ARCHITECT®

SYSTEM

Abbott Standard Interface RS-232 Manual

List Number 06F71-03

Abbott Laboratories
Abbott Park, IL 60064

Foreword

This manual has been designed to help you familiarize yourself with all aspects of the Abbott Standard Interface for the ARCHITECT *i* System.

If you have any questions, do not hesitate to contact your local Abbott Laboratories Diagnostics Division Customer Support Representative to obtain prompt answers to your inquiries.

Customer Support

United States: 1-800-527-1869

Canada: 1-800-387-8378 (English speaking customers)
1-800-465-2675 (French speaking customers)

International: Call your local Abbott Customer Support Representative.

Proprietary Statement

The software and manual were developed solely for use with the ARCHITECT *i* System and for *in vitro* diagnostic applications as specified in the operating instructions.

Pictorial Disclaimer

The sample printouts, screens, and graphics contained in this manual are for information and illustration purposes only. Abbott Laboratories makes no representations or warranties about the accuracy and reliability of this information.

Warranty

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Introduction

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

Topics in this section include:

- Overview of the Manual
- Alternative Reference Materials

NOTES

Overview of the Manual

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

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

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

- How to Use This Manual: Discusses the purpose of the manual and provides a good overview of the information contained within.
- Section 1: Discusses the Abbott implementation of the ASTM E1381-91 and E1394-91 standards. This section is common to all Abbott Standard Interface Manuals.
- Section 2 – Section 6: Discusses specific information about the instrument or system covered by that particular Edition. 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 ARCHITECT *i* System and its specific interface implementation.
- Section 7: Refers to the use of ASIST (Abbott Standard Interface Simulator Tool), and the ARCHITECT Host/Instrument Interface Data Disk.
- Section 8: Discusses the differences between the ARCHITECT *i* System and the AxSYM interface.

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 ARCHITECT *i* System as well as setup and diagnose communications.

Included with this manual is a diskette containing the Instrument Specification File (ISF) for the ARCHITECT *i* System. When this file is loaded as the "current instrument" in the ASIST environment, the user can perform comprehensive testing and validation of communication protocols.

> **NOTE:** The ASIST (Abbott Standard Interface Simulator Tool) is not included with this manual.

- Instrument developers can use ASIST to emulate a Host computer. ASIST sends requests in user-generated test protocols to ensure that the equipment accepts and interprets these communications correctly.
- Host computer software developers can use ASIST to emulate Abbott instruments to test communications without having to invest in the instruments themselves. Test transmissions of report data, using established record layouts and communications protocols, ensure that host software will interface properly with actual instruments after installation.

The diskette is 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. Developers should not rely solely on the use of this product for verification and validation of their interface software.

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

NOTES

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 (USA) 19103-1187
Phone Orders: (215) 299-5585

NOTES

Introduction

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

Topics include:

- Overview of the Abbott Standard Interface (ASI)
- Layered Protocols
- Physical Layer – Electrical, Mechanical, and Signaling Characteristics
- Data Link Layer – Establishment, Transfer, and Termination
- Presentation Layer – Message Content
- Application Layer

NOTES

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.

NOTES

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.

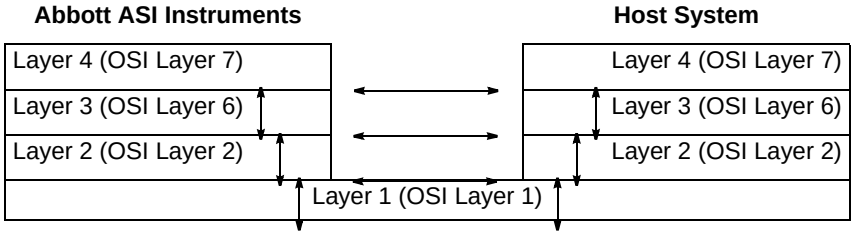


Figure 1.1: Layered Protocol Architecture

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.

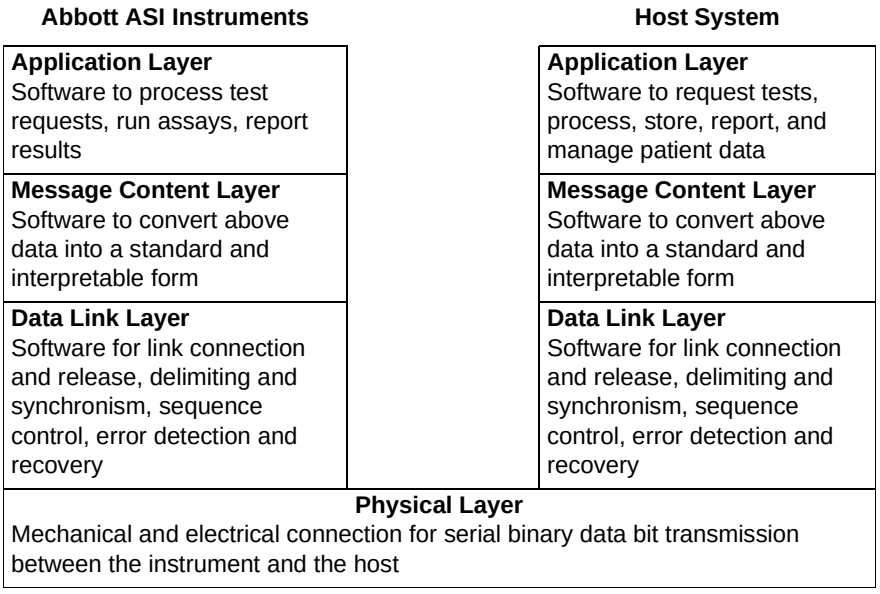


Figure 1.2: ASI Implementations

Physical Layer

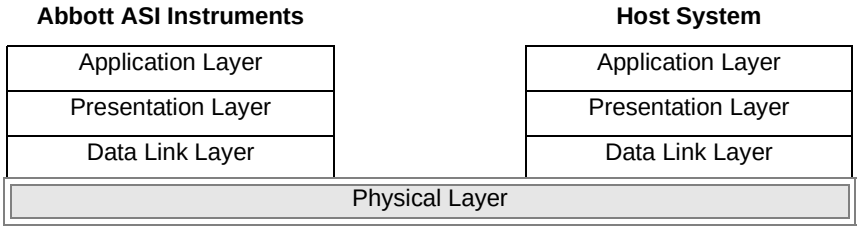


Figure 1.3: Physical Layer

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 connection provided conforms to the requirements of the EIA RS-232D Standard. The ***Communication Setup*** section of each Abbott Standard Interface RS-232 manual covers the specifics for that instrument.

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	–	–

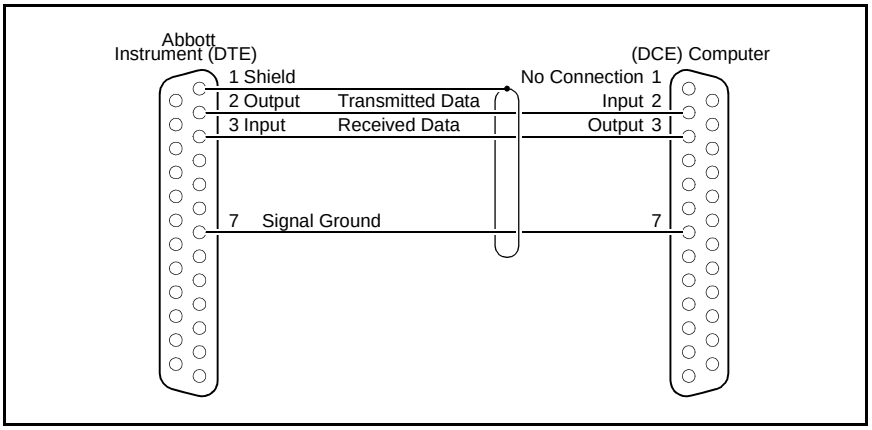


Figure 1.4: Pin-to-Pin Connections (Wiring Diagram)

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.

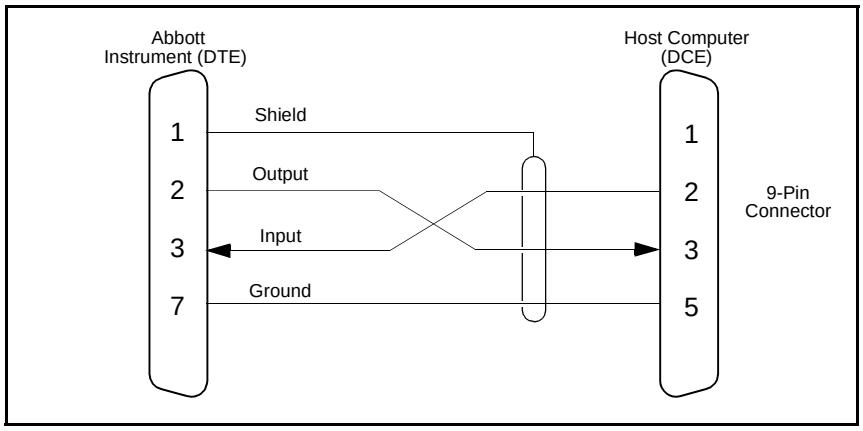


Figure 1.5: Host computer (PC with 9-pin connector) with Non-ASTM compliant connector

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.

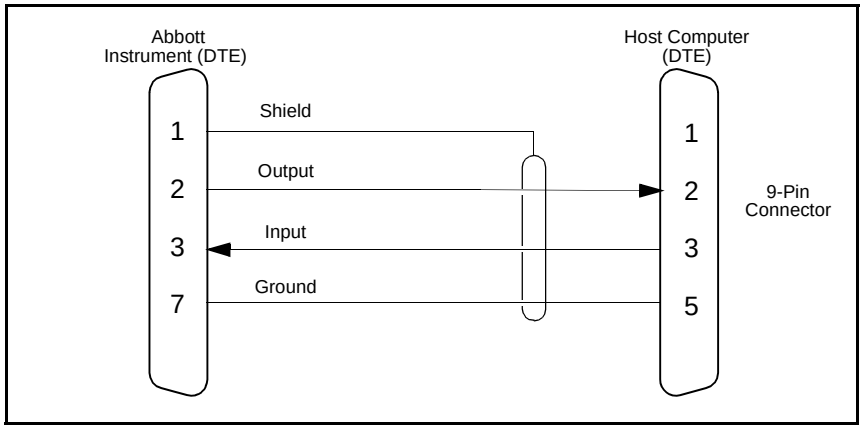


Figure 1.6: Host Computer with 9-Pin PC-AT style connector

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

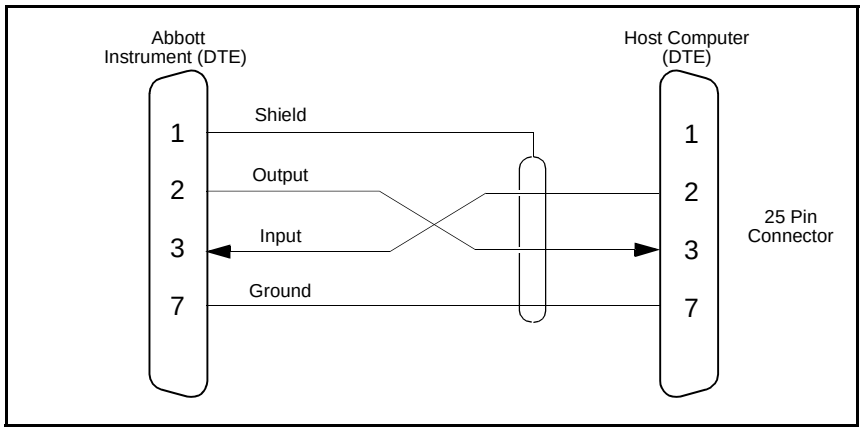


Figure 1.7: Host computer (PC with 25-pin connector) with Non-ASTM compliant connector.

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.

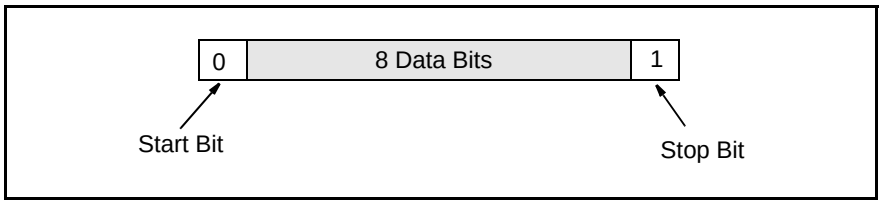


Figure 1.8: Default Abbott Instruments Character Structure. ***The start and stop bits separate ASCII characters which are eight bits long.***

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, 28800]. 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.

NOTES

Data Link Layer

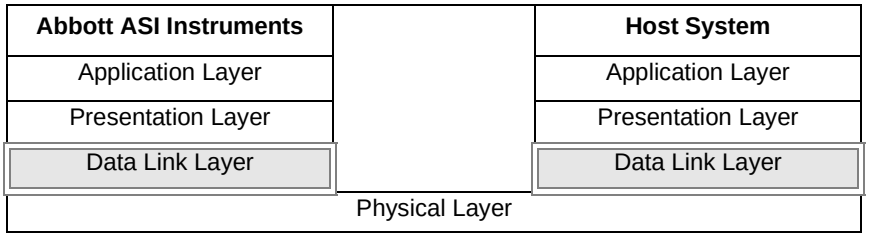


Figure 1.9: Data Link Layer

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].

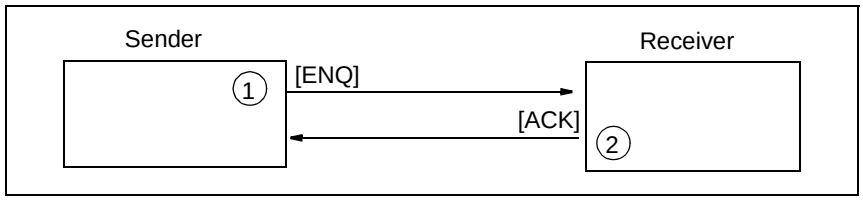


Figure 1.10: Sender Initiating Establishment Phase. ***The receiver returns a signal to the sender acknowledging that it is ready to receive.***

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].

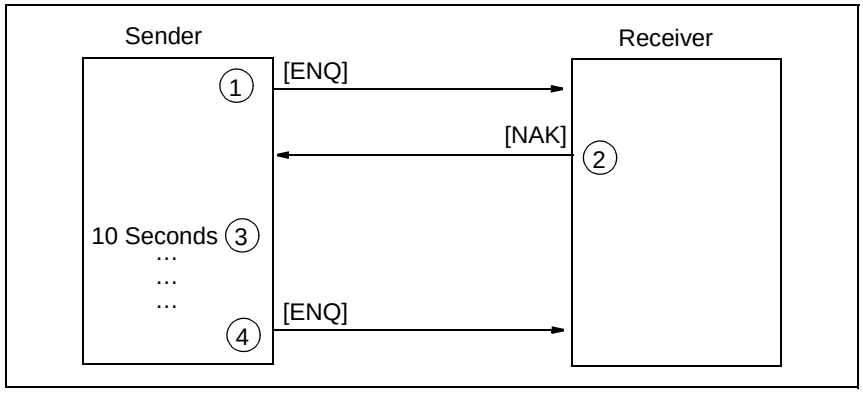


Figure 1.11: Sender Receives an [NAK] Signal. ***If the sender receives an [NAK], the sender waits ten seconds before re-initiating the establishment phase.***

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.

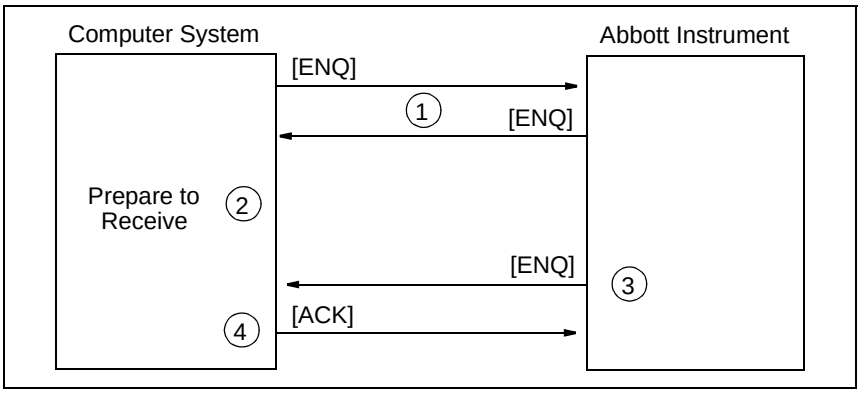


Figure 1.12: Sender Receives an [ENQ] after Sending an [ENQ]. ***The sender prepares to receive.***

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].

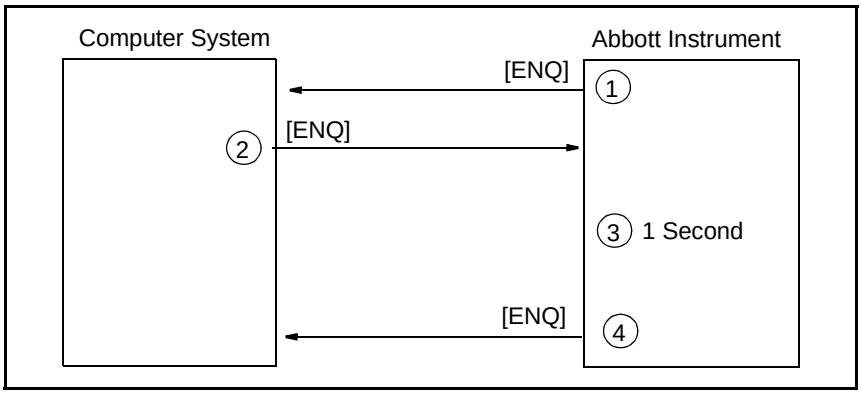


Figure 1.13: Instrument Receives an [ENQ] after Sending an [ENQ]. ***The instrument waits one second before re-sending another [ENQ].***

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 charac-ter	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)*

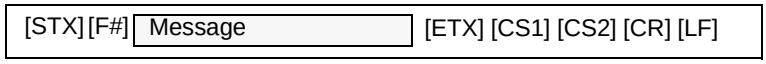
Symbol	Character	Description
CS1	Most significant character of checksum 0 – 9 and A – F	The checksum determines if a frame is defective. The checksum is encoded as two characters and is sent after the ETB or ETX character. The checksum is computed by adding the binary values of the characters (modulo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

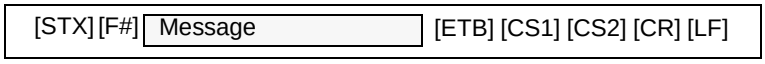
Abbott instruments and systems supporting ASI handle an ASTM E1394-91 record as an ASTM E1381-91 message. If the E1394-91 record is longer than 240 characters, the message is transmitted in multiple frames consisting of end frames and intermediate frames. If the message (*i.e.*, E1394-91 record) is less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

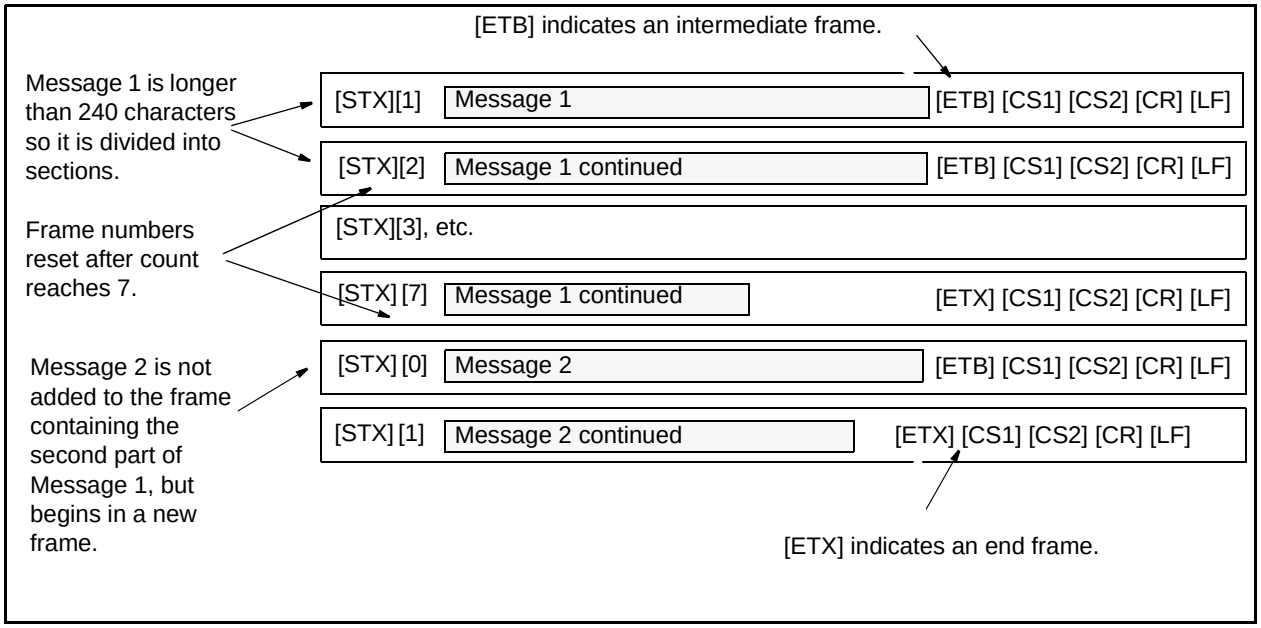


Figure 1.14: Intermediate and End Frames. ***Multiple frame messages start with intermediate frames and end with end frames containing only the end of one message.***

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.

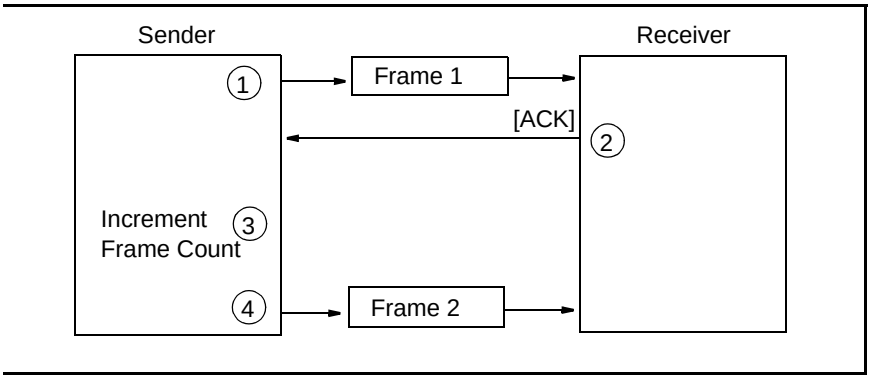


Figure 1.15: Sender Transmitting After Receiving [ACK]. ***The sender sends another frame after successfully transferring a frame.***

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.

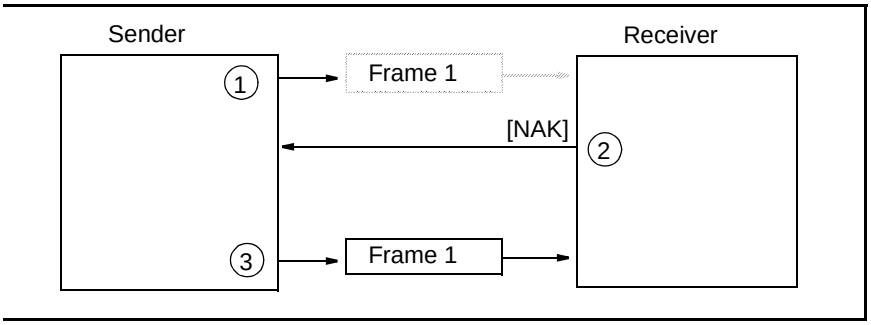


Figure 1.16: Sender Retransmitting a Frame After Transmission Failure. *The receiver indicates transmission failure with [NAK].*

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 a [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.

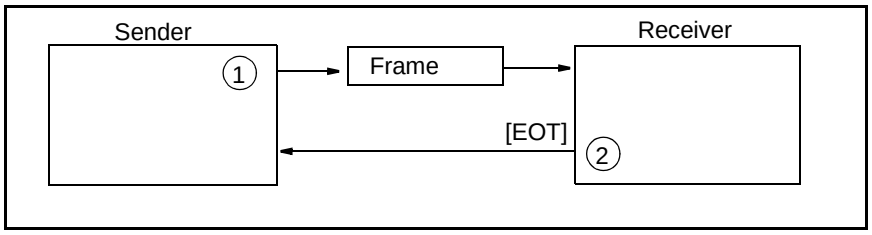


Figure 1.17: End of Transmission. *The receiver indicates successful receipt of the complete message with an [EOT], but requires an interrupt.*

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.

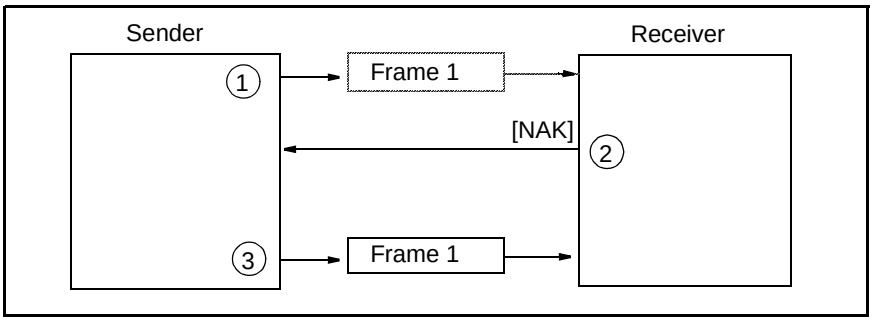


Figure 1.18: Re-sending a Frame After a Transmission Failure. ***The receiver indicates a transmission failure with an [NAK].***

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.

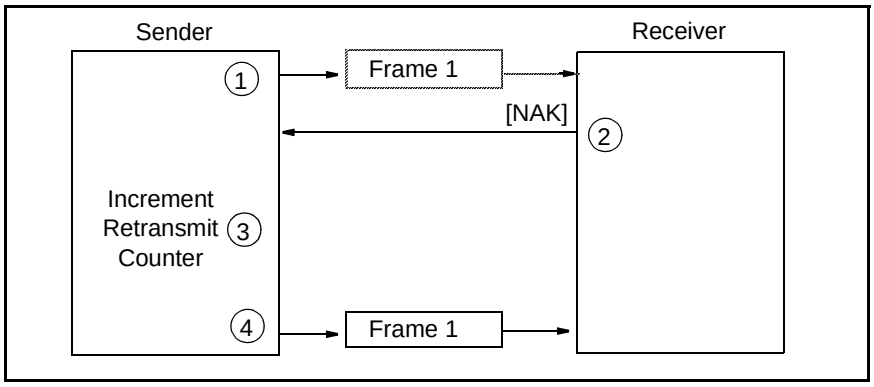


Figure 1.19: Incrementing the Frame Counter. ***The sender keeps track of retransmissions with a frame counter.***

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.

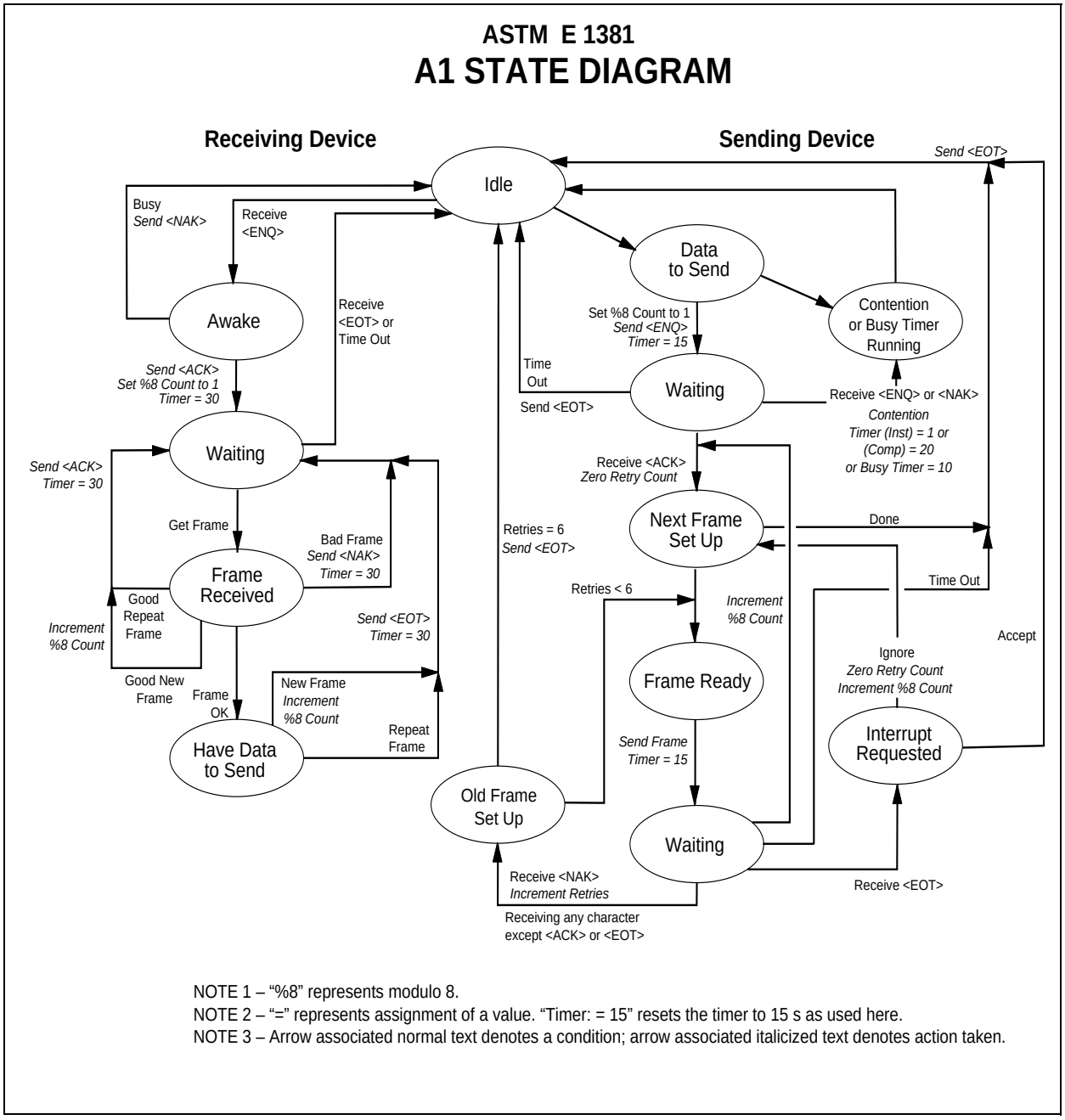
Restricted Message Characters

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

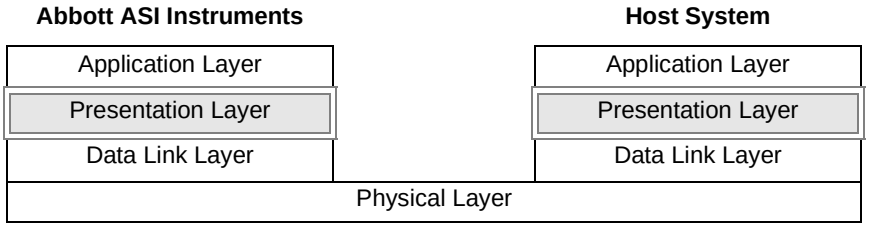


Figure 1.21: Presentation Layer

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.

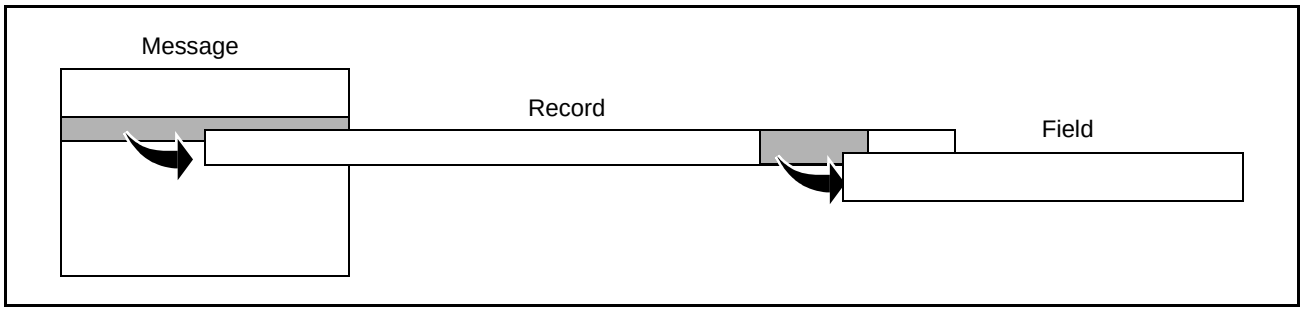


Figure 1.22: Message Logical Structure. ***Messages are subdivided into records which are made up of fields.***

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.

