

Chapter 12 – Interface Specification

12-1 Overview

This document describes how data is transferred between a GEM 4000 and external systems, like a DMS, HIS, LIS or other analyzers.

The data transfer protocol specified in this document is implemented according to ASTM (American Society for Testing and Materials) E1394-91 and E1381-91 high and low level clinical data transfer protocols. The documentation for ASTM E1394-91 and E1381-91 should also serve as reference material.

12-2 Physical Layer

TCP/IP sockets

The GEM 4000 has multiple modes of operation and is configurable for each of the following modes:

- TCP/IP (HIS/LIS as Client).
- TCP/IP (GEM 4000 as Client).

HIS/LIS as Server

Description

The GEM 4000 is considered the client and the remote system is the server (master). The remote system opens a port and listens for a connection request. The GEM 4000 requests for connection. Once the request has been accepted, the GEM 4000 is able to transmit and receive according to the rules specified by the Low Level Protocol.

If connection is lost (remote system closes the server socket or an error occurs), GEM4000 requests a new connection:

- Every second during the first minute.
- Every 5 minutes after that time.

Configuration

The following parameters are configurable

- Port Number: The port used to establish the connection. Allowed values are from 1024 to 65,535, boundaries inclusive. Defaults are 1183 and 1184 (see Volume 4b).

- Server Address: A valid Address (IP or host name). Default is null.

The following parameters are not configurable but are accessible to technical people in case of communication problems:

- Connection Timeout. Timeout set when trying to establish a connection. Allowed values are from 1 to No timeout. Default is 5s.

HIS/LIS as Client

Description

The GEM 4000 is considered the server (master) and the remote system is the client (slave). The GEM 4000 opens a port and listens for a connection request. Once the request has been accepted, the GEM 4000 is able to transmit and receive according to the rules specified by the Low Level Protocol.

If connection is lost (remote system closes connection or an error occurs), GEM4000 waits for another connection.

NOTE: This is the mode used when GEM 4000 connects to IMPACT.

Configuration

The following parameters are configurable

- Port Number: The port used to establish the connection. Allowed values are from 1024 to 65,535 boundaries inclusive. Defaults are 1183 and 1184 (see Volume 4b).

RS-232

Overview

This section describes those issues related to mechanical and electrical connection between the GEM 4000 and external devices like an HIS/LIS or an external instrument. The topology is point-to-point, a direct connection between both devices.

The SW uses a word length (Data Bits) of 8 bits

The rest of settings are configurable as it is described in the next section

Configurable settings

The SW allows the configuration of the following settings.

- Port. The SW displays the ports available in the back panel of the instrument, labeled the same way as on the analyzer'.
- Baud Rate. The SW supports the following baud rates:
 - 1200 bps.
 - 0002400 bps.
 - 4800 bps.

- 9600 bps (default).
- 14400 bps.
- 19200 bps.
- 38400 bps.
- 57600 bps.
- 115200 bps.
- 128000 bps.
- Parity. The SW supports the following parity settings:
 - None (default).
 - Odd.
 - Even.
 - Mark.
 - Space.
- Stop Bits: The SW supports a stop bit value of either 1 or 2 (default is 1).
- Start Bits: The SW supports a start bit value of 1 (default is 1).
- Flow Control. The SW supports the following modes:
 - None (default).
 - RTS/CTS.
 - Xon/Xoff.

Interface connections

The serial ports of the instrument are a PC-standard DB-9 (EIA/TIA 574) male connector (also known as RS-232 connectors). The following are the PIN connections for a standard PC serial communications interface. Note that these ports are wired as DTE (Data Terminal Equipment).

Table 12-1 PIN connections for a standard PC serial communications interface

	EIA/TIA Name	CCITT V.24	Signal direction	DB-9 Pin	DB-25 Pin	Description	Used by the Instrument
TD	BA	103	Out	3	2	Transmitted Data	Yes
RD	BB	104	In	2	3	Received Data	Yes
RTS	CA/CJ	105/133	Out	7	4	Request To Send	Yes
CTS	CB	106	In	8	5	Clear To Send	Yes
DSR	CC	107	In	6	6	Data Ready Set	Yes
SG	AB	102	-	5	7	Signal Ground	Yes
DCD	CF	109	In	1	8	Carrier Detect	No
DTR	CD	108/1, /2	Out	4	20	Data Terminal Ready	Yes
RI	CE	125	In	9	22	Ring Indicator	No

12-3 Low Level Protocol (Data Link Layer)

Background

The data link layer has procedures for link connection and release, delimiting and synchronism, sequential control, error detection and error recovery. The application messages passed from the upper layer are framed and then transmitted. The frames received are packaged and then passed to the upper layer. A primary function of this layer is to prevent loss of data between devices.

