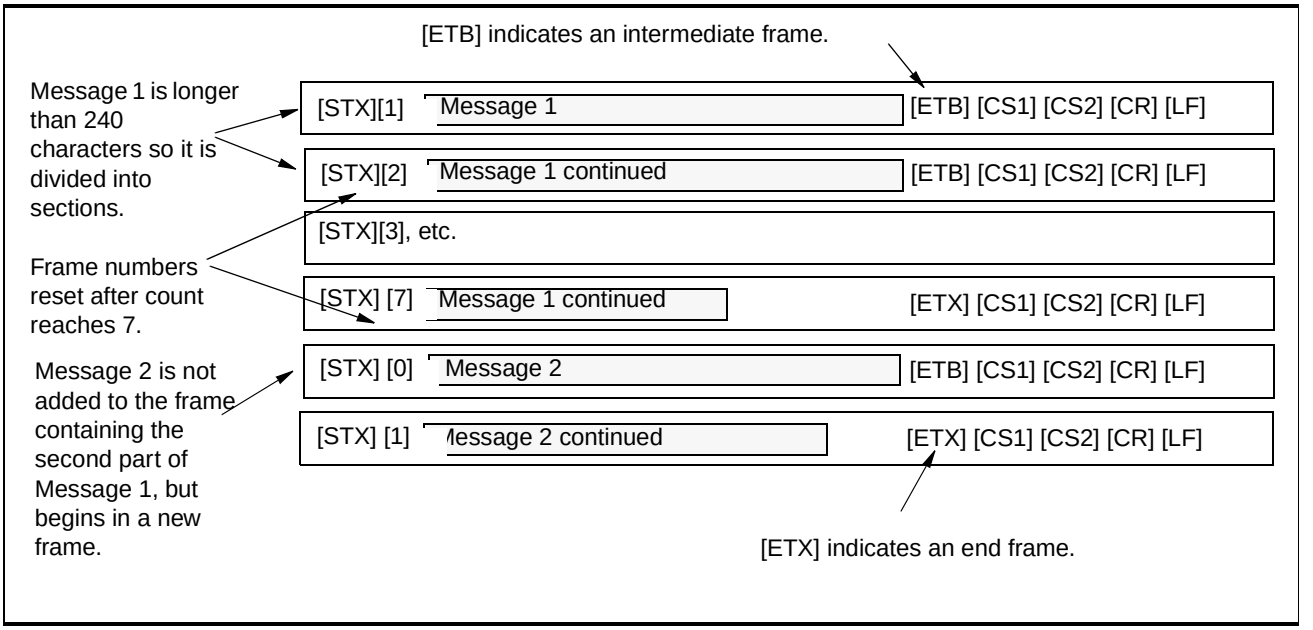


Figure 1-14. Intermediate and End Frames. *Multiple frame messages start with intermediate frames and end with end frames containing only the end of one message***.**

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.

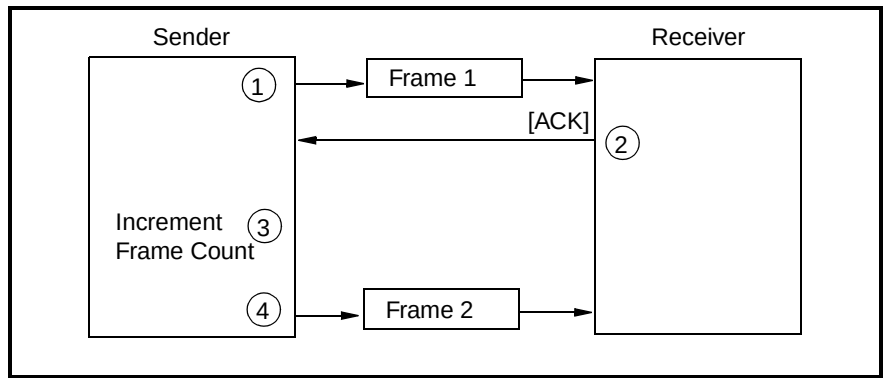


Figure 1-15. **Sender Transmitting After Receiving [ACK].** *The sender sends another frame after successfully transferring a frame.*

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.

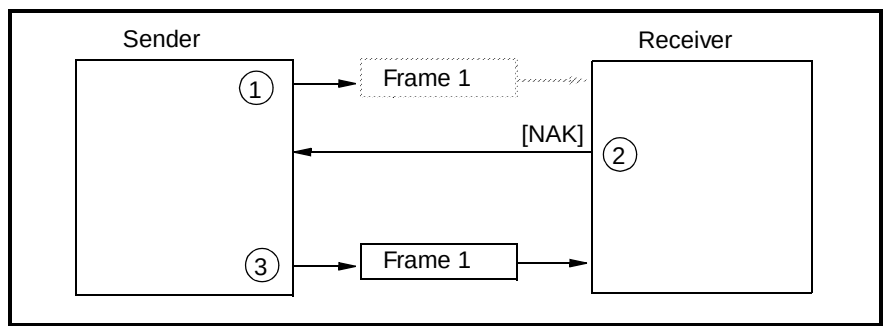


Figure 1-16. **Sender Retransmitting a Frame After Transmission Failure.** *The receiver indicates transmission failure with [NAK].*

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.

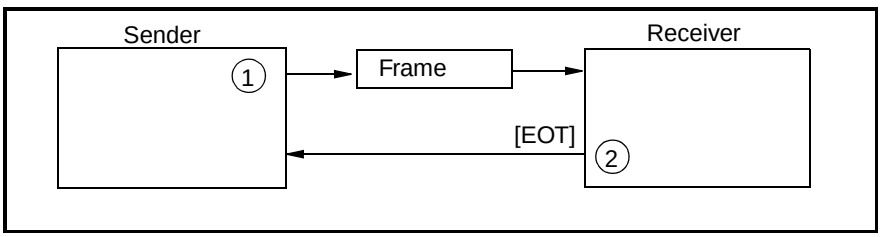


Figure 1-17. **End of Transmission.** *The receiver indicates successful receipt of the complete message with an [EOT], but requires an interrupt.*

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.

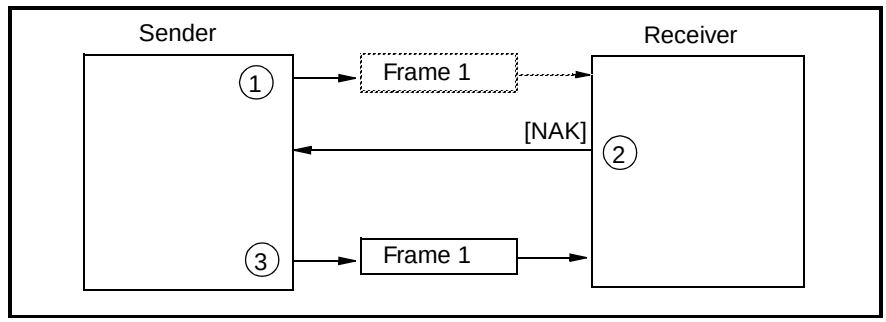


Figure 1-18. Re-sending a Frame After a Transmission Failure. *The receiver indicates a transmission failure with an [NAK].*

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.

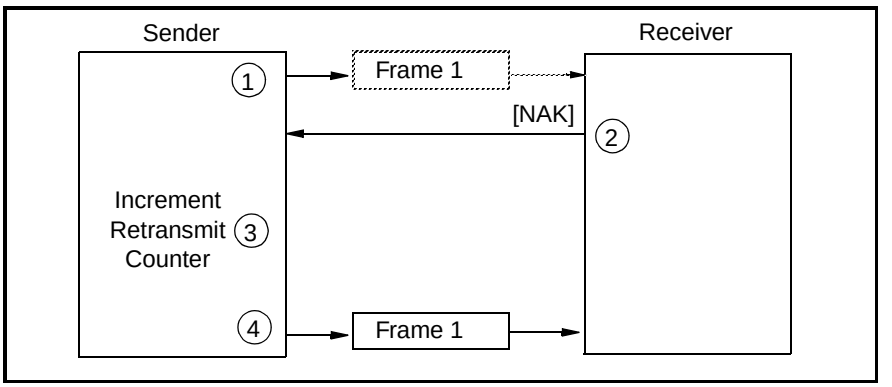


Figure 1-19. **Incrementing the Frame Counter.** *The sender keeps track of retransmissions with a frame counter.*

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.

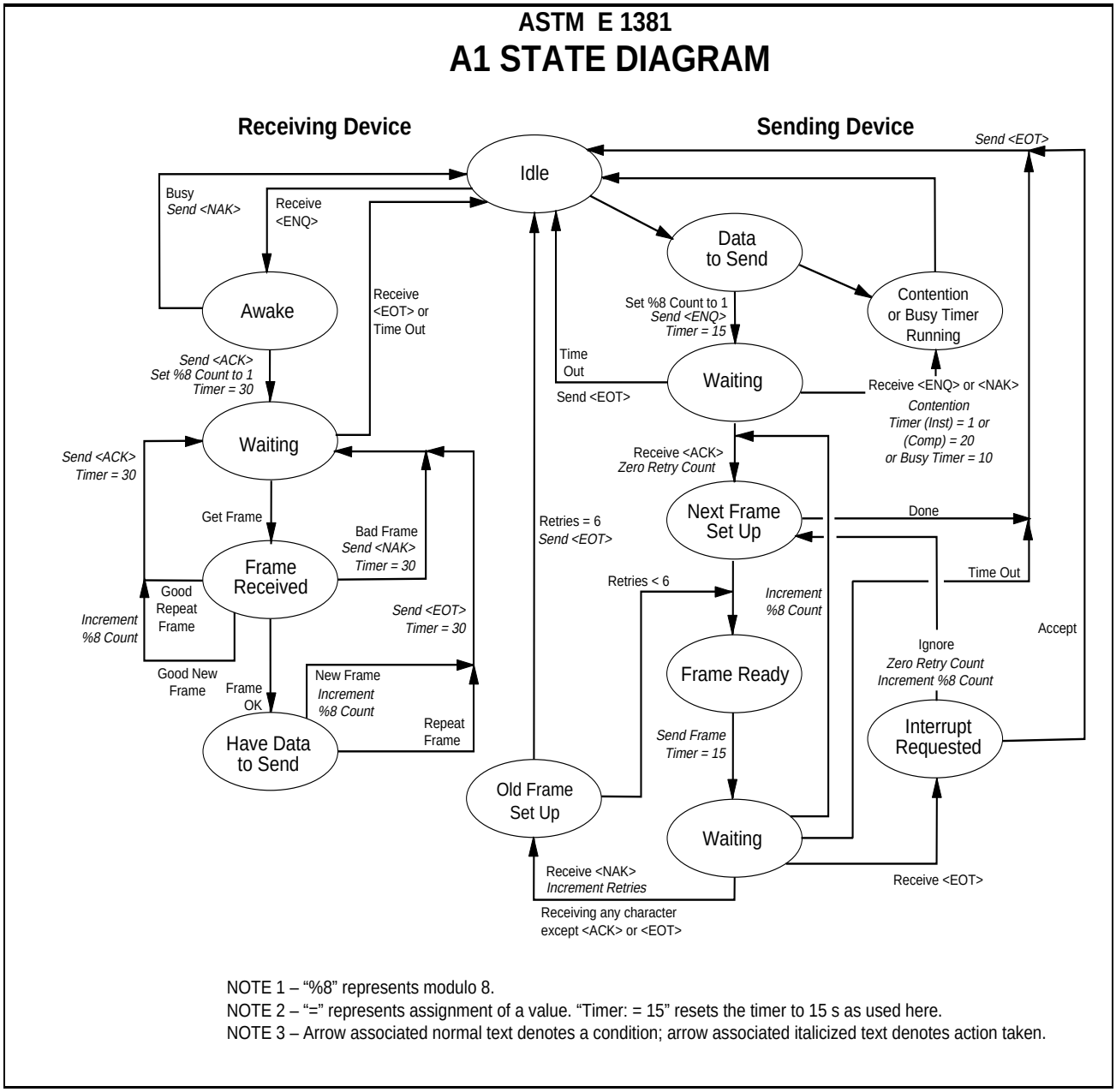
Restricted Message Characters

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
[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 1-20. 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

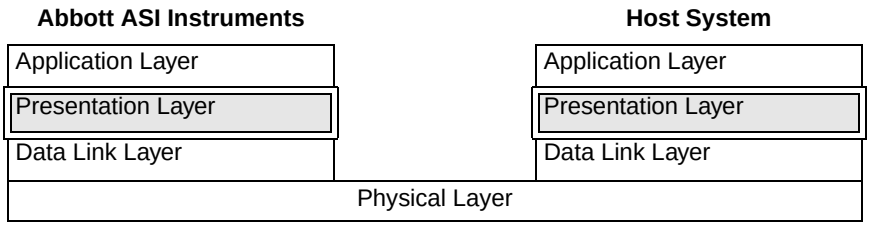


Figure 1-21. Presentation Layer

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.

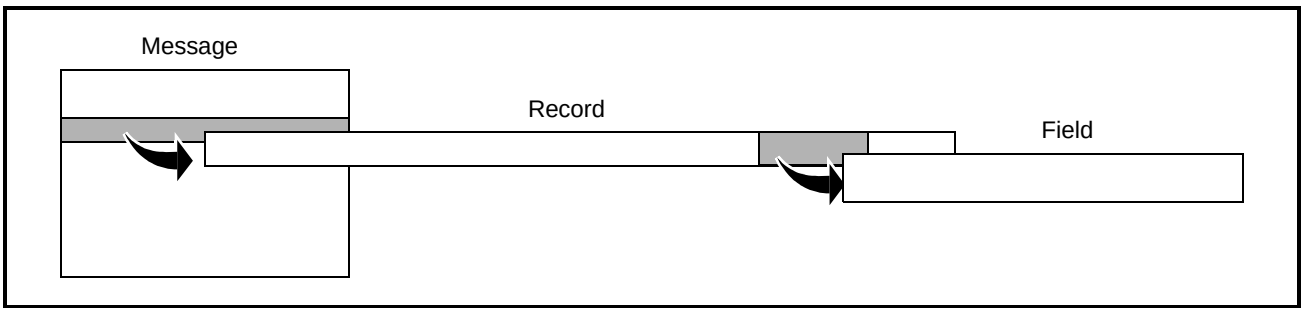


Figure 1-22. Message Logical Structure. *Messages are subdivided into records which are made up of fields.*

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]

ASI instruments use uppercase letters for all record identifiers transmitted. 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.

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 Manufacturer and Comment Records can be inserted at any level in the hierarchy and are considered to be one level below the preceding record.

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.

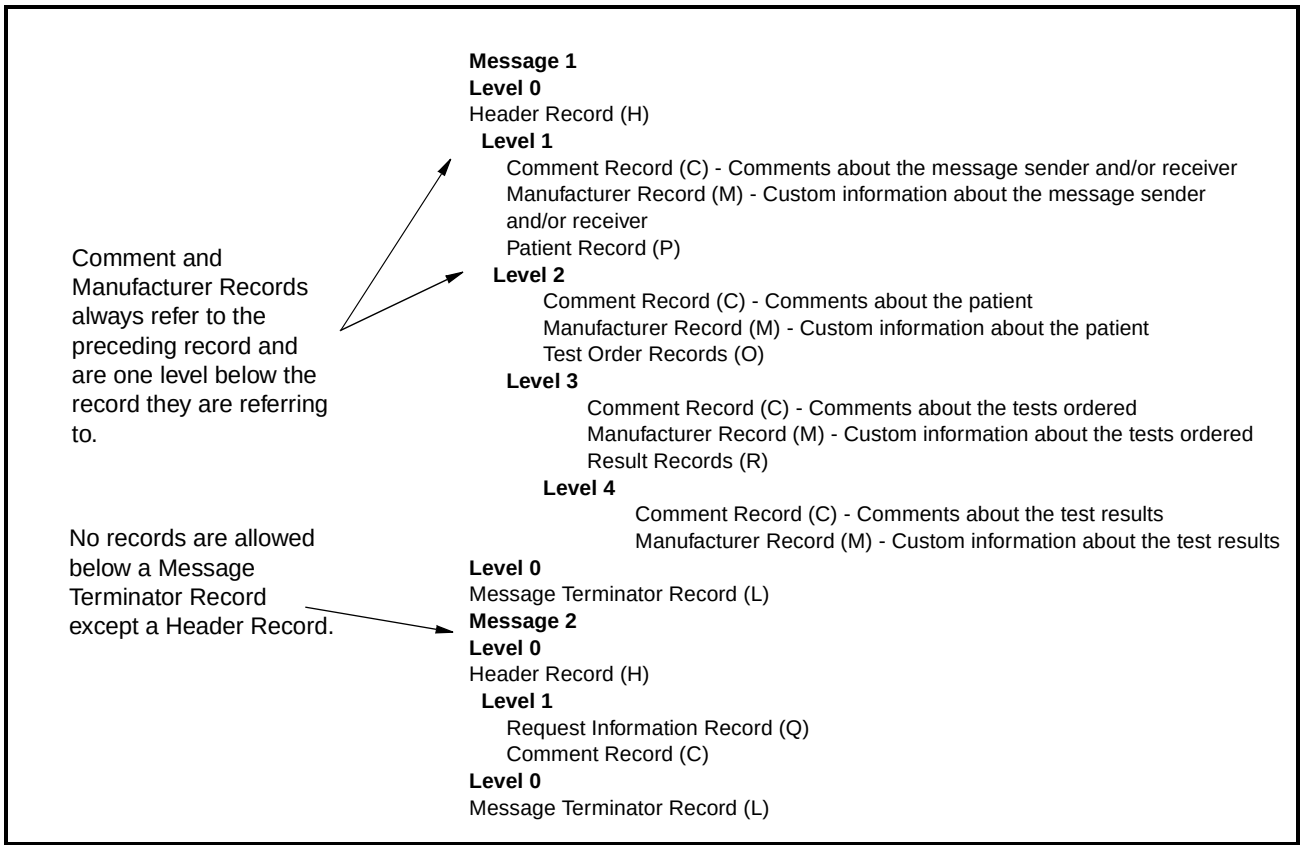


Figure 1-23. Comment and Manufacturer Records. *These records can be placed anywhere in a message between the Header and Message Terminator Records.*

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.

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:

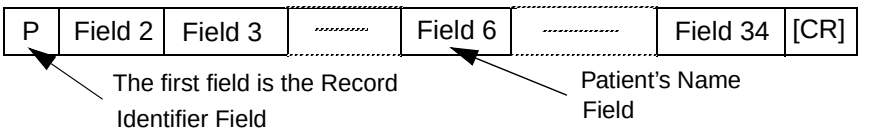
Header Record (H)
Request Information Record (Q)
Terminator Record (L)

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 the 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

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.

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 DelimiterVertical Bar (|)
- Repeat DelimiterBackslash (\)
- Component DelimiterCaret (^)
- Escape DelimiterAmpersand (&)

ASI instruments accept any characters defined in the header record and transmitted by the external system as the delimiters for that message.

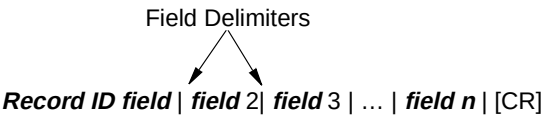
If a received data field contains a character that conflicts with the ASI defined delimiters (| \ ^ &), ASI instruments and systems will use the Escape Delimiter to return the original data (i.e., conflicting character) back to the external system.

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.

Following is a description of how delimiters work.

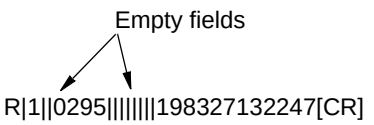
Field Delimiters (|)

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:

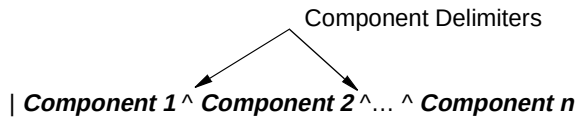
0|1|Sample#1|^^^Test1 . . .
0|2|Sample#1|^^^Test2 . . .
0|3|Sample#1|^^^Test3 . . .

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|

Escape Delimiters (&)

The ASTM E1394-91 protocol allows the use of escape delimiters to provide a method for communicating control characters (i.e., nonprintable ASCII characters, or protocol control characters) that would otherwise create abnormal conditions to occur on the receiving end. The Abbott Standard Interface recognizes the need for using the escape delimiters, and identifies specific conditions that may be supported by ASI instruments. The use of escape delimiters will be limited to communication data characters that are in direct conflict with the delimiters used by the communicating system.

- Field delimiter imbedded within data is communicated as &F&
- Component delimiter imbedded within data is communicated as &S&
- Repeat delimiter imbedded within data is communicated as &R&
- Escape delimiter imbedded within data is communicated as &E& where & is the escape delimiter used by the communicating system

These four conditions may be checked at input and converted to their equivalent characters for viewing. On output, the data will be parsed and any delimiters imbedded within data will be converted to their escape strings. All other uses of the escape delimiters are not recommended.

The following figure summarizes the delimiters used by the Abbott instrument.

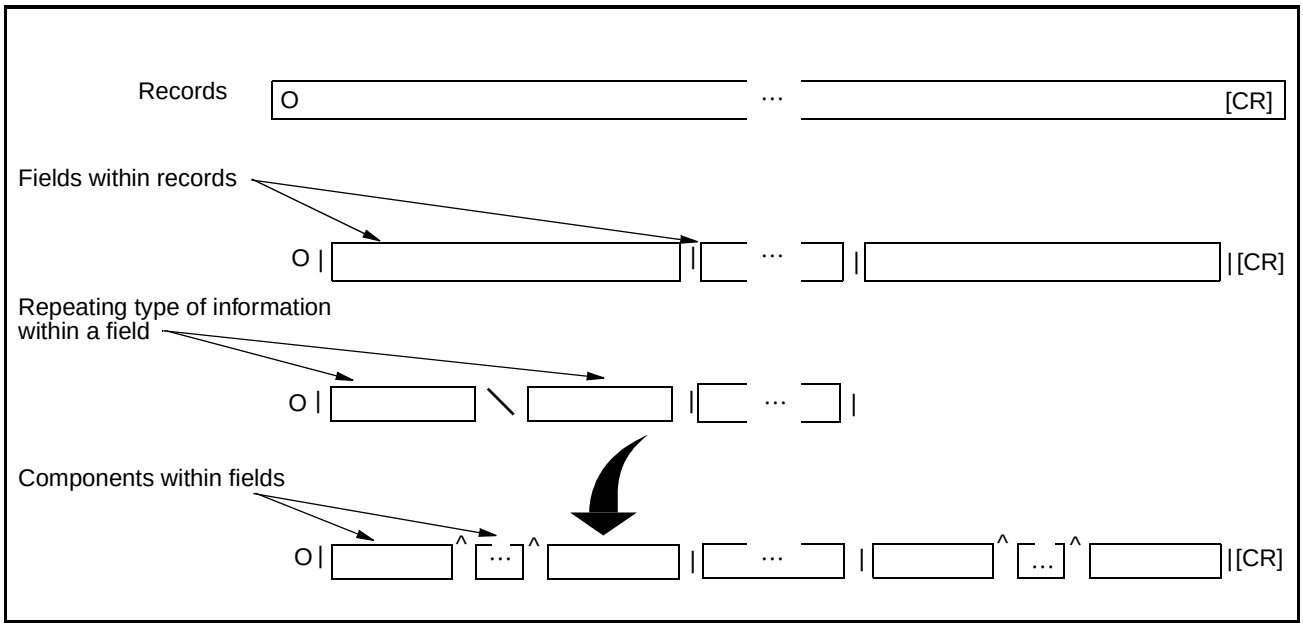


Figure 1-24. Delimiter Summary. *Field delimiters separate fields within records, repeat delimiters separate multiple occurrences of the same type of data within a field, component delimiters separate components within fields.*

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 assist with 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 manufacturer'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.

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.

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.

Specimen IDs (ASTM E1394-91 Field 9.4.3, 9.4.4)

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 Laboratory 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 1-25. 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 1-26. 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 (ASTM E1394-91 Field 9.4.12)

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 and test codes. 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 and test codes. 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 (ASTM E1394-91 Field 9.4.26)

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 or that no orders will be sent in response to a Request Information record. 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 (24 hour clock)
- MM is the minute
- SS is the second

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

YYYYMMDDHHMMSS

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.