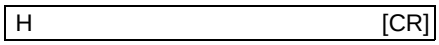
These conventions allow the fields, and thus the records, to vary in length. The ASTM E1394-91 standard allows manufacturers the flexibility to:

- 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.



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

Table 1.6: Record Types *(continued)*

Record Type	Record ID Field	Level	Description	For Field Contents Refer to ASTM E1394-91, Section
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 following figure shows how the Comment and Manufacturer Records fit into a message hierarchy.

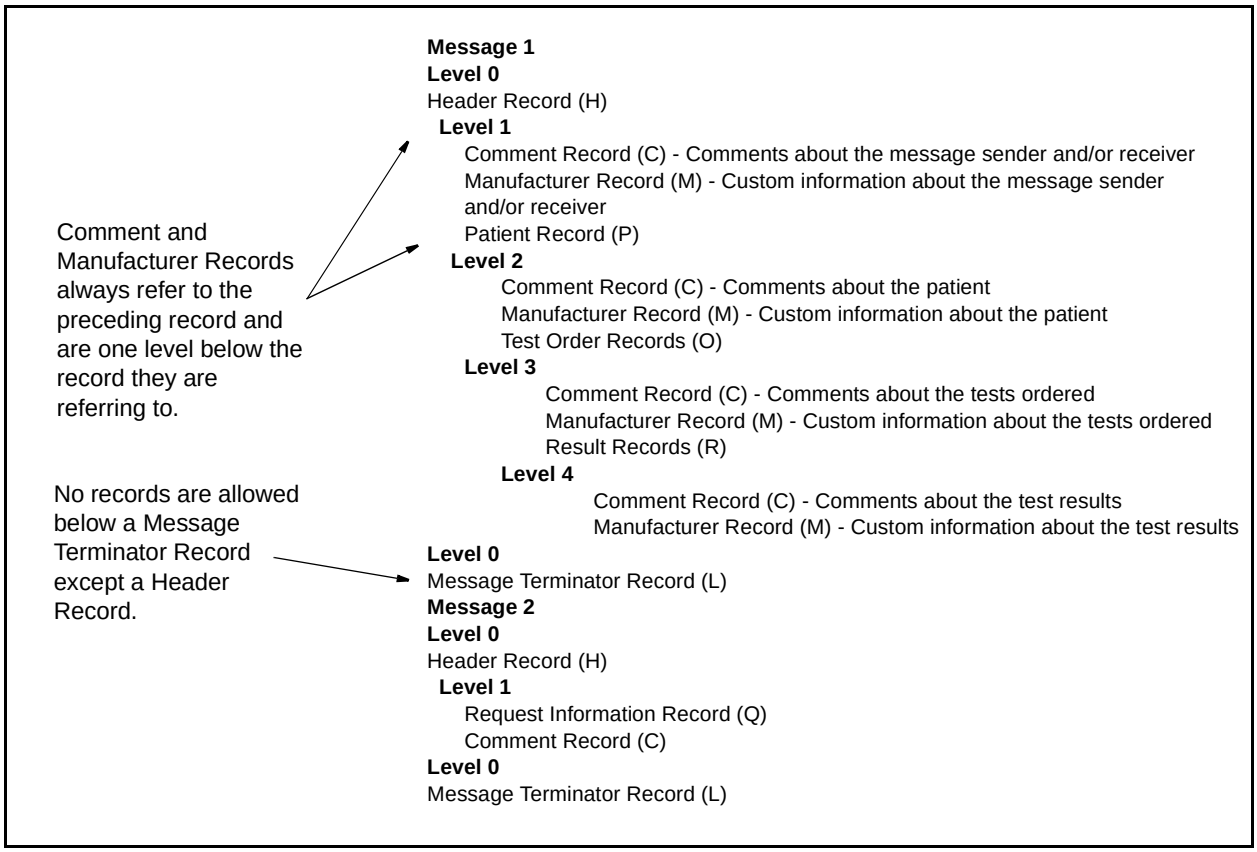


Figure 1.23: Comment and Manufacturer Records. ***These records can be placed anywhere in a message between the Header and Message Terminator Records.***

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:

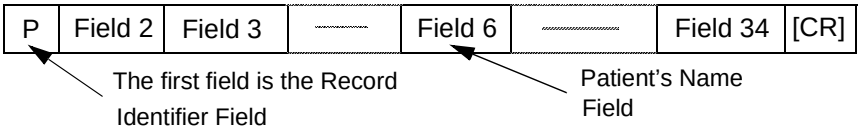
Header Record (H)
Request Information Record (Q)
Terminator Record (L)

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.

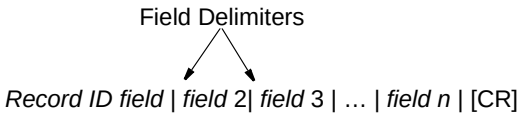
If a received data field contains a character that conflicts with the ASI defined delimiters (| \ ^ &), ASI instruments and systems will use the Escape Delimiter to return the original data (*i.e.*, conflicting character) back to the external system.

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.

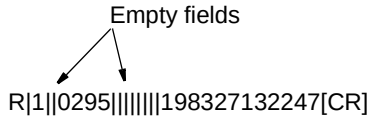
Field Delimiters (|)

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 . . .

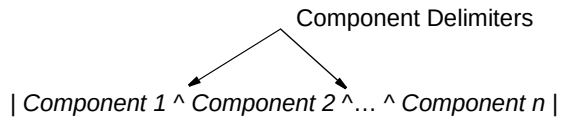
0|3|Sample#1|^^^Test3 . . .

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.

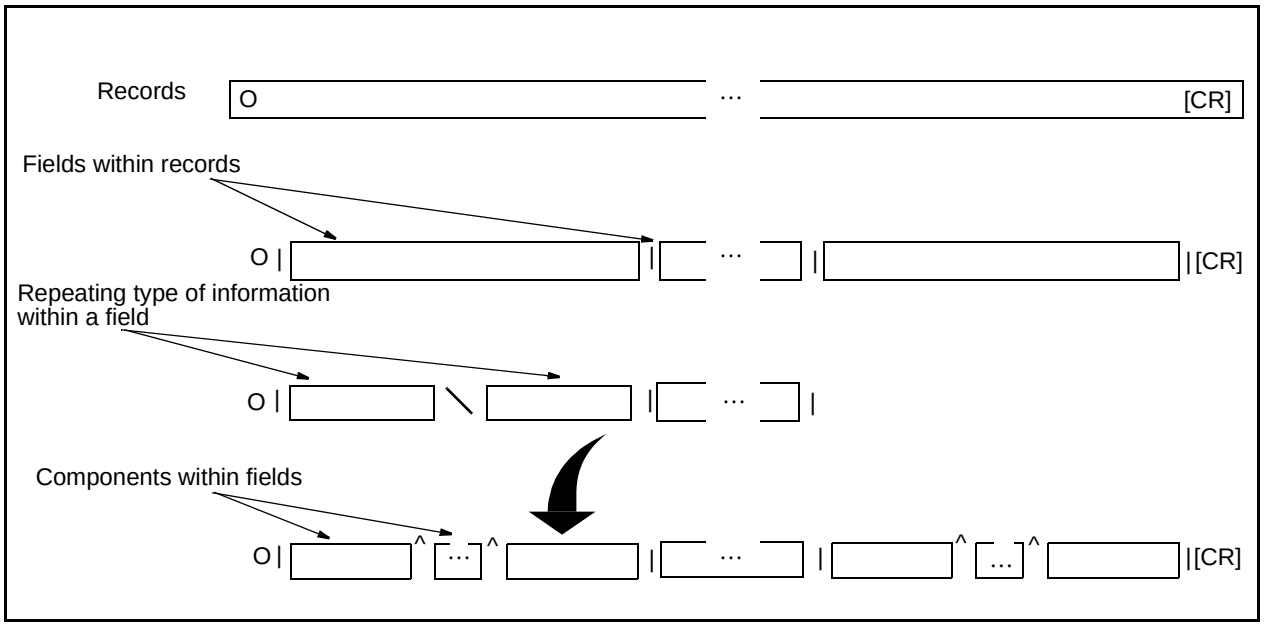


Figure 1.24: Delimiter Summary. ***Field delimiters separate fields within records, repeat delimiters separate multiple occurrences of the same type of data within a field, component delimiters separate components within fields.***

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 IDs (ASTM E1394-91 Field 9.4.3, 9.4.4)
- Patient IDs (ASTM E1394-91 Fields 8.1.3, 8.1.4, and 8.1.5)
- Action Codes (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 Parameter screens 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 (ASTM E1394-91 Fields 8.1.3, 8.1.4, and 8.1.5)

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.

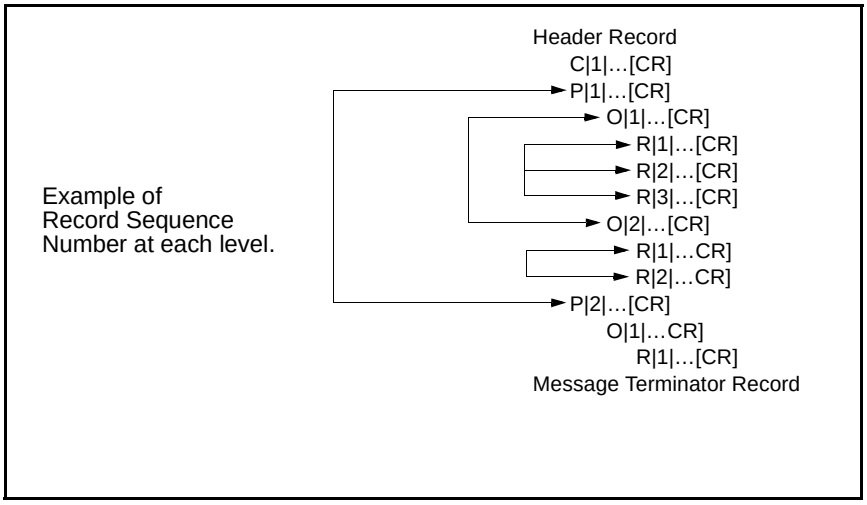


Figure 1.27: Record Sequence Numbers. ***Record Sequence Numbers keep track of the number of records of the same type and at the same hierarchical level.***

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.
7.1.2	Delimiters Field Repeat Component Escape	 | \ ^ &	 * 	ASI instruments accept any valid delimiters specified in the header record.
7.1.3	Message Control ID			Not supported
7.1.4	Access Password			Not supported
7.1.5	Sender Name or ID Name ^Software version ^Serial Number ^Interface version	* * * * (XnXn.....)	*	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 of instrument. Version of system software. Serial number of instrument or system. 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
* 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
7.1.10	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
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	YYYYMMD-DHHMMSS	YYYYMMD-DHHMMSS	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.
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.
* 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
8.1.9	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
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.
* 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
8.1.19	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.
8.1.25	Admission Status	*	*	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
8.1.26	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	*		
* 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
9.4.5	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.
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.
* 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
9.4.12	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.
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
* 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
9.4.24	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	*	*	See the instrument specific section for handling this field.
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.
* 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
10.1.3	Universal Test ID			The manufacturer's local code is made up of five (5) component fields as defined below. ASI instruments do not use repeat delimiters in this field.
	^^^Assay_code ^Assay_name	*		The Test Information (Assay_code^Assay_name) component is used to uniquely identify the test or tests done on the specimen.
	^Assay_protocol	*		Dilution or neutralization protocols defined per assay code. See the instrument specific section for applicable assay protocols.
	^Test Qualifier	*		Further qualification of the test or assay code.
	^Result type	F		(F)inal –Indicates final calculated values of concentrations, etc.
		I		(I)nterpreted –Indicates interpretations of final results based on user-defined criteria.
		P		(P)reliminary – Indicates raw instrument readings such as the RATE.
		Favg		Identifies the average of a set of final results.
		Pavg		Identifies the average of a set of preliminary results.
		Iavg		Identifies the interpretation associated with the average final result. See the instrument specific section for handling this field.
10.1.4	Data/Measurement	*		See the instrument specific section for handling this field.
10.1.5	Units	*		See the instrument specific section for handling this field.
* Indicates supported field. Refer to instrument sections for size of supported fields.				

Table 1.11: Result Records *(continued)*

ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
10.1.6	Reference Ranges			This field is used to communicate the laboratory- defined ranges for this assay. It is composed of two components separated by the component delimiter (^).
	Range	*		Multiple ranges may be communicated using repeat delimiters. The range is of the form, value to value. See the instrument specific section for specific ranges communicated.
	^Description	*		Label assigned by the laboratory to the preceding range. See the instrument specific section for handling this field.
10.1.7	Result Abnormal Flags	L		(L)ess than normal range
		H		(H)igher than normal range
		LL		(LL) – Less than extreme range
		HH		(HH) – Higher than extreme range
		QC		(QC) – Result based on a QC out of range
		>		(>) – Above dynamic range of assay
		<		(<) – Below dynamic range of assay
		EXP		(EXP) - 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 ^Specimen ID	 * ALL * ALL	 * ALL * ALL	 From Host: (ALL) indicates return all information associated with all known Patient IDs and/or Specimen IDs. From Instrument: (ALL) indicates return all requested information associated with known Patient IDs and/or Specimen IDs assigned to this instrument.
12.1.4	Ending Range ID Patient ID ^Specimen ID	 * *	 * *	Used when Patient and/or Specimen IDs are sequential. Standard string comparison rules apply to determine if a Patient ID Specimen ID falls within the range provided by fields 12.1.3 and 12.1.4.
* Indicates supported field. Refer to instrument sections for size of supported fields.				

Table 1.13: Request Information Record *(continued)*

ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
12.1.5	Universal Test ID	^^^ALL	^^^ALL	Used to request test results for the specified test (assay code) on a specific sample or patient ID. 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 F N O D X	A F N O D X	(A)bort – Cancel last request. (F)inal Report (N)ew or Edited Results (O)rders and Demographics (D)emographics only (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.
* 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
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 pipetting information
		^SM		(SM) – Source Maps for pipetting information
		^GR		(GR) – Graphics Record
		^CL		(CL) – Instrument Calibration information
		P		(P)atient class – Contains information relevant to patient demographics.
		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

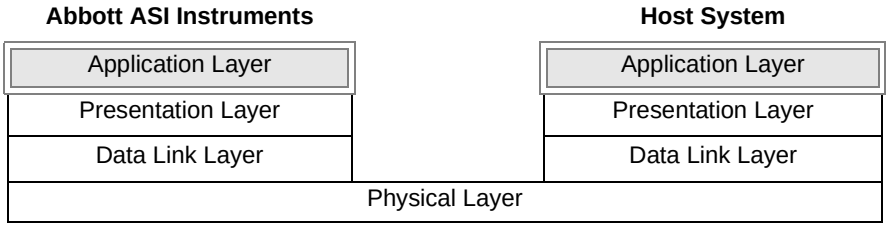


Figure 1.33: Application Layer

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

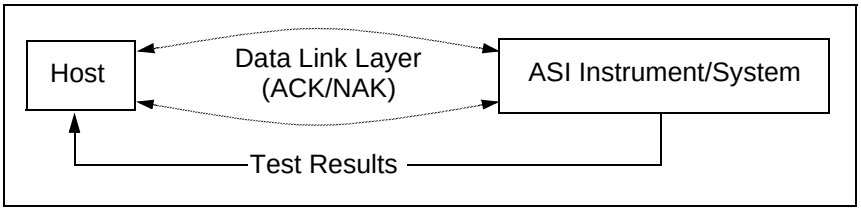


Figure 1.34: Category I Instruments and Systems

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

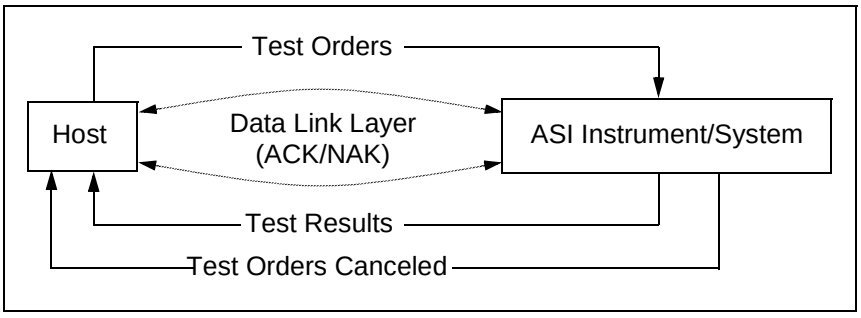


Figure 1.35: Category II Instruments and Systems

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

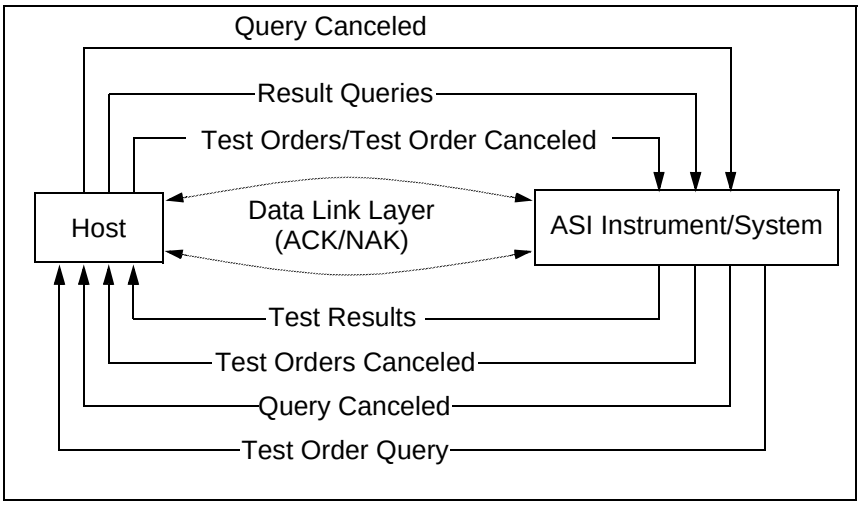


Figure 1.36: Category III Instruments and Systems

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

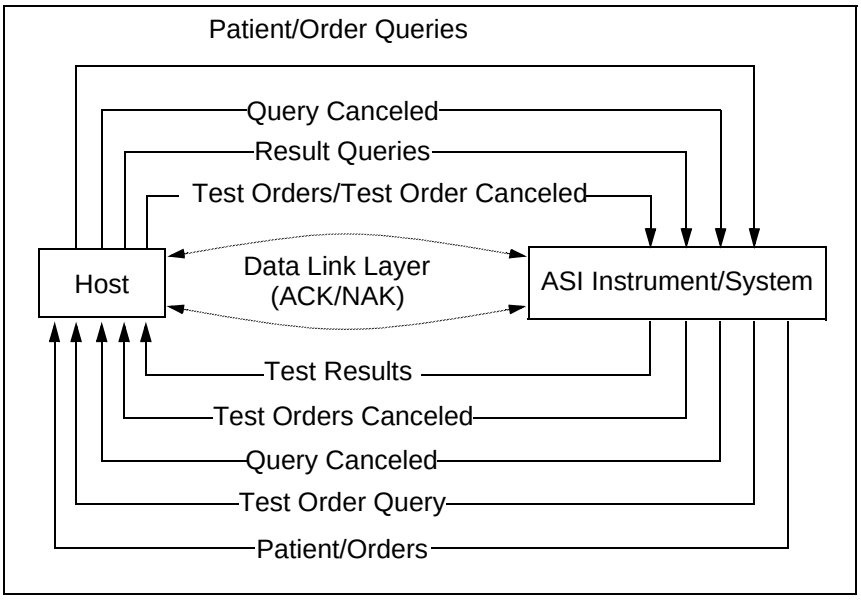


Figure 1.37: Category IV Instruments and Systems

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

Introduction

This section describes the ARCHITECT *i* System, an analyzer designed to perform automated immunoassay tests based on the use of chemiluminescent microparticle immunoassay (CMIA) detection technology. The ARCHITECT *i* System performs random access, continuous access, and priority processing of both large and small molecular weight analytes.

The modular system can consist of up to four ARCHITECT *i* System processing modules, all controlled by one system control center. A single sample handler moves samples through the ARCHITECT *i* System regardless of the number of modules.

Topics include:

NOTES

Primary Components

Figure 2.1 identifies the primary components of the ARCHITECT *i* System.

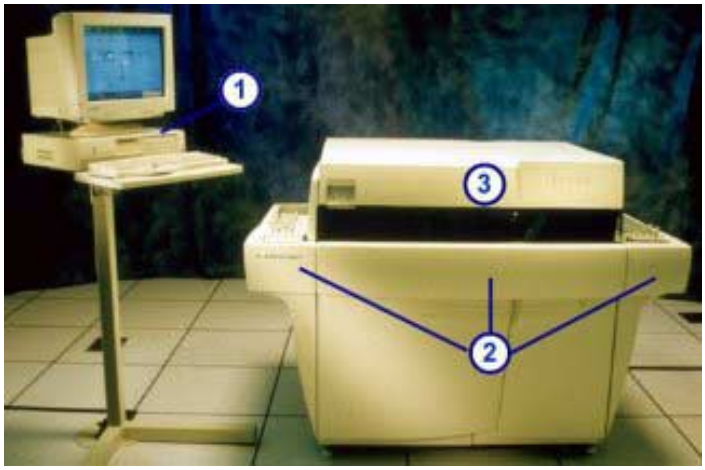


Figure 2.1: Primary Components

1.	System control center
2.	Sample handler **NOTE**: This sample handler is a standard, single-lane sample handler.
3.	Processing Module

System Control Center

The system control center is a computer system that allows you to control the processing module(s) and the sample handler.

The system control center provides the user interface, data management capability, and an interface to a host computer, which allows you to receive test orders and diagnostic data and to transfer test results. You can also perform the following:

- Manually enter patient, control, and calibration orders
- Review patient results, control data, and calibration results
- Perform system diagnostics and maintenance procedures
- Set up system configuration

For additional information on the system control center, see:

- ***Standard Components***
- ***Optional Components***

Standard Components

Figure 2.2 identifies the system control center standard components.

NOTE: Upgrades to the computer hardware may change the location of CPU (central processing unit) components.

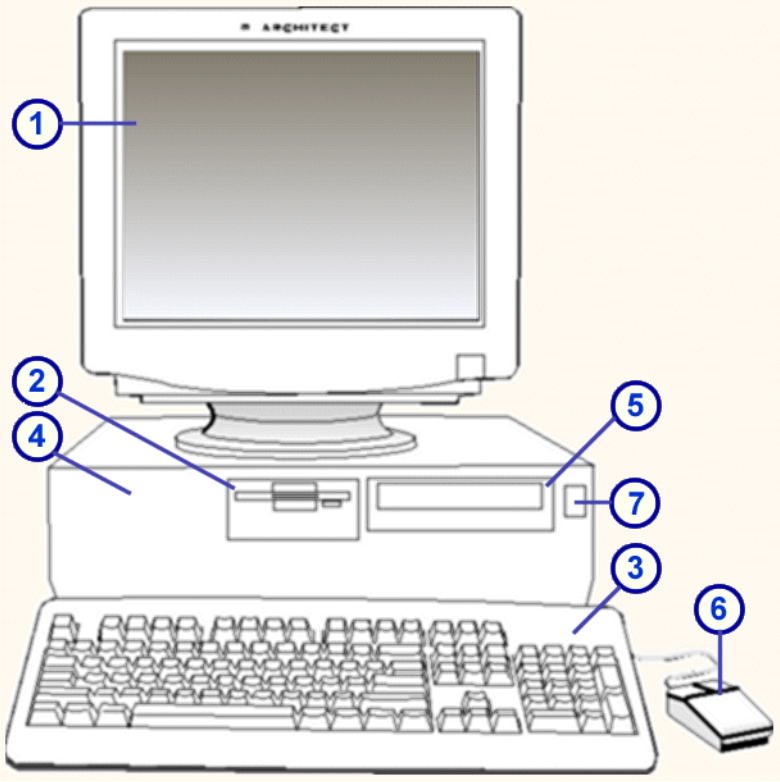


Figure 2.2: System Control Center (Standard Components)

1. Touch-screen monitor: Allows you to make on-screen selections by touching text areas and graphics, icon menu choices, or function key selections. This is the main user interface for the ARCHITECT *i* System.	**2.** Floppy drive: Used to collect system logs for troubleshooting purposes.
3. Keyboard: Used in conjunction with the touch-screen monitor to enter information. You can use the keyboard as an alternate means of performing most touch-screen monitor functions.	**4.** CPU (central processing unit): Houses the microprocessor and other computer components.

5. CD drive: Used to accomplish the following: • Install assay files, maintenance and diagnostic procedures, computer based training, and the online operations manual • Upgrade system software • Archive patient and quality control results	**6.** Mouse (pointing device): Used in conjunction with the touch-screen monitor to make on-screen selections. You can use the mouse as an alternate means of performing most touch-screen monitor functions.
7. Power switch: Used to cycle the power.	

Optional Components

Optional components available for the system control center include:

- **Printer**—provides a hard copy of test results and printed reports.
- **Bar code scanner**—provides a convenient means of scanning sample bar codes to allow for positive sample identification.
- **UPS (uninterruptible power supply)**—provides a temporary, continuous flow of power to the CPU during a power failure, allowing you to save data as necessary and perform a correct shutdown procedure.
- **External modem**—connects the ARCHITECT *i* System to a telephone line, allowing it to communicate with Abbott personnel for training and troubleshooting purposes.
- **Cart**—supports the system control center components.
- **Speakers**—provide audio output

Sample Handler

The sample handler is a transport system that presents samples to the processing module(s). Activities in this area are limited to loading, identification, transport, and unloading of samples.

Two sample handler configurations are available:

- Standard with either a single or double lane
- LAS (laboratory automation system) carousel

> **NOTE:** Unless otherwise indicated, the term sample handler is used generically throughout this documentation to refer to both.

For information specific to a single or double-lane standard sample handler, see ***Standard Sample Handler***.

For information specific to an LAS sample handler, see ***LAS (Laboratory Automation System) Carousel Sample Handler***.

Standard Sample Handler

Samples are placed in sample carriers for transport through the system.

Figure 2.3 identifies the basic components of the standard sample handler.

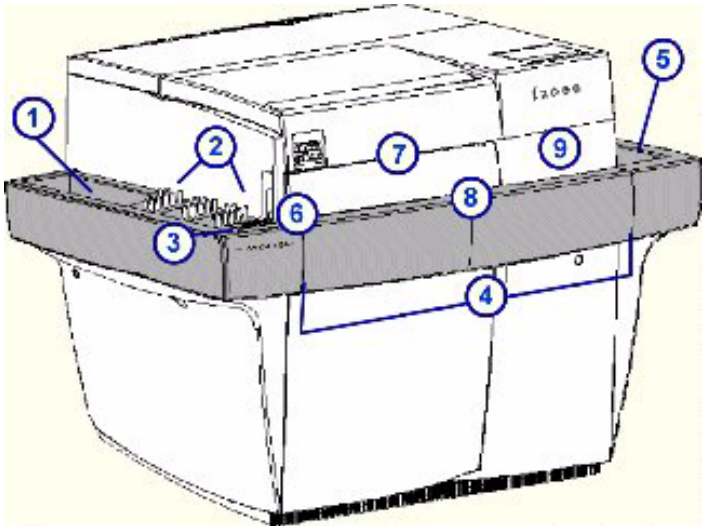


Figure 2.3: Standard sample handler components

1. Sample load queue (single lane): Transfers the sample carrier to the sample processing queue.	**2.** Sample carriers: Hold five primary tubes, aliquot tubes, or sample cups. Different types of sample vessels may be mixed on each carrier.
3. Sample handler keypad: Provides a user interface for controlling the sample handler.	**4.** Sample processing queue: Transfers the sample carrier to the sample pipettor. Once sample is aspirated, the sample carrier is transferred to another processing module or to the sample unload queue.
5. Sample unload queue (single lane): Where sample carriers are transferred for removal.	**6.** Sample load queue bar code reader: Reads the sample carrier ID, position, and sample ID.
7. Left processing queue access door: Provides access to the sample processing queue.	**8.** Sample processing queue bar code reader: Reads the sample carrier ID and position. Does not read the sample ID.
9. Right processing queue access door: Provides access to the sample processing queue.	

The sample handler keypad provides local user interface for controlling the sample handler. Figure 2.4 identifies the components of the sample handler keypad.

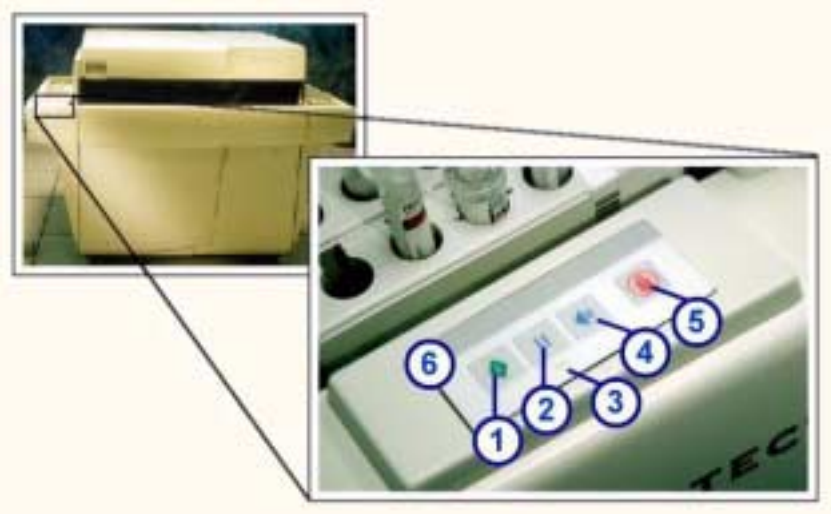


Figure 2.4: Components of the standard sample handler keypad

1. Run key: Resumes or begins the indexing of the sample load queue. The processing module status must be Running to process samples.	**2.** Pause key: Pauses the sample load queue so you can load sample carriers or perform priority loading.
3. Pause indicator (yellow): Illuminates to indicate that the sample load queue is paused and ready for loading of sample carriers.	**4.** Reverse key: Reverses the sample load queue direction for ease of loading priority sample carriers. Functional only when the Pause indicator is illuminated.
5. Stop key: Stops the sample handler, but does not shut down power to the sample handler, and has no effect on the action of the processing module(s). You must perform a startup at the system control center in order to change the sample handler status to Ready.	**6.** Active lane indicators (green; active on double load queues only): Indicate the currently active lane. The lane indicator is used to facilitate priority loading on multi-module systems.

Standard sample handler with double-lane load and unload queues

Multi-module systems are configured with double sample load and unload queues which provide two lanes at a capacity of up to 125 samples each (25 sample carriers) for a total capacity of 250 samples (50 sample carriers). The sample processing queue moves the sample carriers past each module until they reach the sample unload queue.

Figure 2.5 illustrates a standard sample handler configuration with multiple processing modules.

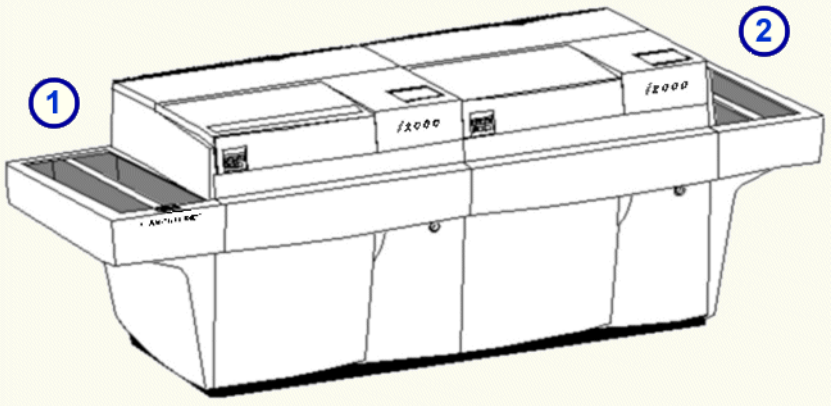


Figure 2.5: Standard sample handler with double-lane load and unload queues

1.	Sample load queue (double lane)
2.	Sample unload queue (double lane)

LAS (Laboratory Automation System) Carousel Sample Handler

The LAS carousel is used for loading calibrators, controls and patient samples when the ARCHITECT *i* 2000 System processing module is integrated with an LAS. In the event of an LAS failure, the LAS carousel can be used as the primary area for loading samples. Under normal operating conditions when both the LAS and LAS carousel are functional, samples on the carousel take priority over those on the LAS.

Figure 2.6 illustrates the LAS carousel sample handler.