The Data Link Layer protocol supported by the GEM 4000 is the ASTM E1381.

NCCLS LIS1-A (formerly ASTM E1381) Data Link Layer

Overview

This standard uses a character-oriented protocol to send messages between directly connected systems. The coding is the ANSI X3.4-1986 and some restrictions are placed on the characters that can appear in the message content.

The data link mode of operation is a one-way transfer of information with alternate supervision. Information flows in one direction at a time. Replies occur after information is sent, never at the same time. It is a simple stop-and-wait protocol. The sender and receiver use timeouts to detect the loss of coordination between them and provide a method for recovery the communication.

The two systems operate actively to transfer information. The remainder of the time the data link is in a Neutral State. There are three phases involved in the transmission of message frames:

- Establishment Phase (or Link Connection). Determines the direction of information flow and prepares the receiver to accept information.
- Transfer Phase in which the sender transmits messages to the receiver using frames.
- Termination Phase in which the link is released and the sender notifies the receiver that all messages are sent.

Establishment Phase (Link Connection)

Operation

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

The system with information available, the sender, initiates the establishment phase to notify the receiver that information is available.

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

The sequence is as follows:

1. The sender determines that the data line is in a Neutral State.
2. The sender sends the <ENQ> transmission control character to the receiver. Sender ignores all responses other than <ACK>, <NAK> or <ENQ>.
3. If the receiver is prepared to receive data, it responds with the <ACK> character to the sender. The link connection is established, entering the Transfer Phase.
4. If the receiver is not ready to receive data it responds with the <NAK> character. Upon receiving a <NAK>, the sender must wait at least 10 seconds before transmitting another <ENQ> transmission control character.

Contention

When the two systems simultaneously transmit <ENQ> the data link is in contention.

In the Observation Reporting Interface (G4K, which acts as an observation reviewer, connected to an observation recipient), the G4K has priority.

In the Device Interface (a device connected to the G4K, which acts as an observation reviewer), the device has priority.

So, when an <ENQ> is received in response to an <ENQ>, the situation is solved as follows:

- The system with priority waits at least 1 second before sending another <ENQ>.
- The system without priority must stop trying to transmit and prepare to receive. When the next <ENQ> is received it replies with an <ACK> or <NAK> depending on its readiness to receive.

Transfer Phase

During the Transfer Phase, the sender transmits messages to the receiver until all messages are sent.

Frames

Messages are sent in frames, each frame contains a maximum of N+7 bytes (N message text plus 7 control characters). N is a configurable number which ranges from 240 to 64,000 (see volume 4a).

Messages longer than N bytes are divided between two or more frames.

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

A frame is one of two types: the Intermediate Frame (IF) and the End Frame (EF). Their only difference relies on one transmission control character, but they are semantically different (see below for details)

- "Intermediate frame <STX> FN Text <ETB> C1 C2 <CR> <LF>
- "End frame <STX> FN Text <ETX> C1 C2 <CR> <LF>

The last frame of a message always is an End Frame. All previous frames are sent as Intermediate Frames.

A message containing 240 characters or less is sent in a single End Frame.

Longer messages are sent in intermediate frames with the last part of the message sent in an end frame.

A brief description for every part of a frame is given in the table below:

Table 12-2 Frame Part

	<i>Frame Part Description</i>
<STX>	<u>S</u> tart of <u>T</u> ext transmission control character
FN	<u>F</u> rame <u>N</u> umber (single digit comprised in the range 0-7) – See details in section Frame Number
Text	Data content of Message
<ETB>	<u>E</u> nd of <u>T</u> ransmission <u>B</u> lock transmission control character
<ETX>	<u>E</u> nd of <u>T</u> ext transmission control character
C1	Most significant character of checksum (belonging to {0-9, A-F}) – See details in section Checksum
C2	Least significant character of checksum (belonging to {0-9, A-F}) – See details in section Checksum
<CR>	<u>C</u> arriage <u>R</u> eturn ASCII character
<LF>	<u>L</u> ine <u>F</u> eed ASCII character

Frame number

The frame number (FN) permits the receiver to distinguish between new and retransmitted frames.