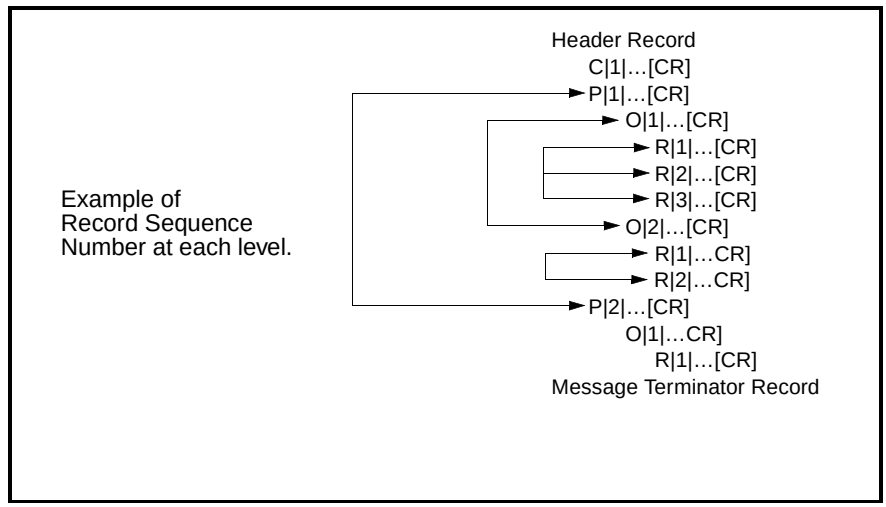


Figure 1-27. **Record Sequence Numbers.** *Record Sequence Numbers keep track of the number of records of the same type and at the same hierarchical level.*

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 of variable length and character, unless explicitly defined 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.
** 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
7.1.2	Delimiters			ASI instruments accept any valid delimiters specified in the header record.
	Field	|		
	Repeat	\	*	
	Component	^		
	Escape	&		
7.1.3	Message Control ID			Not supported
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.
7.1.5 (cont.)	^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 HHMMSS	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		(Continued from previous page) 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 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 order records. 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	*	*	From Host: (ALL) indicates return all information associated with all known Patient IDs and/or Specimen IDs.
		ALL	ALL	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			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.
	Patient ID	*	*	
	^Specimen ID	*	*	

** 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. Also used to request test orders on a specific sample 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 1-28. 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 1-29. Example of Test Ordering

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 1-30. Example of Test Ordering With Repeat Delimiters

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 1-31. 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 1-32. Example of ASI Instrument Query for Test Results

Application Layer

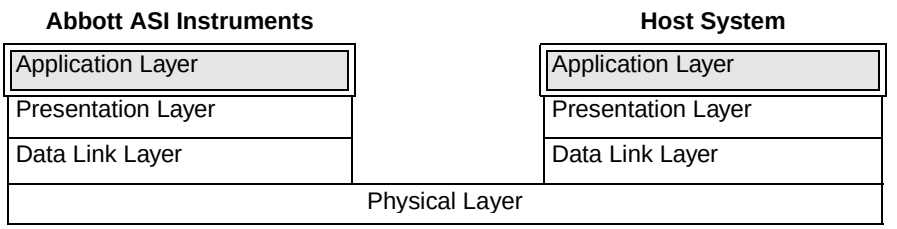


Figure 1-33. Application Layer

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:

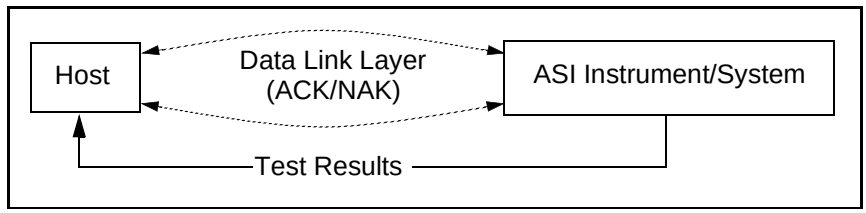


Figure 1-34. Category I Instruments and Systems

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:

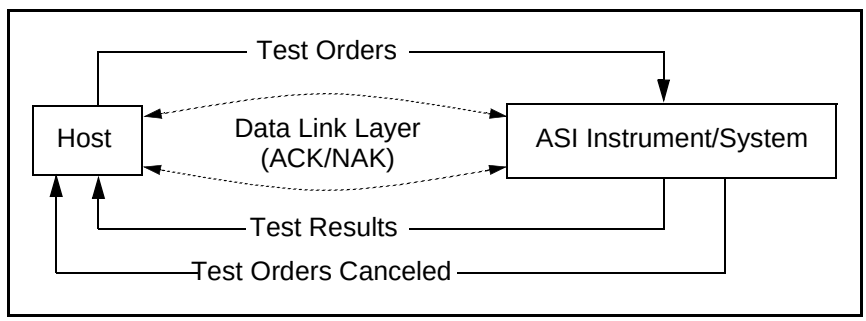


Figure 1-35. Category II Instruments and Systems

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:

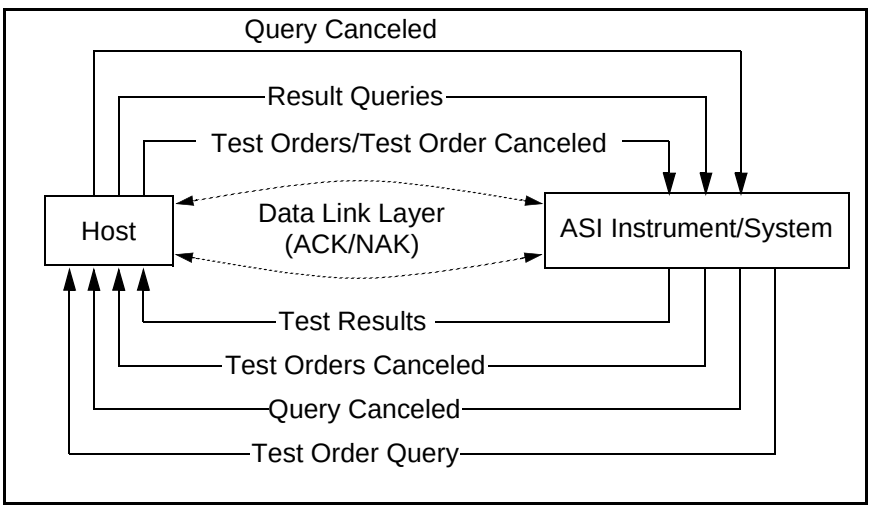


Figure 1-36. Category III Instruments and Systems

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:

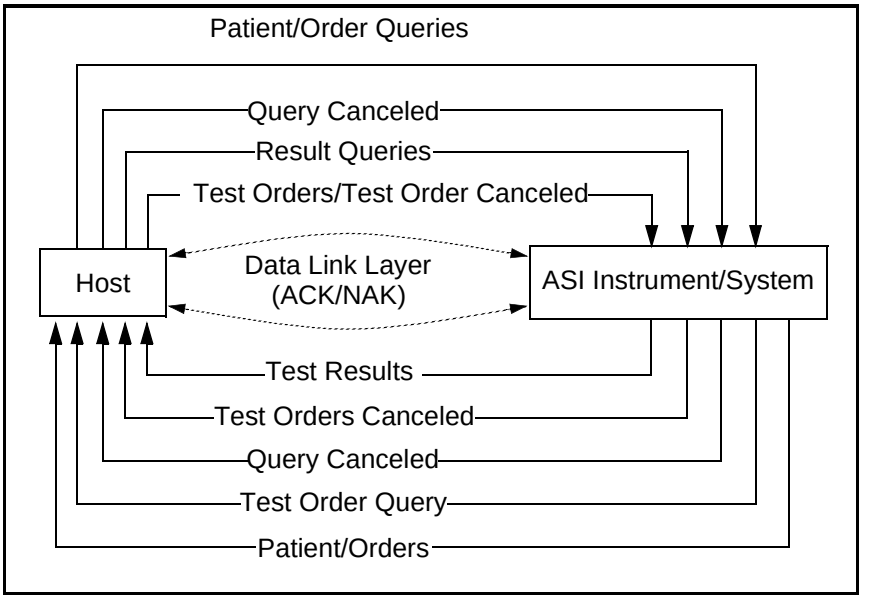


Figure 1-37. Category IV Instruments and Systems

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 maximum 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.

NOTES

Overview of the AxSYM System

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Overview of the AxSYM System

Overview

The Abbott AxSYM System is a random and continuous access immunoassay analyzer which allows bidirectional communication with a host computer.

The AxSYM System was specifically designed to use two different assay technologies: Microparticle Enzyme Immunoassay (MEIA) and Fluorescence Polarization Immunoassay (FPIA).

Results take approximately 8 to 36 minutes for most routine assays and less than 15 minutes for STAT assays. System capacities of Reagent Packs, bulk liquids, and disposables have been balanced with throughput to provide an operator walk-away time of approximately one hour.

General Description

The Abbott AxSYM System is a floor-standing analyzer with dimensions of 61 inches in length x 31 inches in diameter x 40 inches in height (155 cm x 79 cm x 102 cm, respectively).

The AxSYM System has four main areas:

- Sampling Center
- Processing Center
- Waste and Supply Center
- System Control Center

The operator routinely interfaces with the Sampling and System Control Centers.

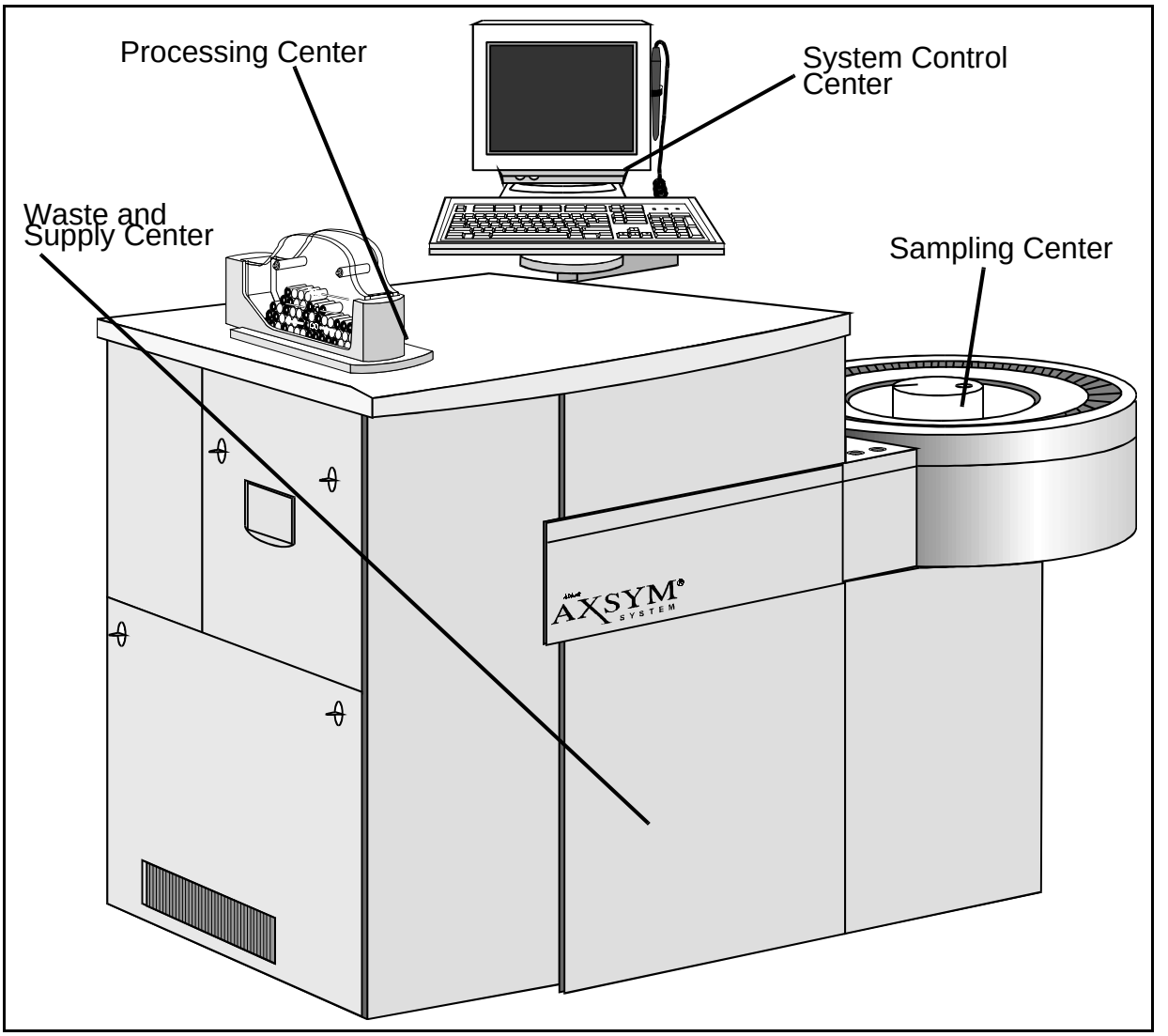

Figure 2.1: The four main areas of the Abbott AxSYM System

Sampling Center

The Sampling Center includes three carousels:

- Sample Carousel which holds either 60 bar coded primary tubes or 90 sample cups
- Reagent Carousel which holds 20 Reagent Packs
- Reaction Vessel Carousel which holds 90 Reaction Vessels

Activities in this area are limited to the loading of samples, reagents, calibrators, controls, and Reaction Vessels.

The Sampling Center pipettes sample and reagents for the requested test into the Reaction Vessel. The Reaction Vessel is then transferred into the thermally-controlled Processing Center.

Processing Center

The Processing Center includes two carousels and other supporting components, including MEIA and FPIA optics. Activities in this area include:

- Mixing and transporting of sample, reagents, and Bulk Solutions
- Incubating
- Optical reading

Waste and Supply Center

The Waste and Supply Center provides storage for:

- Bulk Solutions
- Liquid and consumable waste

System Control Center

The System Control Center consists of:

- Color Touchscreen Monitor
- Keyboard
- Printer
- Floptical disk drive for archiving data and software updates
- Bar Code Wand
- RS-232 Port for bidirectional interface to a host computer

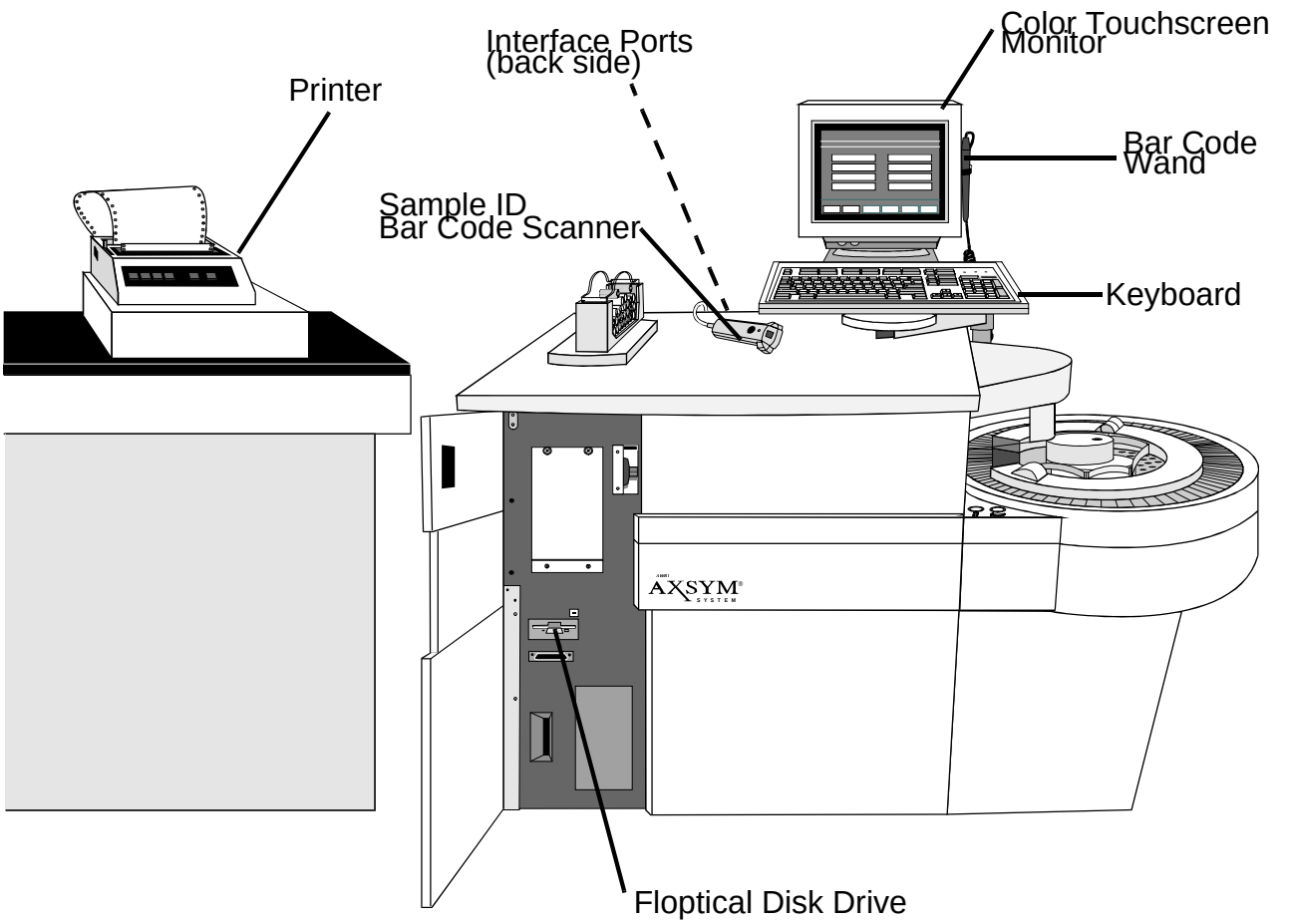

Figure 2.2: Components of the System Control Center

The System Control Center is used to:

- Setup system configuration
- Upload patient results to a host computer
- Download test requests and patient sample information from a host computer
- Enter and review patient information and orders
- Enter calibrator and control orders
- Review results and quality control data
- Perform system maintenance and diagnostic procedures

Color Touchscreen Monitor

The Color Touchscreen Monitor rests on a swing-arm tray. It is the main interface for operators of the AxSYM System. Interactive screens permit access to information by touching text areas, menu choices, or function keys.

Keyboard

The Keyboard rests on a swing-arm tray that can swing over both the Sampling and Processing Centers. It is used in conjunction with the Color Touchscreen Monitor to enter patient and sample information. The operator can use the Keyboard as an alternate method of accessing all of the Touchscreen Monitor functions.

Printer

A Printer provides a hard copy of data or test results, patient reports, calibration, quality control, maintenance, and diagnostics.

Disk Drives

There are two disk drives on the AxSYM System. Both are located behind the Disk Drive Door on the front of the System.

- **Floptical Drive** – used for software updates and archiving stored results from the AxSYM System onto a 3.5" floptical or floppy disk.
- **Hard Drive** – contains the AxSYM System Operating Software. It is the main nonvolatile memory device and stores a variety of data types.

Bar Code Wand

The Bar Code Wand provides the operator with a convenient method of scanning master curve information into the system from the Bar Code label provided with each Assay Reagent Pack that supports a master curve.

Bar Code Label

Bar code label types the AxSYM reads include:

- Code 128
- Interleaved 2 of 5
- Code 39
- Codabar (includes NW7)

Host Interface Port

The Host Interface Port is one of eight interface ports located on the back of the AxSYM System. The Host Interface Port is an RS-232 communication port that is used to connect a laboratory host computer or laboratory information system to the AxSYM System. This port allows the two-way transfer of information between the laboratory host computer and the AxSYM System computer.

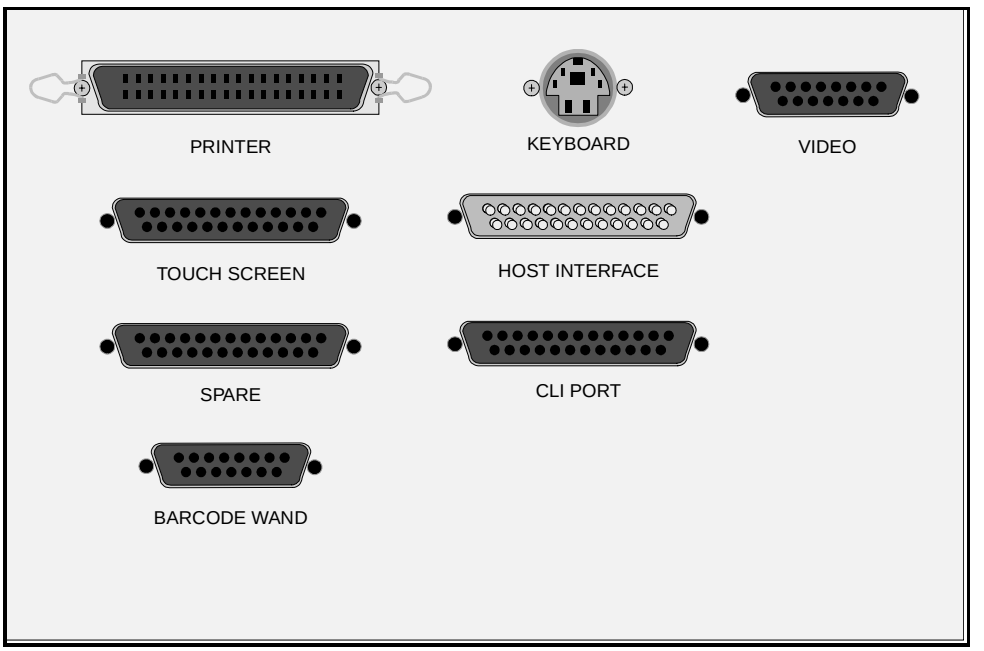

Figure 2.3: Interface Ports

Process Description

The AxSYM System is an automated system that processes test orders as follows:

1. Test orders are downloaded from a host computer or entered directly through the System Control Center.
2. Samples, Reagent Packs, and consumables are loaded into the Sampling Center.
3. When a sample arrives at the Sampling Center Pipetting Station:
   - The sample is identified.
   - The system checks the orderlist to determine the tests to be run on the sample.
   - The system verifies adequate reagent and consumable inventories before each test is scheduled.
   - The Pipettor transfers sample and reagents to a Reaction Vessel for the requested test.
   - The prepared Reaction Vessel is transferred into the thermally-controlled Processing Center.

   Tests are processed in order of presentation to the Sampling Center Pipetting Station. STAT samples and Calibrators are given priority in both the Sampling Center and Processing Center to achieve completion in the shortest possible time.
4. The inventory review and pipetting process is repeated until all tests requested for the sample have been transferred to the Processing Center.

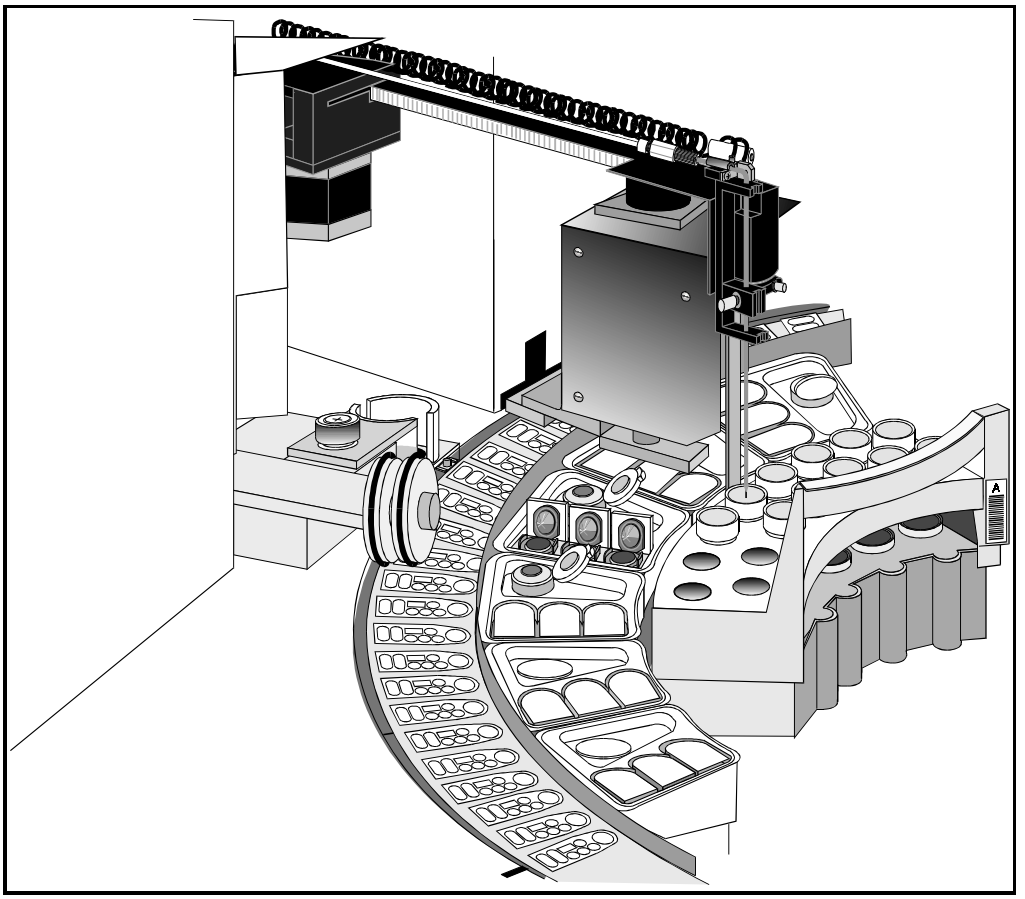

Figure 2.4: The Sampling Pipettor transfers samples.

5. Activities in the Processing Center are precisely regulated by the software. Temperature-controlled assay pipetting steps are performed by the Processing Center Pipettor.

For **FPIA** reactions, all temperature controlled activities including pipetting steps, incubations, and optical reads occur on the Processing Carousel.

MEIA reactions are initiated on the Processing Carousel, but require a Matrix Cell to complete the assay sequence. Matrix Cells are automatically loaded onto the Matrix Cell Carousel prior to use in the assay. **MEIA** wash steps, substrate reactions and optical reads occur on the Matrix Cells.

6. Fluorescent signals are converted to concentrations of analyte by calculation from a stored calibration curve.

7. When tests are completed, consumables are automatically ejected into the Consumable Waste Container. Results can be printed, released to a host computer, and/or stored on the AxSYM System.