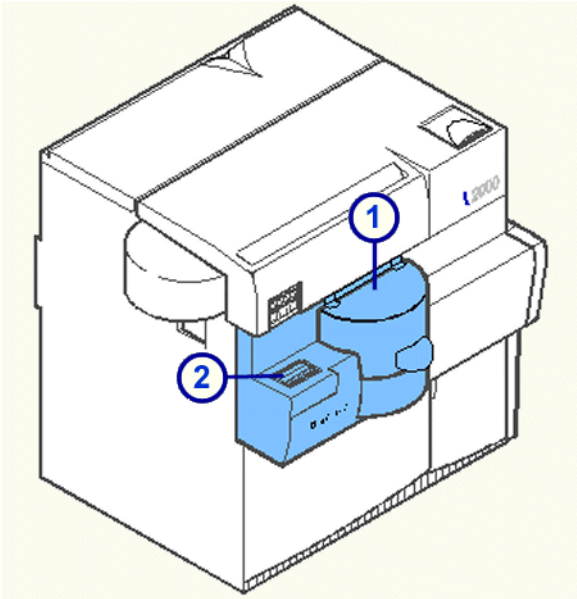


Figure 2.6: LAS Carousel Sample Handler Components

1.	LAS carousel cover
2.	LAS carousel sample handler keypad

LAS carousel sample handler keypad

The LAS carousel sample handler keypad provides local user interface for controlling the LAS carousel. Figure 2.7 identifies the components of the LAS carousel keypad.

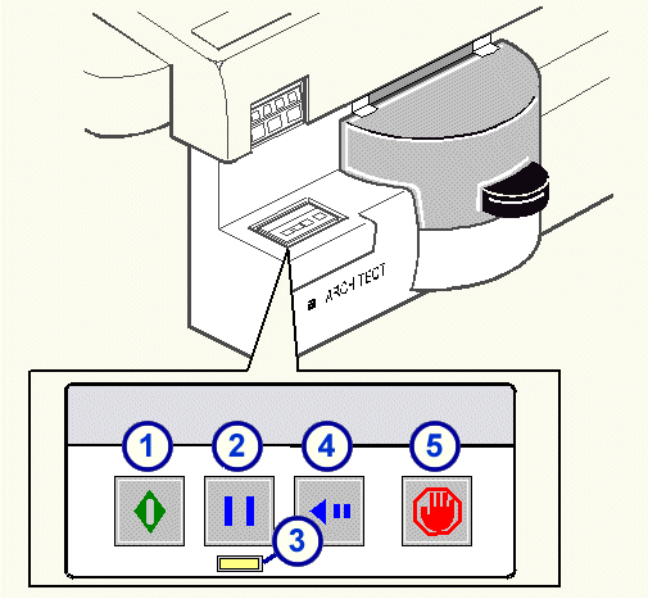


Figure 2.7: Components of the LAS carousel sample handler keypad

1. Run key: Resumes or begins the processing of samples on the LAS carousel. The processing module status must be Running to process samples.	**2.** Pause key: Pauses the LAS carousel after completing aspiration of the current sample or current group of calibrators.
3. Pause indicator (yellow): Illuminates to indicate that the LAS carousel is paused and ready for loading or unloading samples.	**4.** Carousel advance key: Moves the LAS carousel clockwise 5 positions. Functional only when the Pause indicator is illuminated.
5. Stop key: Stops the LAS carousel, but does not shut down the power to the carousel, and has no effect on the action of the processing module. You must perform a startup at the system control center in order to change the sample handler status to Ready.	

Processing Module

The ARCHITECT *i* System processing module performs all sample processing activities—from aspiration to final read.

A single module system performs up to 200 CMIA tests per hour, making use of up to 25 onboard reagent kits in a temperature-controlled reagent carousel.

For a description of the processing module see:

- ***Processing Module View - Standard Sample Handler***
- ***Processing Module View - LAS Carousel Sample Handler***
- ***Processing module keypad***

- ***Processing Center***
- ***Supply and Waste Center***
- ***Optional Components***

Processing Module View - Standard Sample Handler

For systems configured with a standard sample handler, Figure 2.8 and Figure 2.9 identify the components of the processing module.

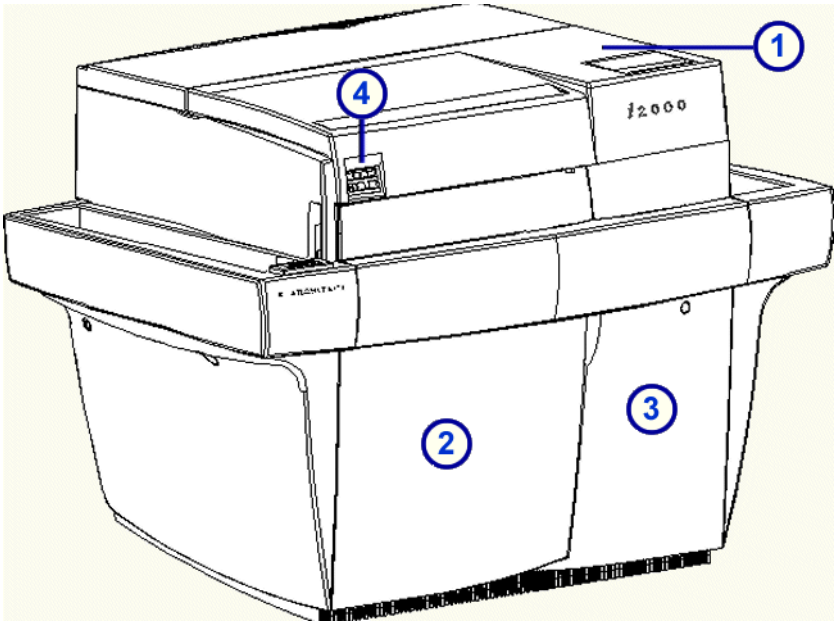


Figure 2.8: Processing module - front view (standard sample handler)

1. Front processing center cover	**2.** Supply and waste center door
3. Card cage door	**4.** Processing module keypad

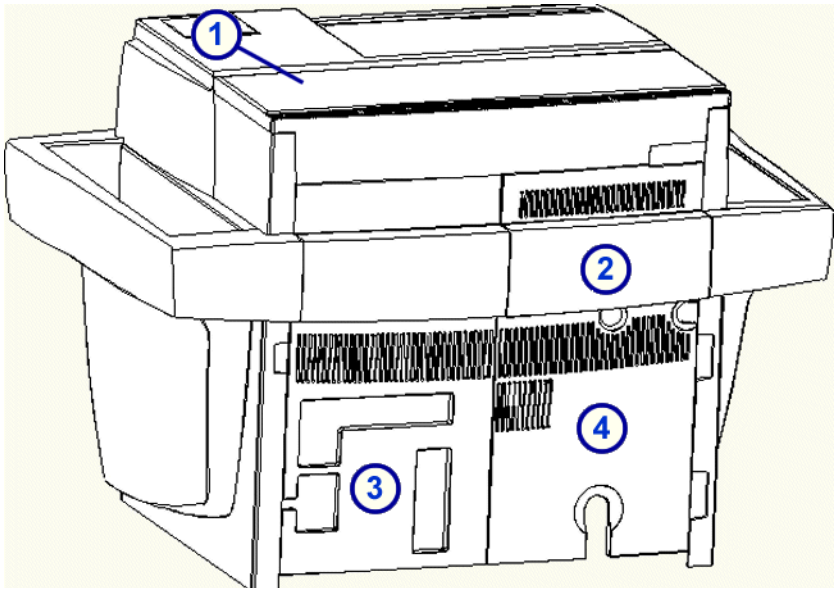


Figure 2.9: Processing module - rear view (standard sample handler)

1. Rear processing center cover	**2.** Rear processing center access panel
3. Power supply panel	**4.** Pump bay panel

Processing Module View - LAS Carousel Sample Handler

For systems configured with an LAS carousel sample handler, Figure 2.10 and Figure 2.11 identify the components of the processing module.

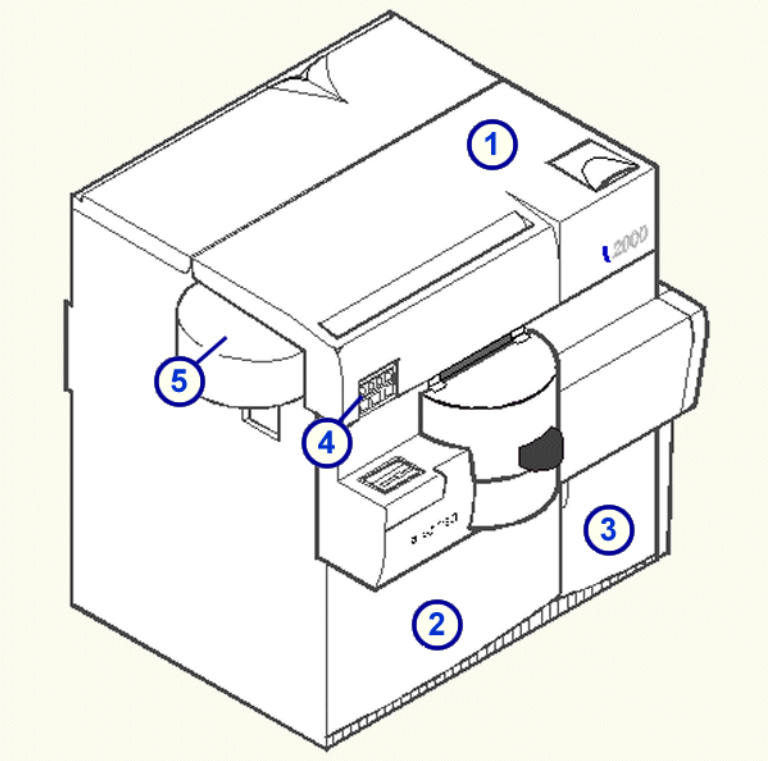


Figure 2.10: Processing Module - Front View (LAS Carousel Sample Handler)

1. Front processing center cover	**2.** Supply and waste center door
3. Card cage door	**4.** Processing module keypad
5. Sample pipettor cover	

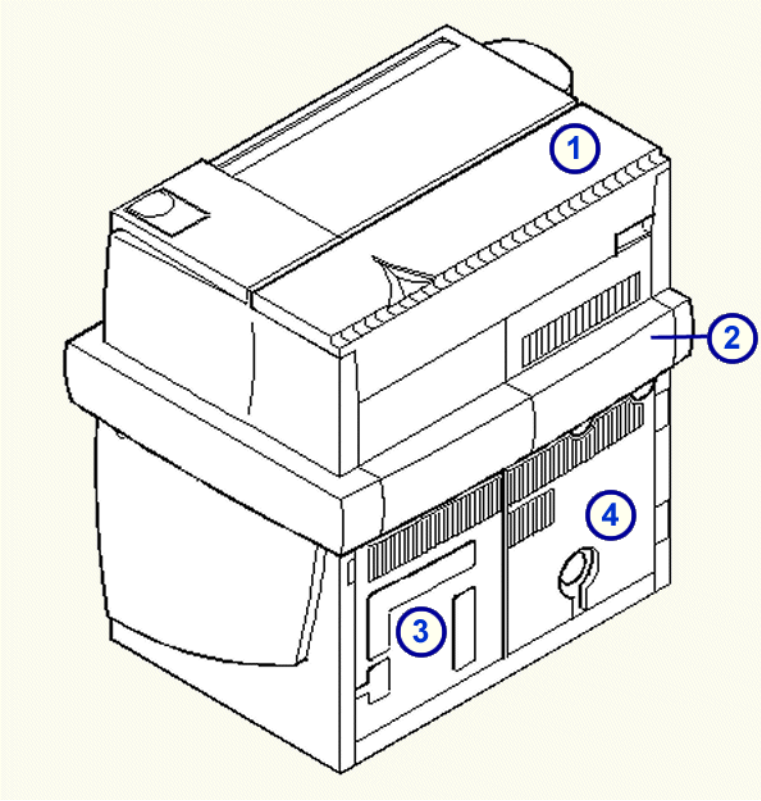


Figure 2.11: Processing Module - Rear View (LAS Carousel Sample Handler)

1. Rear processing center cover	**2.** Rear processing center access panel
3. Power supply panel	**4.** Pump bay panel

Processing module keypad

The processing module keypad, located on the left side of the processing module, provides a local user interface for controlling the processing center.

Figure 2.12 identifies the components of the processing module keypad.

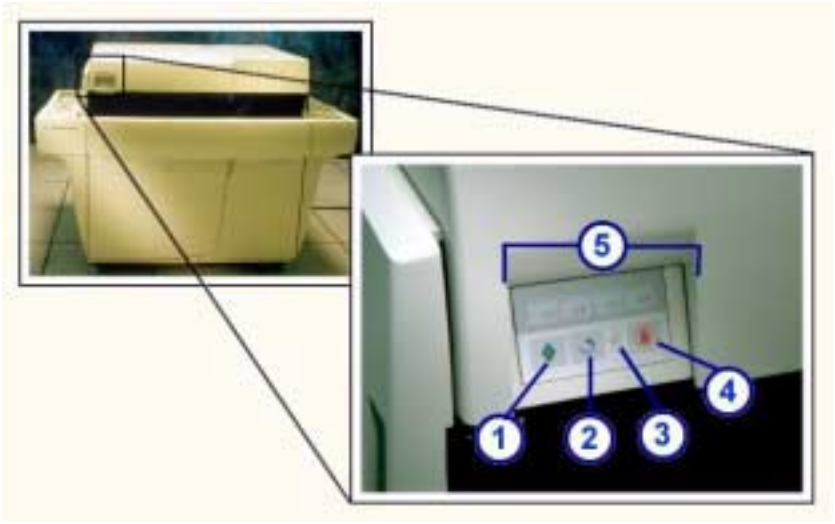


Figure 2.12: Components of the Processing Module Keypad

1. Run key: Places the processing module into Running status and prepares the module to accept samples. Restarts the processing center after a Scheduled Pause.	**2.** Carousel advance key: Aligns the reagent carousel and advances the reagent carousel five positions to aid in loading reagents.
3. Access indicator light: Illuminates to indicate that the processing module is in the Warming or Ready status. The processing module must complete tests in process before you can open the front or back processing module cover. If opened inadvertently, all processing underway terminates and you must rerun the tests.	**4.** Stop key: Stops all processing module activity, but does not shut down power to the processing module. You must perform a startup at the system control center before starting a new run. The processing module stop key has no effect on the sample handler.
5. L1, L2, L3, L4 keys: Used in diagnostic and maintenance procedures. Their functionality is defined on the screen for each procedure.	

Processing Center

The front and rear processing center covers open to the components that perform assay processing activities. The processing center consists of the following:

- Pipettors and syringes, see Figure 2.13 for abbreviations
- Process path components, see Figure 2.14 for abbreviations
- Processing cover components, see Figure 2.15 for abbreviations
- Reagent carousel, see Figure 2.16 for component locations

Assay processing takes place in the process path, a covered circular track that provides incubation temperatures, liquid aspiration, and wash points as necessary for the assay protocol. The process path advances the reaction vessels every 18 seconds and positions them at the designated locations in order to process the CMIA reaction.

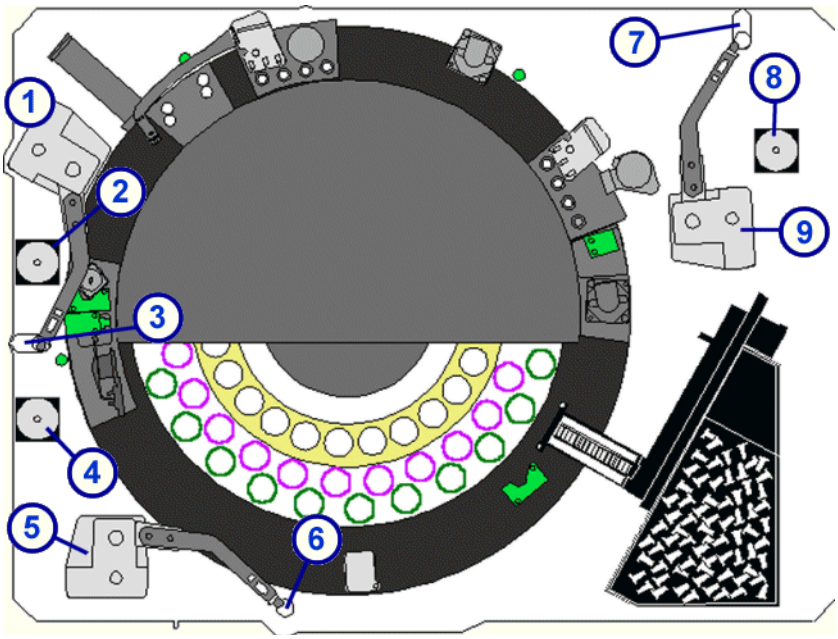


Figure 2.13: Pipettors and Syringes

1. Reagent pipettor 1 – R1	**2.** Reagent syringe 1 – R1S
3. Reagent probe wash station 1 – R1W	**4.** Sample syringe – SS
5. Sample pipettor – S	**6.** Sample probe wash station – SW
7. Reagent probe wash station 2 – R2W	**8.** Reagent syringe 2 – R2S
9. Reagent pipettor 2 – R2	

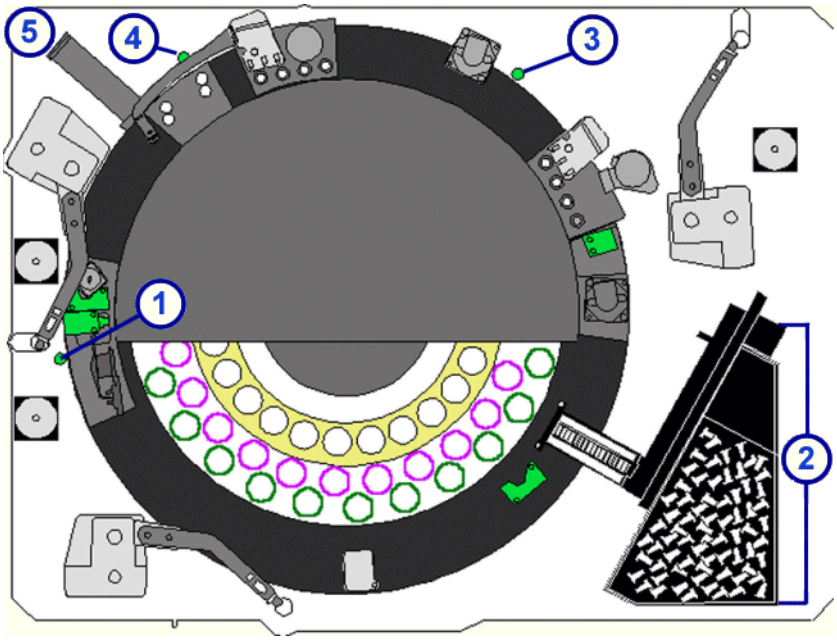


Figure 2.14: Process Path Components

1. Vortexer 1 – VTX1	**2.** RV loader assembly and hopper – RVL
3. Vortexer 2 – VTX2	**4.** Vortexer 3 – VTX3
5. CMIA optics assembly – CMIA	

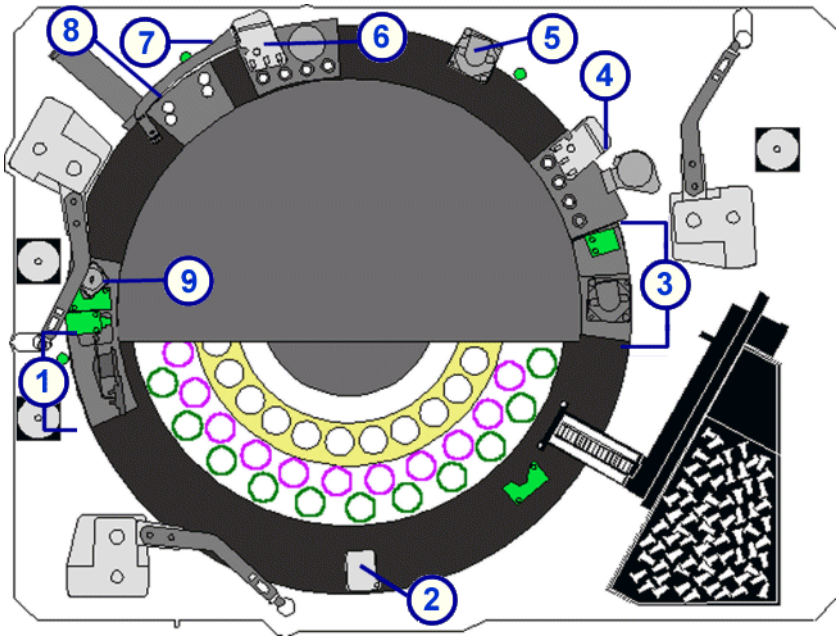


Figure 2.15: Processing Center Cover Components

1. Load diverter – LD	**2.** RV access door – RVA
3. Wash zone diverter – WZD	**4.** Wash zone 1 – WZ1
5. Process path motor – PPM	**6.** Wash zone 2 – WZ2
7. Liquid waste arm – A	**8.** Pre-Trigger/Trigger manifold–PT/T
9. RV unloader – UL	

Reagent carousel

The cooled, temperature-controlled reagent carousel in the center of the process path holds up to 25 reagent kits (75 individual bottles). For easy identification and loading, the reagent carousel is color coded, as follows, to match the color coded reagent bottles:

- Inner reagent location is yellow
- Middle reagent location is pink
- Outer reagent location is green

Reagent bottles containing microparticles are placed in the middle (pink colored) reagent location on the carousel. To provide microparticle dispersion, the microparticle reagent bottles are rotated continuously while the processing module is running. A bar code reader identifies reagents.

Figure 2.16 shows the location of the reagent carousel, reagent bar code reader, and the reagent carousel cover.

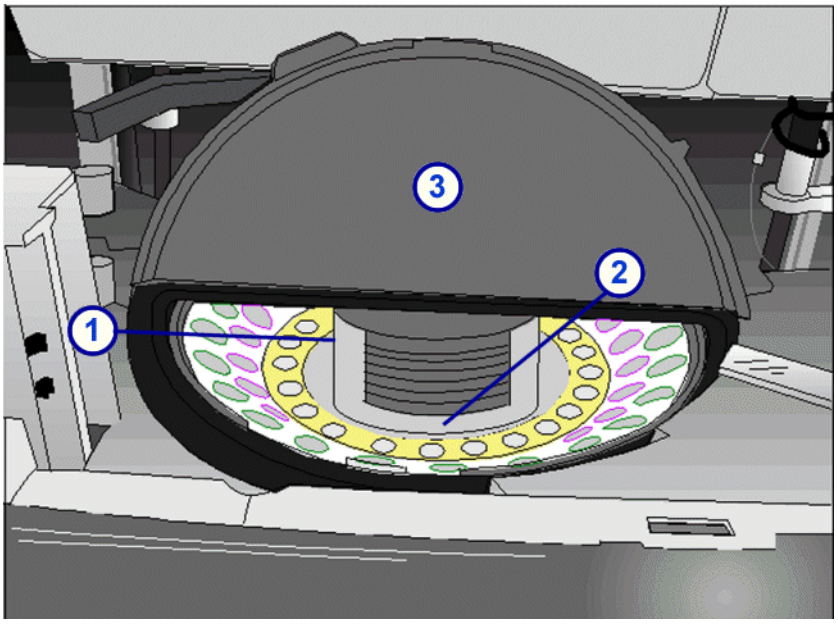


Figure 2.16: Temperature-controlled Reagent Carousel

1.	Bar code reader
2.	Reagent carousel
3.	Reagent carousel cover

The reagent bar code reader reads two dimensional (2D) bar code labels on the reagent bottles that provide assay name, lot number, expiration date, number of tests, and master calibration data to the system control center.

Supply and Waste Center

The supply and waste center door provides access to compartments that provide onboard storage for solid waste and bulk solutions necessary for processing.

Figure 2.17 identifies the onboard storage areas.

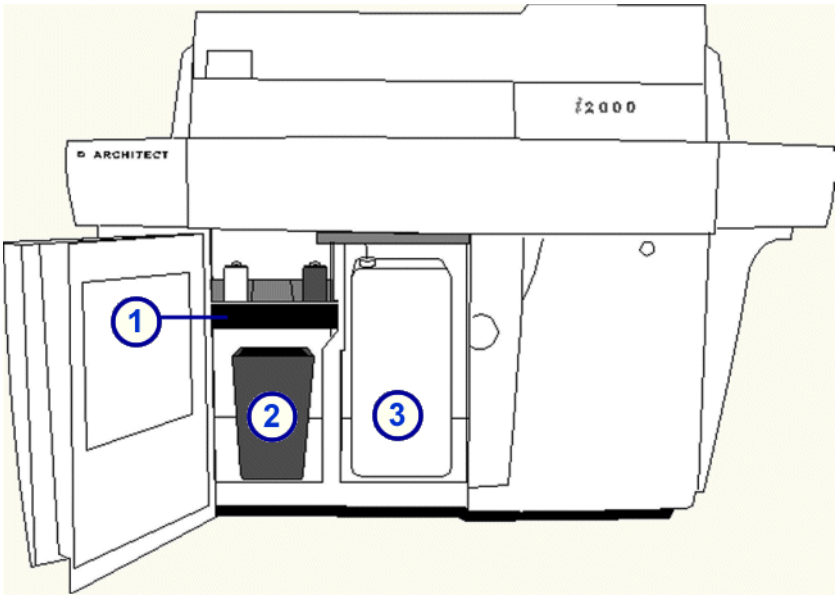


Figure 2.17: Supply and Waste Center

1.	Pre-Trigger and Trigger tray
2.	Solid waste container
3.	25 L wash buffer reservoir

Host Interface Port

The host interface port is a serial RS-232 communication port that is used to connect a laboratory host computer or laboratory information system to the ARCHITECT *i* System. This port, which meets ASTM standard (E 1381-91), allows the two-way transfer of information between the two units.

The port operates at baud rates of 1200, 2400, 4800, 9600, 14400, 19200, or 28800 bps.

NOTES

Software/User Interface

The software that controls the ARCHITECT *i* System provides a graphical user interface for the operator. This interface is navigated by using the mouse (pointing device), touch-screen monitor, and/or keyboard. Detailed steps for navigating through the ARCHITECT *i* System software are contained within each specific procedure.

Screen Layout

The ARCHITECT *i* System screen is divided into three zones that provide a consistent interface to system functions.

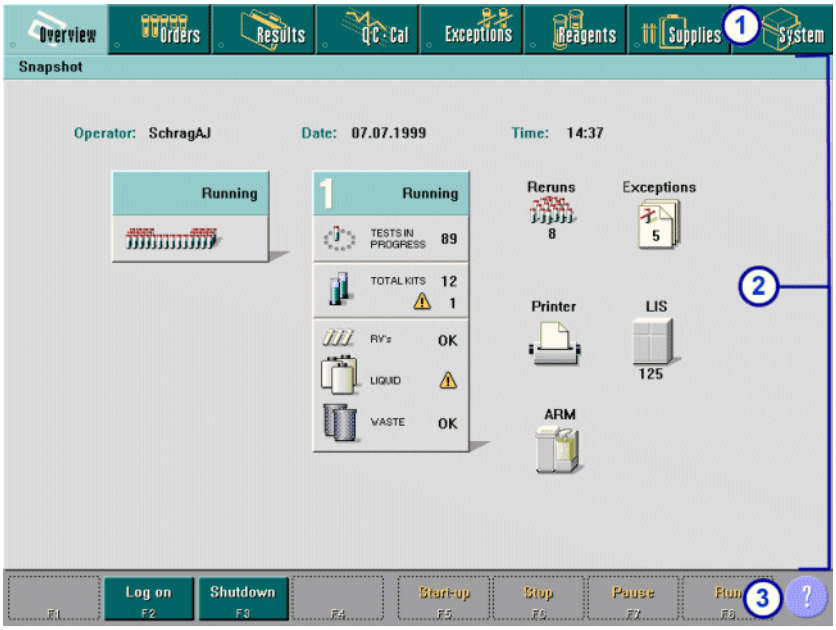


Figure 2.18: Screen Layout

1.	Icon zone: Provides navigational and status indication support. Each icon has a drop-down menu that displays when you select the icon.
2.	Information zone: Contains all information pertaining to a screen, including screen name.
3.	Function key zone: Contains function keys associated with the screen currently displayed in the Information zone.

Software Navigation

The ARCHITECT *i* System software is designed for easy navigation, using the tools shown in Figure 2.19:

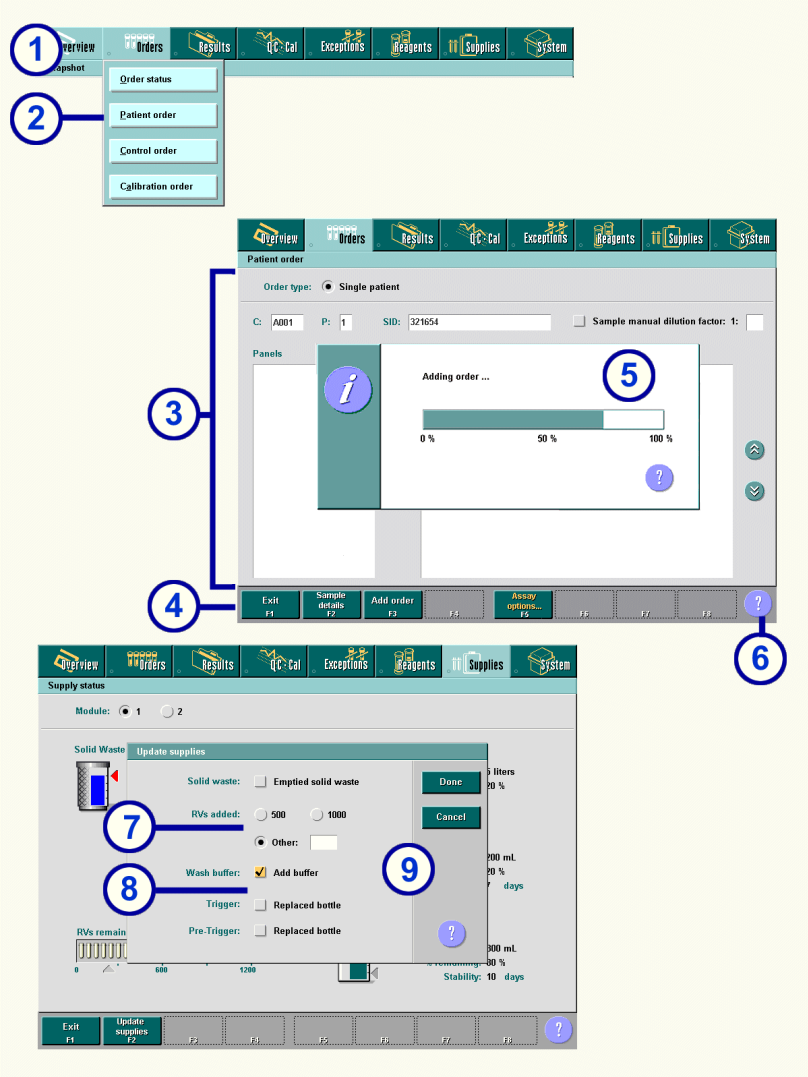


Figure 2.19: Software Navigational Tools

1. Icons	**2.** Drop-down Menus
3. Full-frame Screens	**4.** Function keys
5. Popup Windows	**6.** Help Button
7. Radio buttons	**8.** Check boxes
9. Dialog Windows	

Icons

Icons have the following characteristics:

- Located at the top of the screen
- Serve as the main menu, segmenting the screens into major categories

- Provide a graphic and name that represent a category of screens
- Serve as a blinking indicator to inform you that a condition requiring your attention exists

Figure 2.20: Icons

When you select an icon, its color changes from green to blue and a drop-down menu is displayed below the icon.

Drop-down Menus

Drop-down menus contain items representing each of the screens available for the selected icon. When you select a menu item, the associated information and appropriate function keys are displayed in a full-frame screen.

To close the drop-down menu, select the icon again.

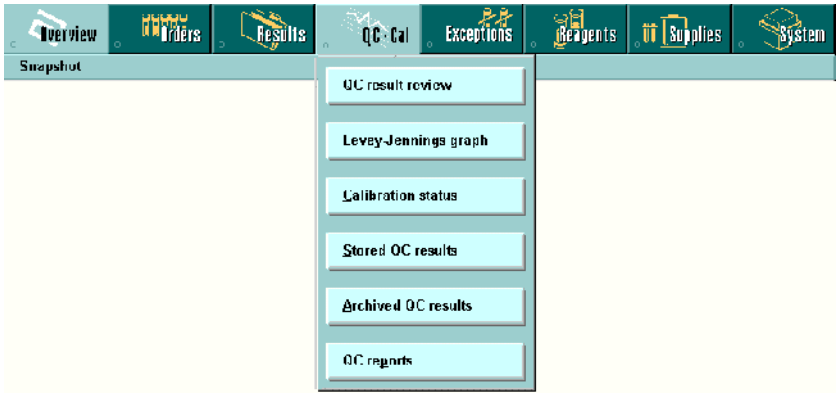


Figure 2.21: Drop-down Menu for the QC-Cal Icon

Full-frame Screens

A full-frame screen is displayed when a drop-down menu option is selected, as shown in Figure 2.22.

Figure 2.22: Full-frame Screen

1. Information zone: Contains all information pertaining to a screen, including screen name. When there is more data than can be displayed, the current page number and the total number of pages is displayed in the top line of the Information zone.	**2.** Function keys: Displayed horizontally at the bottom of the screen and allow you to perform actions associated with the information displayed on the screen. Their arrangement corresponds to the arrangement of the function keys on the keyboard. You can use the touch screen or the keyboard function keys. If a screen has an Exit button, it is always function key F1.
3. Scroll buttons: Allow you to move the cursor up or down to view additional data when there is more data than can be displayed on a single screen. Single arrow buttons move the cursor up or down one line at a time. Double arrow buttons move the cursor up or down one page at a time.	

Column sort headers

When the information zone of a full-frame screen includes a list box with columns, you can click on a column header to sort the contents. An example of the options to sort by are:

- C/P (carrier and position)
- SID
- NAME
- ASSAY
- STATUS
- TIME
- CODE

In Figure 2.23, the Order status screen is used as an example. This example shows the C/P column header selected.

Figure 2.23: Column Sort Headers

Refresh button

The refresh button is a visual indicator that shows you when the ARCHITECT *i* System has new data to display. The refresh button highlights when the system has new data to display.

List box icon

The List box icon is a visual indication that there is a list of options to choose from.

Popup Windows

Popup windows provide important information during the course of normal system operation. They appear at the center of the screen and in front of the currently displayed window. All interaction with the user interface is suspended as long as the popup is displayed.

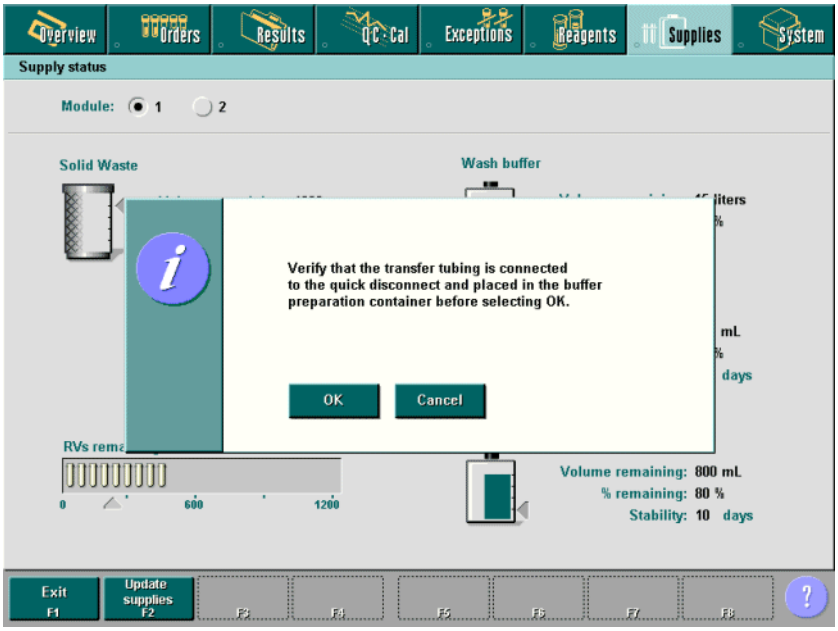


Figure 2.24: Popup Window

The type of message is indicated by one of two symbols at the left of the window:

CAUTION: Indicates a condition that requires you to take corrective action as described in the text of the message

INFORMATION: Provides feedback or other useful information and may require that you acknowledge the message by making a selection from the popup window

Help Button

The Help button, a question mark (?), allows you to access online screen descriptions and troubleshooting information for error codes.

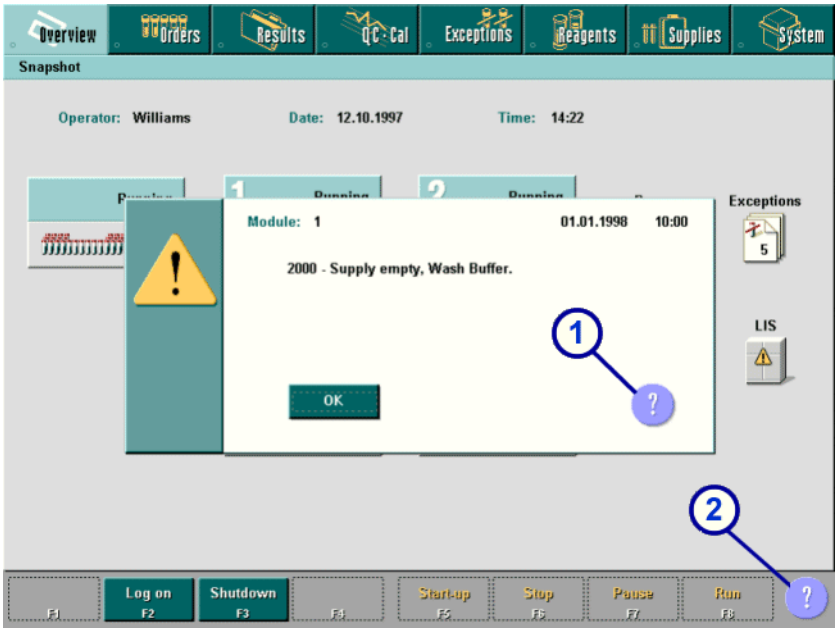


Figure 2.25: Help Buttons

1.	Error code help button
2.	Screen help button

Radio Buttons and Check Boxes

Radio buttons are used when only one selection can be made from multiple options. A black-filled radio button indicates that it has been selected.

Check boxes are used when you can make one or more selections for an item. A black check mark in a check box indicates that it has been selected.

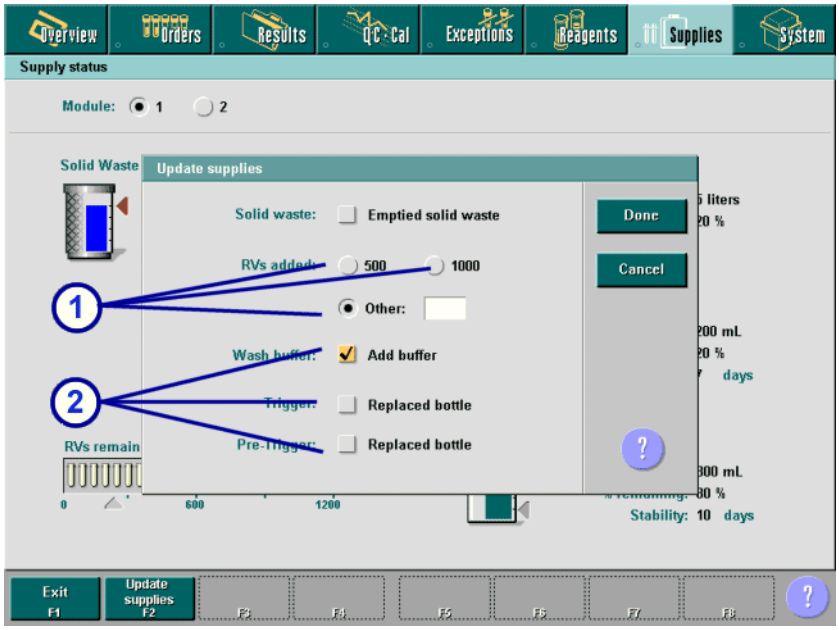


Figure 2.26: Radio Buttons and Check Boxes

1. Radio buttons
2. Check boxes

Dialog Windows

Dialog windows provide additional information, details, or functions. They display on top of, or in front of, full-frame screens. You access dialog windows by selecting an item or function key on the primary full-frame screen.

Dialog windows contain the following:

- Previous and Next buttons for accessing multiple pages if necessary
- Buttons for actions associated with the window, for example Done or Cancel

Figure 2.27: Dialog Window Showing Previous and Next Buttons

1.	Previous and next buttons
2.	Done and Cancel buttons

Snapshot Screen

The Snapshot screen monitors key system and processing module information. It also provides quick access to related screens through the use of drop-down menus. Select a drop-down menu item to automatically navigate to the related screen.

To access the Snapshot screen, select the **Overview** icon, then the **Snapshot** menu option (see Figure 2.28).

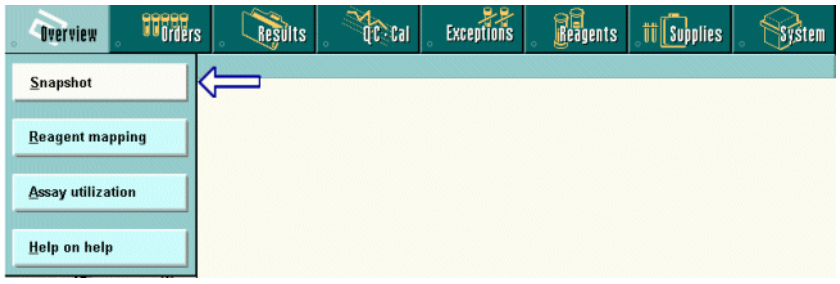


Figure 2.28: Accessing the Snapshot Screen

The Snapshot screen that displays is dependent upon your system configuration. See:

- ***Snapshot Screen - Standard Sample Handler***
- ***Snapshot Screen - LAS Carousel Sample Handler***

Snapshot Screen - Standard Sample Handler

For systems configured with the standard sample handler, Figure 2.29 illustrates the Snapshot screen.

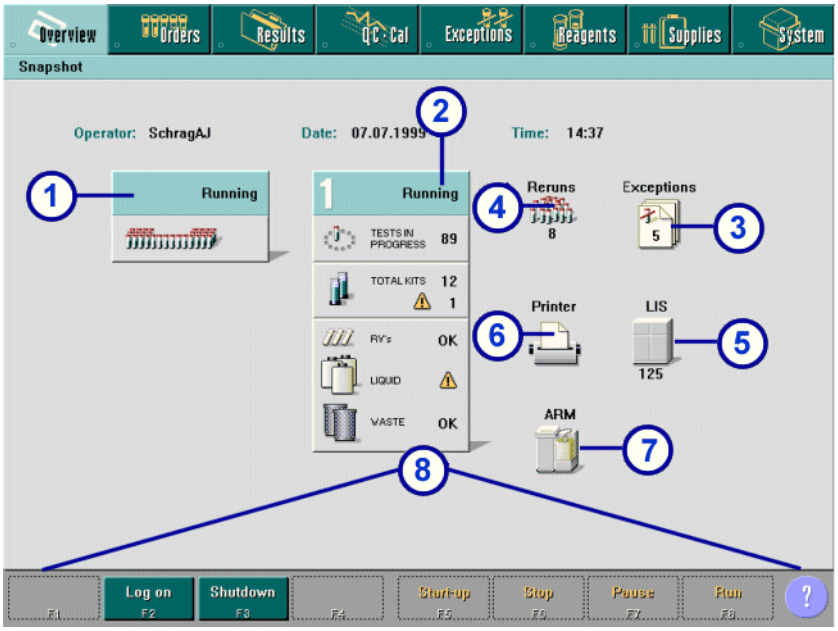


Figure 2.29: Snapshot Screen, Standard Sample Handler

1. Sample handler graphic	**2.** Processing module graphic(s)
3. Exceptions status icon	**4.** Reruns status icon
5. LIS (host) status icon	**6.** Printer status icon
7. ARM status icon	**8.** Function keys

Snapshot Screen - LAS Carousel Sample Handler

For systems configured with the LAS carousel sample handler, Figure 2.30 illustrates the Snapshot screen.

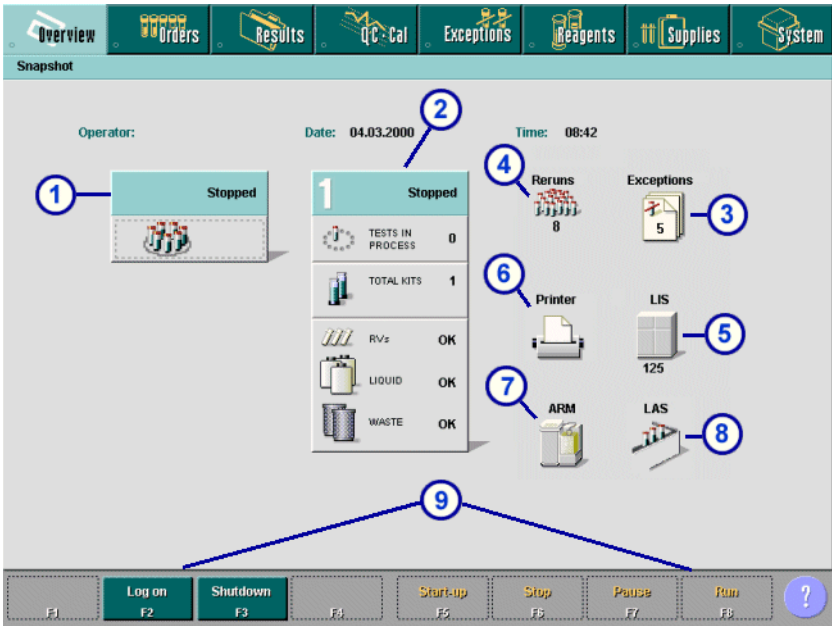


Figure 2.30: Snapshot Screen with LAS Sample Handler

1. Sample handler graphic	**2.** Processing module graphic
3. Exceptions status icon	**4.** Reruns status icon
5. LIS (host) status icon	**6.** Printer status icon
7. ARM status icon	**8.** LAS status icon
9. Function keys	

Processing Module Graphic

The processing module graphic (Figure 2.31) contains key information specific to the processing module, as well as navigational hot spots for accessing related screens. Processing module graphic icons are described in Table 2.1.

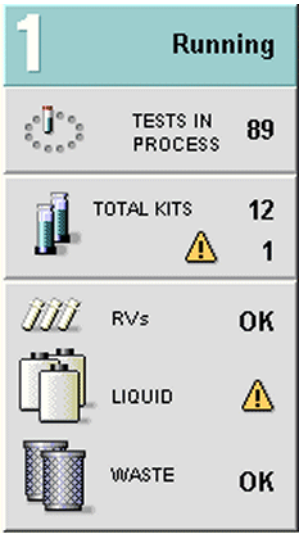
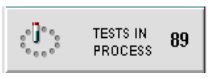


Figure 2.31: Processing Module Graphic

Table 2.1: Processing module graphic icons

Icon	Description
	The module status icon displays the module number (in a multi-module system) and the current status of the module, for example: • Offline • Stopped • Warming • Ready • Running • Scheduled Pause • Initializing • Scanning
	The TESTS IN PROCESS icon displays the number of tests currently processing and assigned to the module. If selected, this icon displays the Order status screen.
	The TOTAL KITS icon displays the total number of reagent kits on the module. If selected, this icon automatically navigates to the Reagent status screen. The caution icon is displayed when you must address a reagent kit problem. The number to the right of the caution icon shows the number of kits with problems.
	This icon displays the status of supplies, including the status of the RVs, LIQUID (bulk solutions), and WASTE (solid) on the processing module. If selected, this icon automatically navigates to the Supply status screen. OK is displayed to indicate inventory status is OK. The caution icon is displayed when an inventory item needs attention.

System Status Icons

The system status icons that display are dependent upon your system configuration. See:

- ***System status icons - standard sample handler***
- ***System status icons - LAS carousel sample handler***

System status icons - standard sample handler

Table 2.2 provides a description of the system status icons for systems configured with a standard sample handler (single or double lane).

Table 2.2: System status icons with standard sample handler configuration

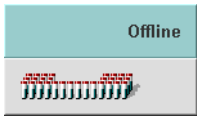
Icon	Description
	The LIS status icon is displayed only when the system is configured to communicate with a host computer. A number is displayed below the icon to indicate the number of results pending transmission to the host. Selecting this icon automatically navigates to the System logs screen. If the caution icon is displayed, review the system logs for associated error messages.
	The ARM status icon is displayed only when the system is configured for use with the ARCHITECT ARM™ (Automatic Reconstitution Module) accessory. Selecting this icon automatically navigates to the System logs screen. If the caution icon is displayed, review the system logs for associated error messages.
	The Printer status icon is displayed only when the system is configured to communicate with a printer. Selecting this icon automatically navigates to the Print options dialog window. If the caution icon is displayed, review the system logs for associated errors.
	The sample handler graphic displays the status of the sample handler as follows: • Offline • Stopped • Ready • Load queue paused • Running • Initializing

Table 2.2: System status icons with standard sample handler configuration *(continued)*

Icon	Description
	The Exceptions status icon displays the number of exceptions waiting to be reviewed. Selecting this icon automatically navigates to the Exception status screen and dialog windows. This icon is only visible when exceptions exist.
	The Reruns status icon displays the number of tests waiting to be rerun, ordered either manually by the operator or automatically by the ARCHITECT *i* System (auto retest). Selecting this icon automatically navigates to the Rerun status screen. This icon is only visible when reruns exist.
	The caution icon appears on top of the LIS, ARM, and/or Printer status icon if an error occurs.

System status icons - LAS carousel sample handler

Table 2.3 provides a description of the system status icons for systems configured with an LAS carousel sample handler (single or double lane).

Table 2.3: System Status Icons with LAS Carousel Sample Handler Configuration

Icon	Description
	The LIS status icon is displayed only when the system is configured to communicate with a host computer. A number is displayed below the icon to indicate the number of results pending transmission to the host. Selecting this icon automatically navigates to the System logs screen. If the caution icon is displayed, review the system logs for associated error messages.
	The ARM status icon is displayed only when the system is configured for use with the ARCHITECT ARM™ (Automatic Reconstitution Module) accessory. Selecting this icon automatically navigates to the System logs screen. If the caution icon is displayed, review the system logs for associated error messages.
	The LAS status icon is displayed only when the system is configured for use with an LAS (laboratory automation system). Selecting this icon automatically navigates to the System logs screen. If the caution icon is displayed, review the system logs for associated error messages.
	The Printer status icon is displayed only when the system is configured to communicate with a printer. Selecting this icon automatically navigates to the Print options dialog window. If the caution icon is displayed, review the system logs for associated error messages.

Table 2.3: System Status Icons with LAS Carousel Sample Handler Configuration *(continued)*

Icon	Description
	The sample handler graphic displays the status of the sample handler as follows: • Offline • Stopped • Ready • Scheduled pause • Running • Initializing
	The Exceptions status icon displays the number of exceptions waiting to be reviewed. Selecting this icon automatically navigates to the Exception status screen and dialog windows. This icon is only visible when exceptions exist.
	The Reruns status icon displays the number of tests waiting to be rerun, ordered either manually by the operator or automatically by the ARCHITECT *i* System (auto retest). Selecting this icon automatically navigates to the Rerun status screen. This icon is only visible when reruns exist.
	The caution icon appears on top of the LIS, LAS, ARM, and/or Printer status icon if an error occurs.

Snapshot Screen Function Keys

The function keys for the Snapshot screen are described in the following table.

Table 2.4: Snapshot Screen Function Keys

	If selected, allows you to log on to the ARCHITECT *i* System. There are different access levels depending on the logon used.
	If selected, allows you to initiate and confirm system control center shutdown.
	If selected, allows you to initiate the startup of the selected processing module(s) and the sample handler.

Table 2.4: Snapshot Screen Function Keys *(continued)*

Stop F6	If selected, allows you to initiate and confirm the stopping of the processing module(s) and the sample handler.
Pause F7	If selected, allows you to initiate and confirm the scheduled pause of the selected processing module(s) and the sample handler.
Run F8	If selected, allows you to initiate a run for the selected processing module(s) and the sample handler.

Menu Hierarchy

The menu hierarchy of the ARCHITECT *i* System user interface is organized using icons with drop-down menus as follows:

Figure 2.32: Interface Menu Icons

The system control center keyboard has a label showing the function key equivalents to the interface menu icons as follows:

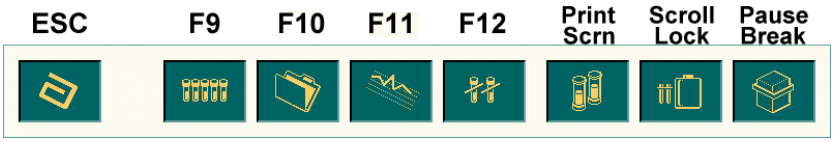


Figure 2.33: Keyboard Label

When you select an icon, a drop-down menu listing each of the available screens in the selected category is displayed. Selecting a menu item displays the associated screen and appropriate function keys.

For more information on each of the drop-down menus, see:

- Overview Icon Menu Options
- Orders Icon Menu Options
- Results Icon Menu Options
- QC-Cal Icon Menu Options
- Exceptions Icon Menu Options
- Reagents Icon Menu Options
- Supplies Icon Menu Option
- System Icon Menu Options

Overview Icon Menu Options

The Overview icon provides access to overall system monitoring data. When you select it, a drop-down menu displays the options shown in Figure 2.34:

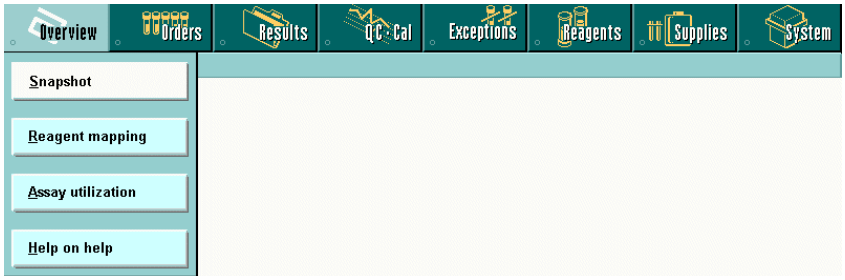


Figure 2.34: Overview Menu

The following options are available from the Overview menu:

- **Snapshot** - Select to obtain system and processing module information. Also provides access to related screens.
- **Reagent mapping** - Not available at this time.
- **Assay utilization** - Not available at this time.
- **Help on help** - Select to access the online ARCHITECT *i* System Operations Manual.

Orders Icon Menu Options

The Orders icon provides access to test ordering functions. When you select it, a drop-down menu displays the following options (Figure 2.35):

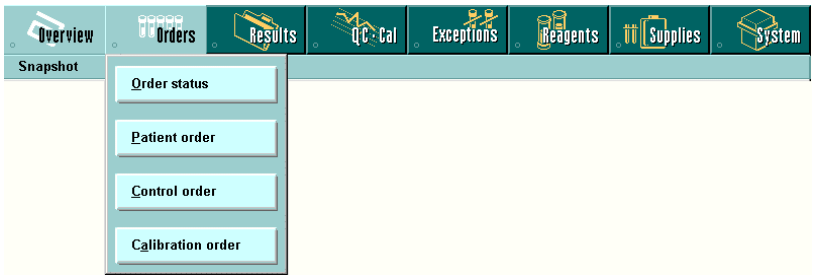


Figure 2.35: Orders Menu

- **Order status** - select to navigate to the Order status screen, which displays information on the patient, control, and calibration orders currently managed by the ARCHITECT *i* System.
- **Patient order** - select to navigate to the Patient order screen, which allows you to enter new patient order information.

- **Control order** - select to navigate to the Control order screen, which allows you to enter single analyte control orders.
- **Calibration order** - select to navigate to the Calibration order screen which allows you to enter a calibration order.

The Orders icon indicator illuminates to notify you that new orders have been downloaded by the host computer and have not been reviewed. The indicator turns off when the new orders are reviewed. To view the orders, access the Order status screen or select the refresh icon from the Order status screen.

Results Icon Menu Options

The Results icon provides access to patient results. When you select it, a drop-down menu displays the following options (Figure 2.36):

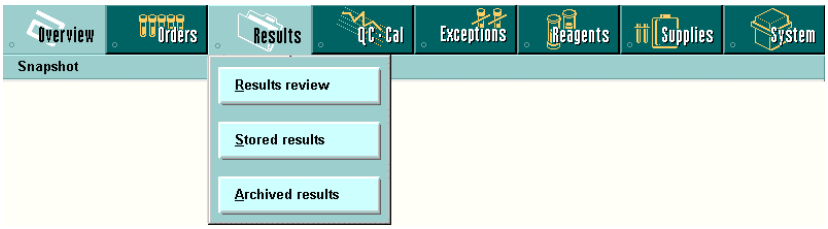


Figure 2.36: Results Menu

- **Results review** - select to navigate to the Results review screen which displays information on the current completed patient results that are waiting to be reviewed and released. From this screen you can select the patient results to rerun.
- **Stored results** - select to navigate to the Stored results screen, which allows you to do the following:
  - View patient results that have been reviewed and released
  - Retransmit patient results to the host computer
  - Archive patient results
- **Archived results** - not available at this time

When illuminated, the Results icon indicator notifies you that results have completed and are waiting to be reviewed prior to release. To view the results, access the Results review screen, or select the refresh icon from the Results review screen.

QC-Cal Icon Menu Options

The QC-Cal icon provides access to QC results, QC graphs, and calibration results. When you select it, a drop-down menu displays the following options (Figure 2.37):

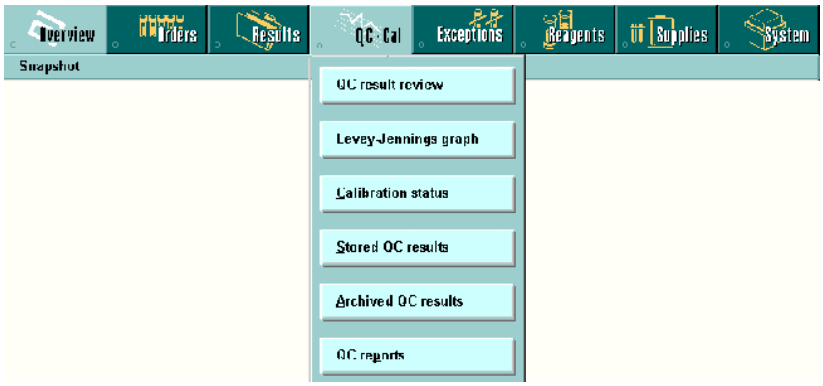


Figure 2.37: QC-Cal Menu

- **QC result review** - select to navigate to the QC result review screen, which displays information on completed QC results awaiting review and release. From this screen you can select the QC results to rerun.
- **Levey-Jennings graph** - allows you to view and manipulate QC data.
- **Calibration status** - select to navigate to the Calibration status screen, which provides a summary list of the current calibration status of each assay and reagent lot for each processing module. You can select and review individual calibration curves.
- **Stored QC results** - select to navigate to the Stored QC results screen, which allows you to do the following:
  - View QC results that have been reviewed and released
  - Retransmit QC results to the host computer
  - Archive QC results
- **Archived QC results** - not available at this time
- **QC reports** - select to navigate to the QC reports screen which allows you to print the QC analysis report. All other QC reports are available through QC result review or Stored QC results.

When illuminated, the QC-Cal icon indicator notifies you that QC samples have completed processing and are awaiting review prior to release. To view the results, access the QC Results review screen or select the refresh icon from the QC Results review screen.

Exceptions Icon Menu Options

The exceptions icon provides access to patient and QC result exceptions. When you select it, a drop-down menu displays the following options (Figure 2.38):

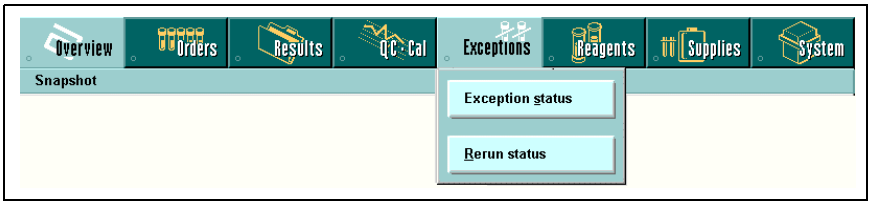


Figure 2.38: Exceptions Menu

- **Exception status** - select to navigate to the Exception status screen, which provides a summary listing of the exceptions that have occurred. From this screen you can select the exception results to rerun.
- **Rerun status** - select to navigate to the Rerun status screen, which provides a listing of the orders that have been requested to be rerun, either manually by the operator or by auto-retest.

When illuminated, the exceptions icon indicator notifies you of the presence of new order exceptions. To view the exceptions, access the Exceptions status screen, or select the refresh icon from the Exceptions status screen.

Reagents Icon Menu Options

The Reagents icon provides access to reagent inventory management functions. When you select it, a drop-down menu displays the following options (Figure 2.39):

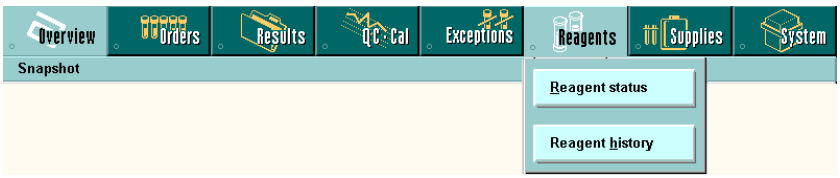


Figure 2.39: Reagents Menu

- **Reagent status** - select to navigate to the Reagent status screen, which provides a summary and listing of the current inventory status of the onboard reagents, and allows you to request a scan of the current reagent kits for a selected processing module.
- **Reagent history** - select to navigate to the Reagent history screen, which provides a historical summary listing of the last 3000 reagent kits that have been scanned by the reagent bar code reader.

When illuminated, the Reagents icon indicator notifies you that a reagent kit has a status other than OK, Mixing or Overridden. The indicator turns off when the status is resolved and all reagent kits onboard have a status of OK, Mixing or Overridden.

Supplies Icon Menu Option

The Supplies icon provides access to reviewing and updating bulk solution and RV inventory, and solid waste management functions. When you select it, a drop-down menu displays the following option (Figure 2.40):

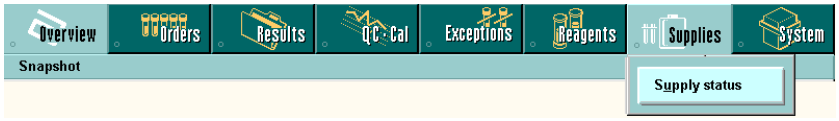


Figure 2.40: Supplies Menu

- **Supply status** - select to navigate to the Supply status screen, which provides inventory information for the onboard supplies for each processing module. This option also allows you to update the status for each item.

When illuminated, the Supplies icon indicator notifies you that an inventory item has a status other than OK. The indicator turns off when the status is resolved and the status of all inventory items onboard is OK.

System Icon Menu Options

The System icon provides the capability to perform system diagnostic and maintenance procedures.

When the System icon is selected, a drop-down menu displays the following options (Figure 2.41):

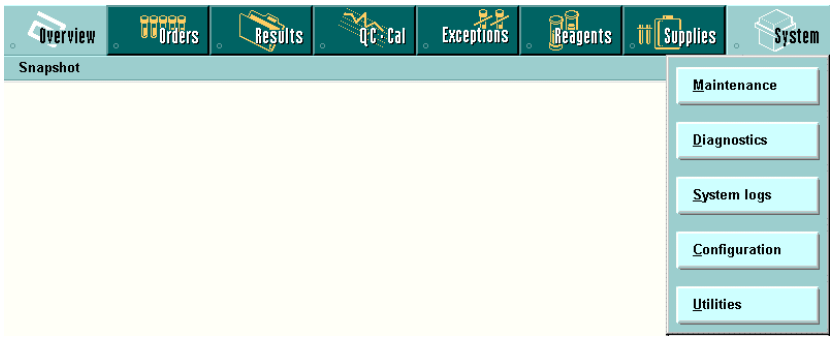


Figure 2.41: System Menu

- **Maintenance** - select to navigate to the Maintenance screen, which allows you to perform system maintenance procedures.
- **Diagnostics** - select to navigate to the Diagnostics screen, which allows you to perform system diagnostic procedures.
- **System logs** - select to navigate to the System logs screen, which allows you to review the Temporary message log, Message history log, and the Host log.
- **Configuration** - select to navigate to the Configuration screen, which allows you to configure system, assay, and QC-Cal parameters. For more information on configuration, see ***Section 3: Communication Setup***, ***Subsection: Setting Communications***.
- **Utilities** - select to navigate to the Utilities screen, which allows you to perform system software maintenance tasks.

When illuminated, the System icon indicator notifies you that a new message has been entered into the Temporary message log. The indicator turns off when the new message is viewed.