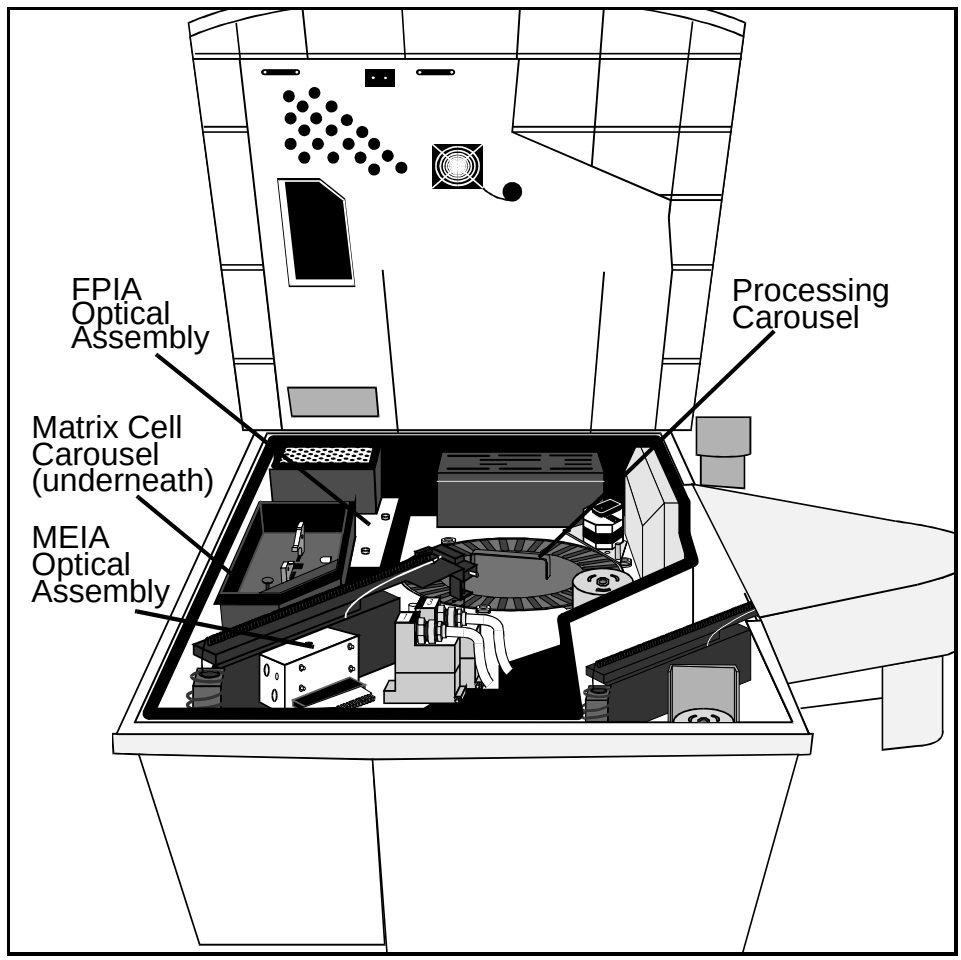

Figure 2.5: MEIA and FPIA reactions occur in the Processing Center.

The AxSYM System and Laboratory Workflow

Three workflow paths are created as a sample is processed through the laboratory:

- Information Flow
- Sample Flow
- Query Mode Flow

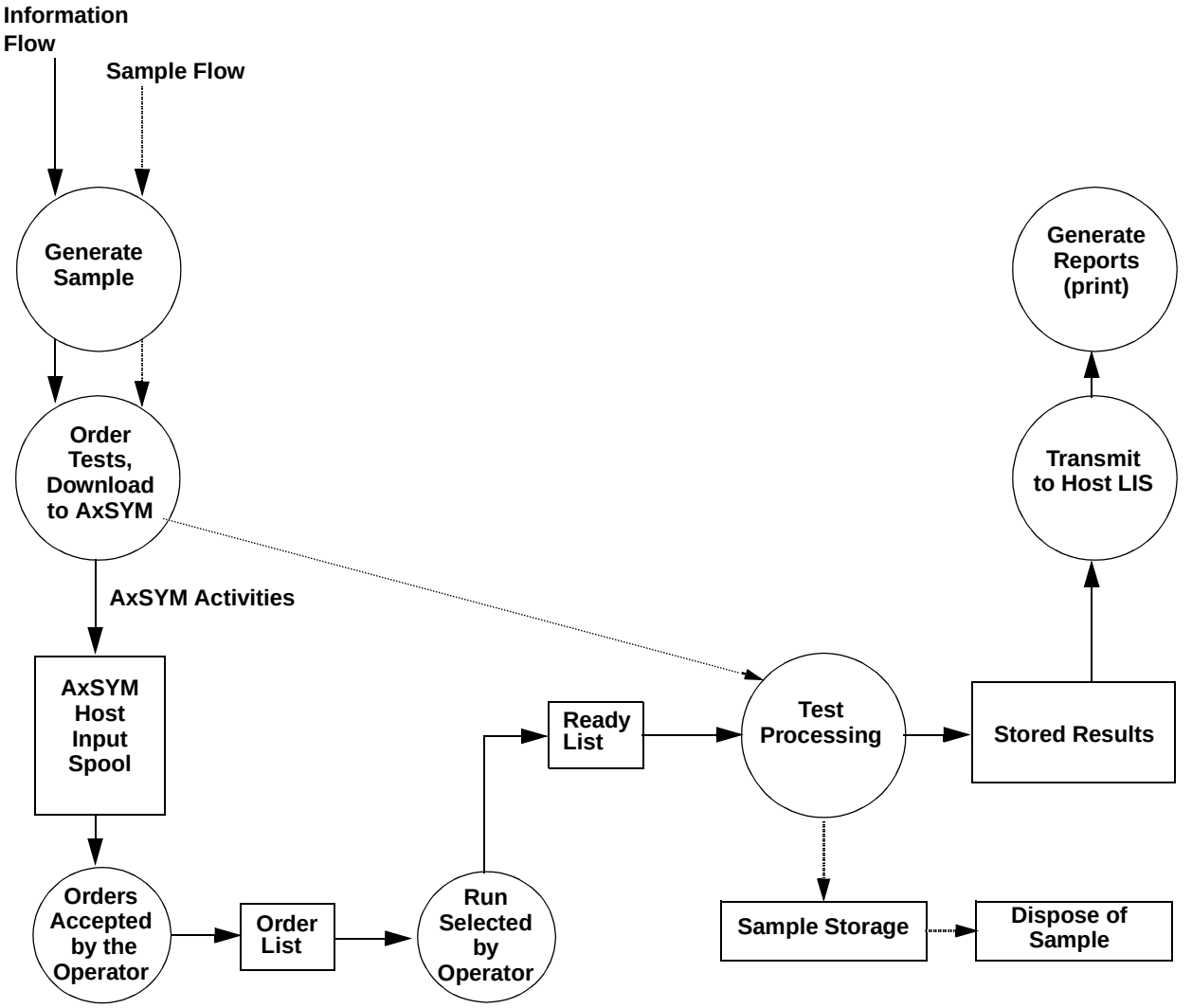

Figure 2.6: Laboratory Workflow and the AxSYM System.

AxSYM workflow steps are as follows:

1. Generate Sample/Assign SID
   - A sample is collected from the patient, physician, or other sources. An identification number (SID) is assigned to the sample.
2. Order Tests, Download

The analysis of the sample is scheduled. The priority of a sample (random access or STAT) is determined and the particular tests are ordered. Other information pertinent to the processing of the sample is entered at this time.

3. Orders from the Host are sent to the AxSYM System Host Input Spool.
4. Orders from the Host are accepted by the operator.
5. Accepted orders are displayed on the Orderlist.1

   Operator selects appropriate assay-specific calibrators and controls.

6. Run is selected by the operator.
7. Orders are displayed on the Orderlist screen after the operator initiates the run.
8. The AxSYM System processes the tests and produces the results.
9. Results are automatically or manually transmitted to stored results and to the Host:
   - **Automatic** – All results are automatically transmitted to the host computer.
   - **Hold** – Results without flags are automatically transmitted to the host computer.
   - **Manual** – All results must be manually transmitted to the host.
   - **Auto with Exceptions** – All results and exceptions are automatically transmitted to the host computer.
10. Dispose of or store samples.

After completion of analysis, a sample can be disposed of or stored for reference.

Laboratory Workflow Using Query Mode

When operating with Enable Host Order Query Mode ON, orders are generally not sent to AxSYM by the LIS until the AxSYM System makes a Query Request. Any orders for the current sample that are already in the readylist will be performed in preference to sending a Query Request.

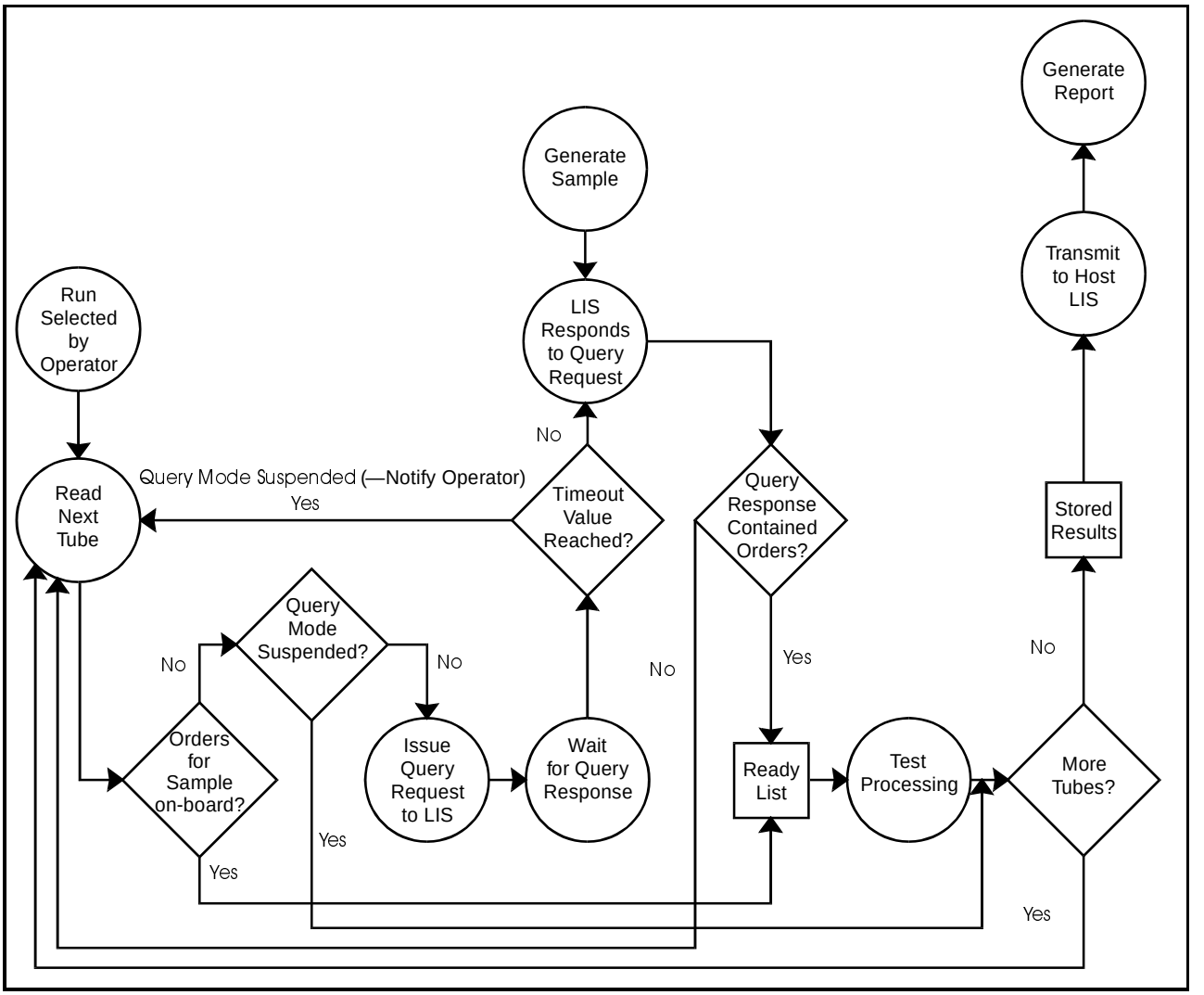

Figure 2.7: Laboratory Workflow Using Query Mode

1. Generate Sample/Assign SID
   - A sample is collected from the patient, physician, or other sources. An identification number (SID) is assigned to the sample.
2. RUN is selected by the operator.
   - After RUN has been selected by the operator, any STATs and Calibrators will be processed first. After STATs and Calibrators, routine samples and controls are then processed as sample tubes are encountered on the carousel.

3. The instrument begins to read each sample position in the sample carousel until a bar code labeled sample is found.
4. After a bar code labeled sample is found, the instrument determines if there are orders already on-board the AxSYM.
   - If orders are found on-board, these orders are run immediately. If no orders are found AxSYM issues a Query Request for the sample to the LIS.
5. AxSYM then waits for the appropriate Query Response from the LIS.
   - If the Query Response does not arrive within the defined timeout period, Query mode is suspended and the next sample is processed. No further Query Requests will be issued for the remainder of the run. Query mode will be automatically resumed the next time RUN is selected.
6. If the Query Response contains orders for the current sample, those orders are placed in the readylist and they are run immediately.
   - If there are no orders for the current sample the user is notified via a message and the next sample is processed.
   - After arrival, orders that are contained in a Query Response are visible in the Order Status screen.
7. After AxSYM has finished kitting a sample, it then searches for the next sample to query. Since the AxSYM is a random access instrument, the operator can place a new sample on the sample carousel at any time. To ensure that a new sample is queried in a timely manner, the AxSYM continues to query samples until the sample carousel travels 360 degrees past the last new sample encountered.
8. When the tests are completed and the results are sent back to the LIS, it is the LIS's responsibility to match the results to the original order. If the LIS does not complete this task in a timely manner, it is possible for the AxSYM to encounter the same sample again. The AxSYM will send another query and the LIS could send a duplicate order for that SID.

Summary

A Query Request will only be issued if ALL the following criteria are met:

1. Enable Host Order Query Mode general configuration parameter is ON (refer toSection 3).
2. A bar code containing a SID is scanned.
3. There are no orders/results for the sample in the Orderlist, Results, or Exceptions screens and there are no results for the sample in the Stored Results screen that are waiting to be transmitted to the Host computer.
4. The sample is not allocated to another segment/position.
5. Query mode has not been suspended due to a previous timeout or communications error.

Query will be suspended for the remainder of a run if any of the following conditions arise.

1. The LIS does not respond to a Query Response within the configured time period.
2. The AxSYM System cannot access the communications port within 60 seconds. This could be due to the LIS sending a large number of Orders to AxSYM. In general, the LIS should avoid sending Orders that are not in response to a Query Request as this may result in a Query timeout situation.
   NOTE: If AxSYM is sending results to the LIS when a Query Request is scheduled to be transmitted, AxSYM will pre-empt the results transmission so that the Query Request can be sent.
3. The LIS does not respond to the initial <ENQ> character when AxSYM is attempting to establish the communications link.
4. Communications fail during the sending of the Query Request. Six successive <NAK>s or a timeout in responding to a frame will cause this situation.

5. The LIS does not respond to a Query Request within the time period defined in the user configurable parameter “Number of seconds to wait for Query Response”. This parameter should be set so that a timeout will only occur in exceptional situations. It should be set according to the performance characteristics of the LIS system and an estimated reasonable response time. The range of this parameter is 5 to 60 seconds. AxSYM will process the current sample as soon as the Query Response is received. It will not wait the full time period defined in this parameter unless no response is received. The LIS should respond to a Query Request as quickly as possible so as not to impede throughput of the AxSYM System.

Menu Navigation

Navigating through the menu hierarchy on the AxSYM System is accomplished through the use of four system features:

- **Menu Options** – displayed as buttons in the activity zone of the screen.
- **Function Keys** – displayed in the Function Key Zone of the screen. The function key options displayed are dependent on selections made and the data entered by the operator.
- **Indicators** – displayed in the Information Zone of the screen. The indicator is displayed when the appropriate system condition exists.
- **Special Keys** – located on the right-hand side of the AxSYM System keyboard.

Screen Layout and Types

The screens are divided into three touch-sensitive zones:

- Information Zone
- Activity Zone
- Function Key Zone

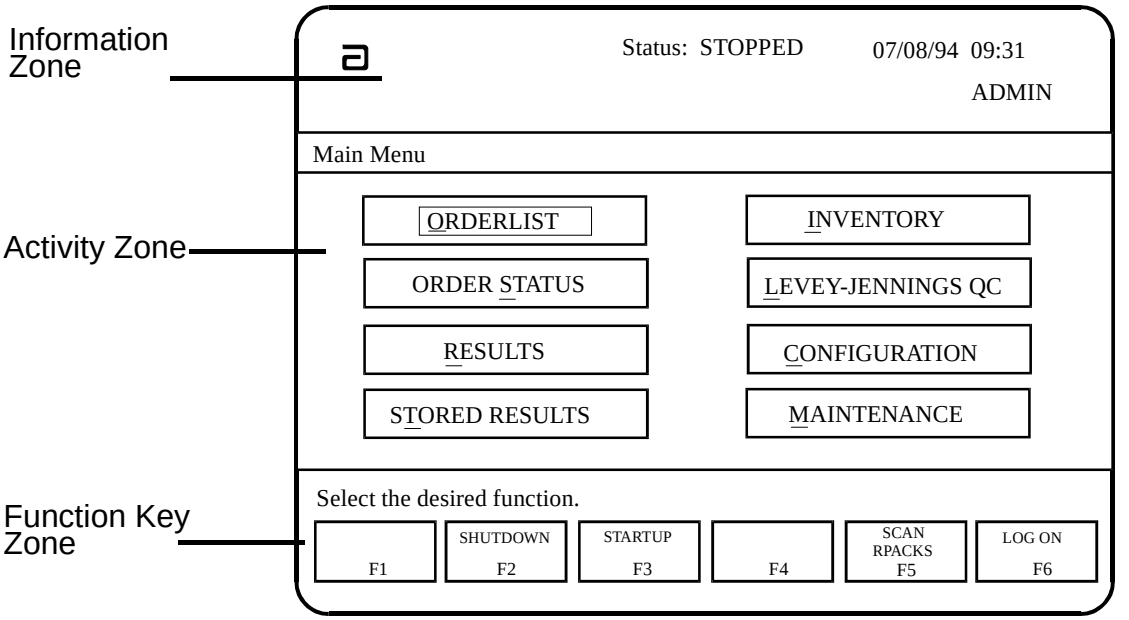

Figure 2.8: Screen Zones

Keyboard and Screen Use

Information Zone

The Information Zone is located at the top of the screen and displays the following:

Abbott "A"

A touch-sensitive character located in the upper left corner of the Information Zone. When selected the Main Menu screen is displayed.

Status

Displays any of six different system conditions on the right side of the Information Zone:

Table 1: System Status Types

Condition	Explanation
READY	Displays when the system is ready to run tests.
WARMING	Displays while the Processing Center comes up to reaction temperature.
MAINT	Displays when a maintenance procedure is active.
RUNNING	Displays when the Processing Center or the Sampling Center is activated by pressing the RUN key.
PAUSED	Displays when the Pause button in the Sampling Center is pressed.
STOPPED	Displays when the motors in the Processing Center and Sampling Center are halted by pressing the STOP key. NOTE: The AxSYM System is configurable only when system status displays READY or STOPPED.

Operator ID

Identifies the last operator to access the system via the Log On screen. Most system functions are tracked with this number.

Date and Time

Displays in the upper right corner of the Information Zone.

Indicators

Touch-sensitive areas located in the center of the Information Zone. One or more of five indicators can be displayed to provide quick access to screens associated with system conditions:

Table 2: Indicator Types

Indicator	Explanation
ORDERS	Displays when the laboratory computer has test orders ready for download. It is displayed until test requests transferred from the laboratory computer to the Orderlist screen are reviewed or updated.
RESULTS	Indicates that test results are available. It is displayed until one or more completed sample or control tests have been reviewed or updated.
MESSAGES	Indicates that one or more messages have been sent to the Temporary Message Log. It is displayed until one or more messages have been reviewed or updated.
EXCEPTIONS	Indicates that a test cannot be completed. It is displayed as an Express Touch Area and in the Test Status screen until a test that cannot be completed is deleted.
INVENTORY	Indicates that an inventory item is nearing its upper or lower limit. These include Bulk Solutions 1, 3, and 4; Matrix Cells; Liquid Waste; and Consumable Waste. They are displayed until high or low levels of consumables or waste are replenished or emptied and updated in the Inventory screen.

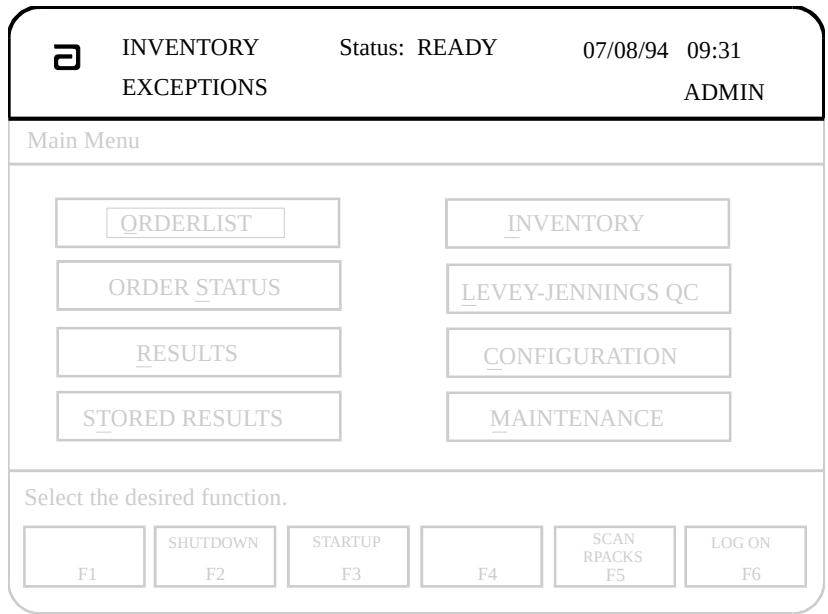

Figure 2.9: Information Zone With EXCEPTIONS and INVENTORY Indicators

Activity Zone

Information needed to operate the AxSYM System is located in the middle of the screen. The Activity Zone contains:

- Data entry areas
- Instructions
- Operator selection options
- Data generated by the system

A title bar indicates the name of the displayed screen and the system menu path. A scroll bar speeds searches of long lists.

There are three types of screens that will be displayed in the Activity Zone:

- Full Screens
- Overlay Screens
- Pop-Up Screens

Full Screens

Full screens occupy the entire Activity Zone.

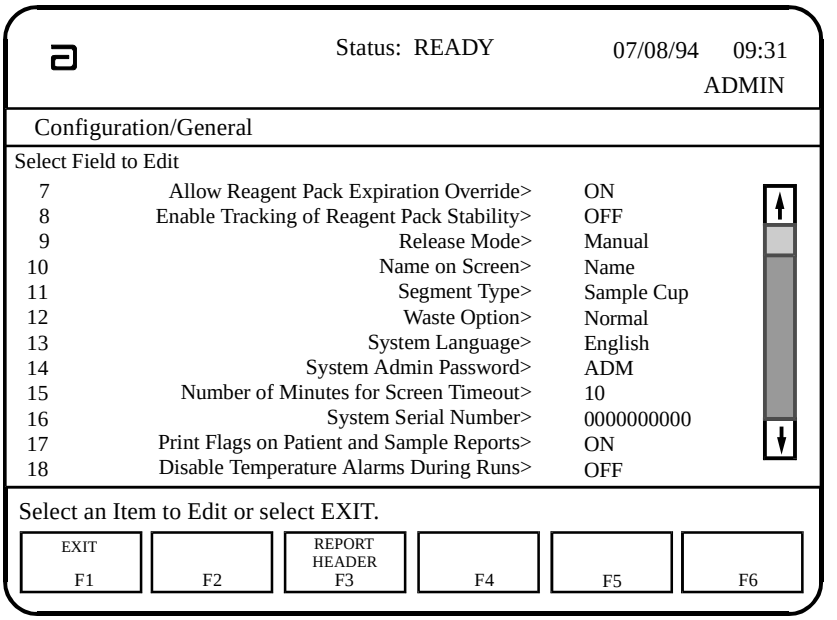

Figure 2.10: Full Screen With Title Bar

Overlay Screens

Up to four smaller overlay screens can be displayed on top of the full screen or other overlay screens.