System Status

This subsection describes ARCHITECT *i* System status. System status refers to the operational modes of the system. There are two status types:

- Processing Module Status Types
- Sample Handler Status Types

Processing Module Status Types

Processing module status types are displayed at the top of the processing module graphic on the Snapshot screen. Each status is described in Table 2.5.

Table 2.5: Description of Processing Module Status Types

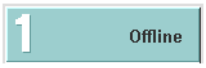
Status	Indicates	Prohibited activities
	One of the following exists: • Power to the processing module is off • Power has been turned on but communication between the processing module and system control center has not been re-established	• You cannot run samples on the module. • You cannot load or unload reagents because the reagent carousel is not aligned correctly. • You cannot load wash buffer.

Table 2.5: Description of Processing Module Status Types *(continued)*

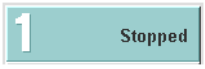
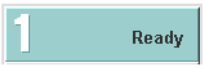
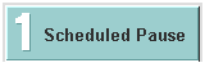
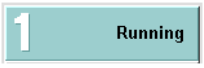
Status	Indicates	Prohibited activities
	One of the following exists: • Power has been turned on but **F5** - **Startup** has not been selected from the Snapshot screen • **F6 - Stop** has been selected from the Snapshot screen • **Stop key** has been selected from the processing module keypad • Processing module diagnostics have been performed • Processing module detected a fatal error while processing	• You cannot run samples on the module. • You cannot load or unload reagents because the reagent carousel is not aligned correctly. • You cannot load wash buffer.
	**F5 - Startup** has been completed and the temperature initialization is not complete	• You cannot run samples on the module.
	One of the following exists: • **F5 - Startup** is complete (including temperature initialization) • Scheduled pause status is complete	
	One of the following conditions exists: • **F7 - Pause** has been selected from the Snapshot screen • **F7 - Replace** has been selected from the Reagent status screen • Supplies ran out • Processing module detected an error while processing	• You cannot open the processing center covers. • You cannot replace Trigger solution or Pre-Trigger solution.
	One of the following functions has been initiated: • **F8 - Run** has been selected from the Snapshot screen • **Run key** has been selected from the processing module keypad	• You cannot open the processing center covers. • You cannot replace Trigger solution or Pre-Trigger solution.

Table 2.5: Description of Processing Module Status Types *(continued)*

Status	Indicates	Prohibited activities
	A temporary status that occurs when the **run key**, **F8 - Run,** or **F5 - Startup** is selected. The following initialization functions are performed by the system: Initialization after selecting **F5 - Startup**: • Homes motors • Initializes the reagent bar code reader • Fills the inner ring of the process path with RVs • Clears any used RVs from the outer ring of the process path Initialization after selecting the **run key** or **F8 - Run**: • Checks door sensors • Scans reagents and starts microparticle dispersion • Washes probes • Checks inventory • Performs a background read Once initialization is complete, the status changes to Running or Ready depending on whether you selected run or startup.	• You cannot run samples on the module. • You cannot load or unload reagents because the reagent carousel is not aligned correctly. • You cannot load wash buffer.
	A temporary status that occurs when **F4 - Scan** has been initiated from the Reagent status screen. Once the scanning is complete, the status changes to Ready.	• You cannot run samples on the module.

Sample Handler Status Types

Sample handler status is displayed at the top of the sample handler graphic on the Snapshot screen. The icons that display are dependent upon your system configuration.

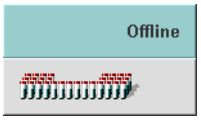
For a description of the sample handler status icons for a system configured with a standard sample handler, see Table 2.6.

For a description of the sample handler status icons for a system configured with an LAS carousel sample handler, see Table 2.7.

Standard sample handler status types

The status types for the standard sample handler are described in the following table.

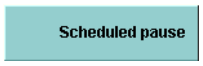
Table 2.6: Description of Standard Sample Handler Status Types

Status	Indicates
	One of the following exists: • Power to the sample handler is off • Power has been turned on but communication between the sample handler and system control center has not been re-established
	One of the following exists: • Power has been turned on, but **F5 - Startup** has not been requested from the Snapshot screen • **F6 - Stop** has been selected from the Snapshot screen • **Stop key** has been selected from the sample handler keypad • Sample handler diagnostic has been completed • One of the processing queue access doors was opened while the sample handler was running
	The following state exists: • **F5 - Startup** is complete
	One of the following functions has been initiated: • **F8 - Run** has been selected from the Snapshot screen • **Run key** has been selected from the sample handler keypad
	One of the following conditions exists: • **F7 - Pause** has been selected from the Snapshot screen • **Pause key** has been selected from the sample handler keypad • After 60 seconds, no samples have been loaded and run has not been initiated • The sample unload and processing queues are full
	A temporary status that occurs when either the **run key**, **F8 - Run,** or **F5 - Startup** is selected. The following initialization functions are performed by the system: • Checks the load and processing queue bar code readers • Homes all moving parts on the sample handler • Starts the load and processing queue Once initialization is complete, the status changes to Running or Ready depending on whether you selected run or startup.

LAS carousel sample handler status types

The status types for the LAS carousel sample handler are described in the following table.

Table 2.7: Description of LAS Carousel Sample Handler Status Types

Status	Indicates
	One of the following exists: • Power to the LAS carousel is off • Power has been turned on but communication between the LAS carousel and system control center has not been established
	One of the following exists: • Power has been turned on, but **F5 - Startup** has not been requested from the Snapshot screen • **F6 - Stop** has been selected from the Snapshot screen • **Stop key** has been selected from the LAS carousel keypad • Sample handler diagnostic has been completed • The LAS carousel cover was opened while the LAS carousel was running
	One of the following exists: • **F5 - Startup** is complete • All samples on the LAS carousel have completed sampling
	One of the following functions has been initiated: • **F8 - Run** has been selected from the Snapshot screen • **Run key** has been selected from the LAS carousel sample handler keypad
	One of the following conditions exists: • **F7 - Pause** has been selected from the Snapshot screen • **Pause key** has been selected from the LAS carousel sample handler keypad **NOTE:** The Pause indicator illuminates.
	A temporary status that occurs when the **run key**, **F8 - Run,** or **F5 - Startup** is selected. The following initialization functions are performed by the system: • Homes the LAS carousel • Checks the processing queue bar code reader Once initialization is complete, the status changes to Running or Ready depending on whether you selected run or startup.

NOTES

ARCHITECT *i* System Support of ASI Options

The following items are defined as optional by the Abbott Standard Interface. The ARCHITECT *i* System supports these items as defined below.

Establishment Phase

During the Establishment Phase, if the ARCHITECT *i* System has information to transmit it attempts to establish a connection with an external host every 75 seconds. After ten attempts to connect to the host, a message is generated and the port is disabled.

Repeat Delimiters

The ARCHITECT *i* System only supports the use of repeat delimiters in the Universal Test ID field during download from a host. The system does not use repeat delimiters when transmitting information to a host.

Query Mode

During Query Mode, if the ARCHITECT *i* System encounters three consecutive host time out errors the Query Mode option is turned off. In order to continue using the Query Mode, the system must be configured to "On with Query" in the Configure Host-Release Mode screen.

Result Transmission

Result transmission is attempted every minute. Up to 40 SIDs can be transmitted in each session.

> **NOTE:** When the ARCHITECT *i* System has information to transmit, it attempts to establish a connection with the host every 75 seconds. After ten unsuccessful attempts to connect to the host, the serial port is disabled.

Calibration Test Orders

Calibration test orders can not be ordered from the host. Calibration results are not transmitted to the host.

ASI Code Page for the ARCHITECT *i* System

Table 2.8 shows the ASI code page supported by the ARCHITECT *i* 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. Certain values are not supported by the ARCHITECT *i* System. These characters are translated to the copyright symbol (©) when received via the host port and again when transmitted to the host system.

Table 2.8: ASI Code Page for ARCHITECT

Decimal		0	16	32	48	64	80	96	112	128	144	160	176	192	208	224	240
	Hex	0	1	2	3	4	5	6	7	8	9	A	B	C	D	E	F
0	**0**	NUL	DLE	SP	0	@	P	`	p	Ç	É	á	*	*	*	Ó	*
1	**1**	SOH	DC1	!	1	A	Q	a	q	ü	æ	Í	*	*	*	ß	*
2	**2**	STX	DC2	"	2	B	R	b	r	é	Æ	ó	*	*	Ê	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	Ì	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	*	*	*	*	*	*	*

* – Unsupported characters.

NOTES

Introduction

This section describes powering the ARCHITECT *i* System and configuring communications to a host computer to meet your site's specific requirements. Configuration is performed at time of installation and may be changed at a later time if necessary.

The following topics are included in this section:

NOTES

System Startup, Pause, and Shutdown

This subsection describes how to pause, shut down, cycle, and remove power to the ARCHITECT *i* System and its components.

Topics include:

- System Control Center Shutdown and Startup
- Processing Module and Sample Handler Cycle Power, Startup, and Pause

System Control Center Shutdown and Startup

The system control center may need to be shut down and powered off prior to:

- SCC component replacement
- Cable or connector reseating
- System configuration

Refer to specific procedures to determine if the SCC must be shut down.

To resume normal operation, you must then start up the SCC.

Shutting Down the System Control Center

Perform this procedure to shut down the SCC (system control center) and to ensure that all data is stored before powering off the system.

This is a short-term shutdown. To shut down the system for more than one week, go to ***Section 2: Installation procedures and special requirements, Subsection: Long-term shutdown***.

> **NOTE:** The sample handler and processing module(s) are not functional when the system control center is off. To prevent flooding when your system is connected to an ARCHITECT ARM™ (Automatic Reconstitution Module) accessory, do not request a Shutdown if the accessory is in the process of filling the wash buffer reservoir. For more information, see ***Section 10: Troubleshooting and Diagnostics, Observed problems, Flood condition***.

To shut down the SCC:

1. From the **Snapshot** screen, ensure that both the sample handler and the processing module status types are **Ready**, **Stopped,** or **Offline**.
2. Select **F3 - Shutdown**.
3. Select **OK** to confirm the shutdown request.
4. When the screen turns blue and a message about shutting down the SCC displays, press the **Ctrl+Alt+Delete** keys simultaneously. A popup message appears.
5. Select **Shutdown**, then **OK**. A message is displayed informing you that the shutdown is complete and it is safe to turn off your computer.
6. Press the power switch on the front of the CPU (central processing unit) to turn off power to the system control center.

Starting Up the System Control Center

To start up the system control center:

1. Before applying power to the system control center, power off the processing module(s).

   NOTE: If processing module(s) power is ON when you power on the system control center, communication is not properly initialized between the system components.

2. Press the power switch to turn on the system control center.

Processing Module and Sample Handler Cycle Power, Startup, and Pause

It may be necessary for you to remove power to the processing module and sample handler to perform certain procedures.

Cycling power involves powering off the processing module and sample handler followed by applying power. Once the power is ON, a startup must be performed to attain a Ready status.

You are required to pause the processing module and sample handler to load samples, reagents, and solutions and to perform maintenance or diagnostic procedures.

Topics include:

Cycling Power to the Processing Module and Sample Handler

In a single module system, the processing module controls power to the sample handler. If you cycle the power to the processing module, you also cycle the power to the sample handler.

In a multi-module system, the processing module attached to the sample unload queue controls power to the sample handler. If you cycle the power to this processing module, you also cycle power to the sample handler.

Use the power switch located on the lower left rear of the processing module (Figure 3.1) to apply and remove power to the processing module.

> **NOTE:** To ensure proper initialization, ensure system control center power is **ON** and the **Snapshot** screen is displayed before turning on the processing module(s)/ sample handler.

Figure 3.1: Location of the Processing Module Power Switch

To power off the processing module in a single module system, go to ***Powering off the processing module in a single module system***.

To power off a processing module in a multi-module system, go to ***Powering off a processing module in a multi-module system***.

To apply power to the processing module and sample handler, go to ***Applying power to the processing module***.

Powering off the processing module in a single module system

To power off the processing module and sample handler:

1. From the **Snapshot** screen, verify that the sample handler and processing module are both in **Ready**, **Stopped,** or **Offline** status. This ensures that the processing of tests is not interrupted. For information on system statuses, see ***Section 1: Use or function, Subsection: System status***.
2. Use the power switch located on the lower left rear of the processing module (Figure 3.1) to power off the module.

   NOTE: Powering off the module also turns off power to the sample handler.

Powering off a processing module in a multi-module system

To power off a processing module:

1. Determine the processing module to turn off.
   - If it is the processing module that is attached to the unload queue, go to ***Powering off the processing module in a single module system***.
   - If it is any other processing module(s), go to Step 2.
2. From the **Snapshot** screen, verify that the processing module(s) you wish to power off is in the **Ready**, **Stopped,** or **Offline** status. This ensures that the processing of tests is not interrupted. For information on system statuses, see ***Section 1: Use or function, Subsection: System status***.
3. Use the power switch located on the lower left rear of the processing module (Figure 3.1) to power off the module(s).

Applying power to the processing module

To apply power to the processing module(s):

1. Ensure that the system control center power is **ON**. For information on SCC startup, see ***Starting Up the System Control Center***.
2. To view the processing module status, ensure that the **Snapshot** screen is displayed on the system control center.
3. Use the power switch located on the lower left rear of the processing module (Figure 3.1) to power on the module(s).

   NOTE: Applying power to the module attached to the unload queue of the sample handler also applies power to the sample handler.

Starting Up the Processing Module and Sample Handler

After power is applied to the processing module and sample handler, a startup must be performed. Perform this procedure to initialize the processing module and sample handler, and to change processing module and sample handler status from Stopped to Ready.

NOTE: Before performing this procedure:

- Power to the system control center, processing module(s), and sample handler must be **ON**.
- Processing module(s) and sample handler status must be **Stopped**.

To start up the processing module(s) and sample handler:

1. From the **Snapshot** screen, select the sample handler graphic and graphic(s) of the processing module(s) that you want to start.
2. Select **F5 - Start-up**.
3. When startup is complete, verify that the sample handler and processing module statuses are **Ready** or **Warming**.

   The sample handler and processing module(s) are now ready to:

   – Load samples or reagents (status may be Ready or Warming)
   – Run initialization (status must be Ready)

Pausing the Sample Load Queue

This procedure changes the status of the standard sample handler from Running to Load queue paused. Perform this procedure to:

- Load a sample carrier
- Priority load a sample carrier
- Request a pause on a processing module

NOTE: This procedure does not pause the processing module(s). For information on pausing a processing module see ***Pausing the Processing Module***.

To pause the sample load queue:

1. From the **Snapshot** screen, select the sample handler graphic, then select **F7 - Pause**. The pause indicator illuminates on the sample handler keypad.

   NOTE: When the sample load queue is paused, the processing queue and unload queue remain active for approximately 20 minutes after the last carrier is unloaded. (For a multi-module system, this time may be increased.) If a run on the sample handler is not initiated during that time, the sample handler status changes to Ready.

2. To priority load a carrier, press the **reverse key** on the sample handler keypad to make space at the front of the sample load queue.
3. To restart the sample load queue, select the sample handler from the **Snapshot** screen, then select **F8 - Run**.

   NOTE: The processing module(s) status must be Running to process samples.

Pausing the LAS Carousel

This procedure changes the status of the LAS carousel sample handler from Running to Ready. Perform this procedure to:

- Priority load a sample or calibrator
- Request a Pause on the processing module

To pause the LAS carousel:

1. From the **Snapshot** screen, select the sample handler graphic, then select **F7 - Pause**. The Pause indicator illuminates on the sample handler keypad.
2. To restart the LAS carousel, select the sample handler graphic from the **Snapshot** screen, then select **F8 - Run**.

   NOTE: The processing module status must be Running to process samples.

Pausing the Processing Module

This procedure changes the status of the processing module from Running to Ready without losing tests currently in process. Perform this procedure when you have to:

- Load reagents
- Load Pre-Trigger solution or Trigger solution
- Perform maintenance or diagnostic procedures

To pause the processing module, go to:

- ***Pausing the processing module - standard sample handler***
- ***Pausing the processing module - LAS carousel sample handler***

Pausing the processing module - standard sample handler

Pause the sample handler to discontinue the transfer of sample carriers. For more information, see ***Pausing the Sample Load Queue***.

To pause the processing module:

1. Wait until all carriers currently in the processing queue are moved to the unload queue.

   NOTE: Failure to pause the sample handler before pausing the processing module causes all tests with a status of Scheduled to be sent to exceptions.

2. From the **Snapshot** screen, select the graphic of the processing module(s) you want to pause, then select **F7 - Pause**.
3. Select **OK** to confirm the pause request.

   NOTE: Do not open the processing module covers until the access indicator on the processing module keypad is illuminated, indicating status is Ready.

4. To resume processing module operation, select the graphic of the processing module(s) you want to resume, then select **F8 - Run**.

Pausing the processing module - LAS carousel sample handler

Pause the LAS carousel to discontinue sampling from the LAS sample carousel. For more information, see ***Pausing the LAS Carousel***.

To pause the processing module:

1. Wait until the sample handler returns to a Ready state.

   NOTE: The processing module completes sampling all calibrator levels and sample replicates before returning to a Ready state. Failure to pause the sample handler before pausing the processing module causes a calibration with a status of Scheduled to be sent to Exceptions.

2. From the **Snapshot** screen, select the processing module graphic, then select **F7 - Pause**.
3. Select **OK** to confirm the pause request.

   NOTE: Do not open the processing module covers until the access indicator on the processing module keypad is illuminated, indicating status is Ready.

4. To resume processing module operation, select the processing module graphic, then select **F8 - Run**.

Setting Communications

This subsection provides information on configuring the ARCHITECT *i* System communication settings to meet your site-specific requirements.

System configuration categories include:

- Host – Release Mode Configuration Windows
- System Control Center Configuration Windows
- Serial Ports Configuration Windows

To access the Configuration screen, select the **System** icon, then select **Configuration** from the drop-down menu (Figure 3.2). The Configuration screen for System settings is displayed (Figure 3.3).

Figure 3.2: Accessing the System Configuration Screen

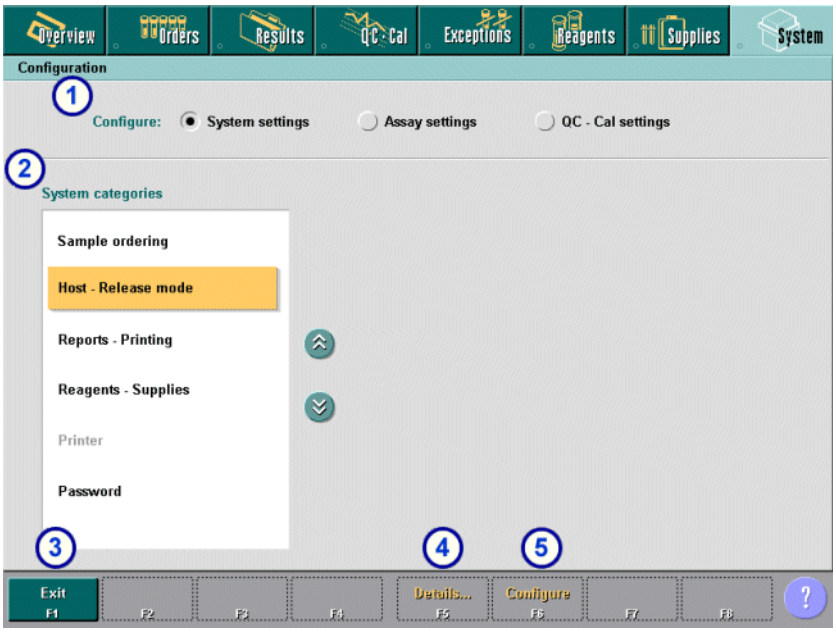


Figure 3.3: Configuration screen - System settings view

1. Configure: Allows you to select one of the following categories for configuration: System settings Assay settings QC-Cal settings	**2.** System categories: Displays the system configuration items. **NOTE**: Printer is not available at this time.
3. F1 - Exit: Allows you to exit to the Snapshot screen.	**4.** F5 - Details: Displays the Details for system parameters dialog windows specific to the system category selected.
5. F6 - Configure: Displays the System configure dialog window specific to the item selected in the System categories list.	

Host – Release Mode Configuration Windows

There are two Host - Release mode windows that allow you to either view or configure the settings for host - release mode.

The Details for host - release mode Dialog Window allows you to view the current settings for bi-directional host communication.

The Configure host - release mode Dialog Window allows the general operator or system administrator to:

- Edit bi-directional host communication configuration settings
- Cancel transmission of results with a status of Pending transmission

For more information on canceling pending transmission orders, refer to ***Section 5***: ***Operating instructions, Subsection***: ***Result transmission***.

Details for host - release mode Dialog Window

The Details for host-release mode window is a read-only window that displays the current settings for release mode and result reporting to a host computer.

To access the Details for host - release mode dialog window, select **Host - Release mode** from the Configuration screen for System settings, then select **F5 - Details**. The Details for host - release mode dialog window is displayed (Figure 3.4).

For information on configuring the settings for host - release mode, see ***Configure host - release mode Dialog Window***.

Figure 3.4: Details for host - release mode Dialog Window

1. Release mode: Displays the current setting for result release mode.	**2.** Host query timeout: Displays the maximum time period (in seconds) that the system waits for the host computer to respond to a query.
3. Communications: Displays the current setting for Bidirectional host transmissions.	**4.** Transmit to host: Displays Collated or Single to indicate the method for transmitting patient results to the host computer. Displays On or Off to indicate that QC results are transmitted to the host computer.
5. Done: Returns to the Configuration screen.	

Configure host - release mode Dialog Window

The Configure host - release mode window allows the general operator or the system administrator to edit the configuration settings for bi-directional host communication.

To access the Configure host - release mode dialog window, select **Host - Release mode** from the Configuration screen for System settings, then select **F6 - Configure**. The Configure host - release mode dialog window is displayed (Figure 3.5).

> **NOTE:** The options on this screen can be changed at any time.

For information on viewing the current settings for host - release mode, see ***Details for host - release mode Dialog Window***.

Figure 3.5: Configure host - release mode Dialog Window

1. Release mode: Allows the general operator to select the release mode for results. Options are: Manual: All results must be manually released. (Default) Hold: All results with flags must be manually released. Automatic: Results are released automatically. Automatic with exceptions: Results and exceptions are automatically released.	**2.** Host query timeout: Allows the general operator to enter the maximum time period that the system will wait for a response after querying the host computer. Range: 5 - 60 seconds Default: 10 seconds **NOTE**: System throughput may degrade if this timeout period is greater than 10 seconds.
3. Communications: Allows the general operator to enable the Bidirectional host mode, so the system can receive orders from and transmit results to a host computer. Options are: On On with query Off (Default) **NOTE**: Turning Bidirectional host **Off** allows you to clear all results waiting to be sent to the host.	**4.** Transmit to host: Allows the general operator to define the results to be transmitted to the host computer. See Table 3.1 for a description of the options.
5. Done: Accepts your selection(s) and returns to the Configuration screen.	**6.** Cancel: Cancels your selection(s) and returns to the Configuration screen.

Table 3.1: Options for Transmitting to Host Computer

Approved patient results (Default: Collated)	
Collated	Allows multiple ASTM records to be sent within a host session. **NOTE:** Results are collated by sample ID. If the release mode is configured for automatic release, results are held in Pending collation status until all the results for a sample ID are released.
Single	Allows for a single result record to be sent within a patient record section of each message.
Approved QC results (Default: Off)	
On	Allows approved QC results to be released to the host computer.
Off	Approved QC results are not sent to host computer. **NOTE**: When the system is configured with the Release mode: Automatic with exceptions and Approved QC results: Off, QC exceptions are transmitted to the host. If the host is not set to accept QC results, the host will NAK these records.

Configuring Host - release mode

To configure Host - release mode, perform the following procedure:

1. Select the **System** icon from the Snapshot screen, then select **Configuration** from the drop-down menu.
2. Select the **System settings** radio button.
3. Select **Host - release mode** from the System categories column.
4. Select **F6 - Configure**. The Configure host - release mode dialog window is displayed.
5. Select settings from this window as appropriate to your ARCHITECT *i* System and host computer.
6. Select **Done** to accept the selections and return to the Configuration screen.

System Control Center Configuration Windows

There are two System control center windows that allow you to either view or configure the settings for the system control center, which include:

- System date
- System time
- Date format
- Daylight savings time
- Number format
- System number
- SCC (system control center) serial number
- System language
- Screen timeout
- Run definition
- Beep volume

The Details for system control center Dialog Window allows you to view the current settings system control center settings.

The Configure system control center Dialog Window allows the system administrator to edit the settings.

Details for system control center Dialog Window

The Details for system control center dialog window is a read-only window that displays the current settings for the system control center.

To access the Details for system control center dialog window, select **System control center** from the Configuration screen for System settings, then select **F5 - Details**. The Details for system control center dialog window is displayed (Figure 3.6).

For information on configuring the settings for the system control center, see ***Configure system control center Dialog Window***.

Figure 3.6: Details for system control center Dialog Window

1. System date: Displays the current system date.	**2.** System time: Displays the current system time.
3. Date format: DIsplays the current date format setting.	**4.** Automatically adjust clock for daylight savings: Checkbox, which if selected, indicates the system automatically adjusts the clock for daylight savings.
5. Number format: Displays the current number format for the thousands separator.	**6.** Architect system no.: Displays the ARCHITECT system number. **NOTE**: This option is only editable by the Abbott service representative.
7. SCC serial no.: Displays the SCC serial number. **NOTE**: This option is only editable by the Abbott service representative.	**8.** System language: Displays the current setting for system language.
9. Screen timeout: Displays the current setting for screen timeout.	**10.** Run definition: Displays the definition of a run which includes start time and number of hours per run. This information is used during Westgard Rule analysis.
11. Beep volume: Displays the beep volume settings for the Alert and Invalid key audible tones. **NOTE**: Only visible if your system is configured with speakers.	**12.** Done: Returns to the Configuration screen.

Configure system control center Dialog Window

The Configure system control center window allows the system administrator to edit the configuration settings for the system control center.

To access the Configure system control center dialog window, select **System control center** from the Configuration screen for System settings, then select **F6 - Configure**. The Configure system control center dialog window is displayed (Figure 3.7).

For information on viewing the current settings for the system control center, see ***Details for system control center Dialog Window***.

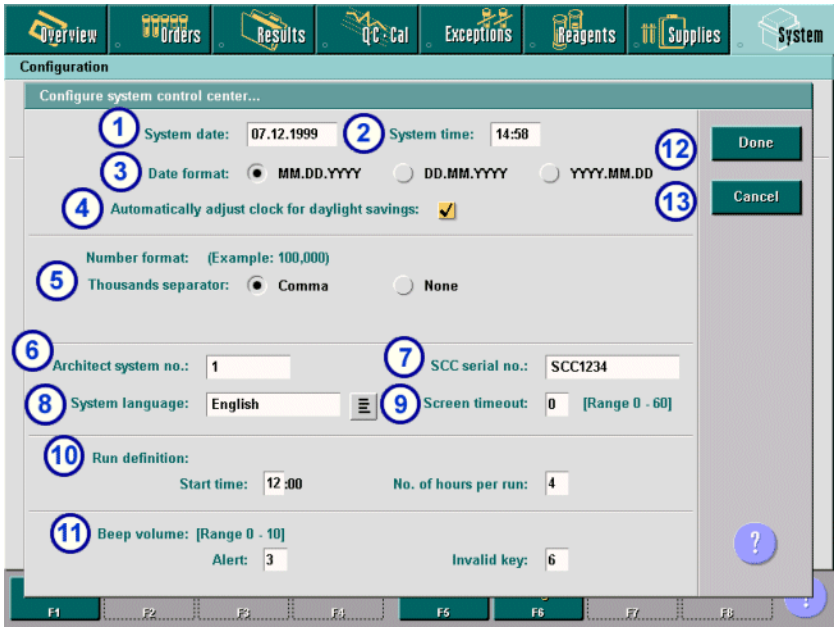


Figure 3.7: Configure system control center Dialog Window

1. System date: Allows you to edit the system date.	**2.** System time: Allows you to edit the system time.
3. Date format: Allows you to edit the date format setting. Options are: MM.DD.YYYY (Default) DD.MM.YYYY YYYY.MM.DD	**4.** Automatically adjust clock for daylight savings: Allows you to select the checkbox to automatically adjust the clock for daylight savings. (Default checked) **NOTE**: When an edit is made to this field, the SCC must be shut down and restarted before the change takes effect.
5. Number format: Allows you to select the number format for the thousands separator. Options are: Thousands separator - Comma None (Default) **NOTE:** Previously generated results are not updated to the new format.	**6.** Architect system no.: Allows the Abbott service representative to enter the ARCHITECT serial number.
7. SCC serial no.: Allows the Abbott service representative to enter the SCC serial number.	**8.** System language: Allows the general operator to select the system language. Option is: English

9. Screen timeout: Allows the general operator to edit the setting for screen timeout. Range: 0 - 60 minutes Default: 0 **NOTE**: System generated information or alert pop-ups do not remove the screen saver. To restore the screen, press **Enter** on the keyboard.	**10.** Run definition: Allows the general operator to enter the run definition which includes start time and number of hours per run. This information is used during Westgard Rule analysis. Default settings are: Start time, 6:00 Hours per run, 12
11. Beep volume: Allows the general operator to enter a value for the beep volume of the following audible tones: Alert (occurs when an alert popup is displayed) Invalid key (occurs when an invalid keyboard key is pressed) Range: 0 – 10 Default: 5 **NOTE**: This setting is only available if your system is configured with speakers.	**12.** Done: Accepts your selection(s) and returns to the Configuration screen.
13. Cancel: Cancels your selection(s) and returns to the Configuration screen.	

NOTE: If a date is entered when you change the date format, the new format does not appear in the system date field until you select **Done** and the dialog window is accessed again.

Serial Ports Configuration Windows

There are two Serial ports windows that allow you to either view or configure the settings for serial ports.

The Details for serial ports Dialog Window allows you to view the current configuration settings for the serial ports.

The Configure serial ports dialog window allows the system administrator to edit the settings.

Details for serial ports Dialog Window

The Details for serial ports window is a read-only window that displays the current configuration settings for the system's serial communications ports.

To access the Details for serial ports dialog window, select **Serial ports** from the Configuration screen for System settings, then select **F5 - Details**. The Details for serial ports dialog window is displayed (Figure 3.8).

For information on configuring the settings for serial ports, see ***Configure serial ports dialog window***.

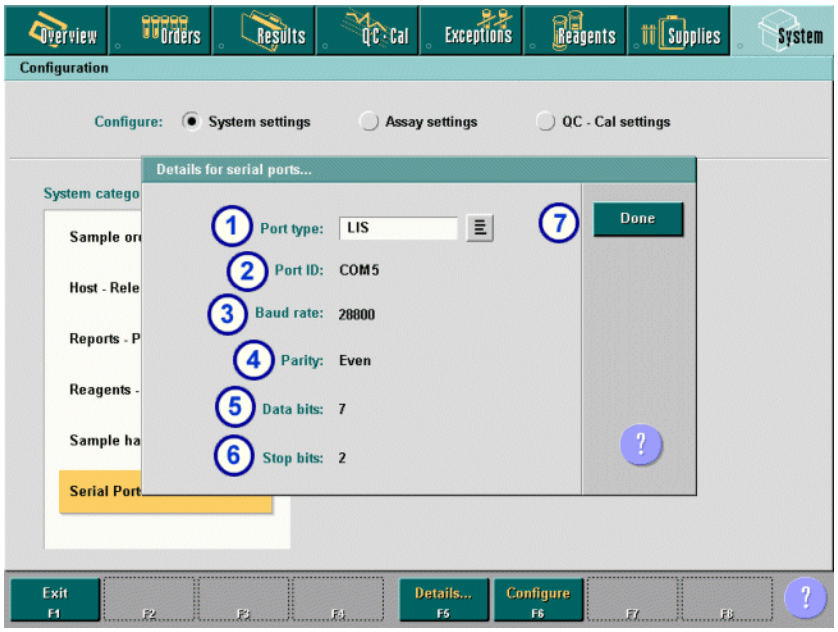


Figure 3.8: Details for serial ports Dialog Window

1. Port type: Displays the selected port type supported by the system. Select the list box icon to view all port types.	**2.** Port ID: Displays the unique ID and the communication connector number for the port.
3. Baud rate: Displays the selected baud rate.	**4.** Parity: Displays the selected parity.
5. Data bits: Displays the selected data bits.	**6.** Stop bits: Displays the selected stop bits.
7. Done: Returns to the Configuration screen.	

Configure serial ports dialog window

The Configure serial ports window allows the system administrator to edit the configuration settings for the serial ports.

To access the Configure serial ports dialog window, select **Serial ports** from the Configuration screen for System settings, then select **F6 - Configure**. The Configure serial ports dialog window is displayed (Figure 3.9).

For information on viewing the current settings for serial ports, see ***Details for serial ports Dialog Window***.

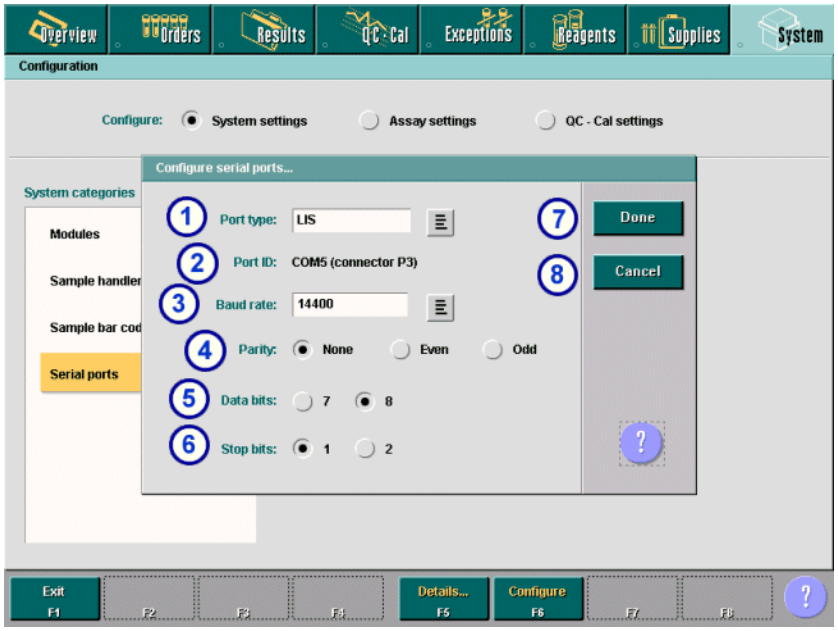


Figure 3.9: Configure serial ports Dialog Window

1. Port type: Allows you to select the list icon to view the port types supported by the system, then select the desired port types. Options are: LIS (Default) ARM LAS	**2.** Port ID: Displays the unique ID for the port. Options are: COM5 (LIS) Connector P3 (Default) COM6 (LAS) Connector P4 COM7 (ARM) Connector P5
3. Baud rate: Allows you to enter the baud rate for the selected port. Options are: 1200 2400 4800 9600 (Default) 14400 19200 28800 **NOTE**: Baud rate is not editable for the ARCHITECT ARM™ serial port.	**4.** Parity: Allows you to select from the following parity options: None (Default) Even Odd **NOTE**: Parity is not editable for the ARCHITECT ARM™ serial port.
5. Data bits: Allows you to select from the following options: 7 8 (Default) **NOTE**: Data bits are not editable for the ARCHITECT ARM™ serial port.	**6.** Stop bits: Allows you to select from the following options: 1 (Default) 2 **NOTE**: Stop bits are not editable for the ARCHITECT ARM™ serial port.
7. Done: Accepts your selection(s) and returns to the Configuration screen.	**8.** Cancel: Cancels your selection(s) and returns to the Configuration screen.

Configuring serial ports

To configure Serial Ports, perform the following procedure:

1. Select the **System** icon from the Snapshot screen, then select **Configuration** from the drop-down menu.
2. Select the **System settings** radio button.
3. Select **Serial Ports** from the System categories column.
4. Select **F6 - Configure**. The Configure serial ports dialog window is displayed.
5. Select **Host / LIS** as the Port type. If necessary, click the List box button to display serial port options.

   The port assigned to the Host / LIS is automatically selected.
6. Type in the **Baud rate** appropriate to the host computer.
7. Select the **Parity** radio button appropriate to the host computer.
8. Select the **Data bits** radio button appropriate to the host computer.
9. Select the **Stop bits** radio button appropriate to the host computer.
10. Select **Done** to accept the selections and return to the Configuration screen.

NOTES

Introduction

This section outlines the ASTM records and field contents needed to establish communication from the ARCHITECT *i* System to a host computer.

Topics include:

- Communication: ARCHITECT i System to Host
- Unicode Support

For information on communicating from the host to the ARCHITECT *i* System, refer to **Section 5: ARCHITECT *i* System-specific Incoming Messages.**

NOTES

Communication: ARCHITECT *i* System 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 is attempted every minute. Up to 40 SIDs can be transmitted in each session.

QC Results Transmission

Successfully completed QC results are transmitted from the ARCHITECT *i* System to the host when Approved QC Results is configured to On. The default is Off. The record hierarchy is the same format as for single approved patient results, see Patient Results Transmission.

Patient Results Transmission

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

1. Single Approved Patient Result:
   Each result is sent as a separate message. Multiple messages may be contained in a single session. When the user-configurable option “Approved Patient Results” is set to “Single”, the record hierarchy of outgoing messages, sent by the ARCHITECT *i* System, is as follows:

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

2. Collated Approved Patient Results:
   If the user-configurable option “Approved Patient Results” is set to “Collated”, multiple ASTM records are sent within a host session. The record 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

Exceptions transmission

Tests for which results cannot be calculated are transmitted from the ARCHITECT *i* System to the host according to one of the following logical record hierarchies depending on the setting of the "Approved patient results" option. 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.

1. "Approved Patient Results" (or QC Results) = "Single". Single results are sent in separate messages.

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

2. "Approved Patient Results" = "Collated"
   Multiple results are sent within a Patient Record section of a single message as follows:

   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 "Bidirectional Host" is set to "On with Query", ARCHITECT *i* System issues Request Information Records for patient samples that do not have pending orders stored on ARCHITECT *i* System. These Request Information Records (Order Queries) are sent during a run when a sample is encountered. The record hierarchy for an Order Query is as follows:

Message Header Record
Request Information Record
Message Terminator Record

Logical Transmission Error Recovery Requirements

Data will be presumed to be saved at the host whenever any decremental change in the hierarchical level is observed.

The example below illustrates the decremental change in the hierarchical level that defines the point where the data is presumed to be saved at the host. At these level changes, all the data received, not including the record at which the decremental change occurred, is saved. In the example below at the left, storage would occur at points E, G, I, M, O, Q and T. (Refer to *ASTM E 1394-91 standard, section 5.2)*

In order to fulfill hierarchical record level requirements, all logical records necessary to reach the restart record point will be sent prior to transmitting the record where line failure originally occurred. A list of which records would be resent in case of a transmission failure is shown at the right.

Line #	Record Type	(Level)	Increment	Action of Host:
A	Header	(Level 0)	+0	
B	Patient1	(Level 1)	+1	
C	Order1	(Level 2)	+1	
D	Result1	(Level 3)	+1	
E	Order2	(Level 2)	–1	⟵ at this point, saves A thru D
F	Comment1	(Level 3)	+1	
G	Order3	(Level 2)	–1	⟵ at this point, saves E thru F
H	Comment1	(Level 3)	+1	
I	Patient2	(Level 1)	–2	⟵ at this point, saves G thru H
J	Order1	(Level 2)	+1	
K	Result1	(Level 3)	+1	
L	Comment1	(Level 4)	+1	
M	Result2	(Level 3)	–1	⟵ at this point, saves I thru L
N	Result3	(Level 3)	+0	
O	Order2	(Level 2)	–1	⟵ at this point, saves M thru N
P	Comment1	(Level 3)	+1	
Q	Patient3	(Level 1)	–2	⟵ at this point, saves O thru P
R	Order1	(Level 2)	+1	
S	Result1	(Level 3)	+1	
T	Terminator	(Level 0)	–3	⟵ at this point, saves Q thru S

(Terminator record is assumed as saved.)

Line # where failure occurred	ARCHITECT would retransmit:
A	A
B	AB
C	ABC
D	ABCD
E	ABCDE
F	ABEF
G	ABEFG
H	ABGH
I	ABGHI
J	AIJ
K	AIJK
L	AIJKL
M	AIJKLM
N	AIJMN
O	AIJMNO
P	AIOP
Q	AIOPQ
R	AQR
S	AQRS
T	AQRST

Figure 4.1: Example of Logical Transmission Error Recovery (ARCHITECT® to Host)

NOTE: If the System Control Center is shutdown in the middle of a transmission, all test results are re-sent to the host from this session once the System Control Center is restarted.

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

The following table details the exact format of the Message Header Record which shall be sent by the ARCHITECT *i* System to the Host.

Table 4.1: Message Header: ARCHITECT *i* System 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	9	ARCHITECT	Instrument Name
	Software Version	4	^Version Number (numeric)	Version number in the format 1.23
	Serial Number	25	^Serial Number (alphanumeric)	SCC Serial Number
	Interface Version	16	^Interface Version (alphanumeric)	Record types the system supports
7.1.12	Processing ID	1	P	Production: Treat message as an active message to be completed according to standard processing
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|\^&|||ARCHITECT^1.00^123456789^H1P1O1R1C1Q1L1||||||P|1|19930330133346[CR]
```

Figure 4.2: Example of Message Header Record: ARCHITECT *i* System to Host

Patient Information Record

The following table details the exact format of the Patient Information Record which shall be sent by the ARCHITECT *i* System to the Host.

Table 4.2: Patient Information Record: ARCHITECT *i* System to Host

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	20	Printable String	Returned unchanged during transmission to the host
8.1.4	Laboratory-Assigned Patient ID	20	Printable String	Returned unchanged during transmission to the host
8.1.5	Patient ID No. 3	20	Printable String	• Optional for Patient test orders • Empty for Control test orders
8.1.6	Patient Name	20	Last (printable string)	• Last, first, and middle patient name • Optional for Patient test orders • Default = empty field • Empty for Control test orders
		20	^First (printable string)	
		12	^Middle (printable string)	
8.1.8	Birth date	8	YYYYMMDD	• Patient birth date • Optional for Patient test orders • Empty for Control test orders.
8.1.9	Patient Sex	1	M, F, U	• Patient's sex (Male, Female, Unknown) • Optional for Patient test orders. • Default = unknown • Empty for Control test orders

```
P|1|||PIDSID13|PATIENT^IM^A||19320122|F[CR]
```

Figure 4.3: Example of Patient Information Record: ARCHITECT *i* System to Host

```
P|1<CR>
```

Figure 4.4: Example of Control Information Record: ARCHITECT *i* System to Host

Test Order Record

The following table details the exact format of the Test Order Record which shall be sent by the ARCHITECT *i* System to the Host.

Table 4.3: Test Order Record: ARCHITECT *i* System to Host

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	20	Printable String	Sample ID downloaded from Host, returned unchanged to the host
9.4.4	Instrument specimen ID	20	Printable String	Instrument Specimen ID, Carrier_ID and Position are returned for all specimen tested, although Instrument Specimen ID maybe different than Specimen ID in 9.4.3 if changed by operator or scanned by the Instrument.
	Carrier ID	4	^alphanumeric	
	Position	2	^numeric	
9.4.5	Universal Test ID Code	3	^^^Assay Number (numeric)	Specific number that identifies the test
	Name	10	^Assay Name (printable string)	Test name
	Assay Protocol	10	^Dilution (printable string)	Dilution protocol name
	Assay Status	1	^Status (P, p, C or c)	Assay status: • P or p if assay is installed as the primary version • C or c if the assay is installed as the correlation version
9.4.6	Priority	1	S *or* R	STAT Routine
9.4.12	Action Code	1	Q	• Quality Control Result • Empty for Patient result
9.4.26	Report Types	1	F *or* X	Final Result Test could not be performed

```
O|1|SID13|SID13^A123^5|^^^123^Assay1^UNDILUTED^P|R|||||||||||||||||||F[CR]
```

Figure 4.5: Example of Test Order Record (Patient): ARCHITECT i System to Host

```
O|1|TSHBIORAD 2|TSHBIORAD 2^A123^2|^^^0241^TSH^UNDILUTED^P|R|||||Q||||||||||||F[CR]
```

Figure 4.6: Example of Test Order Record (Control): ARCHITECT *i* System to Host

The Report Type field (9.4.26) of the Test Order Record contains an X, when the test request cannot be processed. A comment record follows the order record and specifies the reason why the test could not be done.

Result Record

The following table details the exact format of the Result Record which shall be sent by the ARCHITECT *i* System to the Host.

The system shall be capable of transmitting Patient and Control test results to an Host systems.

Separate Result Records identifiable by Universal Test ID shall be sent for each of the following (since multiple result records may be sent for a single test result):

- The final result (concentration)
  — *Result type "F" in field 10.1.3*
- An optional interpretation
  — *Result type "I" in field 10.1.3*
- The instrument response used to calculate a concentration/result. (This Record is not sent for derived results.)
  — *Result type "P" in field 10.1.3*

A Comment record shall follow a Result Record type F if information is entered into the comment section of the Patient or Results Review screen.

Table 4.4: Result Record: ARCHITECT *i* System 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	5	1 to 65535	Must be consistent with sequence number rules.

Table 4.4: Result Record: ARCHITECT *i* System to Host *(continued)*

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
10.1.3	Universal Test ID Code	3	^^^Assay Number (numeric)	Specific number that identified the test
	Name	10	^Assay Name (printable string)	Test name
	Assay Protocol	10	^Dilution (printable string)	Dilution protocol name
	Assay Status	1	^ Status (P, p, C or c)	Assay Status: • P or p if assay is installed as primary version • C or c if assay is installed as correlation version
	Reagent Lot	15	^ alphanumeric	Reagent Master Lot # (empty for derived results)
	Reagent Serial Number	10	^numeric	Serial number of reagent kit used to process the test result (empty for derived results)
	Control Lot Number	15	^alphanumeric	Lot number of the control material (empty for patient results and derived results)
	Result Type	1	^F	Final result concentration or result
			or	
			P	Preliminary instrument result (RLU)
			or	
			I	Interpreted result for a Qualitative test
10.1.4	Data Value	15	Printable String	For Result Type F (concentration value if within dynamic range)
				For Result Type P (numeric response)
				For Result Type I (interpretation)
10.1.5	Units	7	Result Units (printable string)	Result Type F
			or	
			RLU (printable string)	Result Type P
			or	
			Empty	Result Type I
10.1.6	Reference Ranges	25	Normal/Therapeutic Ranges (printable string formatted as minimum value to maximum value)	For Result Type F for Patient Result
			or	
			Control Range (printable string formatted as minimum value to maximum value)	For Result Type F for Control Result
			or	
			Empty	For Result Type I or P and for Result Type F, if range undefined.

Table 4.4: Result Record: ARCHITECT *i* System to Host *(continued)*

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
10.1.7	Result Abnormal Flags	25	LOW or HIGH	Less than or greater than normal therapeutic ranges (for Patient results). Sent only when Result Type in field 10.1.3 is **F**.
			LL or HH	Less than or greater than extreme range (for Patient results). Sent only when Result Type in field 10.1.3 is **F**.
			< or >	Less than or greater than dynamic range of the assay (for Patient and Control results). Sent only when Result Type in field 10.1.3 is **F**.
			EXP	Expired Reagent (for Patient, Calibrator and Control results). Sent only when Result Type in field 10.1.3 is **P**.
			CNTL	Result based on a Control has a Westgard failure rating (for Patient results). Sent only when Result Type in field 10.1.3 is **P**.
			WESTGARD ANALYSIS FLAGS 1-2s 1-3s 2-2s 1R 1M 2-2s 1R xM 2-2s xR 1M R-4s 4-1s 1M 4-1s xM 10x 1M 10x XM	Contains the name of the evaluated and “failed” Westgard Rule (for Control results). Sent only when Result Type in field 10.1.3 is **P**.
			CORR	Correlation assay results. Sent only when Result Type in field 10.1.3 is **P**.
			IUO	Investigational Use Only. Sent only when Result Type in field 10.1.3 is **P**.
10.1.9	Result Status	1	F	Final Results
			or	
			R	Previously Transmitted Results
10.1.11	Operator Identification	12	Order Operator ID (alphanumeric)	ID of Operator logged into system at time of order
		12	^Release Operator ID (alphanumeric)	ID of Operator logged in at time of result release
10.1.13	Date/Time Test Complete	14	YYYYMMDDHHMMSS	
10.1.14	Instrument Identification	25	Alphanumeric	Serial # of the module which performed the test.

```
R|1|^^^0021^B-hCG^UNDILUTED^P^47331M100^00788^^F|<1.20|mIU/mL|0.35 TO
4.94|<||F||||19990715081030|I20100[CR]
```

Figure 4.7: Example of Result Record (Result Type F) for a Patient Result: System to Host

```
R|2|^^^0021^B-hCG^UNDILUTED^P^47331M100^00788^^I|NEGATIVE|||||F||||
19990715081030|I20100[CR]
```

Figure 4.8: Example of Result Record (Result Type I) for a Patient Result: System to Host

```
R|3|^^^0021^B-hCG^UNDILUTED^P^47331M100^00788^^P|9245|RLU||||F||||
19990715081030|I20100[CR]
```

Figure 4.9: Example of Result Record (Result Type P) for a Patient Result: System to Host

```
R|1|^^^0241^TSH^UNDILUTED^P^0607M200^01824^40080^F|4.6011|mIU/mL|4.292500 TO
5.397300|||F||ECB^RY||19990715081030|I20100[CR]
```

Figure 4.10: Example of Result Record for a Control Result: System to Host

The following list of field contents of 10.1.7 (Result Abnormal Flags) are not part of the ASTM standard: EXP, CORR, the Westgard Analysis flags (1-2S, 1-3S, 2-2S, R-4S, 4-1S, 10X), IUO.

NOTE: The number format for the P value is transmitted as configured by the user. Options are:
Comma
None

Comment Record

The following table details the exact format of the Comment Record which shall be sent by the ARCHITECT *i* System to the Host.

Table 4.5: Comment Record: ARCHITECT *i* System 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	5	1 to 65535	Must be consistent with sequence number rules
11.1.3	Comment Source	1	I	Instrument
11.1.4	Comment Text	400	Printable String	Result Comment or Exception String

Table 4.5: Comment Record: ARCHITECT *i* System to Host *(continued)*

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
11.1.5	Comment Type	1	G	Result Comment
			or	
			I	Exception String

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

Figure 4.11: Example of Comment Record: ARCHITECT *i* System to Host

Request Information Record

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

The following table details the exact format of the Request Information Record which shall be sent by the ARCHITECT *i* System to the Host.

Table 4.6: Request Information Record: ARCHITECT *i* System 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	ID Number	20	^Specimen ID	Sample ID read from the bar code label on the sample tube
12.1.5	Universal Test ID	3	^^^ALL	System will always request that ALL outstanding orders be sent
12.1.13	Status Code	1	O	System only requests Orders

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

Figure 4.12: Example of Request Information Record: ARCHITECT *i* System to Host

Message Terminator Record

The following table details the exact format of the Message Terminator Record which shall be sent by the ARCHITECT *i* System to the Host.

Table 4.7: 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 4.13: Example of Terminator Record: ARCHITECT *i* System to Host

NOTES

Unicode Support

NOTE: The following information does not apply to the ARCHITECT *i* System as supplied at market launch. Unicode will be supported in a future version of ARCHITECT *i* System software.

The ARCHITECT *i* System host interface port can be configured to transmit and receive 8 or 16 bit characters. Sixteen bit characters are encoded using Unicode. All eight bit characters assume use of the Code Page 850 (same as AxSYM).

Control Characters

When the ARCHITECT *i* System host interface port is configured to support UNICODE, all control characters ([ENQ], [ACK], [NAK], [STX], [ETB], [ETX], [EOT]) are represented using sixteen bits.

UNICODE ASTM Frames

When the ARCHITECT *i* System host interface port is configured to support UNICODE, the maximum length of an ASTM frame will have the same limitation of 240 characters as with standard ASCII, but requires 480 bytes of transmitted data.

Checksum

When the ARCHITECT *i* System host interface port is configured to support UNICODE, the checksum will be encoded as four characters sent after the ETB or ETX character. The checksum is computed by adding the binary values of the characters (modulo 65536), keeping the least significant 16 bits of the result. The 16 bits are considered as 4 groups of 4 bits. Each group is converted to a character representing a hexadecimal number. The four characters are transmitted as the checksum in order of numeric significance. Each of the checksum characters is represented using 16 bits.

NOTES

Introduction

This section outlines the ARCHITECT *i* System records and field contents needed to establish communications from a host computer to the ARCHITECT *i* System.

For information on communicating from the ARCHITECT *i* System to a host computer refer to ***Section 4: ARCHITECT i System-specific Outgoing Messages.***

NOTES

Communication: Host to the ARCHITECT *i* 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 ARCHITECT *i* System.

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

Message Header Record
Patient Information Record
Test Order Record
Patient Information Record
Test Order Record
Test Order Record
Comment Record (optional)
Patient Information Record
Comment Record (optional)
Test Order 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) utilizes 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 ARCHITECT *i* System, with the Status Code field set to X.

If a record received by the ARCHITECT *i* System:

- Is missing a required field as defined in this section
- Is not defined for ARCHITECT *i* System incoming messages
- Has an invalid sequence number

- Has one or more fields or components that do not conform to requirements as defined further in this section

…an error will be logged and the remainder of the message, up to the message terminator record, will be ignored. Records that were received prior to this record will be accepted and processed further.

Format Detail

The ARCHITECT *i* System recognizes only fields associated with the following records:

- Logical Transmission Error Recovery Requirements
- Message Header Record
- Patient Information Record
- Request Information Record
- Test Order Record
- Comment Record
- Message Terminator Record

The following records are not used by the ARCHITECT *i* System:

- Scientific Record
- Manufacturer Information Record

Logical Transmission Error Recovery Requirements

The ARCHITECT *i* System stores segments of the message as received, according to the following criteria:

- At decremental changes in the hierarchical level. Any unsaved data is saved prior to this record.
- At receipt of a test order. Any unsaved test order record and associated comment record(s) received prior to this record are saved.

According to the hierarchical record level requirements, all logical records necessary to reach the point [record] where transmission failure occurred must be retransmitted.

An example message, showing save points, is provided below at left. A list of which records would need resending in case of transmission failure is shown at right.

Line #	Record Type	(Level)	Increment	Action by ARCHITECT:
A	Header	(Level 0)	+0	
B	Patient1	(Level 1)	+1	
C	Order1	(Level 2)	+1	
D	Order2	(Level 2)	+0	← at this point, saves A thru C
E	Comment1	(Level 3)	+1	
F	Order3	(Level 2)	–1	← at this point, saves D thru E
G	Comment1	(Level 3)	+1	
H	Patient2	(Level 1)	–2	← at this point, saves F thru G
I	Order1	(Level 2)	+1	
J	Order2	(Level 2)	+0	← at this point, saves H thru I
K	Comment1	(Level 3)	+1	
L	Patient3	(Level 1)	–2	← at this point, saves J thru K
M	Comment1	(Level 2)	+1	
N	Order1	(Level 2)	+0	
O	Comment1	(Level 3)	+1	
P	Terminator	(Level 0)	–3	← at this point, saves L thru O

(Terminator record is assumed as saved.)

Line # where failure occurred	ARCHITECT would require retransmission of:
A	A
B	AB
C	ABC
D	ABCD
E	ABDE
F	ABDEF
G	ABFG
H	ABFGH
I	AHI
J	AHIJ
K	AHJK
L	AHJKL
M	ALM
N	ALMN
O	ALMNO
P	ALMNOP

Figure 5.1: Example of Logical Transmission Error Recovery (Host to ARCHITECT®)

Message Header Record

Table 5.1: Message Header: Host to ARCHITECT *i* System

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	4		Bytes 2 and 6 of the record must be the same.
7.1.12	Processing ID	1	P or p	Production: Treat message as an active message to be completed according to standard processing
7.1.13	Version Number	1	1	Must be 1

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

Figure 5.2: Example of Message Header Record: Host to ARCHITECT *i* System

NOTE: The default delimiters (|\& ^) are always accepted even when different delimiters are specified in the host. Use only these delimiters for ARCHITECT *i* System software version 1.60 and below.

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 ARCHITECT *i* System.

Patient Information Record

The following table details the exact format of the Patient Information Record which shall be sent by the Host to the system.

Table 5.2: Patient Information Record: Host to ARCHITECT *i* System

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	20	Printable String	• Returned unchanged during transmission to the host • Optional for Patient test orders • Default = empty field • Empty for Control test orders
8.1.4	Laboratory-Assigned Patient ID	20	Printable String	• Returned unchanged during transmission to the host • Optional for Patient test orders • Empty for Control test orders
8.1.5	Patient ID No. 3	20	Printable String	• Optional for Patient test orders • Empty for Control test orders
8.1.6	Patient Name	20	Last (printable string)	• Last, first, and middle patient name for Patient test orders • Default = empty field • Empty for Control test orders
		20	^First (printable string)	
		12	^Middle (printable string)	
8.1.8	Birth Date	8	YYYYMMDD	• Patient birth date • Optional for Patient test orders • Empty for Control test orders.
8.1.9	Patient Sex	1	M, F, U	• Patient sex (Male, Female, Unknown) • Optional for Patient test orders • Default = Unknown • Empty for Control test orders.

Examples:

Patient Test Order

```
P|1|Practice PID|Lab PID||Doe^John^Q||19320122|F[CR]
```

Figure 5.3: Example of Patient Information Record: Host to ARCHITECT *i* System

Control Test Order

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

Figure 5.4: Example of Patient Information Record for a control: Host to ARCHITECT *i* System

NOTE: If the Date of birth field is left empty, the age defaults to 0.

The field contents of Practice Assigned Patient ID (8.1.3) shall 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) shall 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

The ARCHITECT *i* System Control Center will accept unsolicited Patient and Control test orders from the LIS host regardless of whether the host query option is enabled or not.

The assay name field is dropped from the Test Order Record when the assay name 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.

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

- Use of Repeat Delimiter in Universal Test ID (Field 5) of Test Order Record.
- Multiple Order Records containing Action Code A for Patient test orders.

NOTE: The only field in which the ARCHITECT *i* System supports the repeat delimiters, within Incoming Messages, is the Universal Test ID of the Test Order Record.

The following table details the exact format of the Test Order Record which shall be sent by the Host to the system.

Table 5.3: Test Order Record: Host to ARCHITECT *i* System

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	20	Printable String	Sample ID downloaded from Host
	Carrier ID	4	^alphanumeric	Carrier ID and position are ignored on input
	Position	2	^numeric	
9.4.4	Instrument specimen ID	N/A	N/A	Field ignored on input
	Carrier ID			
	Position			
9.4.5	Universal Test ID (The only required component of this field is the assay number)	3	^^^(numeric)	Specific number that identifies the test
		10	^(printable string)	Test name
		10	^(printable string)	Dilution protocol name
		1	^(P, p, C, or c)	Assay status: • P or p if assay is installed as the primary version • C or c if the assay is installed as the correlation version
9.4.6	Priority	1	S	STAT (otherwise blank for Routine)
9.4.12	Action Code	1	N	New order for a patient sample
			or	
			A	Unconditional Add order for a patient sample
			or	
			C	Cancel or Delete the existing order
			or	
			Q	Control Sample
9.4.13	Danger Code	15	Printable String	Part of the Test Order Comment Field (optional)
9.4.14	Clinical Information	15	Printable String	Part of the Test Order Comment Field (optional)
9.4.16	Specimen Type	5	Printable String	Part of the Test Order Comment Field (optional)
	Specimen Source	15	^(printable string)	

Table 5.3: Test Order Record: Host to ARCHITECT *i* System *(continued)*

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
9.4.26	Report Types	1	O or o *or* Q or q	Order Order in response to a Query Request.

```
O|1|OMEGA_1||^^^16\^^^606|||||||N||||||||||||||O[CR]
```

Figure 5.5: Example of Test Order Record: Host to ARCHITECT *i* System

Refer to the ARCHITECT *i* System configuration details for assay parameters to determine assay numbers and dilution protocol names to be used for Universal Test IDs.

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** for Patient test orders, the test order is considered a new test. However, if the same test order for this sample ID already exists (Pending, Scheduled, or Running), an error message is generated on the ARCHITECT *i* System and the test order is ignored.

If the field content of 9.4.12 (Action Code) is **A**, the test order shall be processed as a mandatory added test order. It shall be added to the test order list regardless of whether or not the same test order exists (Pending, Scheduled, or Running) in the instrument's database.

If the field content of 9.4.12 (Action Code) is **C**, the test order shall be processed as a request to cancel the specified test order. The instrument shall cancel the first pending test order found, from its pending test order list which has the same SID, Assay Number, Dilution Name, and Assay Status.

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

Comment Record

The following table details the exact format of the Comment Record which shall be sent by the Host to the system.

Table 5.4: Comment Record: Host to ARCHITECT *i* System

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
11.1.1	Record Type	1	C	Comment
11.1.2	Sequence Number	5	1 to 65535	Must be consistent with sequence number rules
11.1.3	Comment Source	1	L	Computer system
11.1.4	Comment Text	50	Printable characters	Comment text
11.1.5	Comment Type	1	G	Generic comment

C|1|L|Example Comment|G[CR]

Figure 5.6: Example of Comment Record: Host to ARCHITECT i System

When the Comment Record follows a patient record, the comment in 11.1.4 refers to that patient sample and will be duplicated in the comment field for each test order for that patient sample.

When the Comment Record follows a test order, it refers only to that test order.

> **NOTE:** For identical sample IDs, only the last comment record for a particular patient order is saved when sent by the host.

The following comment text—limited to a maximum of 50 characters in length—is placed in the comment field of an ARCHITECT *i* System test order in the following sequence:

1. Text in field 11.1.4 (refer to table 5.4—Comment Record) of one or more comment records associated with the patient record.

   then

2. Text in fields 9.4.13, 9.4.14 and two components of 9.4.16 (refer to table 5.3—Test Order Record).

   then

3. Text in field 11.1.4 of one or more comment records associated with the test order.

Negative Query Response Record

The system shall accept a Negative Query Response from the Host system. The Negative Query Response is used to indicate that an earlier Query Request from the system resulted in no orders being sent, either due to:

- The sample ID specified in the original Query Request was unknown to the Host system

  or

- The sample ID specified had no outstanding orders at the time the Query Request was received.

The following table details the exact format of the Negative Query Response Record which shall be sent by the Host to the system.

Table 5.5: Negative Query Response Record: Host to ARCHITECT *i* System

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	ID Number	20	^Specimen ID (printable string)	Sample ID that was originally sent by the system
12.1.5	Universal Test ID	3	^^^ALL	Field contents originally sent by the system
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|^SID1234||^^^ALL|||||||X[CR]
```

Figure 5.7: Example of Negative Query Response: Host to ARCHITECT *i* System

The system shall discontinue waiting for either Test Orders or a Negative Query Response in response to an earlier issued Query Request, as defined in the user-configurable option “Host time-out”.

After a predefined number of allowed consecutive host time-out errors (currently set to 3), the software shall:

- Log an error
- Disable the query mode

Message Terminator Record

The following table details the exact format of the Message Terminator Record which shall be sent by the Host to the system.

Table 5.6: Message Terminator Record: Host to ARCHITECT *i* System

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 5.8: Example of Message Terminator Record: Host to ARCHITECT *i* System

Introduction

This section describes error codes and observed problems that are specific to the host interface of the ARCHITECT *i* System. In addition, it describes the probable causes and corrective actions.

If the corrective actions do not solve the problem, call the ARCHITECT *i* System Customer Support Center.

United States: 1-800-527-1869

Canada: 1-800-387-8378 (English speaking customers)
1-800-465-2675 (French speaking customers)

International: Call your local Abbott Customer Support representative.

Topics include:

- Error Codes
- Observed Problems

NOTES

Error Codes

ARCHITECT *i* System error messages are grouped into ten (10) basic categories (Table 6.1). Each message within a category has been assigned a unique four (4) digit error message number to aid in error identification.

Table 6.1: ARCHITECT *i* System Error Codes

Error Code Categories	Description
0000-0999 General	Identifies non-critical messages that provide direct feedback to an operator action.
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.

Error Messages Specific to the RS-232 Interface

Information on error messages specific to the host interface—all from the Computer Hardware category (8000-8999)—is provided 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.

Error Code	Message Text	Probable Cause	Corrective Action
8004	UNICODE data could not be sent to the host.	Hardware failure: Digiboard.	Contact your Area Customer Support.
8005	Exceeded port read timeout.	Hardware failure: Digiboard.	Contact your Area Customer Support.
8050	Unable to open (x) port. x = Serial port (COM1 - COM10)	Hardware failure: Digiboard, LIS cable connection.	Reseat all cables from the SCC and to the host computer. (Contact your Area Customer Support.)
8051	Failure creating thread for (x) port. x = Serial port (COM1 - COM10)	1. System is Running out of resources or memory. 2. Hardware failure: LIS cable connection.	1. Perform a shutdown on the SCC. 2. Reseat all cables from the SCC and to the host computer. 3. Restart the system. 4. If error continues, contact your Area Customer Support.
8053	Failed opening CLI serial port.	1. Hardware failure: Digiboard, LIS cable connection. 2. Serial port configuration.	Reseat all cables from the SCC and to the host computer. (Contact your Area Customer Support.)
8102	ASCII data could not be sent to the host.	Hardware failure: Digiboard, LIS cable connection.	Reseat all cables from the SCC and to the host computer. (Contact your Area Customer Support.)
8150	Invalid Host order, Sample ID (x) already exists. x = Sample ID	The System received an order from the host computer and the order already exists. The new order from the host computer is ignored by the System.	If this error occurs frequently without obvious explanation check the function of the host interface.