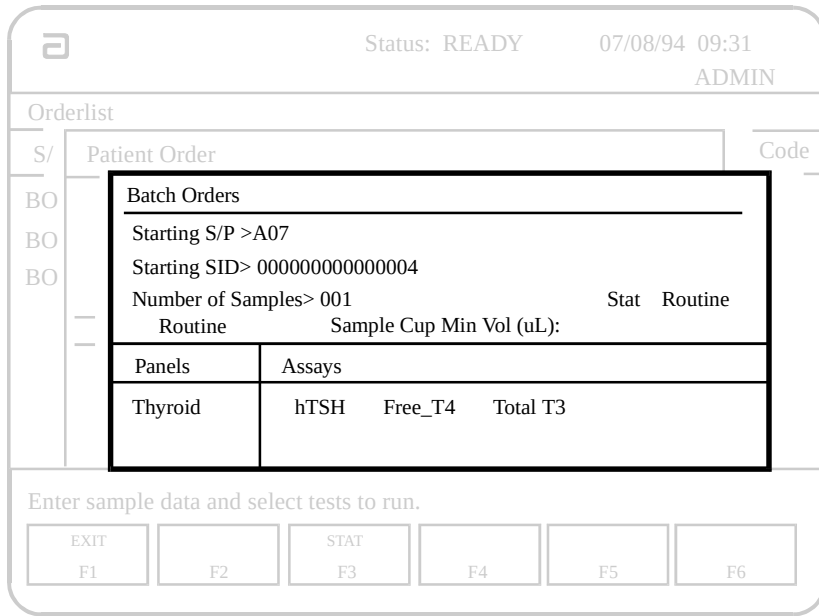

Figure 2.11: Overlay Screen With Two Overlays

Pop-Up Screens

Five small Pop-Up Screen types provide general information or ask for confirmation before proceeding with a request. Most pop-ups require a response before access to another screen or keyboard function is allowed.

Wait Pop-up

Displays when the system is busy. This pop-up does not require operator intervention and disappears when the requested operation has been completed.

Print Pop-up

Displays the options available for printing data associated with the current screen when the PRINT key on the keyboard is pressed.

Confirmation Pop-up

Displays when a request made by the operator requires confirmation before proceeding.

Information Pop-up

Provides information about a system operation or an operator error that occurred while inputting information.

Alert Pop-up

Red in color and accompanied by an audible alarm, this pop-up is reserved for urgent situations requiring operator intervention.

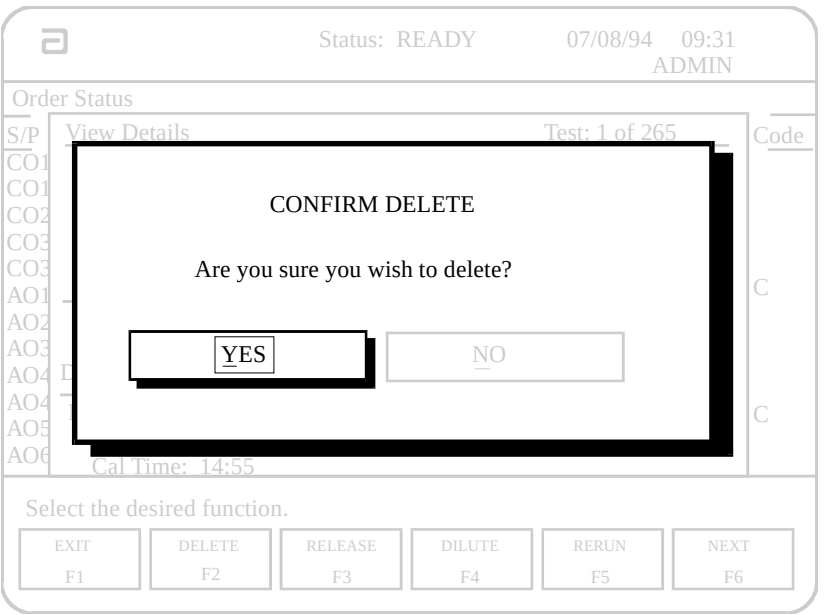

Figure 2.12: Confirm Pop-Up Screen

Function Key Zone

The Function Key Zone, located at the bottom of the screen, contains function keys (F-keys) and a prompt line to help the operator navigate through the menu hierarchy.

Function Keys are labeled F1 through F6 from left to right. The screen F-key names change depending on the active screen and operator actions. The keyboard F-keys serve as alternates.

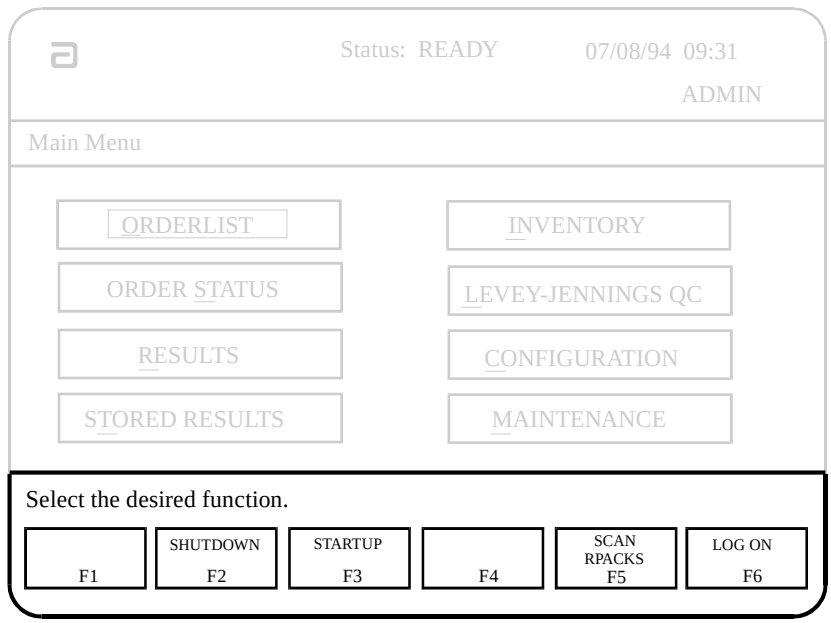

Figure 2.13: Function Key Zone

Special Keys

The keyboard and color touchscreen both provide a means of entering data. The keyboard duplicates many touchscreen functions but is the only data entry method for alphanumeric information.

The following conventions are used to describe operator actions with the color touchscreen and keyboard.

- **SELECT** – indicates the described action can be performed on the keyboard or color touchscreen.
- **PRESS** – indicates the described action can only be performed on the keyboard.
- **TOUCH** – indicates the described action can only be performed on the color touchscreen.

Express Keys

The Express Keys are the four wide keys on the right side of the keyboard. Three of the express keys function like their Information Zone Indicator counterparts.

- Inventory key
- Messages key
- Exceptions key
- Main Menu key

Entering and Editing Data

Information is entered over blank or existing data fields. New characters overwrite old.

Special Purpose Keys

The AxSYM System uses a standard keyboard. There are three special purpose keys.

- **BACKSPACE Key** – used to delete a character.
- **ENTER Key** – accepts data and moves the cursor to the next active field.
- **ARROW Keys** – used to move the cursor to the next active data field, or within the data field.

Character Conventions

Character conventions include the following:

- **Blinking Cursor** – identifies the currently selected area of a field as available for data entry. Arrow keys or touch-selections move the cursor to active data fields.
- **Colon (:)** – identifies a non-editable field, or inactive field. Entry in this type of data field is not allowed.
- **Greater Than Character (>)** – identifies a data field that is active or editable.

Screen Conventions

Screens present only valid lists of options for displayed information and system operations. The following conventions are used when displaying a list of options:

- **Bar Cursor** – identifies a selectable item from a list of options.
- **Frame Cursor** – identifies a selectable button from a list of buttons.

- **Circular Options** – used when more than one option is available. Selection of one option field displays the next available option.
- **Multiple Selection Options** – check boxes are used when more than one option can be selected.
- **Single Selection Options** – circles indicate that only one selection from the options list can be made.
- **Single Selection Lists** – selecting additional items deselects a previous choice.
- **Multiple Selection Lists** – more than one item can be selected at a time.
- **Action Lists** – the selection of only one item results in immediate action by the system.
- **Buttons** – appear as F-keys in active screens within the Activity Zone and result in immediate action by the system.

Exceptions

Exceptions are identified and tagged by the system for any incomplete test result unreported due to system, data reductions, or calibration errors. The System indicator “Exceptions” highlighted in the Screen Information Zone warns the operator that this condition exists. Touching the Indicator displays the Results Exceptions screen.

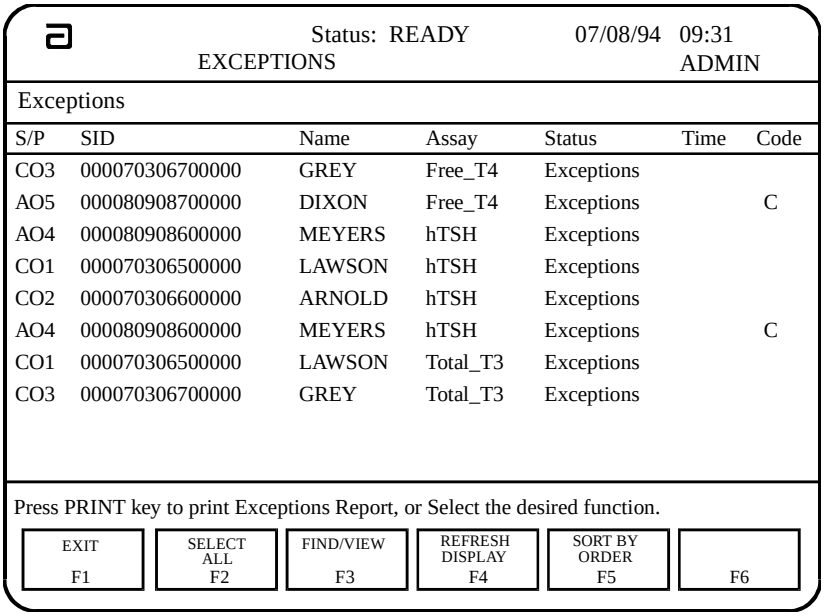

Figure 2.14: Exceptions Screen

Selecting F6 – DETAILS displays the highlighted test result and an associated error message. This information is used to resolve the root cause of the exception.

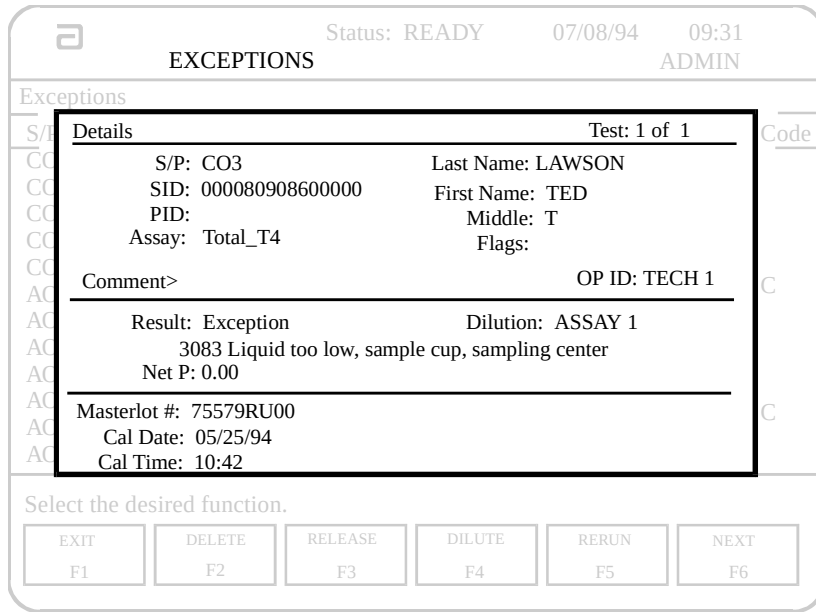

Figure 2.15: Exceptions Details Screen

The test must be deleted in order to remove it from the exceptions list and free up the segment/position.

Message History Log

The Message History Log keeps a log of system problems and maintenance issues. It is useful in evaluating trending of system problems and provides a limited maintenance history. The log may be viewed and sorted by a number of options.

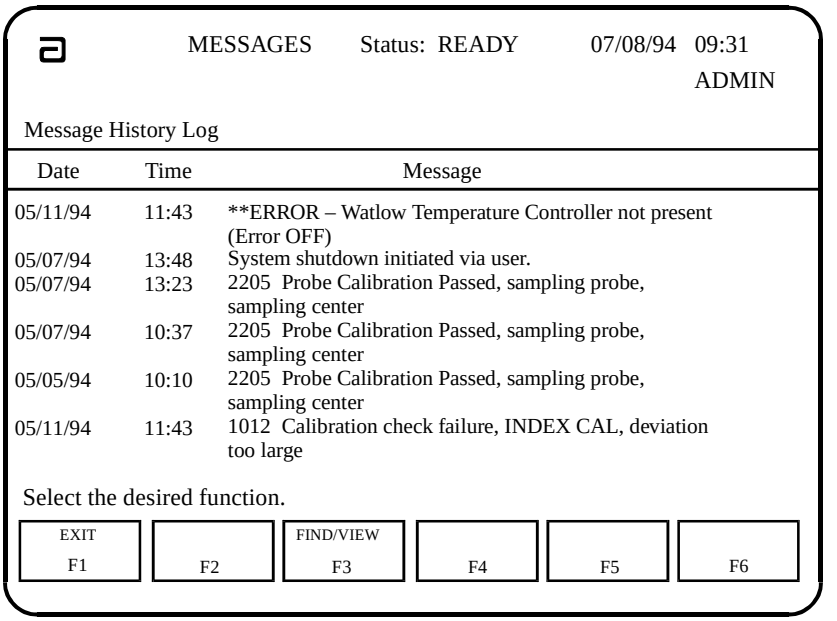

Figure 2.16: Message History Log Screen

Selecting a specific FIND/VIEW option, such as Robotics/ Sensors, displays the history related to that selection and identifies the associated hardware mechanism and system location.

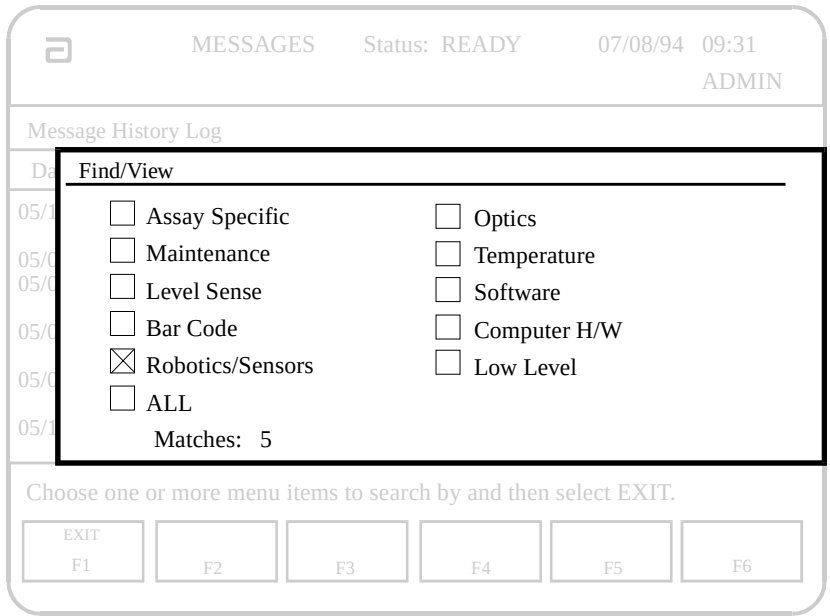

Figure 2.17: Message History Log Find/View Screen

Host Download

To display information that has been downloaded from your host computer into the AxSYM System for routine and STAT orders:

1. Check the screen Information Zone for the ORDERS Indicator.

Figure 2.18: Orderlist Screen with ORDERS Indicator

2. Access the Orderlist screen.

Choose one:

- Select ORDERS Indicator
- Select ORDERLIST on the Main Menu screen.

3. Select F3 – HOST DOWNLOAD.

The Orderlist screen displays information from your host computer:

- S/P segment and position number
- SID
- Patient Name or PID
- Assays Ordered
- Code – appears in the “code” column of the orderlist.
  - S = stat
  - D = dilution
  - C = comment

Transmit Results

To transmit to a host computer:

Getting Started

1. Select RESULTS on the Main Menu screen.

The Results screen displays the results for all completed orders. Single, multiple, or all results on the Results screen can be selected for viewing result details.

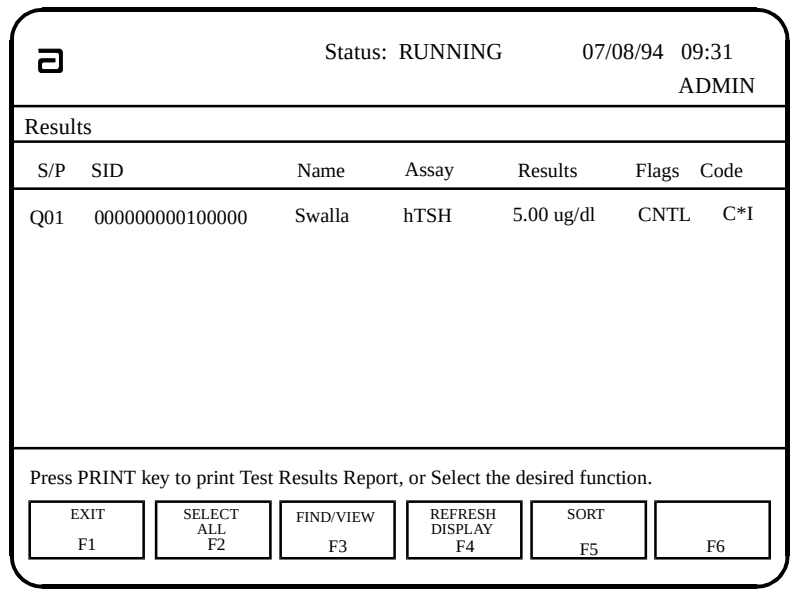

Figure 2.19: Results Screen

F-Key choices:

- Select F1 – EXIT to return to the Main Menu.
- Select F2 – SELECT ALL to select all results on the Results screen.
- Select F3 – FIND/VIEW to display options available for viewing Results.
- Select F4 – REFRESH DISPLAY to update the display with the most current results.
- Select F5 – SORT to view options available for sorting results.

Selecting Results

2. Select the results to be viewed.

Choose one:

- Select one or more results from the Activity Zone.
- Select F2 – SELECT ALL to select all results.

When one or more results are selected on the Results screen, several of the function key options change.

Releasing a Result

This option is available for results with a test status of Complete and Exception when the system is configured Release Mode: Manual, or Hold.

NOTE: Results can also be released through the Results screens and Exceptions screens.

3. Select F3 – RELEASE on the Order Status or Result screen to release the assay result.

Figure 2.20: Confirm Release Screen

Confirm Release

4. Confirm the release.

Choose one:

- Select YES.
- Select NO to cancel the release request.

If your system is interfaced with a host computer, the results will be removed from the Order Status and Results screens, transmitted to the host computer, and stored in Stored Results.

If your system is not interfaced with a host computer, results will be removed from the Order Status and Results screen and stored in Stored Results.

Transmit Stored Results

The AxSYM System is capable of storing up to 1,500 released patient test results in Stored Results. Once 1,500 records are reached, the system will replace the oldest record with the newest addition. To transmit stored results:

Getting Started

1. Select STORED RESULTS on the Main Menu screen.

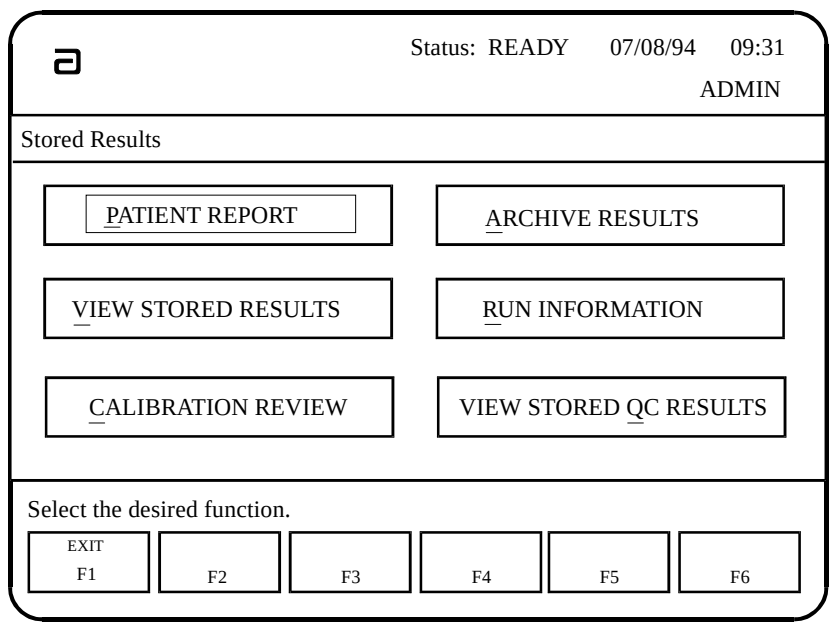

Figure 2.21: Stored Results Menu

The Stored Results Menu offers seven options:

- Select F1 – EXIT to return to the Main Menu.
- Select PATIENT REPORT to access the Patient Report screen.
- Select VIEW STORED RESULTS to access the Stored Results screen.
- Select ARCHIVE RESULTS to access the Archive Retrieve screen.
- Select RUN INFORMATION to access the Run Information screen.
- Select CALIBRATION REVIEW to access the Calibration Review screen.
- Select VIEW STORED QC RESULTS to access the Stored QC Results screen.

2. Select VIEW STORED RESULTS on the Stored Results Menu.

Single, multiple, or all results on the Stored Results screen can be selected for viewing test details.

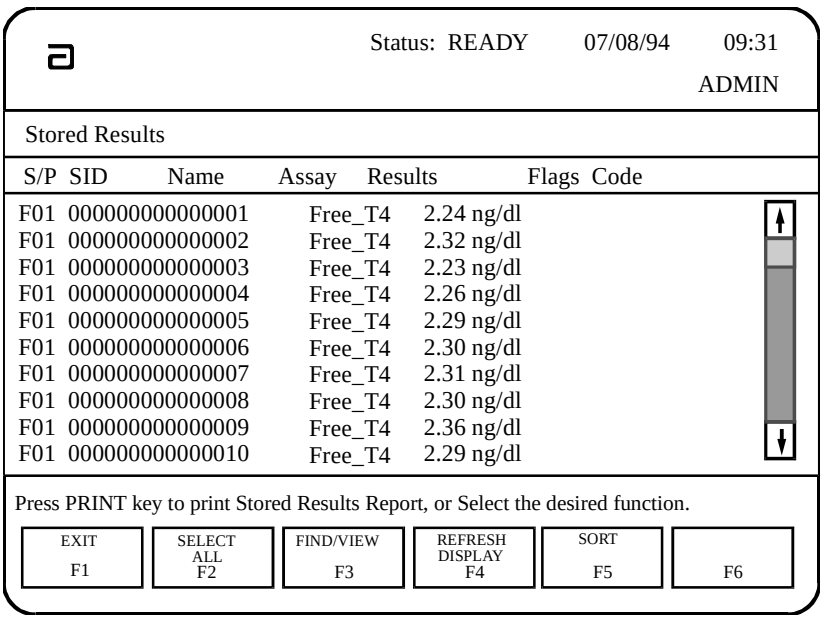

Figure 2.22: Stored Results Screen

F-Key choices:

- Select F1 – EXIT to return to the Stored Results Menu.
- Select F2 – SELECT ALL to select all results on the Stored Results screen.
- Select F3 – FIND/VIEW to display options available for viewing stored results.
- Select F4 – REFRESH DISPLAY to update the display with the most current stored results.
- Select F5 – SORT to view options available for sorting results.

Selecting Results

3. Select the results to be viewed.

Choose one:

- Select one or more tests from the Activity Zone.
- Select F2 – SELECT ALL to select all the results.

Transmit Results

NOTE: When one or more results are selected on the Stored Results screen, several of the function key options change.

4. Select F5 – TRANSMIT TO HOST.

NOTE: The system must be configured to Transmit Approved Patient Results to Host> ON for the F5 – TRANSMIT TO HOST option to be displayed.

AxSYM Support of ASI Options

The following items are defined as optional by the Abbott Standard Interface. AxSYM supports these items as defined below.

Establishment Phase

During the Establishment Phase, if the AxSYM System has information to transmit it attempts to establish a connection with an external host every 60 seconds.

Transfer Phase

The AxSYM System does not currently support the ability to delete contents of previously transmitted fields.

Repeat Delimiters

AxSYM only supports the use of repeat delimiters in the Universal Test ID field during download from a host. AxSYM does not use repeat delimiters when transmitting information to a host.

Canceling of Test Orders

AxSYM does not currently support the ability for a host to cancel a previously downloaded test order through the use of the Action Code field.

Primary Character Set for AxSYM

The following table shows the character set supported by the AxSYM System. Characters with values between 0 and 127 are as defined by the ASTM E1381-91 and ANSI X3.4-1986 Standards. Characters with values between 128 and 255 are defined as shown below. Certain values are reserved for use by the AxSYM System for graphic purposes. Reserved characters are ignored when received via the host port.