Error Code	Message Text	Probable Cause	Corrective Action
8151	Invalid Host cancel, Sample ID (x) does not exist. x = Sample ID	The System received a cancellation request from the host computer on a test order and the order does not exist in the database. The cancellation request from the host computer is ignored by the System.	If this error occurs frequently without obvious explanation check the function of the host interface.
8153	Invalid Host order, no quality control information for Assay (x) number (y). x = Assay name y = Assay number	The System received a QC order for an assay from the host computer but no control is configured for that assay. The order from the host is ignored by the System.	Use the Control configuration screen to configure a control for the requested assay then download the order from the host.
8154	Invalid Host order for Sample ID (x), specified dilution for Assay number (y) not found. x = Sample ID y = Assay number	The System received a test order from the host computer requesting a dilution that does not exist for the specified assay. The order from the host is ignored by the System.	Order a dilution available for the specified assay. Dilution Name is case sensitive, ensure the host computer dilution name is exactly the same as the Dilution Name in the SCC.
8155	Invalid Host order, Assay number (x) not installed. x = Assay number	The System received a test order from the host computer requesting an assay that has not been installed on the SCC.	Install the requested assay using 6034 Install Assay. After assay is installed, download the order from the host.
8156	Syntax error found when parsing a record or a record field (x) from Host. x = Record string or field string	The System detected a syntax error while parsing the record from the host.	Attempt to re-send the order from the host. Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.
8157	Unexpected data type specified for component (x) validation. x = Component string	The System detected a data type error while parsing a component of an ASTM field.	Attempt to re-send the order from the host. Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.
8158	Component (x) did not contain a value. x = Component string	Mandatory component string was empty.	Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.
8159	Incoming frame is longer than allowed by ASTM specification.	Frame received from the host computer exceeds ASTM length limit.	For specifications, refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.
8160	Illegal repeat delimiter in field (x). x = Field name	Record received from the host computer contains an illegal repeat delimiter.	Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.

Error Code	Message Text	Probable Cause	Corrective Action
8161	Host sent illegal record type (x). x = Record text	Record received from the host computer is not recognized by the System.	Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.
8162	Host sent record (x) containing incorrect sequence numbers. x = Record received	Record received from the host computer contains a number sequencing error.	Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.
8163	Host sent record (x) for a negative query response. x = Record received	Record received from the host computer contains an invalid query response.	Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.
8164	Host sent an invalid ASTM record (x). x = Invalid record string	ASTM format error occurred while decoding a record from the host computer.	Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.
8165	Host sent record (x) containing improper ASTM level transition. x = Record received	Violation of ASTM record hierarchy detected while interpreting a message from the host computer.	Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.
8166	Invalid ASTM record (x) in test order message. x = Record name	Test order message received from the host computer contains an unacceptable ASTM record. Acceptable records in a test order message: Header, Patient, Test Order, Comment and Terminator records.	Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.
8167	Invalid component value in ASTM field (x), component (y). x = Field position y = Component position	ASTM record received from the host computer contains an invalid component.	Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.
8169	Invalid message sent by Host.	Query response received form the host computer was incorrectly formatted, missing the Sample ID or requested an unsupported query.	Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.

Error Code	Message Text	Probable Cause	Corrective Action
8170	Negative query response for Sample ID (x) received after a host query timeout. x = Sample ID	1. Negative query response message contained a SID which was different than the one contained in the earlier issued query message. The negative query response message is received within the query time out period. 2. Negative query response message contained a SID which was different than the one contained in the earlier issued query message. The query had either timed out or was responded to by either a test order message or a negative query response message containing the correct SID. 3. A query message was never issued to the host. (Negative query response message received after the host computer timed out.)	Increase the host query time-out value. Refer to Section 3: Setting Communications, Host-Release Mode.
8171	Invalid query response, response received for a preceding query.	The host computer responded to the current System query request with an order designated for a previous query request.	Increase the host query time-out value. Refer to Section 3: Setting Communications, Host-Release Mode.
8172	Host query time-out exceeded for Sample ID (x).	The host computer did not respond to the query message within the time period specified in the configuration.	Optimize the host query time-out value. Refer to Section 3: Setting Communications, Host-Release Mode.

Error Code	Message Text	Probable Cause	Corrective Action
8173	Terminator record not received.	1. Cabling problem on Host port. 2. Incorrect Baud rate on Host port. 3. Incorrect ASTM format.	1. Reseat the cables at the LIS and the SCC (COM5, Connector P3). 2. Reconfigure the host computer baud rate if required. Refer to Section 3: Setting Communications, Serial Ports. **NOTE:** If configuration is changed, reboot the host computer. 3. Re-send the order from the host. 4. Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.
8174	Carriage return not receive at the end of the record (x). x = Record string	1. The System received a record from the host computer and the record contained an illegal ASTM frame. 2. Cabling not properly shielded or too long.	1. Host must be modified to follow line feed requirements as outlined in Section 5: ARCHITECT *i* System-specific Incoming Messages. 2. Use shorter or shielded cable 3. Re-send the order from the host.
8175	Length of the component (x) exceeded specified maximum length. x = Component string	The System received a record from the host computer and the record specified component length is longer than the maximum allowed.	Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.
8176	Component (x) accepts only numeric values. x = Component string	The specified component accepts only numeric values.	For specifications, refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.
8177	Component (x) accepts only alphanumeric characters. x = Component string	The specified component accepts only alphanumeric values.	Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.
8178	Component (x) accepts only specified alpha characters. x = Component string	The specified component accepts only specified alpha characters.	Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.

Error Code	Message Text	Probable Cause	Corrective Action
8179	Invalid host order for Sample ID (x), Assay number (y) status type does not exist. x = Sample ID y = Assay status	The System received a test order from the host computer for an assay that was not installed.	Install the assay with the correct assay status using 6034 Install Assay. When assay is installed, re-send the order from the host.
8180	Required ASTM field missing (x). x = Field name	Mandatory ASTM field is blank.	Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.
8181	Invalid host order, incorrect birth date (y) for Sample ID (x). x = Sample ID y = Birth date	The System received an order from the host computer and the order contained a birth date that is later than the current date.	Correct birth date in the host computer, then re-send the order from the host.
8182	Unsupported character received from host for patient record. Original: (x), Translated: (y). x = Input string y = Output string	A record was transmitted to the SCC that contained a character that is not supported in the ASI Code page. This character will be translated as the copyright symbol (© or code 0169).	Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.
8183	Unsupported character sent to host for patient record. Original: (x), Translated: (y). x = Input string y = Output string	A record was transmitted to the host that contained a character that is not supported in the ASI Code page. This character will be translated as the registered trademark symbol (® or code 0174).	Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.
8250	Invalid frame number received.	The System received a record from the host computer and the record did not contain the frame in sequence.	Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.
8251	Received <NAK> for outgoing frame.	Normal LIS communication.	Status message. No corrective action required.

Error Code	Message Text	Probable Cause	Corrective Action
8252	Sent <NAK> for incoming frame to (x). x = Remote destination name.	1. Frame received from the host is invalid. 2. When establishing a connection, if the host receives a negative acknowledgement (<NAK>), the system has reached unreleased results capacity. Unreleased results capacity includes unreleased patient and QC results, test orders, and exceptions.	1. Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages. 2. Release patient and QC results. Delete or release exceptions or pending orders below 10% of maximum capacity (Currently 13000 is max capacity, 11,700 = 90 percent). Once unreleased patient results, QC results, and exceptions have been released or deleted, the system will resume accepting test orders from the host computer
8253	Invalid checksum received in incoming frame.	The System received an incoming frame from the host computer and the incoming frame contained an invalid checksum.	Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.
8254	Restricted character in message text.	The System received a message from the host computer and the message contained a restricted character.	For specifications, refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.
8255	Expected printable characters not found in field (x), component (y). x = ASTM field number y = ASTM component number	The System received an ASTM component/field from the host computer and it contained characters that were not printable.	Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.
8256	Expected printable string not found in component (x). x = Component string	The System received an ASTM component from the host computer and it contained a string that was not printable.	Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.
8257	Invalid date format in component / field (x). x = Component / field string	The System received an ASTM component from the host computer and the date format received for the specified component/field was not correct.	For specifications, refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.

Error Code	Message Text	Probable Cause	Corrective Action
8258	Record (x) received before header record. x = Record string which was received as the first record of the message	The System received a record from the host computer and the record Header record was not received as the first record of this message.	Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.
8259	ASTM message contains invalid field (x). x = Field name	The System received a record from the host computer and the ASTM message contains an invalid field.	Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.
8260	Unexpected field delimiter in Host record (x). x = Record received	The System received a record from the host computer and the record has an unexpected field delimiter.	Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.
8261	Negative query received for Sample ID (x), in Carrier/Position (y). x = Sample ID y = Carrier and Position number	There are no test orders in the host for the specified sample ID or the sample ID is unknown to the host.	1. Ensure the specified sample ID has test orders in the host. 2. Place the sample carrier containing the specimen onto the load queue. 3. If unable to place test orders in the host, manually order the required tests on the SCC.
8350	Maximum number of query timeouts exceeded. Host query mode disabled.	Three consecutive timeouts received while requesting orders from the host computer. The host port is disabled after this error. 1. Host computer did not respond within the time period configured. 2. Cabling problem on host port. 3. Incorrect baud rate on host port. 4. Host query not configured on the SCC.	1. Optimize host query timeout value. 2. Reseat the cable at the SCC and the host computer (COM5, Connector P3). 3. Reconfigure the host computer baud rate if required. **NOTE:** If configuration is changed, reboot the host computer. 4. Re-enable the host query mode in the System configuration. Refer to Section 3: Setting Communications, Host-Release Mode. **NOTE:** If configuration is changed, reboot the SCC.

Error Code	Message Text	Probable Cause	Corrective Action
8351	Maximum contention retries exceeded with (x). x = Remote destination name	When results/query is sent to the host, the System sends a request for connection by sending <ENQ>. If the host responds with a request for connection by sending <ENQ>, there is a contention.	Refer to Section 4: ARCHITECT *i* System-specific Outgoing Messages and Section 5: ARCHITECT *i* System-specific Incoming Messages.
8353	Maximum retries exceeded for outgoing frame.	The System is unable to send a frame to the host computer, because the host sent a negative acknowledgment <NAK> for the frame received. 1. Communication failure. 2. Checksum is invalid. 3. Frame is not received in sequence.	1. Reseat the cable at the SCC and the host computer (COM5, Connector P3). Reconfigure the host computer baud rate if required. Refer to Section 3: Setting Communications, Serial Ports. **NOTE:** If configuration is changed, reboot the host computer 2. Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.
8354	(x) connection cannot be established. x = Remote destination name	The System is unable to establish a connection to the host computer. 1. Cabling problem on host port. 2. Incorrect baud rate on host port.	1. Reseat the cable at the SCC and the host computer (COM5, Connector P3). 2. Reconfigure the host computer baud rate if required. Refer to Section 3: Setting Communications, Serial Ports. **NOTE:** If configuration is changed, reboot the host computer.
8355	Time out on frame sent to (x). x = Remote destination name	The host did not respond within 15 seconds, the connection is terminated by the Architect system. 1. Cabling problem on host port. 2. Incorrect baud rate on host port. 3. Host query not configured on the SCC.	Refer to Section 3: Communication Setup.

Error Code	Message Text	Probable Cause	Corrective Action
8356	Query for sample ID (x) deleted, connection could not be established. x = Sample ID	Host communication error. 1. Cabling problem on Host port. 2. Incorrect Baud rate on Host port. 3. Host query not configured on the SCC.	1. Reseat the cable at the SCC and the host computer (COM5, Connector P3). 2. Reconfigure the host computer baud rate if required. Refer to Section 3: Setting Communications, Serial Ports. **NOTE:** If configuration is changed, reboot the host computer. 3. Re-enable the host query mode in the System configuration. Refer to Section 3: Setting Communications, Host-Release Mode. **NOTE:** If serial port configuration is changed, reboot the SCC.
8357	Unable to transmit results to Host, Host access turned off.	This error occurs when the System tries to transmit approved results and the host interface is turned off or the host query mode is turned off.	1. Turn on the host interface and re-transmit the data. 2. Re-enable the host query mode in the System configuration. Refer to Section 3: Setting Communications, Host-Release Mode.
8358	Query for Sample ID (x) deleted, response to an earlier transmitted record not received in time. x = Sample ID	Host communication error. 1. Cabling problem on host port. 2. Host not responding in allotted time.	1. SCC is busy printing, releasing results, etc. Wait until the process is complete, then resend the query. 2. Verify the host query timeout value is correct. Refer to Refer to Section 3: Setting Communications, Host-Release Mode. 3. Reseat the cable at the LIS and at the SCC (COM5, Connector P3).
8450	Sent <ACK> for incoming frame to (x). x = Remote destination name	Normal communication.	Status message. No corrective action required.

Error Code	Message Text	Probable Cause	Corrective Action
8451	Outgoing connection terminated with (x). x = Remote destination name	Normal communication.	Status message. No corrective action required.
8452	Outgoing connection established with (x). x = Remote destination name	Normal communication.	Status message. No corrective action required.
8453	Incoming connection established.	Normal LIS communication.	Status message. No corrective action required.
8454	Incoming connection from (x) terminated. x = Remote destination name	Normal communication.	Status message. No corrective action required.
8455	Received <ACK> for outgoing frame from (x). x = Remote destination name	Normal communication.	Status message. No corrective action required.
8456	Received <ENQ> from (x). x = Remote destination name	Normal communication.	Status message. No corrective action required.
8457	Host port disabled.	The host communication port is disabled due to multiple failures while attempting to communicate with the host computer. 1. Cabling problem on host port. 2. Incorrect baud rate on host port.	1. Reseat the cable at the LIS and at the SCC (COM5, Connector P3). 2. Reconfigure the host computer baud rate if required. **NOTE:** If configuration is changed, reboot the host computer.
8458	Unable to accept test orders from Host. Unreleased results are at 90 percent of capacity.	System has reached unreleased result capacity. This includes unreleased patient and QC results, test orders, and exceptions.	Release patient and QC results. Delete or release exceptions or pending orders below 10% of maximum capacity (Currently 13000 is max capacity, 11,700 = 90 percent). Once unreleased patient results, QC results, and exceptions have been released or deleted, the system will resume accepting test orders from the host computer

Error Code	Message Text	Probable Cause	Corrective Action
8459	Test orders may be downloaded from the Host.	The number of unreleased patient and QC results, pending orders, and exceptions was reduced to a level that is 10 percent below the maximum capacity.	Test orders from the host computer will now be accepted if the feature is enable in the system configuration.
8461	Query for Sample ID (x) deleted because of an earlier query time out. x = Sample ID	A time out occurred on an earlier query to the host.	Optimize the host query timeout value. Refer to Refer to Section 3: Setting Communications, Host-Release Mode.
8462	Negative query response for Sample ID (x), did not match the Sample ID sent to the host. x = Sample ID	Sample ID indicated did not match the sample ID sent to the host.	Optimize the host query timeout value. Refer to Refer to Section 3: Setting Communications, Host-Release Mode.
8463	Unable to change configuration, host transmission is in process.	Attempting to configure a new processing module while a host transmission is in process.	1. Wait until host transmission is complete, or turn off the host port. 2. Configure the new processing module.
8465	Host transmission canceled by user.	The user chose to cancel results transmission to the host.	Status message. No corrective action is required.

Observed Problems

The following information describes problems that may be observed on the ARCHITECT *i* System. Corrective action steps to help resolve these problems are also included.

Observed Problem	Probable Cause	Corrective Action
QC exceptions are sent to the host when Transmit to host option “Approved QC results” is configured to Off.	QC exceptions are transmitted to the host if the Release mode selected is “Automatic with exceptions.”	If you do not want QC exceptions to be sent to the host, configure Release mode to any selection except Auto with exceptions.
Results were sent to the host twice.	Test results are re-sent to the host as initial results if the SCC is shutdown in the middle of a transmission.	Prior to shutting down the SCC, view the LIS status icon on the Snapshot screen to verify no results are pending transmission.
Unable to delete results.	1. Results are being transmitted to the host. 2. Transmission requested when System is configured for host and there is no host connected. Result status is pending transmission. 3. The host mode is set to collate and not all of the results for the SID have been released. Result status is pending collation.	1. Wait until transmission is complete, then delete the required results. 2. Reconfigure the host communication to Off. A popup will appear. Select **OK** to clear results waiting to be sent to the host, then delete results. Refer to Refer to Section 3: Setting Communications, Host-Release Mode. 3. Release or delete associated SIDs, then delete the result.

Introduction

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

The Abbott ARCHITECT Host/Instrument Interface Data Disk includes the following:

- Host/Instrument Interface Simulator scripts
- Actual Data files captured, from the instrument or system, under the directory “a:\arch”.
- “Readme.txt” file, in each directory (“A:\arch” and “A:\host”) describing the contents of the different data files found under this directory.

The Abbott Standard Interface Simulator Tool (ASIST) is provided to assist customers and LIS Vendors with the development of interface software to Abbott instruments and systems supporting the ASTM communication protocols.

NOTES

ASIST Tool Overview

Abbott customers and LIS vendors can use the ASIST Tool 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’ responses to error conditions.

Refer to the ASIST Version 2.0/2.1 Installation/Quick Reference Guide (List No. 6D02-01) for more information.

NOTES

Abbott ARCHITECT Host/Instrument Interface Data Disk

This data diskette is for use concurrently with the ASIST Tool. It provides scripts and examples to simulate different scenarios of ASTM interface functioning with the Abbott ARCHITECT *i* System. In this diskette, there are 3 subdirectories:

- "A:\arch" subdirectory contains necessary scripts, and data files to simulate the data sent by the ARCHITECT *i* System. You will need to use the "arch.scr" script file with ASIST Tool to simulate different pre-defined scenarios. Please refer to the "ReadmeA.txt" and the "arch.scr" script files, under this sub-directory, for details.
- "A:\host" subdirectory contains necessary scripts, and data files to simulate the data expected by the ARCHITECT *i* System from a Host system. You will need to use the "host.scr" script file with ASIST Tool to simulate different pre-defined scenarios. Please refer to the "ReadmeH.txt" and the "host.scr" files, under this subdirectory, for details.
- "A:\specs" subdirectory contains common configuration files, that need to be installed, for successful simulations of bi-directional communication from and to the ARCHITECT *i* System. Please refer to the "ReadmeA.txt" and "ReadmeH.txt" files for installation instructions.

NOTES

Introduction

This section provides a comparison of RS-232 interface specifications between the ARCHITECT *i* System and the AxSYM System including:

- A functional comparison between the two systems.
- A document comparison between the Abbott Standard Interface RS-232 Manuals of the two systems covering *Section 4: System-specific Outgoing Messages* and *Section 5: System-specific Incoming Messages*. This document comparison is based on the:
  - ***Abbott Standard Interface RS-232 Manual/ ARCHITECT® i System Edition (91407-103–November, 2000)***
  - ***Abbott Standard Interface RS-232 Manual/ AxSYM® Edition (66-6837/R3–February 1996)***

NOTES

Functional Comparison

Background

As the ARCHITECT *i* System is primarily designed for high volume immunoassay markets, its Host Interface is also designed to enhance the speed and the data communicated with a host system.

The following is a brief description of the major functional differences between the ARCHITECT *i* System and AxSYM System.

Physical Layer

Speed

AxSYM System

Supported baud rates are:

1200, 2400, 4800, 9600, 19200

ARCHITECT *i* System

Supported baud rates are:

1200, 2400, 4800, 9600, 14400, 19200, 28800

Host Interface Port

AxSYM System

The Host Interface Port is one of the eight interface ports located on the back of the AxSYM system.

ARCHITECT *i* System

The COM5 Port (Connector P3) is used as the Host Interface Port and is located at the back of the System Control Center (SCC).

Data Link Layer

Establishment Phase

AxSYM System

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.

ARCHITECT *i* System

During the Establishment Phase, if the ARCHITECT *i* System has information to transmit, it attempts to establish a connection with a host every 75 seconds.

If, after ten unsuccessful attempts to establish the connection with the host system *(e.g.*, the host system is down), the ARCHITECT *i* System will display an alert message, and discontinue attempts to establish a connection with the host system.

In the case of discontinuation of attempts, the Host Interface Port will be disabled and the user will need to re-enable Host Communication via the Configure host-release mode dialog window. Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages.

Message Content Layer

Canceling of Test Orders

AxSYM System

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.

ARCHITECT *i* System

ARCHITECT currently supports the ability for a host to cancel a previously down-loaded test order through the use of the Action Code field. Refer to Section 5: ARCHITECT *i* System-specific Incoming Messages, Test Order Records.

Transmission Modes

AxSYM System

Has 2 separate options for transmission as:

- Select Transmit Approved Patient Results to Host: ON/OFF

  If set to ON, the AxSYM System sends patient results to the host computer upon approval.
  Default = OFF.

- Select Accept Order Requests from Host: ON/OFF

If set to ON, the AxSYM System is enabled to receive orders from a host computer.
Default = OFF

ARCHITECT *i* System

Provides a single option for both transmission modes as:

- Bi-directional Interface to Host:
  ON/ON WITH QUERY/OFF

  If set to ON, the ARCHITECT *i* System is enabled to receive test orders downloaded from the host system and send approved results to the host system.
  If set to ON WITH QUERY, the ARCHITECT *i* System is enabled to receive test orders downloaded from the host system or queries and send approved results to the host system.
  Default = OFF.

The ARCHITECT *i* System also provides options for transmitting results to the host as described in the following table.

Table 8.1: Options for transmitting to host computer

Approved patient results (Default: Collated)	
Collated	Allows multiple ASTM records to be sent within a host session. **NOTE**: Results are collated by sample ID. If the release mode is configured for automatic release, results are held in Pending collation status until all the results for a sample ID are released.
Single	Allows for a single result record to be sent within a patient record section of each message.

Table 8.1: Options for transmitting to host computer *(continued)*

Approved QC results (Default: Off)	
On	Allows approved QC results to be released to the host computer.
Off	Approved QC results are not sent to host computer. **NOTE**: When the system is configured with the Release mode: Automatic with exceptions and Approved QC results: Off, any QC exceptions are transmitted to the host. If the host is not set to accept QC results, the host will NAK these records.

Transmission of Multiple Flags

AxSYM System

Provides an option to configure the Transmission of Multiple Result Flags to the Host (ON/OFF).

If set to OFF, the AxSYM system sends the highest priority result flag to be transmitted to the host.

If set to ON, all result flags (up to 12 characters) will be transmitted to the host separated by Component Delimiters (^).

There is no requirement for all component delimiters (^) to be present.

ARCHITECT *i* System

Automatically sends:

- One direct result related flag (*i.e.*, LOW, HIGH, LL, HH, >, <) in the Result Record Type F (Result Type = “F” of Result record messages).
- Up to 5 different flags (one or multiple of the following: EXP, CNTL, 1-2S, 1-3S, 2-2S 1R 1M, 2-2S 1R xM, 2-2S xR 1M, R-4S, 4-1S 1M, 4-1S xM, 10x 1M, 10x XM, CORR, IUO) are located in the Result Record type P.

Comment Record

AxSYM System

- **For Outgoing messages:** Allows 100 characters maximum in the comment record to be sent to the host system.

- **For Incoming messages:** Not supported.

ARCHITECT *i* System

- **For Outgoing messages:** Allows 400 characters maximum in the comment record to be sent to the host system.
- **For Incoming messages:** Allows 50 characters maximum in the comment record to be sent from the host system. The comment may be associated with and follow either a patient record or a test order record.

Query Mode

AxSYM System

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.

ARCHITECT *i* System

Allows three consecutive Query time-out errors (pre-defined by the system) occurring due to the inability of the host system to reply within the Query time-out period configured via the "Host query timeout" option on the Configure host-release mode dialog window. If this number is reached, the system will alert the user about the encountered error, and disable the host query mode.

Logical Transmission Error Recovery Requirements

AxSYM System

- **Incoming messages:** During transmission failure, will expect to receive the whole message that was unsuccessfully received.
- **Outgoing messages:** During transmission failure, will retransmit the whole message that was unsuccessfully transmitted.

ARCHITECT *i* System

- **Incoming messages:** stores segments of the message as received, according to the following criteria:
  - At decremental changes in the hierarchical level. Any unsaved data is saved prior to this record.

– At receipt of a test order. Any unsaved test order record and associated comment record(s) received prior to this record are saved.

According to the hierarchical record level requirements, all logical records necessary to reach the point [record] where transmission failure occurred must be retransmitted.

An example message, showing save points, is provided below at left. A list of which records would need resending in case of transmission failure is shown at right.

Line #	Record Type	(Level)	Increment	Action by ARCHITECT
A	Header	(Level 0)	+0	
B	Patient1	(Level 1)	+1	
C	Order 1	(Level 2)	+1	
D	Order 2	(Level 2)	+0 ←	at this point, saves A thru C
E	Comment1	(Level 3)	+1	
F	Order 3	(Level 2)	-1 ←	at this point, saves D thru E
G	Comment1	(Level 3)	+1	
H	Patient2	(Level 2)	-2 ←	at this point, saves F thru G
I	Order 1	(Level 2)	+1	
J	Order 2	(Level 2)	+0 ←	at this point, saves H thru I
K	Comment1	(Level 3)	+1	
L	Patient3	(Level 1)	-2 ←	at this point, saves J thru K
M	Comment1	(Level 2)	+1	
N	Order1	(Level 2)	+0	
O	Comment1	(Level 3)	+1	
P	Terminator	(Level 0)	-3 ←	at this point, saves L thru O

(Terminator record is assumed as saved.)

Line # where failure occurred	ARCHITECT would require retransmission of:
A	A
B	AB
C	ABC
D	ABCD
E	ABDE
F	ABDEF
G	ABFG
H	ABFGH
I	AHI
J	AHIJ
K	AHJK
L	AHJKL
M	ALM
N	ALMN
O	ALMNO
P	ALMNOP

Figure 8.1: Example of Logical Transmission Error Recovery (Incoming)

- **Outgoing messages:** Data will be presumed to be saved at the host whenever any decremental change in the hierarchical level is observed.

  The example below illustrates the decremental change in the hierarchical level that defines the point where the data is presumed to be saved at the host. At these level changes, all the data received, not including the record at which the decremental change occurred, is saved. In the example below at the left, storage would occur at points E, G, I, M, O, Q and T.

  In order to fulfill hierarchical record level requirements, all logical records necessary to reach the restart record point will be sent prior to transmitting the record where line failure originally occurred. A list of which records would be resent in case of a transmission failure is shown at the right.

Line #	Record Type	(Level) Increment	Action of Host:
A	Header	(Level 0) +0	
B	Patient1	(Level 1) +1	
C	Order 1	(Level 2) +1	
D	Result1	(Level 3) +1	
E	Order 2	(Level 2) -1 ←	at this point, saves A thru D
F	Comment1	(Level 3) +1	
G	Order 3	(Level 2) -1 ←	at this point, saves E thru F
H	Comment1	(Level 3) +1	
I	Patient2	(Level 2) -2 ←	at this point, saves G thru H
J	Order 1	(Level 2) +1	
K	Result1	(Level 3) +1	
L	Comment1	(Level 4) +1	
M	Result2	(Level 3) -1 ←	at this point, saves I thru L
N	Result3	(Level 3) +0	
O	Order2	(Level 2) -1 ←	at this point, saves M thru N
P	Comment1	(Level 3) +1	
Q	Patient3	(Level 1) -2 ←	at this point, saves O thru P
R	Order1	(Level 2) +1	
S	Result1	(Level 3) +1	
T	Terminator	(Level 0) -3 ←	at this point, saves Q thru S

(Terminator record is assumed as saved.)

Line # where failure occurred	ARCHITECT would require retransmission of:
A	A
B	AB
C	ABC
D	ABCD
E	ABCDE
F	ABEF
G	ABEFG
H	ABGH
I	ABGHI
J	AIJ
K	AIJK
L	AIJKL
M	AIJKLM
N	AIJMN
O	AIJMNO
P	AIOP
Q	AIOPQ
R	AQR
S	AQRS
T	AQRST

Figure 8.2: Example of Logical Transmission Error Recovery (Outgoing)

Other specific field format and content differences

Please refer to Sections 4 and 5 of the respective RS-232 Manuals. A comparison of these sections follows.

Document Comparison

System-Specific Outgoing Messages

The following information provides a comparison between Section 4 of the ARCHITECT *i* System vs. AxSYM System Abbott Standard Interface RS-232 Manuals:

Overview

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

For information on communicating from the host to the ARCHITECT *i* / AxSYM System, refer to ***Section 5: System-Specific Incoming Messages*** in the respective Abbott Standard Interface RS-232 Manuals.

Communication: (ARCHITECT *i* vs. 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.

For ARCHITECT *i* System only:

Results transmission will be attempted every 75 seconds. Up to 40 SIDs can be transmitted in each session.

Results Transmission Mode

Single Results

Transmission of single results is the same for both systems.

Collated Results

ARCHITECT *i* System:

If the user-configurable option “Approved Patient Results” is set to “Collated”, multiple ASTM records are sent within a host session. The record 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)

⇓

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⇓

Message Terminator Record

The ARCHITECT *i* System collates all the results for a sample and transmits to the host only after the last test for that sample has been completed and released.

AxSYM System:

The AxSYM system collates all the results for a sample and transmits to the host only after the last test for that sample has been completed and released.

Order Query Transmission

Order Query transmission is the same for both systems.

ASTM Record Formats

The following sections detail the 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

The following table details the format of the Message Header Record sent by the ARCHITECT *i* System or AxSYM System to the Host.

Table 8.2: Message Header: ARCHITECT *i* / AxSYM System to Host

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
7.1.1	Record Type ID (Same for both)	1	H	Header
7.1.2	Delimiter Definition (Same for both)	4	|	Field delimiter: vertical bar
			\	Repeat delimiter: backslash
			^	Component delimiter: caret
			&	Escape delimiter: ampersand
7.1.5	Sender Name or ID	ARCHITECT: 9	ARCHITECT	Instrument Name
		AxSYM 5	AxSYM	
	Software Version (Same for both)	4	^Version Number (numeric)	Version number in the format 1.23
	Serial Number	ARCHITECT: 25	^Serial Number (alphanumeric)	ARCHITECT: SCC Serial Number
		AxSYM: 10		AxSYM: Instrument Serial Number
	Interface Version (Same for both)	16	^Interface Version (alphanumeric)	Record types the system supports
7.1.12	Processing ID	1	P	ARCHITECT: Production: Treat message as an active message to be completed according to standard processing AxSYM: Patient results
			Q	**AxSYM:** Quality Control results
7.1.13	Version No. (Same for both)	1	1	Mandatory Field
7.1.14	Date and Time (Same for both)	14	YYYYMMDDHHMMSS	Date and Time of transmission in ASTM format.

```
H|\^&|||ARCHITECT^1.00^123456789^H1P1O1R1C1Q1L1||||||P|1|19930330133346[CR]
```

Figure 8.3: Example of Message Header Record: ARCHITECT *i* System to Host

```
H|\^&|||AxSYM^1.00^1234567-89^H1P1O1R1C1Q1L1||||||P|1|19930330133346[CR]
```

Figure 8.4: Example of Message Header Record: AxSYM System to Host

Patient Information Record

The following table details the format of the Patient Information Record sent by the ARCHITECT *i* System or AxSYM System to the Host.

Table 8.3: Patient Information Record: ARCHITECT *i* / AxSYM System to Host

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
8.1.1	Record Type	1	ARCHITECT: P or p AxSYM: P	Patient
8.1.2	Sequence Number	ARCHITECT: 5	ARCHITECT: 1 to 65535	Must be consistent with sequence number rules.
		AxSYM: 1	AxSYM: 1 to n	n represents any number.
8.1.3	Practice-Assigned Patient ID	ARCHITECT: 20	Printable String	Returned unchanged during transmission to the host
		AxSYM: 15	(Any character)	Always returned unchanged to the host.
8.1.4	Laboratory-Assigned Patient ID	ARCHITECT: 20	Printable String	Returned unchanged during transmission to the host
		AxSYM: 15	(Any character)	Always returned unchanged to the host.
8.1.5	Patient ID No. 3	ARCHITECT: 20	Printable String	• Optional for Patient test orders • Empty for Control test orders
		AxSYM: 15	(Any character)	Instrument PID assigned by operator.

Table 8.3: Patient Information Record: ARCHITECT *i* / AxSYM System to Host *(continued)*

8.1.6	Patient Name	ARCHITECT: 20	Last (printable string)	• Last, first, and middle patient name ARCHITECT ONLY: • Optional for Patient test orders • Default = empty field • Empty for Control test orders
		AxSYM: 15	Last (any character)	
		ARCHITECT: 20	^First (printable string)	
		AxSYM: 20	^First (any character)	
		ARCHITECT: 12	^Middle (printable string)	
		AxSYM: 1	^Middle Initial (any character)	
ARCHITECT: 8.1.8	Birth date	8	YYYYMMDD	• Patient birth date • Optional for Patient test orders • Empty for Control test orders.
ARCHITECT: 8.1.9	Patient Sex	1	M, F, U	• Patients sex (Male, Female, Unknown) • Optional for Patient test orders. • Default = unknown • Empty for Control test orders

```
P|1|||PIDSID13|PATIENT^IM^A|19320122|F[CR]
```

Figure 8.5: Example of Patient Information Record: ARCHITECT *i* System to Host

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

Figure 8.6: Example of Patient Information Record: AxSYM System to Host

Test Order Record

The following table details the format of the Test Order Record sent by the ARCHITECT *i* System or AxSYM System to the Host.

Table 8.4: Test Order Record: ARCHITECT *i* / AxSYM System to Host

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
9.4.1	Record Type	1	ARCHITECT: O or o AxSYM: O	Order
9.4.2	Sequence Number	ARCHITECT: 5	1 to 65535	Must be consistent with sequence number rules.
		AxSYM: 1	1 to n	n represents any number
9.4.3	Specimen ID	ARCHITECT: 20	ARCHITECT: Printable String	Sample ID downloaded from Host, returned unchanged to the host
		AxSYM: 15	AxSYM: Specimen (any character)	
9.4.4	ARCHITECT: Instrument specimen ID	20	Printable String	Instrument Specimen ID, Carrier_ID and Position are returned for all specimen tested, although Instrument Specimen ID may be different than Specimen ID in 9.4.3 if changed by operator or scanned by the instrument
	Carrier ID	4	^alphanumeric	
	Position	2	^numeric	
	AxSYM: Instrument specimen ID	15	Specimen (any character)	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 the operator. NOTE: The information in the Segment/ Position portion of the field is invalid for Control Orders.
	^location_ID	1	^segment (Alphanumeric)	
	^position	2	^position (Numeric)	

Table 8.4: Test Order Record: ARCHITECT *i* / AxSYM System to Host *(continued)*

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
9.4.5	Universal Test ID Code (Same for both)	3	^^^Assay Number (numeric)	Specific number that identifies the test
	Name	ARCHITECT: 10	^Assay Name (printable string)	Test name
		AxSYM: 9	^Assay Name (alphanumeric)	
	Assay Protocol	10	ARCHITECT: ^Dilution (printable string)	Dilution protocol name
			AxSYM: ^Dilution (Alphanumeric)	
	ARCHITECT ONLY: Assay Status	1	^Status (P, p, C or c)	Assay status: • P or p if assay is installed as the primary version • C or c if the assay is installed as the correlation version
9.4.6	Priority (Same for both)	1	S *or* R	STAT Routine
9.4.12	Action Code (Same for both)	1	Q	• Quality Control Result • Empty for Patient result
9.4.26	Report Types (Same for both)	1	F *or* X	Final Result Test could not be performed

```
O|1|SID13|SID13^A123^5|^^^123^Assay1^UNDILUTED^P|R|||||||||||||||||||F[CR]
```

Figure 8.7: Example of Test Order Record: ARCHITECT *i* System to Host

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

Figure 8.8: Example of Test Order Record: AxSYM System to Host

Result Record

The following table details the format of the Result Record sent by the ARCHITECT *i* System or AxSYM System to the Host.

Table 8.5: Result Record: ARCHITECT *i* / AxSYM System to Host

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
10.1.1	Record Type (Same for both)	1	R	Result
10.1.2	Sequence Number	ARCHITECT: 5	1 to 65535	Must be consistent with sequence number rules.
		AxSYM: 1	1 to n	n represents any number
10.1.3	Universal Test ID Code (Same for both)	3	^^^Assay Number (numeric)	Specific number that identified the test
	Name	ARCHITECT: 10	^Assay Name (printable string)	Test name
		AxSYM: 9	^Assay Name (alphanumeric)	
	Assay Protocol	10	ARCHITECT: ^Dilution (printable string)	Dilution protocol name
			AxSYM: ^Dilution (alphanumeric)	
	ARCHITECT ONLY: Assay Status	1	^ Status (P, p, C or c)	Assay Status: • P or p if assay is installed as primary version • C or c if assay is installed as correlation version
	ARCHITECT ONLY: Reagent Lot	15	^ alphanumeric	Reagent Master Lot # (empty for derived results)
	ARCHITECT ONLY: Reagent Serial Number	10	^numeric	Serial number of reagent kit used to process the test result (empty for derived results)
	ARCHITECT ONLY: Control Lot Number	15	^alphanumeric	Lot number of the control material (empty for patient results and derived results)
	AxSYM ONLY: Test_Qualifier		^^	Always null
	Result Type	1	ARCHITECT: ^F AxSYM: F *or*	ARCHITECT: Final result concentration or result AxSYM: Final result concentration
			P *or*	ARCHITECT: Preliminary instrument result (RLU) AxSYM: • Preliminary instrument result
			I	Interpreted result for a Qualitative test

Table 8.5: Result Record: ARCHITECT *i* / AxSYM System to Host *(continued)*

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
10.1.4	Data Value	15	ARCHITECT: Printable String	For Result Type F (concentration value if within dynamic range)
				For Result Type P (numeric response)
				For Result Type I (interpretation)
			AxSYM: Numeric	For Result Type F
			AxSYM: Numeric Response	For Result Type P (Float decimal position or comma for both Result Type F and P.)
			AxSYM: Interpretation String	For Result Type I
10.1.5	Units	7	ARCHITECT: Result Units (printable string)	Result Type F
			AxSYM: Concentration Units	
			or	
			ARCHITECT: RLU (printable string)	Result Type P
			AxSYM: Rate or mP or Percent	
			or Empty	Result Type I
10.1.6	Reference Ranges	25	Normal/Therapeutic Ranges ARCHITECT ONLY: (Printable string formatted as minimum value to maximum value)	For Result Type F for Patient Result
			or	
			AxSYM: Control Range	For Result Type F for QC Result
			ARCHITECT ONLY: Control Range (Printable string formatted as minimum value to maximum value)	For Result Type F for Control Result
			or	
			Empty	For Result Type I or P and for Result Type F, if range undefined.

Table 8.5: Result Record: ARCHITECT *i* / AxSYM System to Host *(continued)*

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
10.1.7	Result Abnormal Flags	ARCHITECT: 25 AxSYM: 12	ARCHITECT: LOW or HIGH	Less than or greater than normal therapeutic ranges
			AxSYM: L or H	ARCHITECT ONLY: (for Patient results). Sent only when Result Type in field 10.1.3 is **F**.
			LL or HH (Same for both)	Less than or greater than extreme range ARCHITECT ONLY: (for Patient results). Sent only when Result Type in field 10.1.3 is **F**.
			< or > (Same for both)	Less than or greater than dynamic range of the assay ARCHITECT ONLY: (for Patient and Control results). Sent only when Result Type in field 10.1.3 is **F**.
			AxSYM: QC	Assay Quality Control out of range.
			ARCHITECT ONLY: EXP	Expired Reagent ARCHITECT ONLY: (for Patient, Calibrator and Control results). Sent only when Result Type in field 10.1.3 is **P**. AxSYM Only: 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.
			AxSYM: EX	
			ARCHITECT ONLY: CNTL	Result based on a Control has a Westgard failure rating (for Patient results). Sent only when Result Type in field 10.1.3 is **P**.
			ARCHITECT ONLY: WESTGARD ANALYSIS FLAGS 1-2s 1-3s 2-2s 1R 1M 2-2s 1R xM 2-2s xR 1M R-4s 4-1s 1M 4-1s xM 10x 1M 10x XM	Contains the name of the evaluated and "failed" Westgard Rule (for Control results). Sent only when Result Type in field 10.1.3 is **P**.
			ARCHITECT ONLY: CORR	Correlation assay results. Sent only when Result Type in field 10.1.3 is **P**.
			ARCHITECT ONLY: IUO	Investigational Use Only. Sent only when Result Type in field 10.1.3 is **P**.

Table 8.5: Result Record: ARCHITECT *i* / AxSYM System to Host *(continued)*

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
10.1.9	Result Status (Same for both)	1	F *or* R	Final Results Previously Transmitted Results
10.1.11	Operator Identification	ARCHITECT: 12	Order Operator ID (alphanumeric)	ID of Operator logged into system at time of order
			^Release Operator ID (alphanumeric)	ID of Operator logged in at time of result release
		AxSYM: 6	Alphanumeric	
10.1.13	Date/Time Test Complete (Same for both)	14	YYYYMMDDHHMMSS	
ARCHITECT ONLY: 10.1.14	Instrument Identification	25	Alphanumeric	Serial # of the module which performed the test.

```
R|1|^^^16^TSH^DIL1^P^12345AB89^12345^^F|28.275|mIU/mL|30.000TO500.000|LOW|
|F||OP345^OP346||19930330132949|IA200A345[CR]
```

Figure 8.9: Example of Result Record: ARCHITECT *i* System to Host

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

Figure 8.10: Example of Result Record: AxSYM System to Host

ARCHITECT:

The following list of field contents of 10.1.7 (Result Abnormal Flags) are not part of the ASTM standard: EXP, CNTL, CORR, the Westgard Analysis flags (1-2S, 1-3S, 2-2S 1R 1M, 2-2S 1R xM, 2-2S xR 1M, R-4S, 4-1S 1M, 4-1S xM, 10x 1M, 10x XM), IUO.

Comment Record

AxSYM:

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

The following table details the format of the Comment Record sent by the ARCHITECT *i* System or AxSYM System to the Host.

Table 8.6: Comment Record: ARCHITECT *i* / AxSYM System to Host

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
11.1.1	Record Type (Same for both)	1	C	Comment
11.1.2	Sequence Number	ARCHITECT: 5	1 to 65535	Must be consistent with sequence number rules
		AxSYM: 1	1 to n	n represents any number
11.1.3	Comment Source (Same for both)	1	I	Instrument
11.1.4	Comment Text	ARCHITECT: 400	Printable String	Result Comment or Exception String
		AxSYM: 100		
11.1.5	Comment Type (Same for both)	1	G *or* I	Result Comment
				Exception String

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

Figure 8.11: Example of Comment Record: ARCHITECT *i* / AxSYM System to Host

Request Information Record

The following table details the format of the Request Information Record sent by the ARCHITECT *i* System or AxSYM System to the Host.

ARCHITECT:

The following table details the exact format of the Request Information Record which shall be sent by the ARCHITECT i System to the Host.

Table 8.7: Request Information Record: ARCHITECT *i* / AxSYM System to Host

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
12.1.1	Record Type ID (Same for both)	1	Q	
12.1.2	Sequence Number (Same for both)	1	1	Will always contain 1
12.1.3	ARCHITECT: ID Number	20	^Specimen ID	Sample ID read from the bar code label on the sample tube
	AxSYM: Starting Range ID Number	15		
12.1.5	Universal Test ID	ARCHITECT: 3	^^^ALL	System will always request that ALL outstanding orders be sent
		AxSYM: [blank]		
12.1.13	Status Code (Same for both)	1	O	System only requests Orders

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

Figure 8.12: Example of Request Information Record: ARCHITECT *i* / AxSYM System to Host

Message Terminator Record

The following table details the format of the Message Terminator Record sent by the ARCHITECT i System or AxSYM System to the Host.

Table 8.8: Message Terminator Record: ARCHITECT i / AxSYM System to Host

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
13.1.1	Record Type (Same for both)	1	L	Last
13.1.2	Sequence Number (Same for both)	1	1	

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

Figure 8.13: Example of Terminator Record: ARCHITECT *i* / AxSYM System to Host

System-Specific Incoming Messages

The following information provides a comparison between Section 5 of the ARCHITECT *i* System and AxSYM System Abbott Standard Interface RS-232 Manuals.

Overview

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

For information on communicating from the ARCHITECT *i* / AxSYM System to a host computer, refer to ***Section 4: System-Specific Outgoing Messages*** in the respective Abbott Standard Interface RS-232 Manuals.

Communication: Host to the System (ARCHITECT *i* vs. AxSYM)

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 ARCHITECT *i* / AxSYM System.

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

ARCHITECT:

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

AxSYM:

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

Both
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 ARCHITECT *i* / AxSYM System, with the Status Code field set to X.

ARCHITECT:

An error is logged and the remainder of the message—up to the message terminator record—is ignored if the ARCHITECT *i* System receives a record that:

- Is missing a required field as defined in this section
- Is not defined for ARCHITECT *i* System incoming messages
- Has an invalid sequence number

- Has one or more fields or components that do not conform to requirements as defined further in this section

...an error will be logged and the remainder of the mesage, up to the message terminator record, will be ignored. Records that were received prior to this record are accepted and processed further.

Format Detail

The ARCHITECT *i* / AxSYM System recognizes fields when parsing for the following records:

- Message Header Record
- Patient Information Record
- Request Information Record
- Test Order Record
- Comment Record [ARCHITECT *i* System ONLY]
- Message Terminator Record

ARCHITECT:

The following records are not used by the ARCHITECT *i* System:

- Scientific Record
- Manufacturer Information Record

AxSYM:

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 8.9: Message Header: Host to ARCHITECT *i* / AxSYM System

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
7.1.1	Record Type (Same for both)	1	H or h	Header
7.1.2	Delimiter Definition	ARCHITECT: 4 AxSYM: [blank]		Bytes 2 and 6 of the record must be the same.

Table 8.9: Message Header: Host to ARCHITECT *i* / AxSYM System *(continued)*

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
7.1.12	Processing ID	1	P or p	ARCHITECT: Production: Treat message as an active message to be completed according to standard processing
				AxSYM: Processing ID
7.1.13	Version Number (Same for both)	1	1	Must be 1

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

Figure 8.14: Example of Message Header Record: Host to ARCHITECT *i* / AxSYM **System**

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 ARCHITECT *i* / AxSYM System.

> **NOTE:** The default delimiters (|\& ^) are always accepted even when different delimiters are specified in the host. Use only these delimiters for ARCHITECT *i* System software version 1.60 and below.

Patient Information Record

The following table details the format of the Patient Information Record sent by the Host to the ARCHITECT *i* System or AxSYM System.

Table 8.10: Patient Information Record: Host to ARCHITECT *i* / AxSYM System

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
8.1.1	Record Type (Same for both)	1	P or p	Patient
8.1.2	Sequence Number (Same for both)	5	1 to 65535	Must be consistent with sequence number rules
8.1.3	Practice-Assigned Patient ID	ARCHITECT: 20	Printable String	• Returned unchanged during transmission to the host • Optional for Patient test orders • Default = empty field • Empty for Control test orders
		AxSYM: 15	Any character	Returned unchanged during transmission to the host.
8.1.4	Laboratory-Assigned Patient ID	ARCHITECT: 20	Printable String	• Returned unchanged during transmission to the host • Optional for Patient test orders • Empty for Control test orders
		AxSYM: 15	Any character	Returned unchanged during transmission to the host.
8.1.5	Patient ID No. 3	ARCHITECT: 20	Printable String	• Optional for Patient test orders • Empty for Control test orders
		AxSYM: 15	Any character	See note below.

Table 8.10: Patient Information Record: Host to ARCHITECT *i* / AxSYM System *(continued)*

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
8.1.6	Patient Name	ARCHITECT: 20	ARCHITECT: Last (printible string)	ARCHITECT: • Last, first, and middle patient name for Patient test orders • Default = empty field • Empty for Control test orders AxSYM: • Last, first, and middle initial of the patient name.
		AxSYM: 15	AxSYM: Last (any character)	
		20	ARCHITECT: ^First (printible string)	
			AxSYM: First (any character)	
		ARCHITECT: 12	ARCHITECT: ^Middle (printible string)	
		AxSYM: 1	AxSYM: Middle initial (any character)	
ARCHITECT: 8.1.8	Birth Date	8	YYYYMMDD	• Patient birth date • Optional for Patient test orders • Empty for Control test orders.
ARCHITECT: 8.1.9	Patient Sex	1	M, F, U	• Patient sex (Male, Female, Unknown) • Optional for Patient test orders • Default = Unknown • Empty for Control test orders.

Examples:

Patient Test Order

```
P|1|Practice PID|Lab PID||Doe^John^Q|19320122|F[CR]
```

Figure 8.15: Example of Patient Information Record: (Patient Test Ordering): Host to ARCHITECT *i* System

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

Figure 8.16: Example of Patient Information Record: (Patient Test Ordering): Host to AxSYM System

Control Test Order

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

Figure 8.17: Example of Patient Information Record (Control Test Ordering): Host to ARCHITECT *i* System

NOTE: The field contents of Practice Assigned Patient ID (8.1.3) shall 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) shall be copied into Patient ID No. 3 filed 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

ARCHITECT:

The ARCHITECT *i* System Control Center will accept unsolicited Patient and Control test orders from the LIS host regardless of whether the host query option is enabled or not.

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

- Use of Repeat Delimiter in Universal Test ID (Field 5) of Test Order Record.
- Multiple Order Records containing Action Code A for Patient test orders.

AxSYM:

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.

The following table details the format of the Test Order Record sent by the Host to the ARCHITECT *i* System or AxSYM System.

Table 8.11: Test Order Record: Host to ARCHITECT *i* / AxSYM System

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
9.4.1	Record Type (Same for both)	1	O or o	Order
9.4.2	Sequence Number (Same for both)	5	1 to 65535	Must be consistent with sequence number rules

Table 8.11: Test Order Record: Host to ARCHITECT *i* / AxSYM System *(continued)*

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
9.4.3	ARCHITECT: Specimen ID	20	Printable String	Sample ID downloaded from Host
	Carrier ID	4	^alphanumeric	Carrier ID and position are ignored on input
	Position	2	^numeric	
	AxSYM: Specimen ID ^location_ID ^position	15	Specimen	Sample ID downloaded from Host. Location and position are ignored on input.
9.4.4	ARCHITECT: Instrument specimen ID Carrier ID Position AxSYM: Instrument specimen ID ^location_ID ^position	N/A	N/A	Field ignored on input
9.4.5	ARCHITECT: Universal Test ID (The only required component of this field is the assay number)	3	^^^(numeric)	Specific number that identifies the test
		10	^(printable string)	Test name
		10	^(printable string)	Dilution protocol name
		1	^(P, p, C, or c)	Assay status: • P or p if assay is installed as the primary version • C or c if the assay is installed as the correlation version
	AxSYM: 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 (Same for both)	1	S	STAT (otherwise blank for Routine)

Table 8.11: Test Order Record: Host to ARCHITECT *i* / AxSYM System *(continued)*

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
9.4.12	Action Code	1	N	ARCHITECT: New order for a patient sample AxSYM: New Patient or New Order for an existing Sample
			or	
			A	ARCHITECT: Unconditional Add order for a patient sample. AxSYM: Add order for Patient
			or	
			Q	ARCHITECT: Control Sample AxSYM: Quality Control
			or	
			ARCHITECT ONLY: C	Cancel or Delete the existing order
9.4.13	Danger Code	ARCHITECT: 15	Printable String	Part of the Test Order Comment Field (optional)
		AxSYM: [blank]	Alphanumeric	Part of the Sample Comment Field
9.4.14	Clinical Information	ARCHITECT: 15	Printable String	Part of the Test Order Comment Field (optional)
		AxSYM: [blank]	Alphanumeric	Part of the Sample Comment Field
9.4.16	ARCHITECT: Specimen Type	5	Printable String	Part of the Test Order Comment Field (optional)
	Specimen Source	15	^Printable String	
	AxSYM: Specimen Descriptor Specimen Type Specimen Source	[blank]	^Alphanumeric ^Alphanumeric ^Alphanumeric	Part of the Sample Comment Field
9.4.26	Report Types (Same for both)	1	O or o	Order
			or	
			Q or q	Order in response to a Query Request.

```
O|1|OMEGA_1||^^^16\^^^606||||||N||||||||||||O[CR]
```

Figure 8.18: Example of Test Order Record: Host to ARCHITECT *i* System

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

Figure 8.19: Example of Test Order Record: Host to AxSYM System

AxSYM only:

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.

ARCHITECT:

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 for Patient test orders, the test order is considered a new test. However, if the same test order for this sample ID already exists (Pending, Running, or Scheduled), an error message is generated on the ARCHITECT *i* System and the test order is ignored.

If the field content of 9.4.12 (Action Code) is A, the test order shall be processed as a mandatory added test order. It shall be added to the test order list regardless of whether or not the same test order exists in the instrument's database.

If the field content of 9.4.12 (Action Code) is C, the test order shall be processed as a request to cancel the specified test order. The instrument shall cancel the first pending test order found, from its pending test order list which has the same SID, Assay Number, Dilution Name, and Assay Status. Cancellation is done on a first-in/first-out basis.

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

ARCHITECT ONLY: Comment Record

The following table details the exact format of the Comment Record which shall be sent by the host to the ARCHITECT *i* System.

Table 8.12: Comment Record: Host to ARCHITECT *i* System

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
11.1.1	Record Type	1	C	Comment
11.1.2	Sequence Number	5	1 to 65535	Must be consistent with sequence number rules
11.1.3	Comment Source	1	L	Computer system
11.1.4	Comment Text	50	Printable characters	Comment text
11.1.5	Comment Type	1	G	Generic comment

```
C|1|L|Example Comment|G[CR]
```

Figure 8.20: Example of Comment Record: Host to ARCHITECT *i* System

When the Comment Record follows a patient record, the comment in 11.1.4 refers to that patient sample and will be duplicated in the comment field for each test order for that patient sample.

When the Comment Record follows a test order, it refers only to that test order.

> **NOTE:** For identical sample IDs, only the last comment record for a particular patient order is saved when sent by the host.

The following comment text—limited to a maximum of 50 characters in length—is placed in the comment field of an ARCHITECT *i* System test order in the following sequence:

1. Text in field 11.1.4 (refer to table 5.9—Comment Record) of one or more comment records associated with the patient record.

   then

2. Text in fields 9.4.13, 9.4.14 and two components of 9.4.16 (refer to table 5.3—Test Order Record).

   then

3. Text in field 11.1.4 of one or more comment records associated with the test order.

Negative Query Response Record, ARCHITECT

Request Information Record, AxSYM

ARCHITECT:

The system shall accept a Negative Query Response from the Host system. The Negative Query Response is used to indicate that an earlier Query Request from the system resulted in no orders being sent, either due to:

- The sample ID specified in the original Query Request was unknown to the Host system

  or

- The sample ID specified had no outstanding orders at the time the Query Request was received.

The following table details the exact format of the Negative Query Response Record which shall be sent by the Host to the system

Table 8.13: Request Information Record: Host to AxSYM System
Negative Query Response Record: Host to ARCHITECT *i* System

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
12.1.1	Record Type ID (Same for both)	1	Q	
12.1.2	Sequence Number (Same for both)	1	1	Will always contain 1
12.1.3	ARCHITECT: ID Number	20	^Specimen ID (printable string)	Sample ID that was originally sent by the system
	AxSYM: Starting Range ID Number	15	^Specimen ID	
12.1.5	Universal Test ID	ARCHITECT: 3	^^^ALL	Field contents originally sent by the system
		AxSYM: [blank]		

Table 8.13: Request Information Record: Host to AxSYM System
Negative Query Response Record: Host to ARCHITECT *i* System *(continued)*

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
12.1.13	Status Code (Same for both)	1	X	Indicates that either the Sample ID is unknown to the Host, or there are no outstanding orders for the specified Sample ID

ARCHITECT

```
Q|1|^SID1234||^^^ALL|||||||X[CR]
```

Figure 8.21: Example of Negative Query Response Record: Host to ARCHITECT *i* System

AxSYM

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

Figure 8.22: Example of Request Information Record: Host to AxSYM System

The system shall discontinue waiting for either Test Orders or a Negative Query Response in response to an earlier issued Query Request, as defined in the user-configurable option “Host time-out”.

After a predefined number of allowed consecutive host time-out errors, the software shall:

- Log an error
- Disable the query mode

AxSYM:

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 he original Query Request with the Status Code set to X.

Message Terminator Record

The following table details the exact format of the Message Terminator Record which shall be sent by the Host to the system.

Table 8.14: Message Terminator Record: Host to ARCHITECT *i* System

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 8.23: Example of Message Terminator Record: Host to ARCHITECT *i* System

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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.

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

Analysis to determine the presence, absence, or quantity of one or more analytes.

Assay calibration

The generation of a calibration curve for use in determining the concentration of an analyte present in samples.

Assay parameters

Settings that define specific characteristics or verify the performance of an assay.

Assay protocols

Assay processing steps that provide the system with information which allows pipetting, incubation, washing and reading to occur at specific volumes and times throughout the reaction sequence. Protocol types include: One-step, Two-step, and Pre-Treatment.

Assay settings

Individual settings within each assay configuration category which you can edit to meet your site-specific requirements.

ASTM

American Society for Testing and Materials. Consists of specifications that define the transferring of information between laboratory instruments and computer systems.

Bulk solutions	The solutions found in the supply and waste center which are used on the system (Pre-Trigger Solution, Trigger Solution, Wash Buffer).
Calibration curve	Created when an operator performs an assay calibration. Used for determining the concentration of analyte in a sample.
Calibrator	Material with a known concentration of specific analyte used to create a calibration curve.
Check boxes	A user interface input area where you can make one or more selections for an item. A black check mark in the box indicates that it has been selected.
Chemiluminescense	Emission of light produced by a chemical reaction.
CMIA	Chemiluminescent Microparticle Immunoassay; the detection technology the ARCHITECT *i* System uses to perform automated immunoassays.
Configuration	The process by which you can edit System, Assay, and QC-Cal settings that provide the system with information to meet your site-specific requirements.
Consumables	Items that are exhausted in the process of running assays (reagents, calibrators, controls, bulk solutions, septums, replacement caps, sample cups, reaction vessels)
Control	Material with a known concentration of a specific analyte. Controls are run with patient samples and are used to monitor assay and system performance over time.
Dialog windows	Overlay screens that appear on top of, or in front of, full-frame screens. They provide additional information, details, or functions. They appear after an item or function key has been selected on the primary full-frame screen.
Drop-down menu	List of items that appear when an icon is selected that represents each of the screens available for the specific icon.
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.

Exceptions — Test orders that fail to complete.

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

Full-frame screen — Screen displayed when a drop-down menu option is selected.

Function key zone — Located at the bottom of the software screens containing function keys associated with a particular screen.

Host — An auxiliary computer system that can communicate back and forth with the ARCHITECT *i* System.

Icon — Symbol providing a graphic and name that represent a category of screens or additional functionality.

Icon zone — Located at the top of the software screens providing navigational and status indication support. Each icon in the icon zone has a drop-down menu that is displayed when you select the icon.

Immunoassay — Analytical procedure based on reactions between antigens and antibodies.

Information zone — The main area of the software screens containing information pertaining to a particular screen, including screen name.

Multi-module — ARCHITECT *i* System configuration containing more than one (1) *i* 2000 processing module.

Popup windows — Overlay screens that appear at the center of a full-frame screen and in front of the currently displayed window. All interaction with the user interface is suspended until you acknowledge the popup by selecting one of the buttons in the window.

Process path — A covered temperature controlled circular track that moves RVs; provides liquid aspiration, and wash points as necessary for the assay.

Processing center — Area in which assay processing activities take place. Contains the process path.

Processing module — Light sealed area where sample processing takes place. Functions that occur here include mixing and delivering of reagents, solutions, and samples, incubations, all optical reads and disposal of used RVs.

Processing module graphic — Located in the center of the Snapshot screen, and contains key information specific to the processing module, as well as navigational hot spots for accessing related screens.

Processing module status — Information regarding the operational mode of the processing module. Status types include: Offline, Stopped, Warming, Ready, Scheduled Pause, Running, Initializing, and Scanning.

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

Query Response — A message sent to the ARCHITECT *i* System 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.

Radio buttons — A user interface input area where you can only make one selection from multiple options. A black-filled circle indicates that it has been selected.

Reaction Vessel (RV) — A disposable that carries a specified volume of sample, reagent, and solution through the processing center path.

Reagent carousels — Carousels located in the refrigerated compartment of the processing center where reagent bottles are loaded.

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 double load / Unload queues — Configured on multi-module systems to provide two load queue lanes with a capacity of up to 125 samples each (25 sample carriers) for a total capacity of 250 samples (50 sample carriers).

Sample handler — Module that transports samples from the load queue to the Processing Center queue and then to the unload queue.

Sample handler keypad — Used to provide extended system control center functionality at the sample handling center.

Sample handler status — Information regarding the operational mode of the sample handler. Status types include: Offline, Stopped, Ready, Running, and Load queue paused.

Sample load queue	Track on the left side of the processing module where sample carriers are loaded.
Sample load queue bar code reader	Used to scan carrier ID bar codes, carrier position bar codes, and primary tube bar codes to identify the sample.
Sample processing queue	Track in front of the processing module where sample carriers are transported from the load queue to the sample aspiration position and then down the track to the unload queue.
Sample syringe (SS)	Aspirates and dispenses sample by moving the piston in the syringe body.
Sample unload queue	Track on the right side of the processing module where sample carriers are unloaded
Serial port	A connection point between the ARCHITECT *i* System and an external device.
Snapshot screen	The Main Menu screen of the ARCHITECT *i* System. Monitors key system and processing module information. Also provides quick access to related screens through the use of icons and drop-down menus.
System control center	Computer workstation that provides a centralized interface by which the operator can control one or more processing modules.
System software	Software that controls operation of the ARCHITECT *i* System.
System status	Information regarding the operational modes of the system. The processing module and the sample handler each have separate statuses.
Unicode	Character encoding scheme that supports internationalization of textual information. The encoding scheme uses 16 data bits to represent each character which provides for definition of 65536 unique characters.
User interface	Graphical screens that an operator uses to control and navigate through the ARCHITECT *i* System software. Navigate by using a mouse, touchscreen monitor, and/or keyboard.

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Revision history

The revision history table provides a high level summary of content that has changed in this document since the last revision (LN 06F71-02).

How to Use this Manual	1. Added description of Section 8: ARCHITECT *i* System and AxSYM System comparison. 2. Removed statement that ASIST is included in the manual.
Section 1 **Abbott Standard Interface**	Removed information concerning Abbott data management systems.
Section 2 **Overview of the ARCHITECT *i* System**	1. Added Laboratory Automation System (LAS) sample handler information. 2. Updated ARCHITECT i System support of ASI Options topic (Establishment Phase and Result Transmission).
Section 3 **Communications Setup**	1. Updated System startup, pause, and shutdown topic with Laboratory Automation System (LAS) sample handler information. 2. Updated Setting Communications topic. 3. Added number format configuration information (Configure System Control Center Dialog Windows).
Section 4 **ARCHITECT i System-specific Outgoing Messages**	1. Clarified information on Patient and QC Results Transmission. 2. Updated the following topics for patient results transmission: • 7.1.12 - removed Q as processing ID • 10.1.7 - expanded Westgard flags 3. Added examples of records
Section 5 **ARCHITECT *i* System Incoming Messages**	1. Clarified the following topics: • Patient Information Record • Result Record • Test Order Record • Comment Record 2. Removed Unicode support information.
Section 6 **Troubleshooting**	1. Updated the following error messages: 8154, 8158-8178, 8180, 8250, 8253-8357, 8457, and 8458. 2. Added error messages: 8102, 8182, 8183, 8261, 8358, 8461, 8462, 8463, and 8465.
Section 7 **Abbott ARCHITECT Host/Instrument Interface Simulation**	Updated ASIST Tool Overview topic.

Section 8 **ARCHITECT *i* System *and AxSYM System Comparison***	Updated the following topics: • Introduction • Physical Layer - Host Interface Port • Message Content Layer - Canceling of Test Orders, Transmission Modes, Transmission of Multiple Flags, and Query Mode • Document Comparison (System-Specific Outgoing Messages) - Communication: (ARCHITECT i vs. AxSYM) to Host, Patient Record, Test Order Record, Result Record, and Comment Record • Document Comparison (System-Specific Incoming Messages) - Message Header Record, Patient Information Record, and Test Order Record • ARCHITECT ONLY: Comment Record