Table 1-1: Primary Character Set for AxSYM

Decimal		0	16	32	48	64	80	96	112	128	144	160	176	192	208	224
	Hex	0	1	2	3	4	5	6	7	8	9	A	B	C	D	E
0	0	NUL	DLE	SP	0	@	P	`	p	Ç	É	á	*	*	*	Ó
1	1	SOH	DC1	!	1	A	Q	a	q	ü	æ	Í	*	*	*	P
2	2	STX	DC2	"	2	B	R	b	r	é	Æ	ó	*	*	É	Ô
3	3	ETX	DC3	#	3	C	S	c	s	â	ô	ú	*	*	Ë	Ò
4	4	EOT	DC4	$	4	D	T	d	t	ä	ö	ñ	*	*	È	õ
5	5	ENQ	NAK	%	5	E	U	e	u	à	ò	Ñ	Á	*	*	Õ
6	6	ACK	SYN	&	6	F	V	f	v	å	û	*	Â	ã	í	µ
7	7	BEL	ETB	'	7	G	W	g	w	ç	ù	*	À	Ã	î	p
8	8	BS	CAN	(	8	H	X	h	x	ê	ÿ	¿	*	*	ï	P
9	9	HT	EM	)	9	I	Y	i	y	ë	Ö	*	*	*	*	Ú
10	A	LF	SUB	*	:	J	Z	j	z	è	Ü	*	*	*	*	Û
11	B	UT	ESC	+	;	K	[	k	{	ï	*	*	*	*	*	Ù
12	C	FF	FS	,	<	L	\	l	|	î	*	*	*	*	*	ý
13	D	CR	GS	-	=	M	]	m	}	ì	*	¡	*	*	*	Ý
14	E	SO	RS	.	>	N	^	n	~	Ä	*	*	*	*	Ì	*
15	F	SI	US	/	?	O	_	o	*	Å	*	*	*	*	*	*

*Reserved characters used for graphics.

NOTES

Communication Setup

Section Table of Contents

Communication Setup

Overview

This section explains system, Assay parameter and control configuration and details system startup procedures.

Authority to make configuration changes may be established by entering a password at the System Administrator Password prompt in GENERAL Configuration.

If the system is configured with a System Administrator Password:

- A **General Operator**, with no password entered, may not change any configuration options. This level of operator may access configuration screens for viewing purposes only.
- A **System Administrator** password enables almost all configuration changes described in this section.

An operator who calls the Abbott Customer Support Center for troubleshooting purposes may be given the Temporary Customer Support Center password. Entry of this password authorizes selected functions in addition to those allowed the System Administrator, as noted in the text.

The Abbott Field Service Engineer has access to all configuration functions.

NOTE: Configuration changes may be performed only when the system status displays STOPPED or READY.

Power On

Before doing anything you must turn on the System.

1. Flip the power switch to the “on” position indicated by the symbol “|” on the power switch plate.

The Boot-Up screen is displayed.

Power On is complete when the Main Menu is displayed.

NOTE: You cannot run an assay until you perform the Start-up procedure.

Start-up

Start-up of the AxSYM System is required after a system power on and after any diagnostic procedure. A Start-up request is performed through the Main Menu screen.

Getting Started

1. Select F3 – START-UP from the Main Menu screen.

The Home Motors screen is displayed while all the system motors are checked by AxSYM.

The motors have completed homing when the System Cleanup screen is displayed.

The System Cleanup Wait screen is displayed while the system performs cleanup procedures.

> **NOTE:** Start-up can be requested only when system status is STOPPED. You cannot run an assay until you perform the Start-up procedure.

After system Start-up is performed, the Main Menu screen appears. The status field on the screen displays READY.

System Configuration

This function allows for communication between the AxSYM System and the host computer.

Access the function

1. Select CONFIGURATION from the Main Menu.

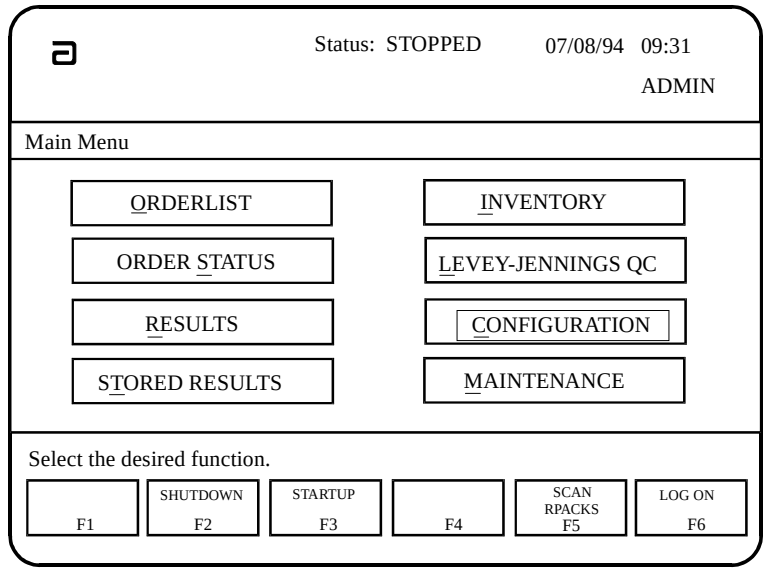

Figure 3.1: Main Menu With Configuration Selected

2. Select GENERAL from the System Configuration Menu.

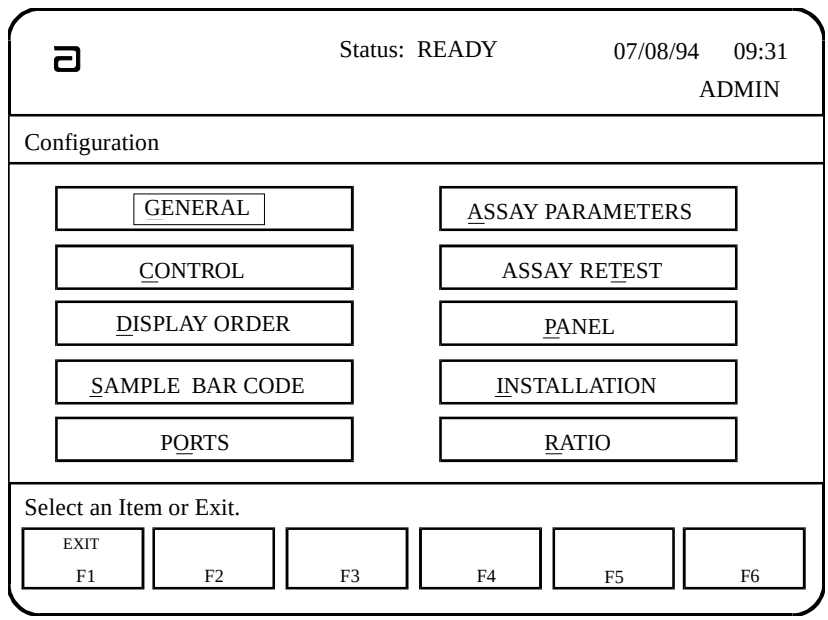

Figure 3.2: System Configuration Menu

3. The Configuration/General Screen is displayed, listing the first of several screens of configurable items.

   Settings that can be edited by the operator are indicated by the symbol ">". Settings that cannot be edited are indicated by a ":". Whether the ">" or ":" is displayed is determined by the LOGON entered by the operator in the Log On screen.

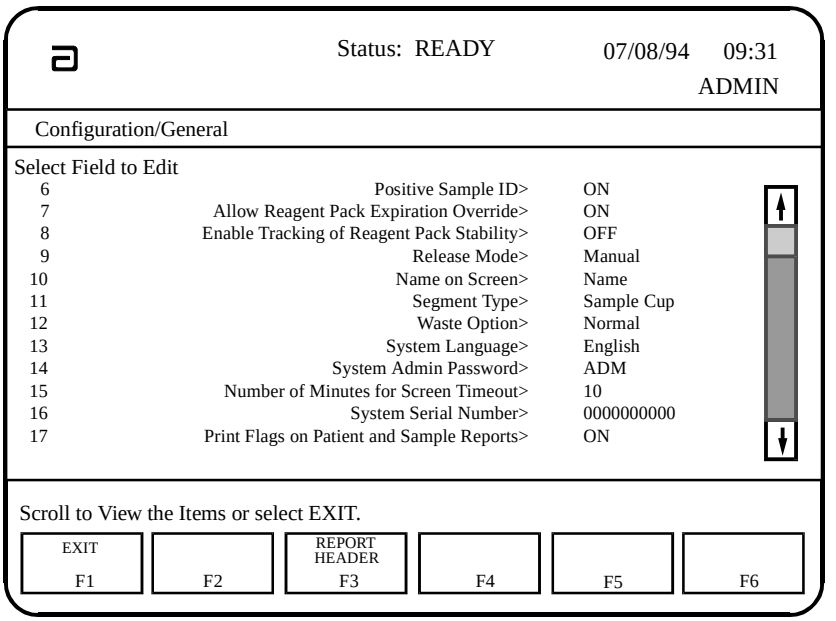

Figure 3.3: Configuration/General Screen. *This screen displays 12 settings at a time. Only those with the ">" symbol may be changed.*

Select a setting

1. Select Auto Assign SID> OFF.

   Auto Assign SID>
   OFF allows assignment of sample identification by the Host Computer.
   Default = OFF

2. Select Release Mode> Manual, Automatic, Hold, or Auto with Exceptions.

   Release Mode> selects the mode for the release of results to a host computer, stored results, and Levey-Jennings QC screens. Options are Manual, Automatic, Hold, and Auto with Exceptions. Default=Manual.

3. In the Release Mode Window, select an option to release results.
4. Select F1-EXIT to return to the Configuration/General screen.

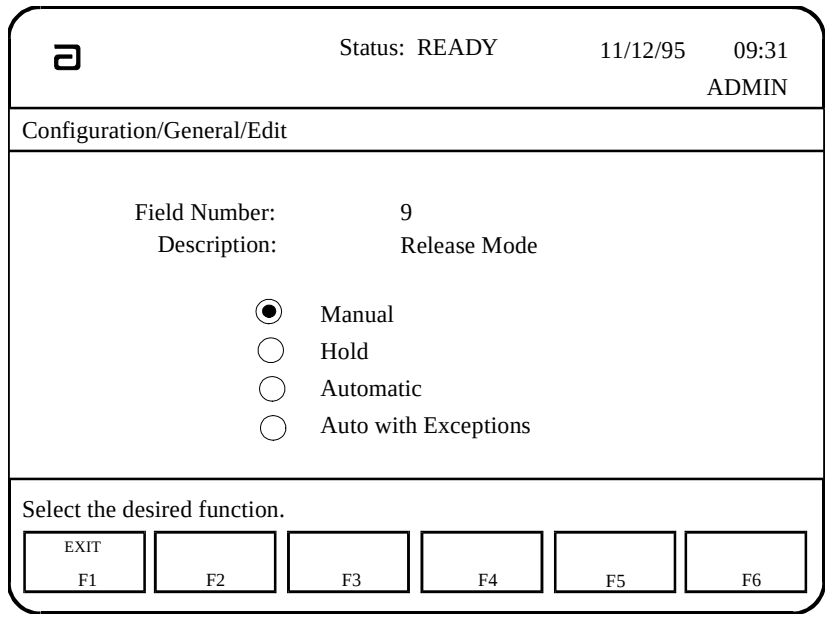

Figure 3.4: Release Mode Window

5. Scroll to select more fields.
6. Select Transmit Approved Patient Results to Host> ON.

   Transmit Approved Patient Results to Host>
   ON sends patient results to the host computer upon approval.
   Default = OFF

7. Select Transmit Approved QC Results to Host> ON.

   Transmit Approved QC Results to Host>
   ON sends control results to the host computer upon approval.
   Default= OFF

8. Select Accept Order Requests from Host> ON.

   Accept Order Request from Host>
   ON enables the system receipt of orders from a host computer.
   Default = OFF

9. Select Enable Host Order Query Mode> ON (optional).

   Enable Host Order Query Mode> ON allows the system to issue query requests to the Host when a Bar Code sample is encountered with no on-board orders.
   Default = OFF

10. Select Number of seconds to wait for Query Response> [number] (optional).

    Enter the time span (in seconds) that the system will use to determine if a query request has timed-out.

    Range = 5 - 60 seconds
    Default = 10 seconds

11. Select Sample collation host transmission> ON (optional).

    Sample collation host transmission> ON makes the AxSYM System collate all results for a sample and allow automated transmission to the host only after the last test for that sample has been completed and released.
    Default = OFF

12. Select revised result message hierarchy> ON (optional).

    Revised result message hierarchy> ON enables a revised method of transmitting results to the host (see **Section 4: *Communication, Subsection: AxSYM to Host***). If OFF, results are sent un-revised.
    Default = OFF

13. Select Messages and Exceptions destination> Screen Only.

    NOTE: Refer to the Robotics Manual for a complete description of this option. Default=Screen Only.

14. Select Transmit Multiple Result Flags to Host>OFF (optional).

    Transmit Multiple Result Flags to Host>OFF causes the highest priority result flag to be transmitted to the host. If ON, all result flags will be transmitted to the host.

15. Select F6 – SAVE to store the change and exit.

To exit without storing the change and return to the General Configuration screen, select F1 – CANCEL.

If a value is outside the acceptable range, the system rejects it and prompts for new input.

16. Continue or Exit.

    Choose one:

    - Select another configurable item for editing.
    - Select F1 – EXIT to return to the System Configuration Menu.

Port Configuration

This function allows the operator to set up configuration of ports for communication between the AxSYM System and the host computer.

The AxSYM System communication settings for the Host RS-232 ports include:

- Baud Rate
- Parity
- Number of Data Bits
- Number of Stop Bits

NOTE: Unused ports need not be configured.

Access the function

1. Select CONFIGURATION from the Main Menu.
2. Select PORTS from the System Configuration Menu.

   The Port Interface Configuration Screen is displayed, showing settings for a previously selected port.

Select the port

3. Select the port to be configured in the Ports window.

   Port Settings displayed change to current settings for Host Interface Configuration.

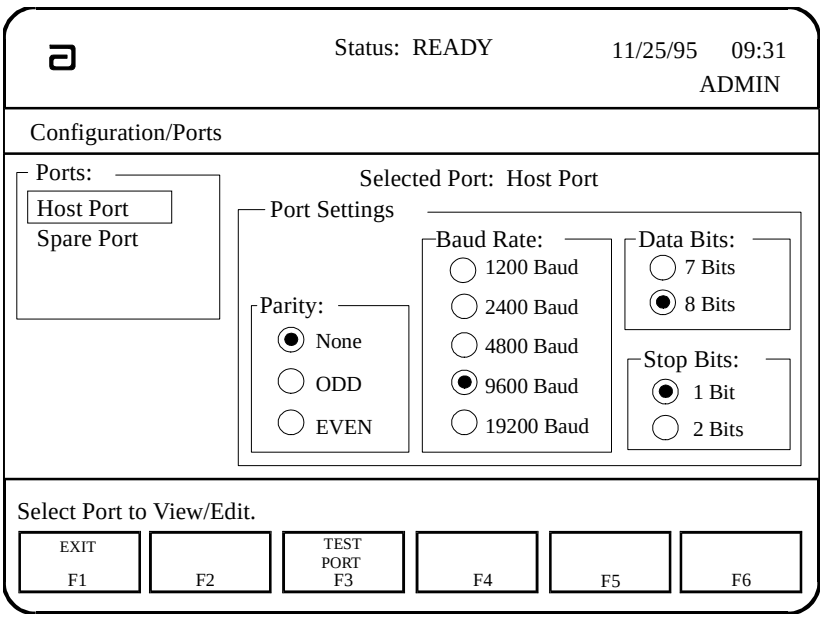

Figure 3.5: Ports Interface Configuration Screen

Change settings

4. In the Port Settings window, select settings for Parity, Baud Rate, Data Bits, and Stop Bits as required.

   Defaults = Parity: None

   Baud Rate: 9,600

   Data Bits: 8

   Stop Bit: 1

5. Choose one:

   - Select F6 – SAVE to store the settings.
   - Select F1– CANCEL to cancel setting.

6. Select "A" to return to the Main Menu.

Test the Port

The Host Port Test enables the operator to test whether or not the Host Port is working. You must be signed on as ADMIN or above to access this test. You will also need the Loopback Connector accessory.

To initiate a Host Port Test:

1. Select CONFIGURATION from the Main Menu screen.
2. Select PORTS from the Configuration screen.

   The Configuration/Ports screen is displayed.

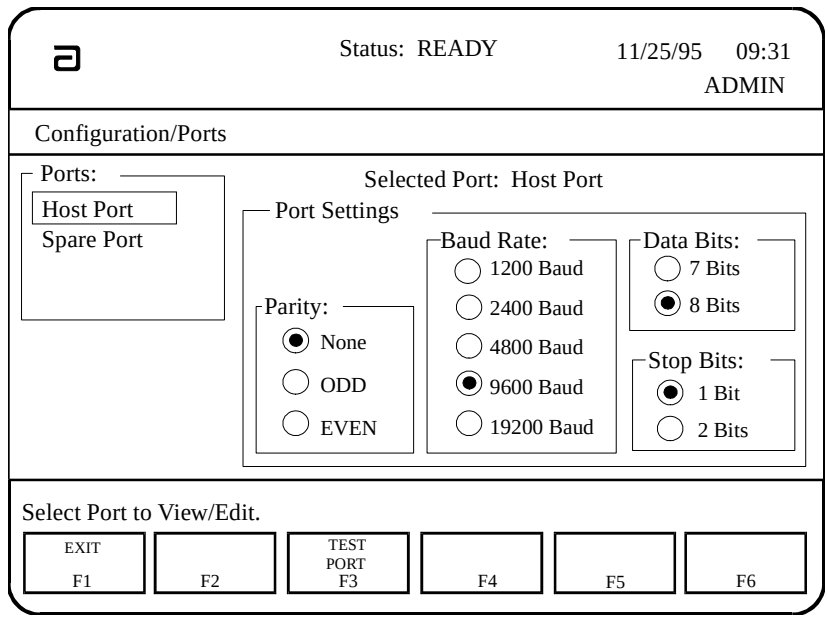

Figure 3.6: Configuration/Ports screen

3. Select Host Port from the list of ports.

   The Host Port Configuration settings are displayed along with the F3 - TEST PORT key.

4. Select F3 - TEST PORT.

   An informational pop-up screen appears instructing you to install the Loopback Connector on the port labeled HOST INTERFACE.

5. Install the Loopback Connector onto the Host Interface Port.

6. Confirm or cancel the Host Port Test request.

   Choose one:

   - Select OK to continue
   - Select CANCEL to cancel the test

   Selecting OK initiates the test that confirms whether or not the Host Port is working properly. You will receive one of the following three messages as a result.

   - 8503 Host Port Test denied, LIS port busy.
   - 8501 Host Port Test Failed, Status (code name).
   - 8502 Host Port Test passed.

7. Select OK to continue.

   A message indicating whether the test passed or failed is recorded in the Message History Log.

   For more information on what to do after receiving error message 8501 (test failed) or 8503 (port busy) refer to **Section 6: *Troubleshooting***.

8. Return to the Main Menu.

   Choose one:

   - Touch the Abbott “A” logo
   - Press the Main Menu key

Store Settings

In order for the edited port configurations to take effect, the AxSYM System must be reinitialized.

1. Access the Main Menu screen:

Choose one:

- Select the Abbott “A” logo on the screen.
- Press the MAIN MENU key on the keyboard.

2. Select F2 – SHUTDOWN.

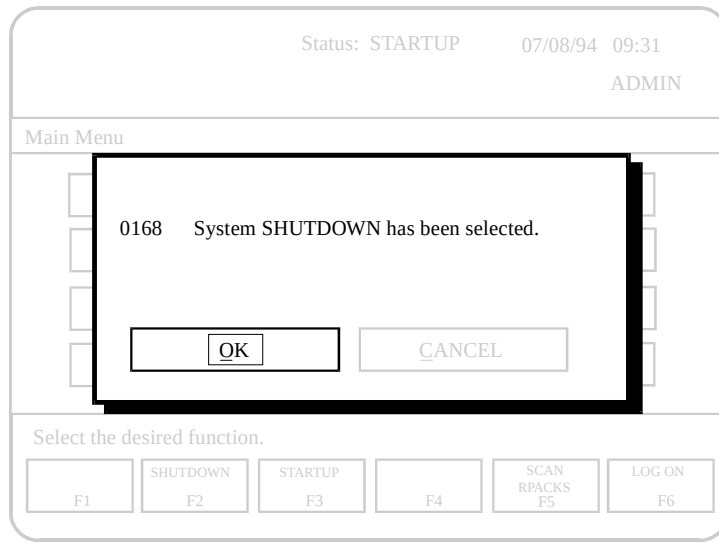

Figure 3.7: Confirm Shutdown Screen

3. Select OK to confirm the Shutdown request.

   F1 – CANCEL will cancel Shutdown request and display the Main Menu screen.

   Shutdown is complete. You may now turn off the power.

Power Off

4. Flip the power switch to the “off” position, indicated by the symbol “0” on the power switch plate. Wait 30 seconds and turn the power switch back on.

   Refer to the Power On procedure for instructions on powering on the system.

Assay Parameters Configuration

When an assay is installed, the system stores the assay parameters to control performance of that assay. Most parameters are fixed, and may not be changed. The Assay Parameters Configuration function provides for viewing and changing these settings.

Getting Started

1. Select CONFIGURATION from the Main Menu.
2. Select ASSAY PARAMETERS from the Configuration Menu.

   The Assay Parameters Assay Selection Screen is displayed, listing available assays.

Select Assay

3. To view parameters for a specific assay, select the assay.

   The Assay Parameters/View screen is displayed.

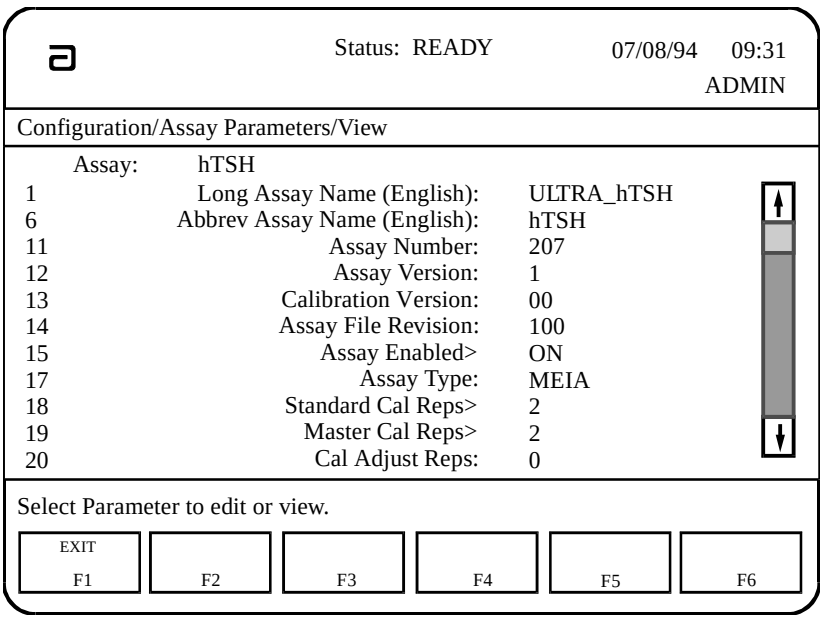

Figure 3.8: The View Screen displays 11 parameters at a time. Only those with the > may be changed.

For each assay there are several screens of numbered parameters which may be viewed by scrolling. Parameter numbers are uniform from assay to assay.

4. To return to System Configuration Menu, select F1 – EXIT .

Assay Parameters Descriptions

The following is a list of Assay Parameters and a description of their use.

If the parameter is one that the System Administrator may change, indicated by ">", the available options or acceptable value ranges are shown.

Certain parameters establish criteria for the generation of system flags. Where this is the case, it is noted.

Table 3: Assay Parameters Descriptions

#	Configuration Item	Setting	Explanation
1.	Long Assay Name (Language):		Full name of the assay in the selected language
6.	Abbrev Assay Name (Language):		Abbreviated name of the assay in the selected language
11.	Assay Number:		Number used to identify the assay
12.	Assay Version:		Number used in combination with configuration 13 and 14 to identify the version of the assay software
13.	Calibration Version:		Number used in combination with configuration 12 and 14 to identify the version of the assay software
14.	Assay File Revision:		Number used in combination with configuration 12 and 13 to identify the version of the assay software **NOTE**: The Assay File Version number on the Assay File Disk appears as x.xx.x (i.e. 1.00.1 where 1 = Assay Version number, 00 = Calibration Version number, and 1 = Assay File Revision). The last two digits of the Assay File Revision number displayed on the Assay Parameters View Parameters screen do not appear on the Assay File Disk.
15.	Assay Enabled>	Default is ON.	Disables the assay so it can not be ordered.
17.	Assay Type:		Defines the assay as FPIA or MEIA
18.	Standard Cal Reps>	Range is 1 - 5.	Number of replicates of the standard calibrators.

Table 3: Assay Parameters Descriptions

#	Configuration Item	Setting	Explanation
19.	Master Cal Reps>	Range is 1 - 5.	Number of replicates of calibrators used in the Master Cal (2-point calibration).
20.	Cal Adjust Reps>	Range is 1 - 5.	Number of replicates of the calibrator used in the Cal Adjustor.
21.	Cal A Concentration:		Concentration of Calibrator A **NOTE**: If an assay result's concentration is less than the Calibrator A concentration, a <flag appears on the results screen and on patient reports.
22.	Cal B Concentration:		Concentration of Calibrator B
23.	Cal C Concentration:		Concentration of Calibrator C
24.	Cal D Concentration:		Concentration of Calibrator D
25.	Cal E Concentration:		Concentration of Calibrator E
26.	Cal F Concentration:		Concentration of Calibrator F **NOTE**: If an assay result's concentration is greater than the Calibrator F concentration, a >flag appears on the results screen and on patient reports.
27.	Master Calibrator 1 Concentration:		Calibration concentration of the first Master Calibrator (M-CAL 1) used in the Master Cal (2-point calibration).
28.	Master Calibrator 2 Concentration:		Calibration concentration of the second Master Calibrator (M-CAL 2) used in the Master Cal (2-point calibration).
29.	Cal Adjust Concentration:		Calibration concentration of the calibrator used in the calibration adjustment.

Table 3: Assay Parameters Descriptions

#	Configuration Item	Setting	Explanation
43.	Default Dilution Protocol>	OPTIONS: UNDILUTED DILUTION PROTOCOL 1 DILUTION PROTOCOL 2 DILUTION PROTOCOL 3	The type of dilution protocol executed if none is selected by the operator when ordering a dilution on a patient sample or Control. **NOTE**: Actual protocol names are assay specific.
44.	Default Calibration Method>	OPTIONS: 6-POINT CALIBRATION (STANDARD) 2-POINT CALIBRATION (MASTER) 1-POINT CALIBRATION (INDEX) 1-POINT CALIBRATION (CAL ADJUSTOR)	Assay calibration method employed if none is selected by the operator when ordering a calibration to be run. Only those options valid for the assay are displayed.
45.	Selected Result Concentration Units>	OPTIONS: no units meq/L Fmol/mL Uptake U/mL %INH mIU/L ng/mL mIU/mL uIU/mL ug/L nM S/CO %Uptake ug/mL IU/L ug/dL AU/mL ng/dL S/N meq/mL IU/mL pg/mL %ACT %SAT Index mg/L pmol/L nmol/L umol/L mg/mL % ng/L ppm mg/dL	Concentration units currently in use.
46.	Selected Result Decimal Places>	Range is 0 - 3, where 0 = no decimal placement.	Number of digits to the right of the decimal for concentration results for a current result unit
62.	Blank I - Max background intensity:		Maximum allowed background intensity
63.	Min Tracer – Min net intensity:		Minimum allowed net intensity

Table 3: Assay Parameters Descriptions

#	Configuration Item	Setting	Explanation
64.	Max Intercept – Max MUP intercept:		Maximum allowed MUP intercept
65.	Min Intercept – Min MUP intercept:		Minimum allowed MUP intercept
66.	Upper limit for NRMSE for low rates:		Maximum Normal Root Mean Square Error (NRMSE) allowed for rate calculation for rates less than the minimum rate parameter.
67.	Upper limit for NRMSE for high rates:		Maximum Normal Root Mean Square Error (NRMSE) allowed for rate calculation for rates greater than the minimum rate parameter.
68.	Max Rate – Max rate used to check Min MUP Intercept:		Maximum Rate used to check Min MUP intercept.
69.	Min Rate – Rate cut-off for NRMSE and Corr. Coef.:		Minimum Rate used for Normal Root Mean Square Error (NRMSE) calculation and correlation coefficient calculation.
70.	Min correlation coefficient for low rates:		Minimum correlation coefficient allowed for rate calculation for rates less than Minimum Rate parameter.
71.	Min correlation coefficient for high rates:		Minimum correlation coefficient allowed for rate calculation for rates greater than Minimum Rate parameter.
72.	MUP T Delay – Time delay following MUP:		Time delay between addition of MUP and first subread for calculation of MUP intercept
73.	Low Limit – Normal/ Therapeutic Range lower limit>	Range allowed: 0.000 - 999999.999 If 0 (zero) is entered, this parameter is not checked.	The low concentration used to flag samples less than the normal/therapeutic range **NOTE**: If an assay result is lower than the limit, a **LOW** flag appears on the results screen and, if General Configuration item 17 is so configured, on patient reports as well.

Table 3: Assay Parameters Descriptions

#	Configuration Item	Setting	Explanation
74.	High Limit – Normal/ Therapeutic Range upper limit>	Range allowed: 0.000 - 999999.999 If 0 (zero) is entered, this parameter is not checked.	The high concentration used to flag samples greater than the normal/therapeutic range **NOTE**: If an assay result is higher than the limit, a **HIGH** flag appears on the results screen and, if General Configuration item 17 is so configured, on patient reports as well.
75.	Low Extreme Value>	Range allowed: 0.000 - 999999.999 If 0 (zero) is entered, this parameter is not checked.	The concentration used to flag samples less than the extreme value **NOTE**: If an assay result value is lower than this parameter, an **LL** flag appears on the results screen and, if General Configuration item 17 is so configured, on patient reports as well.
76.	High Extreme Value>	Range allowed: 0.000 - 999999.999 If 0 (zero) is entered, this parameter is not checked.	The concentration used to flag samples greater than the extreme value **NOTE**: If an assay result value is higher than this parameter, an **HH** flag appears on the results screen and, if General Configuration item 17 is so configured, on patient reports.
77.	Lo Norm – % Uptake Normal Range Low>	Range allowed: 0.000 - 9999.999, or Not Used	Lowest value in normal range for %Uptake when T-Uptake units are converted to %Uptake
78.	Hi Norm – % Uptake Normal Range High>	Range allowed: 0.000 - 9999.999, or Not Used	Highest value in normal range for %Uptake when T-Uptake units are converted to %Uptake
80.	Interpretation Option to use>		Number of the interpretation option in use; option labels vary from assay to assay.
84.	Hold results with POS interpretation>		If ON, test results with a positive interpretation must be released manually.

Table 3: Assay Parameters Descriptions

#	Configuration Item	Setting	Explanation
85.	Hold results with NEG interpretation>		If ON, test results with a negative interpretation must be released manually.
86.	Hold results with GRY interpretation>		If ON, test results with a grayzone interpretation must be released manually.
91.	Low Range Undiluted:		Low limit for concentration for a sample processed with the UNDILUTED protocol. Concentrations below this limit are reported as less than (<) the Low Range Neat concentration value.
92.	High Range Undiluted:		High limit for concentration for a sample processed with the UNDILUTED protocol. Concentrations above this limit are reported as greater than (>) the High Range Neat concentration value.
96.	Low Range Dil 1:		Low limit for concentration for a sample processed with DILUTION PROTOCOL 1. Concentrations below this limit are reported as less than (<) the Low Range Dil 1 concentration value.
97.	High Range Dil 1:		High limit for concentration for a sample processed with DILUTION PROTOCOL 1. Concentrations above this limit are reported as greater than (>) the High Range Dil 1 concentration value.
101.	Low Range Dil 2:		Low limit for concentration for a sample processed with DILUTION PROTOCOL 2. Concentrations below this limit are reported as less than (<) the Low Range Dil 2 concentration value.
102.	High Range Dil 2:		High limit for concentration for a sample processed with DILUTION PROTOCOL 2. Concentrations above this limit are reported as greater than (>) the High Range Dil 2 concentration value.

Table 3: Assay Parameters Descriptions

#	Configuration Item	Setting	Explanation
106.	Low Range Dil 3:		Low limit for concentration for a sample processed with DILUTION PROTOCOL 3. Concentrations below this limit are reported as less than (<) the Low Range Dil 3 concentration value.
107.	High Range Dil 3:		High limit for concentration for a sample processed with DILUTION PROTOCOL 3. Concentrations above this limit are reported as greater than (>) the High Range Dil 3 concentration value.
112.	Max End-Point Deviation:		Maximum end-point deviation allowed for %transmission values less than or equal to the Maximum Percent Transmission parameter.
113.	Max Baseline Intensity:		Maximum allowed baseline intensity.
114.	Min Baseline Intensity:		Minimum allowed baseline intensity.
115.	Max Percent Transmission		Maximum percent transmission value for which the end-point deviation calculation will be performed.

Table 3: Assay Parameters Descriptions

#	Configuration Item	Setting	Explanation
116.	Positive Interpretation Cutoff >	Default = 0.0	This parameter allows you to edit the default cutoff value for positive interpretations, thereby affecting the grayzone range for those assays that offer a grayzone interpretation. The positive interpretation editable range varies from assay to assay. Whenever this parameter is edited and saved, a message is placed in both the Temporary Message and Message History Logs. In addition, an Assay Parameter report is automatically printed. This parameter is only visible, and therefore editable, for certain assays. For information on grayzone interpretation availability and acceptable interpretation ranges, refer to the ***AxSYM Assay-specific Package Insert***.
117.	Negative Interpretation Cutoff >	Default = 0.0	This parameter allows you to edit the default cutoff value for negative interpretations, thereby affecting the grayzone range for those assays that offer a grayzone interpretation. The negative interpretation editable range varies from assay to assay. Whenever this parameter is edited and saved, a message is placed in both the Temporary Message and Message History Logs. In addition, an Assay Parameter report is automatically printed. This parameter is only visible, and therefore editable, for certain assays. For information on grayzone interpretation availability and acceptable interpretation ranges, refer to the ***AxSYM Assay-specific Package Insert***.

Control Configuration

The system can be configured with single analyte and multi-constituent controls for each assay run.

NOTE: Control names must match control sample IDs downloaded by the host. See Test Order Record, ASTM Field 9.4.3, Specimen ID.

Getting Started

1. Select CONTROL from the System Configuration Menu.

   The Configuration/Control Assay Selection screen is displayed, with assays listed.

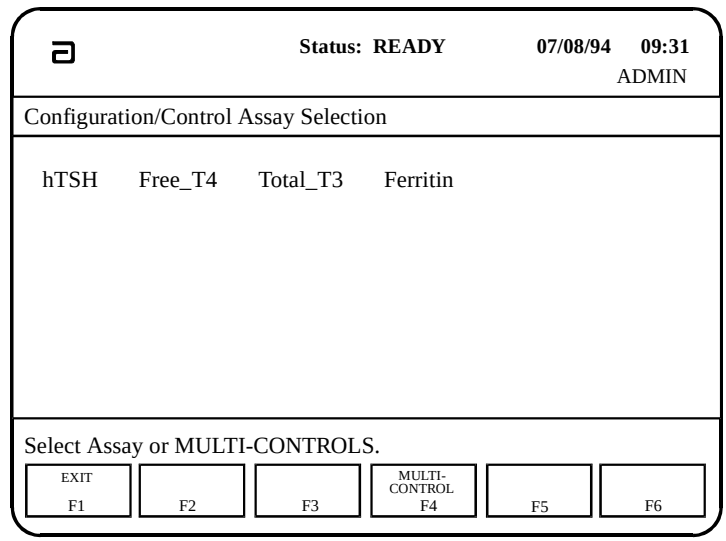

Figure 3.9: Configuration/Control Assay Selection Screen

Access Desired Control Type

2. Access the control to configure.

Choose one:

- Select the assay to configure single analyte controls for an assay.
- Select F4 – MULTI-CONTROL to configure multiple constituent control for an assay.

The Control Selection screen lists existing controls of the selected type for the selected assay.

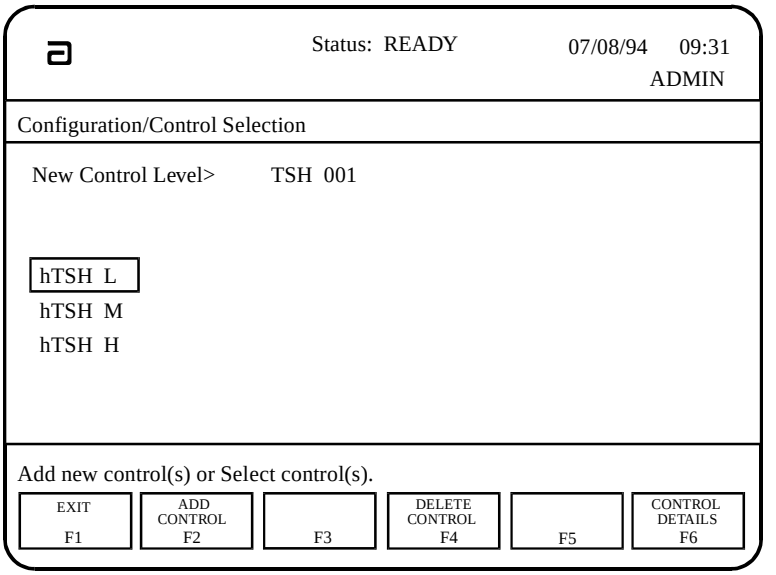

Figure 3.10: Configuration/Control Selection Screen

Edit Control List

For both types—single analytes or multi-controls—adding and deleting control names is the same.

3. To create a new control, enter a unique name in the New Control Name field.

   NOTE: Enter the control names for an assay in the Configuration/Control Selection screen in the order you want them to appear in the Orderlist screen. Each analyte control must have a unique name (e.g., Assay 1-L, Assay 2-L, etc.).

4. Select F2 – ADD CONTROL to add the new control.

Delete Control

5. Select the control on the list.
6. Select F4 – DELETE CONTROL.

AxSYM Specific Outgoing Messages

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AxSYM Specific Outgoing Messages

Overview

The following section outlines the ASTM records and field contents needed to establish communication from the AxSYM System to a host computer.

For information on communicating from the host to the AxSYM System refer to **Section 5: *AxSYM Specific Incoming Messages*.**

Communication: AxSYM to Host

Transmission of Patient Results, Quality Control Results and Order Query Requests utilize the high level ASTM records and fields described in this section. Unused fields are not listed.

Results Transmission

Successfully completed test results are transmitted from the AxSYM System to the host according to one of the two following logical record hierarchies:

1. Original hierarchy as used in Revision 1.x AxSYM software: Each result is sent as a separate message. Multiple messages may be contained in a single session. To produce this form of record hierarchy, the user configurable option “Revised Result Message Hierarchy” must be turned **OFF** (default).

   Message Header Record
   Patient Information Record
   Test Order Record
   Result Record
   Comment Record (optional)
   Message Terminator Record

2. Revised hierarchy: If the user configurable option “Revised Result Message Hierarchy” is **ON**, multiple results are sent in single messages. Multiple messages may be sent in a single session. The revised hierarchy is as follows:

Message Header Record
Patient Information Record
Test Order Record
Result Record
Comment Record (optional)
Test Order Record
Result Record
Comment Record (optional)
Patient Information Record
Test Order Record
Result Record
Comment Record (optional)
•
•
•
Message Terminator Record

Tests for which results cannot be calculated are transmitted from the AxSYM System to the host according to one of the following logical record hierarchies depending on the setting of “Revised Result Message Hierarchy”. In such a case, the Report Type field of the Test Order Record contains an “X”. The comment record contains the reason why the test could not be done. Two comment records may be sent.

1. “Revised Result Message Hierarchy” OFF. Single results sent in separate messages.

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

2. “Revised Result Message Hierarchy” ON. Multiple results sent in a single message.

Message Header Record
Patient Information Record
Test Order Record
Comment Record
Test Order Record
Comment Record
Patient Information Record
Test Order Record
Comment Record
•
•
•
Message Terminator Record

Order Query Transmission

If the user configurable option “Enable Host Order Query Mode” is turned ON, AxSYM will issue Request Information Records for samples that do not have pending orders stored on AxSYM. These Request Information Records (Order Queries) will be sent during a run as and when a sample is encountered. The record hierarchy for an Order Query is as follows:

Message Header Record
Request Information Record
Message Terminator Record

Format Detail

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

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

ASTM records that are not used:

- Scientific Record
- Manufacturer Information Record

Message Header Record

Table 1-1: Message Header: AxSYM 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	5 4 10 16	AxSYM ^Version Number (Numeric) ^Serial Number (Alphanumeric) ^Interface Version (Alphanumeric)	Instrument Name Version Number in the format 1.23. Instrument Serial Number Record types the AxSYM System supports.
7.1.12	Processing ID	1	P Q	Patient results or Quality Control 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|\^&|||AxSYM^1.00^1234567-89^H1P1O1R1C1Q1L1||||||P|1|19930330133346[CR]

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

Patient Information Record

Table 1-2: Patient Information Record: AxSYM to Host

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
8.1.1	Record Type	1	P	Patient
8.1.2	Sequence Number	1	1 to n	n represents any number.
8.1.3	Practice Assigned Patient ID	15	(Any character)	Always returned unchanged to the host.
8.1.4	Laboratory Assigned Patient ID	15	(Any character)	Always returned unchanged to the host.
8.1.5	Patient ID No. 3	15	(Any character)	Instrument PID assigned by operator.
8.1.6	Patient Name	15 20 1	Last ^First ^Middle Initial (Last, First, and Middle Initial can be any character.)	Last, first, and middle initial of Patient Name.

P|1|||PIDSID13|PATIENT^IM^A[CR]

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

Test Order Record

The assay name field is dropped from the Test Order Record when the assay ordered is invalid. Only the assay number is returned.

The assay name field is ignored when an order record mismatches an assay name with an assay number. An error message is not generated.

Table 1-3: Test Order Record: AxSYM to Host

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
9.4.1	Record Type	1	O	Order
9.4.2	Sequence Number	1	1 to n	n represents any number.
9.4.3	Specimen ID	15	Specimen(any character)	Sample ID downloaded from Host, returned unchanged to Host.
9.4.4	Instrument specimen ID ^location_ID ^position	15 1 2	Specimen(any character) ^segment (Alphanumeric) ^position (Numeric)	Instrument Sample ID, segment, 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. **NOTE:** The information in the Segment/ Position portion of the field is invalid for Control Orders.
9.4.5	Universal Test ID Code Name Assay Protocol	 3 9 10	 ^^^ Assay Number (Numeric) ^Assay Name (Alphanumeric) ^Dilution (Alphanumeric)	 Specific number that identifies the test Test name Dilution protocol name
9.4.6	Priority	1	R S	Routine STAT test
9.4.12	Action Code	1	Q	Quality Control Result (empty if Patient Result)
9.4.26	Report Types	1	F X	Final Result Test could not be performed

O|1|SID13|SID13^A^1|^^^16^Assay1^NEAT|R||||||||||||||||||F[CR]

Figure 4.3: Example of Test Order Record: AxSYM 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:

- The final result (concentration)
- An optional interpretation
- The instrument response used to calculate a concentration

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

The field contents, QC and EX, of Result Abnormal Flags are not part of the ASTM Standard.

Table 1-4: Result Record: AxSYM to Host

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
10.1.1	Record Type	1	R	Result
10.1.2	Sequence Number	1	1 to n	n represents any number
10.1.3	Universal Test ID Code Name Assay Protocol Test_Qualifier Result Type	 3 9 10 1	 ^^^Assay Number (Numeric) ^Assay Name (Alphanumeric) ^Dilution (Alphanumeric) ^^ F P I	 Specific number that identified the test Test name Dilution protocol name Always null Final result concentration Preliminary instrument result Interpreted result for a Qualitative test
10.1.4	Data Value	15	Numeric Numeric Response Interpretation String	For Result Type F For Result Type P (Float decimal position or comma for both Result Type F and P.) For Result Type I
10.1.5	Units	7	Concentration Units Rate or mP or Percent Empty	Result Type F Result Type P Result Type I
10.1.6	Reference Ranges	25	Normal/Therapeutic Ranges Control Range Empty	For Result Type F for Patient Result For Result Type F for QC Result For Result Type I or P and for Result Type F, if range undefined
10.1.7	Result Abnormal Flags	12	L or H LL or HH < or > QC EX	Less than or greater than normal therapeutic ranges. Less than or greater than extreme range. Less than or greater than dynamic range of the assay . Assay Quality Control out of range. Expired Reagent **NOTE:** If configured for Multiple Result Flags this field can contain up to 12 characters. An example of the maximum number of flags is EX^QC^>^HH^H. Another example is <^LL^L. There is no requirement for all ^ delimiters to be present.
10.1.9	Result Status	1	F R	Final Results Previously Transmitted Results

Table 1-4: Result Record: AxSYM to Host (Continued)

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
10.1.11	Operator Identification	6	Alphanumeric	
10.1.13	Date/Time Test Complete	14	YYYYMMDDHHMMSS	

R|1|^^^16^Assay1^UNDILUTED^^F|28.275|mIU/mL|30.000 TO 500.000|EX^L||F|||| 19930330132949[CR]

Figure 4.4: Example of Result Record: AxSYM to Host

Comment Record

A Comment Record follows a Result Record if information is entered into the comment section of the Patient or Results Review screen.

A Comment Record follows an Order Record if the Order Record Report Type is ‘X’. In this case, the Comment record contains the reason a result could not be reported for the test request.

Table 1-5: Comment Record: AxSYM to Host

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
11.1.1	Record Type	1	C	Comment
11.1.2	Sequence Number	1	1 to n	n represents any number
11.1.3	Comment Source	1	I	Instrument
11.1.4	Comment Text	100	Result Comment or Exception String	
11.1.5	Comment Type	1	G I	Result Comment Exception String

C|1|I|Example Result Comment|G[CR]

Figure 4.5: Example of Comment Record: AxSYM to Host

Request Information Record

A Request Information Record will be used to request that the host immediately send any outstanding orders for the specified sample. The Request Information Record will request orders for a single patient sample only.

Table 1-6: Request Information Record: AxSYM to Host

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
12.1.1	Record Type ID	1	Q	
12.1.2	Sequence Number	1	1	Will always contain 1.
12.1.3	Starting Range ID Number	15	^Specimen ID	Sample ID read from the bar code label on the sample tube.
12.1.5	Universal Test ID		^^^ALL	AxSYM will always request that ALL outstanding orders be sent.
12.1.13	Status Code	1	O	AxSYM only requests Orders.

Q|1|^SID12345||^^^ALL|||||||O[CR]

Figure 4.6: Example of Request Information Record: AxSYM to Host

Message Terminator Record

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

Table 1-7: Message Terminator Record

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

L|1[CR]

Figure 4.7: Example of Terminator Record: AxSYM to Host

AxSYM Specific Incoming Messages

Section Table of Contents

Overview

The following section outlines the AxSYM records and field contents needed to establish communications from a host computer to the AxSYM System.

For information on communicating from the AxSYM System to a host computer refer to **Section 4: *AxSYM Specific Outgoing Messages*.**

Communication: Host to the AxSYM System

Transmission of Patient Demographics, Patient ID, Sample ID, Test Orders, and Query Responses utilize the high level ASTM records and fields described in this section. Unlisted fields are ignored by the AxSYM System.

Transmission of patient orders to the AxSYM System from the host takes place according to the following logical record hierarchy.

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

Transmission of a negative Query Response (those responses that indicate that the Query Request SID is unknown, or has no outstanding orders) utilize the following logical record hierarchy.

Message Header Record
Request Information Record
Message Terminator Record

NOTE: In the case of a negative Query Response, the Request Information Record is a copy of the original record sent from AxSYM, with the Status Code field set to X.

Format Detail

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

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

All other *fields* are ignored regardless of content.

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

- Comment Record
- Scientific Record
- Manufacturer Information Record

Message Header Record

Table 5-1: Message Header: Host to AxSYM

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
7.1.1	Record Type	1	H or h	Header
7.1.2	Delimiter Definition			Bytes 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 AxSYM

Processing ID must be P and Version Number must be 1 or the message “Message Header Record to Terminator Record” will be ignored.

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 AxSYM System.

Patient Information Record

Table 5-2: Patient Information Record: Host to AxSYM

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
8.1.1	Record Type	1	P or p	Patient
8.1.2	Sequence Number	5	1 to 65535	Must be consistent with sequence number rules.
8.1.3	Practice Assigned Patient ID	15	Any character	Returned unchanged during transmission to the host.
8.1.4	Laboratory Assigned Patient ID	15	Any character	Returned unchanged during transmission to the host.
8.1.5	Patient ID No. 3	15	Any character	See below
8.1.6	Patient Name	15 20 1	Last First Middle Initial (Last, First, and Middle Initial can be any character.)	Last, first, and middle initial of the patient name.

P|1|Practice PID|Lab PID||Doe^John^Q[CR]

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

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

The field contents of Practice Assigned Patient ID (8.1.3) will be copied into the Patient ID No. 3 field upon transmission back to the host (8.1.5), if the field contents of both the Laboratory Assigned Patient ID (8.1.4) and the Patient ID No. 3 (8.1.5) are blank.

The field contents of Laboratory Assigned Patient ID (8.1.4) will be copied into Patient ID No. 3 field upon transmission back to the host (8.1.5), if the field contents of the Patient ID No. 3 (8.1.5) are blank.

Test Order Record

A host-defined panel is not recognized by the AxSYM System. Panels must be converted into individual tests and then regrouped into predefined panels by the host computer.

Replicates for an assay may be ordered using one of two methods:

1. Use of Repeat Delimiter in Universal Test ID (Field 12).
2. Multiple Order Records containing Action Code “A.”

NOTE: The only field in which the AxSYM System supports the repeat delimiter, within Incoming Messages, is the Universal Test ID of the Test Order Record.

Table 5-3: Test Order Record: Host to AxSYM

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
9.4.1	Record Type	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 ^location_ID ^position	15	Specimen	Sample ID downloaded from Host. Location and position are ignored on input.
9.4.4	Instrument specimen ID ^location_ID ^position	N/A	N/A	Field ignored on input.
9.4.5	Universal Test ID	N/A	^^^Assay Number ^Name ^Dilution	Specific number that identifies the test Test Name Dilution protocol (The only required component of this field is the assay number.)
9.4.6`	Priority	1	S or s	STAT (otherwise Routine for any other character)
9.4.12	Action Code	1	N A Q	New Patient or New Order for an existing Sample Add order for Patient Quality Control
9.4.13	Danger Code		Alphanumeric	Part of the Sample Comment Field
9.4.14	Clinical Information		Alphanumeric	Part of the Sample Comment Field
9.4.16	Specimen Descriptor Specimen Type Specimen Source		^Alphanumeric ^Alphanumeric ^Alphanumeric	Part of the Sample Comment Field
9.4.26	Report Types	1	O or o Q or q	Order Order in response to a Query Request.

O|1|OMEGA_1||^^^16\^^^606|||||||Q|||||||||||||O[CR]

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

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 AxSYM System.

Text in fields 9.4.13, 9.4.14 and two components of field 9.4.16 (Refer to Table 5.3), limited to a maximum of 50 characters in length, is placed sequentially in the Comment field of an AxSYM System order.

If a dilution is specified for supported assays, the dilution will be run. If a dilution is not specified, default dilution is ordered for that assay.

If the field content of 9.4.12 (Action Code) is N, the test order is considered a new patient. However, if the sample and test already exists in the host input spool, an error message is generated on the instrument and the test order record is ignored.

If the field content of 9.5.12 (Action Code) is A, the test order will be processed as a patient request. If the sample exists, the test requests will be added to the sample. If the sample does not exist, a patient request will be created.

If the field content of 9.5.12 (Action Code) is Q the sample will be created and verified as a control for the requested analytes. If verified, the QC tests will be created.

Request Information Record

The only form of the Request Information Record that is supported by AxSYM as an incoming transmission, is that of the Negative Query Response. The Negative Query Response is used to indicate that an earlier Query Request from the AxSYM System results in no orders being sent. This can be due to (1) the Sample ID specified in the original Query Request was unknown to the Host system, or (2) the Sample ID specified has no outstanding orders at the time the Query Request was received.

The Negative Query Response is essentially a copy of the original Query Request with the Status Code set to X.

The host system MUST respond to a Query Request within the time-out period defined in the user configurable option “Number of seconds to wait for Query response”. If a Query Request is not responded to by either Orders or a Negative Query Response, the AxSYM System will discontinue waiting for the response, and will no longer issue Query Requests for the remainder of the current run. It is important that the configurable option “Number of seconds to wait for Query response” be set appropriately for the individual Host LIS system.

Table 5-4: Request Information Record: Host to AxSYM

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
12.1.1	Record Type ID	1	Q	
12.1.2	Sequence Number	1	1	Will always contain 1.
12.1.3	Starting Range ID Number	15	^Specimen ID	Sample ID that was originally sent by AxSYM.
12.1.5	Universal Test ID		^^^ALL	Field contents originally sent by AxSYM.
12.1.13	Status Code	1	X	Indicates that either the Sample ID is unknown to the Host, or there are no outstanding orders for the specified Sample ID.

```
Q|1|^SID12345||^^^ALL|||||||X[CR]
```

Figure 5.4: Example of Request Information Record: Host to AxSYM

Message Terminator Record

Table 5-5: Message Terminator Record: Host to AxSYM

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
13.1.1	Record Type	1	L	Last
13.1.2	Sequence Number	1	1	Must be 1

```
L|1[CR]
```

Figure 5.5: Example of Message Terminator Record: Host to AxSYM

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

Troubleshooting

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Overview

Error messages are grouped into ten (10) basic categories. Each message within a category has been assigned a unique four (4) digit error message number to aid in error identification. The following categories of error messages have been established:

0000-0999 Informational

Identifies non-critical messages that provide direct feedback to an operator action. Not all informational messages are recorded in the history log.

1000-1999 Assay-Specific

Identifies that an assay calibration or patient sample test result has passed or failed the assay-specific parameters specifications.

2000-2999 Maintenance

Identifies that a maintenance procedure passed, failed, or was canceled.

3000-3999 Level Sense

Identifies a liquid level sense problem.

4000-4999 Bar Code Reader

Identifies Bar Code Reader failures or Bar Code Label misreads.

5000-5999 Robotic and Sensor

Identifies hardware problems and failures or that a system sensor has detected a hardware problem.

6000-6999 Optics

Identifies optical system problems or failures.

7000-7999 Temperature

Identifies temperature control conditions on the system that may impact test results.

8000-8999 Computer Hardware

Identifies problems or failures with system initialization, the printer, the Host Interface, the hard disk drive, and system shutdown.

9000-9999 Software

Identifies system software problems or problems with system files.

AxSYM Customer Support Center

Some informational error codes (0001-0999) reflect AxSYM System configuration conflicts with Host Interface compatibility.

The Computer Hardware category (8000-8999) which includes more error messages specific to Host Interface errors are described on the following pages. 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 AxSYM Customer Support Center.

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

Error Codes

0216 Host Query configuration conflicts with Accept Orders from Host configuration. Accept Orders from Host option must be set to "ON" before turning Host Query Mode to "ON".

Probable Cause(s)	Corrective Action
AxSYM General Configuration Parameter 28, Accept Order Request from Host> was set to OFF when an attempt was made to turn General Configuration Parameter 29, Enable Host Order Query Mode> ON.	AxSYM General Configuration Parameter 28, Accept Order Request from Host> must be ON before turning General Configuration Parameter 29, Enable Host Order Query Mode> ON.

0217 Host Query configuration conflicts with Positive Sample ID configuration. Positive Sample ID option must be set to "ON" before turning Host Query Mode to "ON".

Probable Cause(s)	Corrective Action
AxSYM General Configuration Parameter 6, Positive Sample ID> was set to OFF when an attempt was made to turn General Configuration Parameter 29, Enable Host Order Query Mode> ON.	AxSYM General Configuration Parameter 6, Positive Sample ID> must be ON before turning General Configuration Parameter 29, Enable Host Order Query Mode> ON.

8200 Invalid Host request, assay (assay number) not on board or not enabled.*

Probable Cause(s)	Corrective Action
Test request was made by the Host for an unsupported assay.	1. Install the assay on the AxSYM System. 2. Enable the assay on the AxSYM System.

* If AxSYM rejects the order, the order will be sent back to the Host.

8201 Invalid Host request, assay (assay number), protocol (#) not found.*

Probable Cause(s)	Corrective Action
Test request was made by the Host for an unsupported dilution assay.	Ensure a Default Dilution is defined in the assay parameters for that assay. If a dilution protocol is not defined, resend the test request without indicating a dilution protocol.

8202 ASTM record format error found during host download, record (#).

Probable Cause(s)	Corrective Action
Format error occurred while processing an ASTM record.	Modify Host to send all fields identified as "Required" in Section 5: ***AxSYM Specific Incoming Messages***.

8203 ASTM field error, field terminated prematurely while downloading from Host, record (#).

Probable Cause(s)	Corrective Action
Format error occurred while processing a field within an ASTM record.	Modify Host to send all fields and components identified as "Required" in Section 5: ***AxSYM Specific Incoming Messages***.

* If AxSYM rejects the order, the order will be sent back to the Host.

8204 Numeric field error, improper numeric field conversion during Host download.

Probable Cause(s)	Corrective Action
Error in interpreting a numerical field.	Modify Host to send only valid number strings, as defined in Section 5: ***AxSYM Specific Incoming Messages, Subsection: Test Order Record***, Field 9.4.5.

8205 Record level hierarchy error, improper level transition during Host download.

Probable Cause(s)	Corrective Action
Violation of ASTM Record Hierarchy was detected while interpreting a message from the Host.	Modify Host to send appropriate level transitions identified in Section 5: ***AxSYM Specific Incoming Messages, Subsection: Communication: Host to the AxSYM System***.

8206 Invalid ASTM sequence number found during Host download.

Probable Cause(s)	Corrective Action
Error in record sequencing.	Modify Host to sequence all record types identified in Section 2: ***Overview of the AxSYM System***.

8207 Improper field length identified during Host download, field length too large.

Probable Cause(s)	Corrective Action
Field received from Host exceeded the maximum allowed for a particular field length.	Modify Host to follow field requirements as designated in Section 5: ***AxSYM Specific Incoming Messages***, Maximum Characters for all records.

8208 Invalid action code encountered during Host download.

Probable Cause(s)	Corrective Action
Host cannot send order records with unspecified action codes.	Modify Host to use action codes identified in Section 5: ***AxSYM Specific Incoming Messages, Subsection: Test Order Record***, Field 9.4.12.

8209 Invalid report type found during Host download.

Probable Cause(s)	Corrective Action
Host sent orders with unspecified report type.	Modify Host to use record types identified in Section 5: ***AxSYM Specific Incoming Messages, Subsection: Test Order Record***, Field 9.4.26.

8210 Terminator record not found when two header records were received.

Probable Cause(s)	Corrective Action
AxSYM received a message containing two ASTM header records.	Modify Host to send a header record and a terminator record as described in Section 5: ***AxSYM Specific Incoming Messages***.

8211 Invalid record type found during Host download.

Probable Cause(s)	Corrective Action
Record received from Host with a record type not recognized by AxSYM specifications.	Modify Host to use record types identified in Section 5: ***AxSYM Specific Incoming Messages***.
Misplaced or embedded carriage returns within the record.	Modify Host to use record formats identified in Section 5: ***AxSYM Specific Incoming Messages***.

8212 Error during Host Download, (#), contact Abbott Laboratories.

Probable Cause(s)	Corrective Action
Internal software error during Host download.	1. Copy all information on the screen. 2. Call AxSYM Customer Support Center.

8213 Host does not respond, results cannot be sent.

Probable Cause(s)	Corrective Action
Transmission error between AxSYM System and Host.	1. Edit the port configuration in the Port Configuration screen of the AxSYM System to match the Host computer as described in Section 3: ***Communication Setup*** 2. Reseat the RS-232 port connectors on the back of the AxSYM System and the Host computer.

8214 Invalid Host request, assay (assay name), controls not found.*

Probable Cause(s)	Corrective Action
Host requested an assay control that is not defined on the AxSYM System.	Rename the control to exactly match the control name downloaded by the Host computer as described in Section 3: ***Communication Setup, Subsection: Control Configuration***. See also Section 5: ***AxSYM Specific Incoming Messages, Subsection: Test Order Record***, ASTM Field 9.4.3, Specimen ID.

* If AxSYM rejects the order, the order will be sent back to the Host.

8215 ASTM specification violation, invalid character (x) was received.

Probable Cause(s)	Corrective Action
Host sent a character that cannot be used in a message text.	Modify characters as defined in Section 1: ***Abbott Standard Interface, Subsection: Restricted Message Characters***.
Noise on the Host serial interface resulted in data corruption.	Replace cable with a shorter or shielded cable.

8216 ASTM specification violation, invalid end of frame character (x) found at (x).

Probable Cause(s)	Corrective Action
Host not following ASTM standard.	Modify Host to follow End-of-Frame character requirements as described in ***Section 1: Abbott Standard Interface, Special Control Characters***.
Cabling problem on Host port.	Replace cable with a shorter or shielded cable.
Baud rate problem on Host port.	Edit the baud rate in the Port Configuration screen of the AxSYM System to match the Host computer as described in Section 3: ***Communication Setup, Subsection: Port Configuration***

8217 ASTM specification violation, invalid line feed character received.

Probable Cause(s)	Corrective Action
Host sent illegal ASTM frame.	Modify Host to follow line feed requirements as outlined in ***Section 1: Abbott Standard Interface, Special Control Characters***.
Data was corrupt when received from Host.	Replace cable with a shorter or shielded cable.

8218 ASTM specification violation, invalid number of characters received before end of frame.

Probable Cause(s)	Corrective Action
Frame violation occurred at Host.	Modify character length for end of frame as outlined in Section 1: ***Abbott Standard Interface, Subsection: Frames***.
Data was corrupt when received from Host.	Replace cable with a shorter or shielded cable.

8219 Invalid Host request, new order already exists.

Probable Cause(s)	Corrective Action
Order received has a new order action code, but the SID already exists.	1. If the orders indicator light is on, download orders and run the tests. Resend the refused order to the AxSYM. 2. Modify Host for action codes as defined in Section 5: ***AxSYM Specific Incoming Messages***.

8220 Invalid Host request, SID (x).

Probable Cause(s)	Corrective Action
Result transmission is disabled and an invalid order is received from Host.	Modify Host configuration as defined in Section 5: ***AxSYM Specific Incoming Messages***.

8221 ASTM specification violation, unsupported use of repeat delimiter by Host.

Probable Cause(s)	Corrective Action
The Host computer sent the AxSYM an ASTM record that contained a repeat delimiter in a field in which it was not supported. This would normally only appear during installation of the Host connection.	Modify Host for support of the repeat delimiter as defined in Section 5: ***AxSYM Specific Incoming Messages, Subsection: Test Order Record***, Field 9.4.5.

8222 Invalid Host request, SID must be specified, sample order not accepted.

Probable Cause(s)	Corrective Action
An order was received from the Host without a SID.	Modify Host to specify a specimen ID as defined in Section 5: ***AxSYM Specific Incoming Messages, Subsection: Test Order Record***, Field 9.4.3.

8223 Host communication error, Host connection lost during message transmission.

Probable Cause(s)	Corrective Action
Problem with the cabling from the Host to the AxSYM.	1. Reseat the RS-232 port connector on the back of the AxSYM System and the Host computer. 2. Replace cable with a shorter or shielded cable.

8224 ASTM specification violation, 20 attempts have been made to receive a valid Header Record.

Probable Cause(s)	Corrective Action
The Host is sending an invalid ASTM header record.	Modify Host for record content as defined in Section 5: ***AxSYM Specific Incoming Messages, Subsection: Message Header Record***, Field Contents.
Noisy line.	Replace cable with a shorter or shielded cable.
AxSYM is ignoring further data in an attempt to find another valid header record after receiving a record format error in the middle of a message.	Modify Host for record content as defined in Section 5: ***AxSYM Specific Incoming Messages***.

8225 Invalid Host request, more than 50 test requests were received for a single sample.

Probable Cause(s)	Corrective Action
A single sample order was made with more than 50 tests ordered.	Cancel test requests made for that sample until less than 50 tests are downloaded by the Host computer.

8226 Host request denied, insufficient system capacity for new test orders.*

Probable Cause(s)	Corrective Action
Host has ordered a new test for a sample, but the AxSYM database capacity has been reached. The order is rejected and sent back to the Host.	Delete Orderlist entries to create more capacity.

8228 Host request(s) denied, insufficient system capacity for new test order(s).

Probable Cause(s)	Corrective Action
Host has ordered a new test(s) for a sample(s), but the AxSYM database capacity has been reached. The order(s) is rejected and sent back to the Host.	Existing Orderlist entries can be run or deleted to create more capacity.

8230 Host Query suspended, query request for sample has been disrupted.

Probable Cause(s)	Corrective Action
One of the query message records sent to the LIS was not acknowledged or not received.	Make sure LIS is connected and functioning. Query Mode will be reactivated once a new run is started or the current run is resumed.

* If AxSYM rejects the order, the order will be sent back to the Host.

8231 Host Query suspended, LIS does not respond, communication error.

Probable Cause(s)	Corrective Action
The LIS did not respond to the initial request for communications.	Make sure LIS is connected and functioning. Query Mode will be reactivated once a new run is started or the current run is resumed.

8232 Host Query suspended, LIS port busy.

Probable Cause(s)	Corrective Action
Host Port was in use for more than 60 seconds. This can happen when the LIS sends a large number of orders to the AxSYM.	The AxSYM should wait until the LIS has finished sending, then resume the run. Query Mode will be reactivated once a new run is started or the current run is resumed.

8233 Host Query response contained no orders. SID (#), Position (#).

Probable Cause(s)	Corrective Action
The LIS either had no outstanding orders for the SID, or did not have the SID on record.	Verify that the SID is registered on the LIS.

8234 Host orders can not be processed, system queried for SID (#), received SID (#).

Probable Cause(s)	Corrective Action
The LIS may be excessively slow in responding to a previous order. When this occurs, the Host Query Mode is suspended. If the operator reactivates Host Order Query before the LIS responds to the previous order, this error can occur.	Ensure the LIS has the ability to respond within the time period entered in the AxSYM General Configuration Parameter 30 (Number of seconds to wait for Query Response). If this error occurs often, increase the time period for this parameter.

8235 Host Query suspended, AxSYM orderlist capacity full.

Probable Cause(s)	Corrective Action
While receiving a Query Response, the AxSYM database capacity was reached. AxSYM cannot accept any more orders.	Wait until the current orders being processed are completed and released from the AxSYM. Query Mode will be reactivated once a new run is started or the current run is resumed.

8236 Host Query suspended, query time-out exceeded.

Probable Cause(s)	Corrective Action
LIS did not respond to a query message within the time period entered in the AxSYM General Configuration Parameter 30 (Number of seconds to wait for Query Response>).	Make sure that the LIS is capable of responding to query messages within the time period entered in the AxSYM General Configuration Parameter 30 (Number of seconds to wait for Query Response>). This may entail changing the AxSYM configuration parameter. Query Mode will be reactivated once a new run is started or the current run is resumed.
LIS not connected or functioning properly.	Ensure that the LIS is connected and functioning. Query Mode will be reactivated once a new run is started or the current run is resumed.

8237 Unexpected query response received, SID (#), orders stored in ready list.

Probable Cause(s)	Corrective Action
A Query Response for a SID was received while there was no query pending. The AxSYM was not expecting to receive this query response.	Check the Temporary Message Log for a prior Query Timeout message (error code 8236). Ensure the LIS has the ability to respond within the time period entered in the AxSYM General Configuration Parameter 30 (Number of seconds to wait for Query Response>). If this error occurs often, increase the time period for this parameter.

8238 Invalid Host request, unsupported request received, check LIS interface.

Probable Cause(s)	Corrective Action
LIS sent an unsupported or incorrectly formatted query request.	Check LIS interface for correct functionality.

8239 Host request denied, database error encountered, SID (#) (status code).

Probable Cause(s)	Corrective Action
While checking for the necessary conditions to send a query request or process a query response, the Host Query Manager encountered a database error. The status code describes the nature of the error.	Call AxSYM Customer Support Center.

8240 Host request denied order for assay (#), SID (#) currently exists, order will not be duplicated.

Probable Cause(s)	Corrective Action
An order that was marked as NEW, was received from the host. The order already existed in the Host Spool or Orderlist.	The host could flag the order as an ADD order. In this case the order would be added.

8241 Host request incorrect, reserved character (name) received, reserved character ignored.

Probable Cause(s)	Corrective Action
A reserve character was detected in the input from the host.	Reserved characters cannot be used. For more information on reserved characters, refer to Section 2: ***Overview of the AxSYM System***

8242 Host Message Dispatcher Task, unable to send message to Host.

Probable Cause(s)	Corrective Action
The Host did not respond to the AxSYM request for communication.	Verify that the Host is connected and functioning.

8243 Host Message Dispatcher Task, LIS does not respond, communication error.

Probable Cause(s)	Corrective Action
Problem with the cable from the Host to the AxSYM.	Verify that the cable is fully connected and undamaged.

8244 Host Message Dispatcher Task, LIS port busy.

Probable Cause(s)	Corrective Action
Host port was in use or not responding when the AxSYM attmepted to transmit a message(s).	The AxSYM will continue to try to transmit the message(s) to the Host. If this error code continues to reoccur, verify tht the Host is connected and functioning.

8501 Host Port Test Failed, Status (code name).

Probable Cause(s)	Corrective Action
The Loopback Connector is not properly installed.	Securely insert the male pins on the Loopback Connector into the female Host Interface port.
Hardware failure: -Host Interface Port -Loopback Connector	Call AxSYM Customer Support Center.

8502 Host Port Test passed.

Probable Cause(s)	Corrective Action
Host Port test passed.	None.

8503 Host Port Test denied, LIS port busy.

Probable Cause(s)	Corrective Action
The LIS is currently transmitting data.	Wait until the LIS transmission is complete before performing the Host Port test.

Abbott Host/Instrument Interface Simulator

Section Table of Contents

Abbott Host/Instrument Interface Simulator

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 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.

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

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- 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.

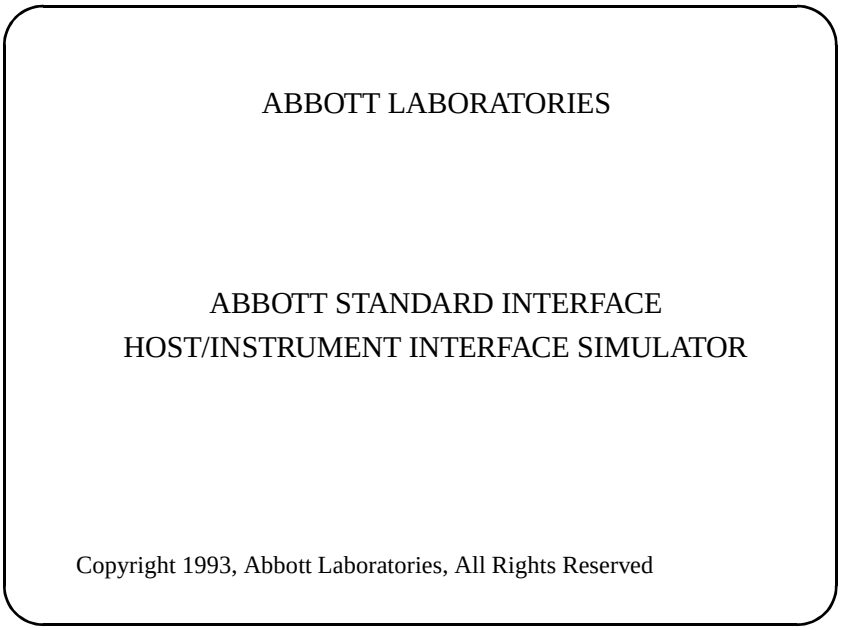

Figure 7.1: HIISIM Copyright Screen

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.

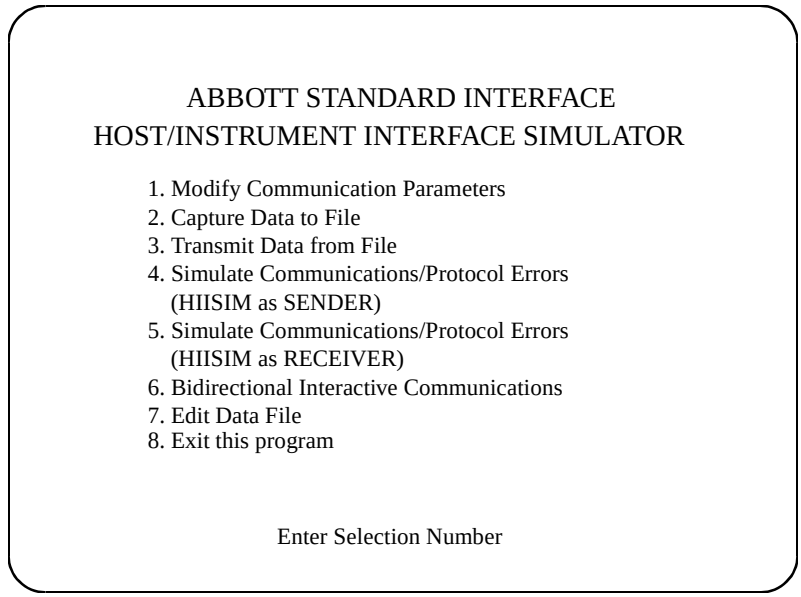

Figure 7.2: HIISIM Main Menu Screen

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.

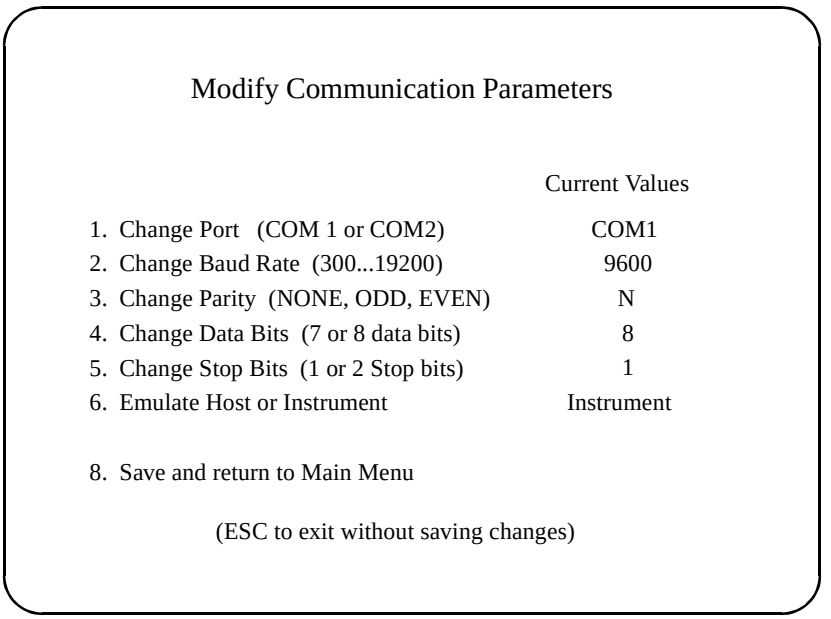

Figure 7.3: HIISIM Modify Communication Parameters Screen

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.

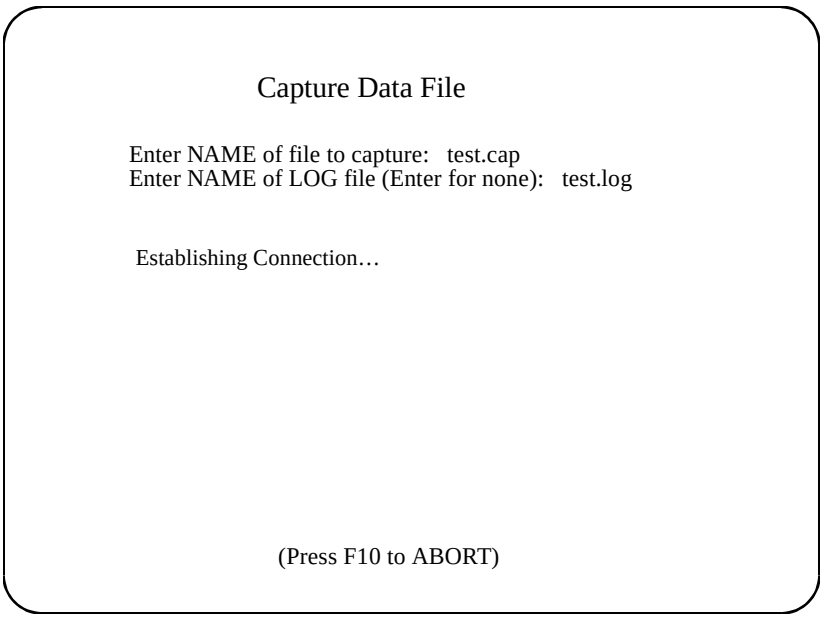

Figure 7.4: Capture Data File Screen

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.

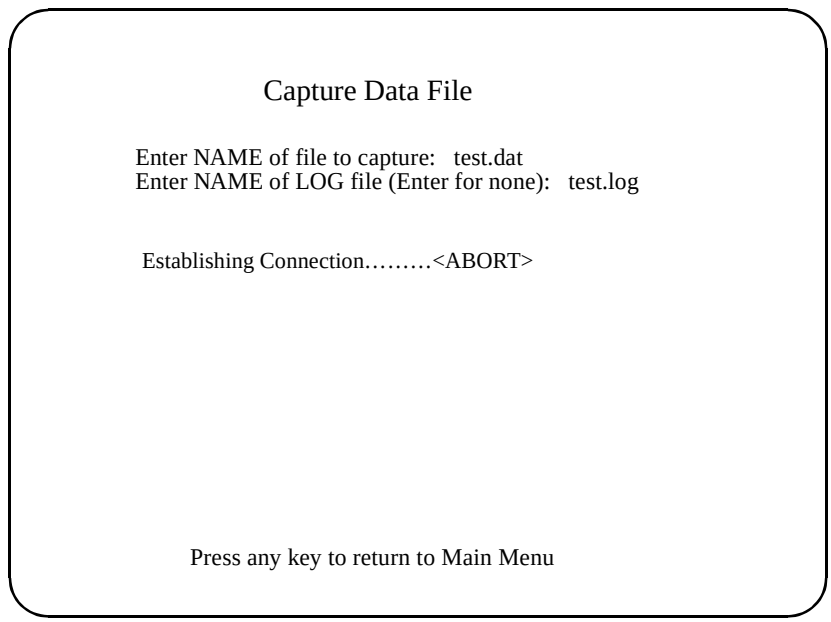

Figure 7.5: Abort Capture Mode

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.

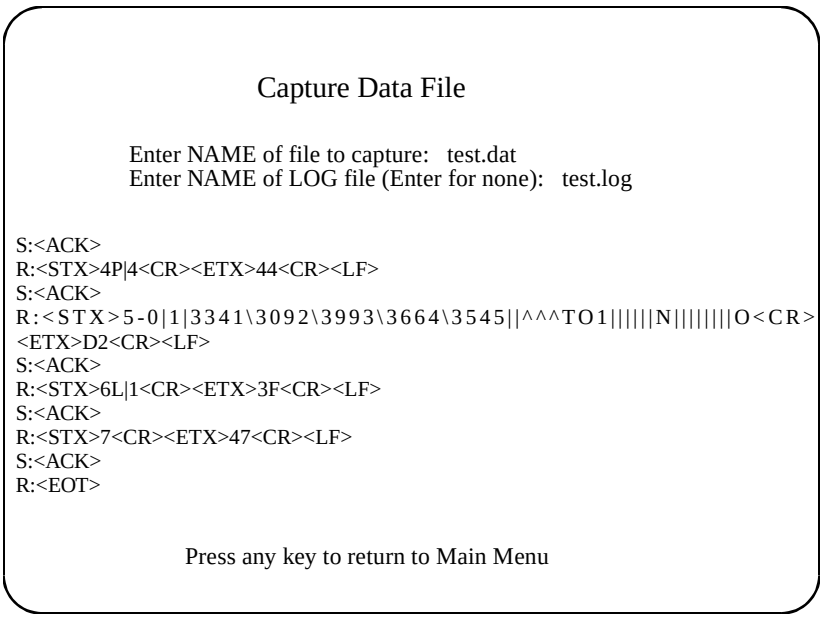

Figure 7.6: Capture Data Communications Session

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.

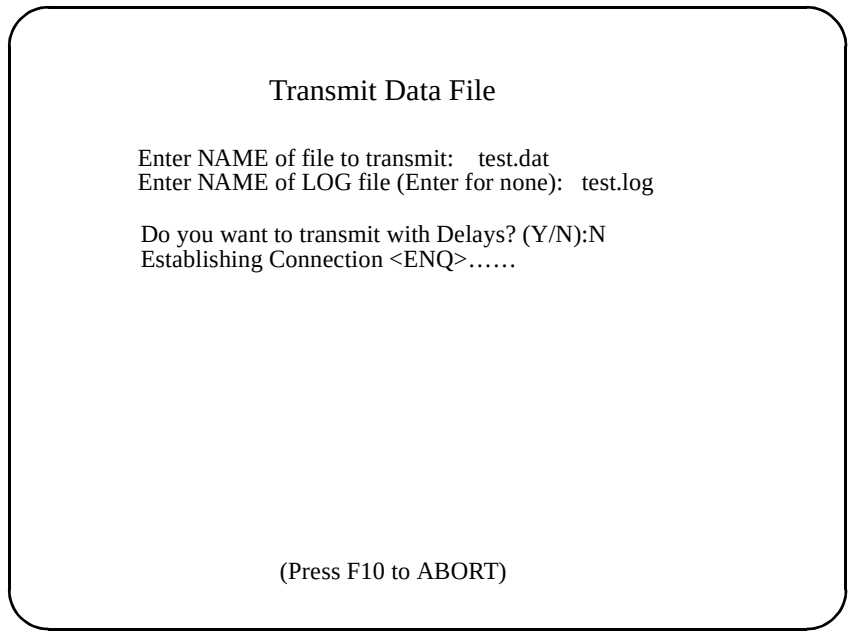

Figure 7.7: Transmit Data File

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.

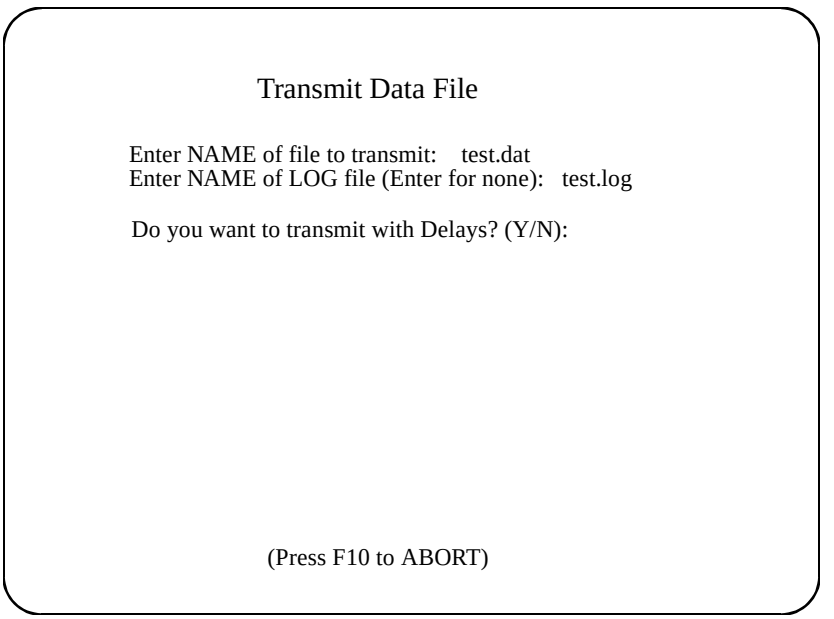

Figure 7.8: Transmit Data File With Time Delays Screen

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.

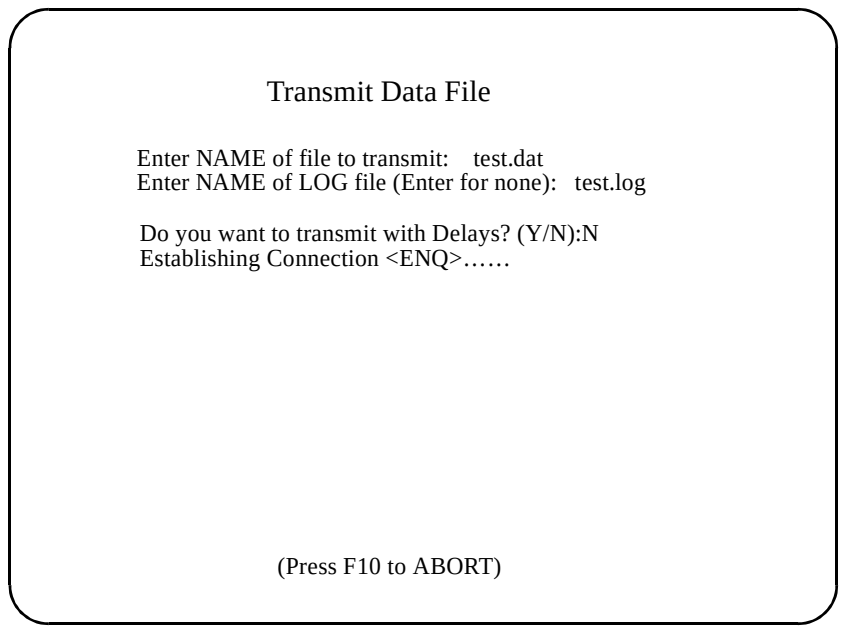

Figure 7.9: Transmit Data File Screen

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.

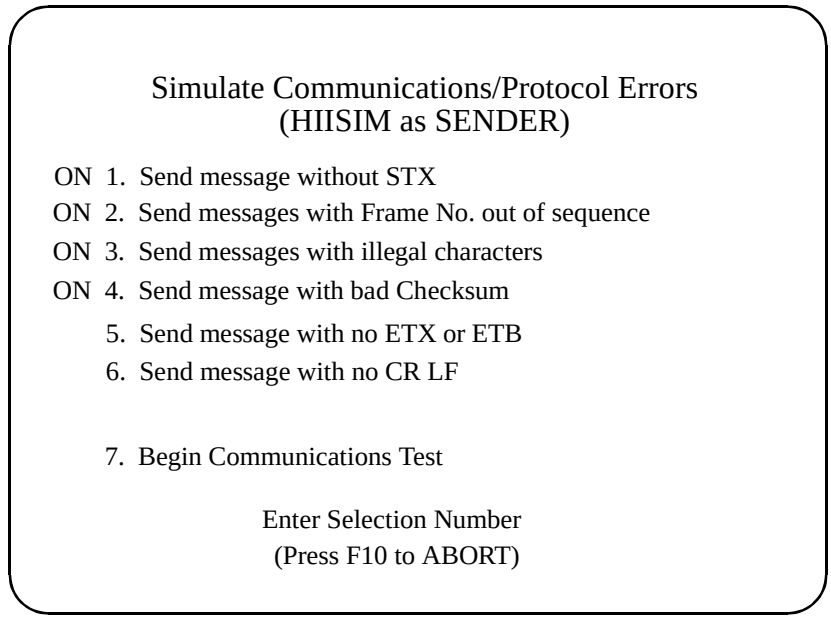

Figure 7.10: Simulate Communications/Protocol Errors Screen

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.

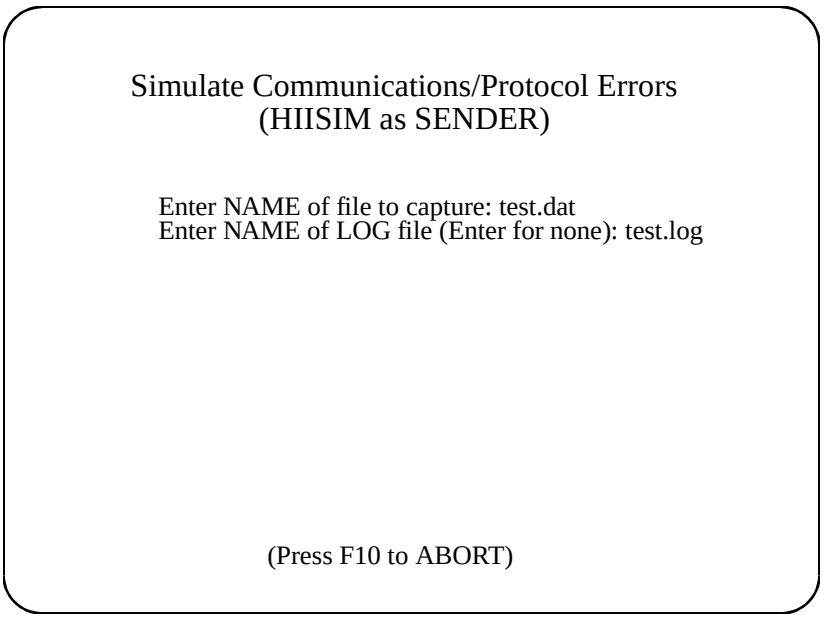

Figure 7.11: Simulate Communications/Protocol Errors

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.

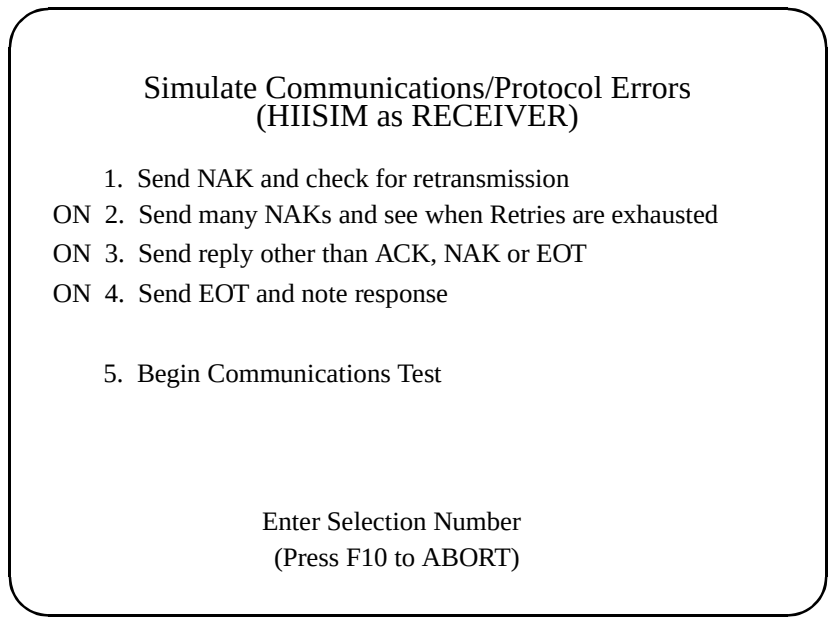

Figure 7.12: Simulate Communications/Protocol Errors Screen

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 (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.

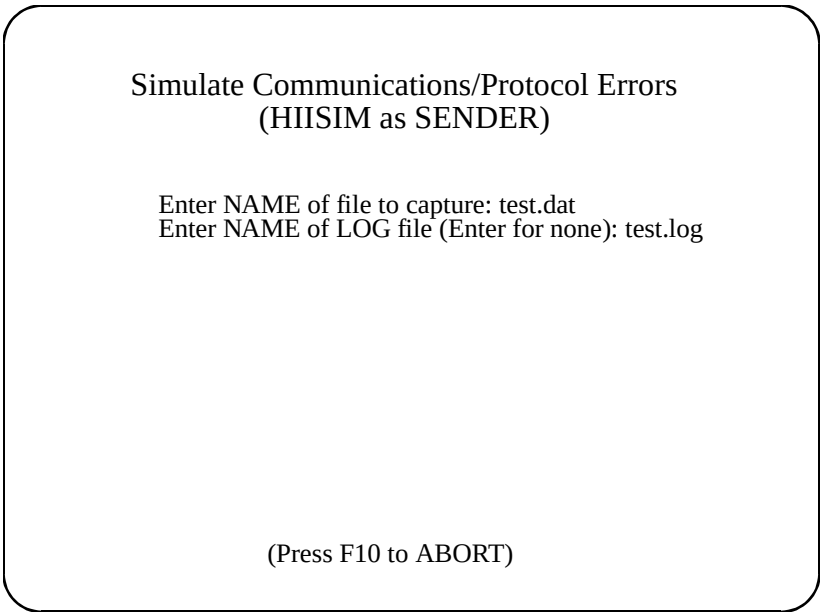

Figure 7.13: Simulate Communications/Protocol Errors

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:

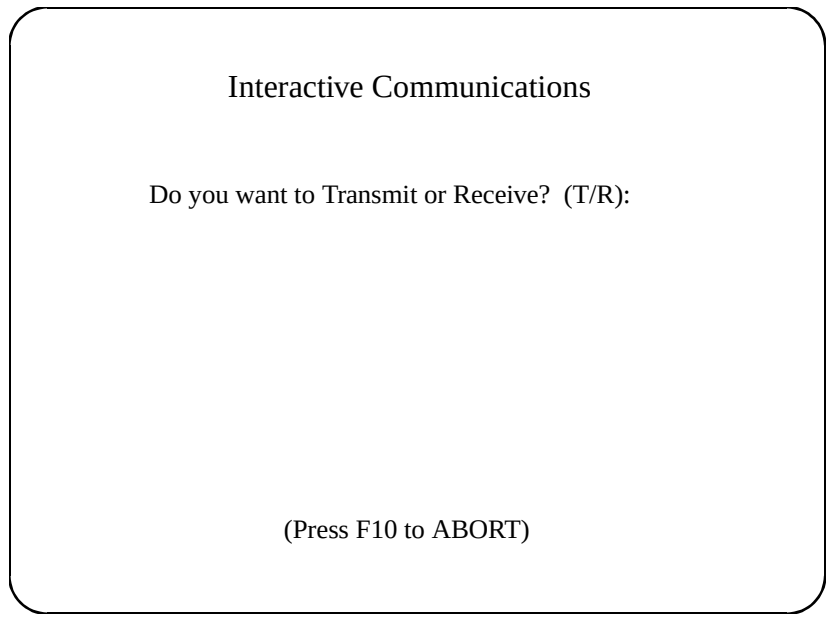

Figure 7.14: Interactive Communications Screen

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:

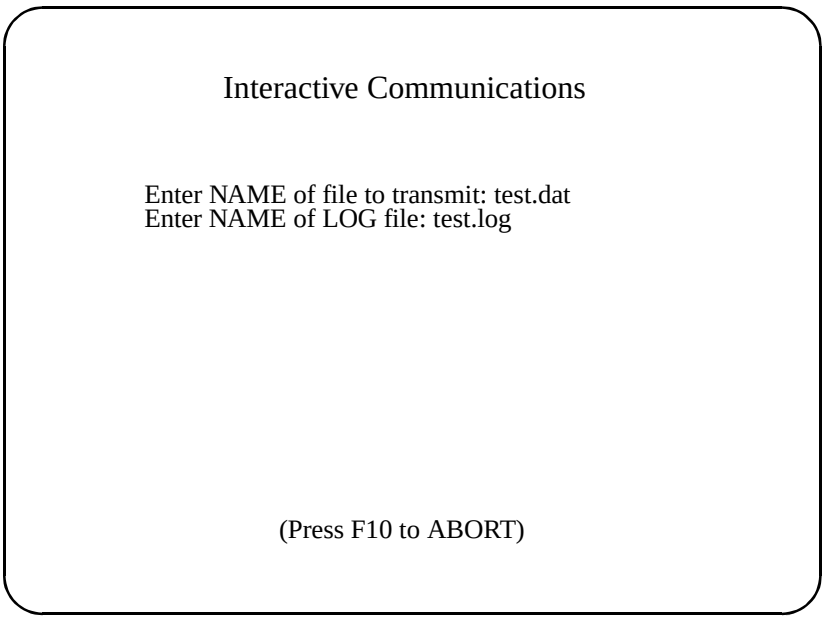

Figure 7.15: Interactive Communications Screen

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.

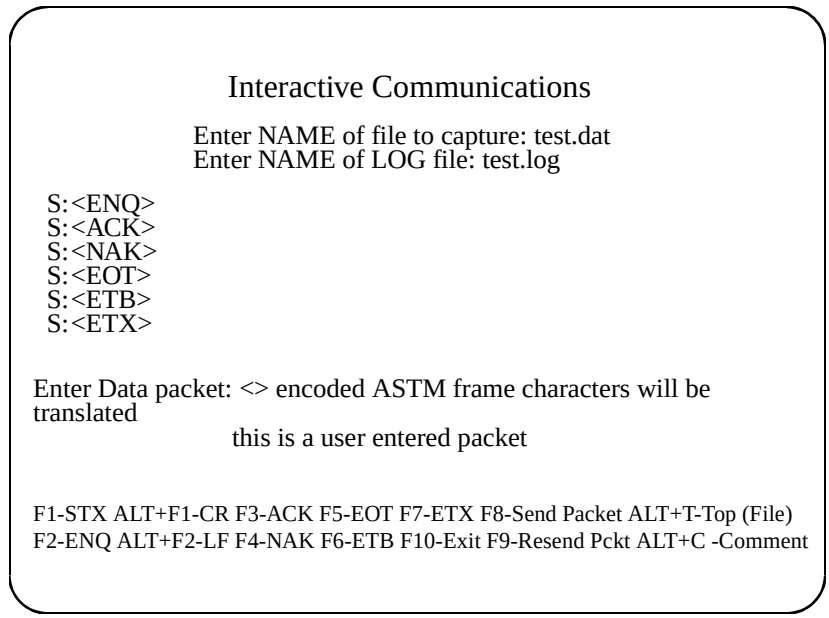

Figure 7.16: Interactive Communications Screen

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.

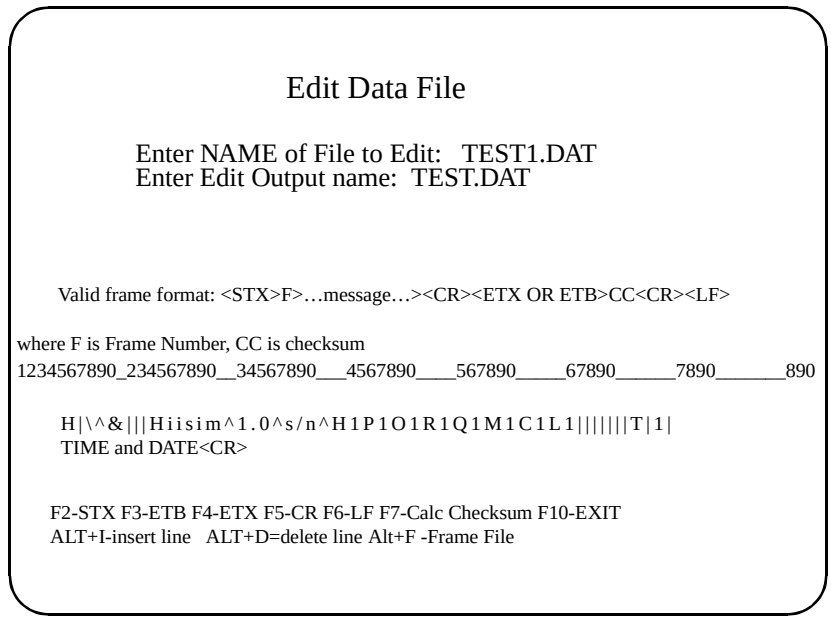

Figure 7.17: Edit Data File Screen

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>
```

Figure 7.21: Log File

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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 text field does not contain any delimiters. The record identified 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.

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).

Battery

A group of tests that are ordered together. You can order multiple tests by specifying a single name.

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.

Continuous access — The capability to process new tests while the instrument is in the processes of testing currently scheduled samples.

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.

FPIA	Fluorescence Polarization Immunoassay. A homogeneous technology used for low molecular weight analytes.
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).
Hi Norm/Lo Norm **High Extreme Value/** **Low Extreme Value** **High Limit/Low Limit** **Immunoassay**	A testing method using antibodies, a class of proteins that can identify specific molecules.
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.
Matrix Cell Carousel	Thirty-two position carousel that provides a holding area for the Matrix Cells.
MEIA	Microparticle Enzyme Immunoassay. 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	A list of tests requested by the operator, either through the Data Management Center or through the host computer.
Processing Carousel	Thirty-six position carousel that receives Reaction Vessels from the Sampling Center.

Processing Center Area of the instrument where the tests are processed and optical readings are taken.

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.

Query Request A message sent to the LIS requesting test orders for a specific sample ID.

Query Response A message sent to the AxSYM containing orders for the sample ID specified in the prior Query Request. A Query Response may also indicate that no orders are required at the time the Query Request was made.

Random access The capability to process tests in a random manner, independent of the assays requested and dependent on the sample status.

Reaction Vessel A multi-well disposable which carries a specified volume of sample, reagent and solution through the sample and processing center.

Ready list A list of tests from the order list ready to be scheduled for processing.

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 (^)

Sample cup — A disposable container that holds patient samples, calibrators, and controls.

Sample cup segment — Holds 15 sample cups.

Sampling Center — Area of the instrument where the user may load samples, controls, calibrators, reaction vessels and reagents.

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 — An area for storing Bulk Solutions and liquid and solid waste.

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