The frame number begins at 1 with the first frame of the Transfer phase (see below). The frame number is incremented by one for every new frame transmitted. After 7, the frame number rolls over to 0, and continues in this fashion.

Checksum

The checksum permits the receiver to detect a defective frame. The checksum is encoded as two characters.

The checksum is computed by adding the binary values of the characters, and keeping the least significant eight bits of the result. It is an addition module 256.

The checksum is initialized to zero with the <STX> character. The checksum computation uses the FN, all characters belonging to Text and <ETB> or <ETX>. The computation for the checksum does not include <STX>, the checksum characters, or the trailing <CR> and <LF>.

The checksum is an integer of eight bits, and can be considered as two groups of four bits. Both groups of four bits are converted to the ASCII characters of the hexadecimal representation, and transmitted as the message checksum.

Example: A checksum of 89 can be represented as 01011011 in binary or 5B in hexadecimal. The checksum is transmitted as the ASCII character 5 followed by the ASCII character B.

Acknowledgements

After a frame is sent, the sender stops transmitting until a reply is received (stop-and-wait protocol). The receiver can reply to each frame in three ways:

- A reply of <ACK> means the last frame was successfully received and the receiver is ready to receive the next one. The sender must send a new frame or terminate.
- A reply of <NAK> signifies the last frame was not successfully received and the receiver is prepared to receive the frame again.
- A reply of <EOT> means the last frame was successfully received, but the receiver requests the sender to stop transmitting.

This reply must be transmitted within the timeout period specified in the timeouts section

Receiver Interrupts

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

If the sender chooses to ignore the <EOT>, the receiver must re-request the interrupt for the request to remain valid.

If the sender chooses to honor the <EOT>, it must first enter the termination phase to return the data link to the neutral state. The original sender must not enter the establishment phase for at least 15 seconds or until the receiver has sent a message and returned the data link to the neutral state.

G4K usage: G4K ignores the interrupt request. G4K ignores the <EOT> until the message transmission is completed. If G4K receives and <EOT> as an answer to the last frame, it waits 15 seconds until it goes to the establishment phase.

Termination Phase (link release)

The Termination Phase returns the data link to the neutral state. The sender initiates the Termination Phase by transmitting the <EOT> character and then regards the line to be in the Neutral State. After receiving the <EOT> the receiver also regards the line to be in the neutral state.

Error Recovery

Defective frames

A receiver checks every frame to guarantee it is valid. A reply of <NAK> is transmitted for invalid frames. Upon receiving the <NAK>, the sender retransmits the last frame with the same frame number.

- A frame should be rejected because take place some of the following situations:
- Any character errors are detected (parity errors, framing error...).
- The frame checksum does not match the checksum computed on the received frame.
- The frame number is not the same as the last accepted frame or one number higher (modulo 8).
- There are invalid characters in the message body. See section 4.2.6 or invalid characters

Any characters occurring before <STX> or <EOT>, or after the end of the block characters (<ETB> or <ETX>), are ignored by the receiver when checking for frame validity.

Every time the sender tries to transmit a particular frame, and receives a <NAK> or any other character different from <ACK> or <EOT> (a <NAK> condition), a retransmission counter for the given frame is increased. If this counter shows a single frame was sent and not accepted six times, the sender must abort this message by proceeding to the termination phase.

Timeouts

The sender and the receiver use timers to detect loss of coordination between them:

- During the establishment phase, the sender sets a timer when transmitting the <ENQ>. A timeout occurs if a reply of an <ACK>, <NAK> or <ENQ> is not received within 15 seconds. After a timeout, the sender enters the termination phase.
- During the establishment phase, if the system without priority detects contention, it sets a timer. If the subsequent <ENQ> is not received within 20 seconds, it regards the line to be in the neutral state.
- During the transfer phase, the sender sets a timer when transmitting the last character of a frame. If the reply is not received within 15 seconds, a timeout occurs. After a timeout, the sender aborts the message transfer by proceeding to the termination phase.
- During the transfer phase, the receiver sets a timer when first entering the transfer phase or when replying to a frame. If a frame or an <EOT> is not received within 30 seconds, a timeout occurs. After a timeout, the receiver discards the last incomplete message and regards the line to be in the neutral state.
- A receiver must reply to a frame within 15 seconds or the sender times out.

Valid Characters in the Text part

The data link protocol is designed for sending character based message text. There are restrictions on which characters may appear in the message text. These restrictions make it simpler to recognize frames, replies and avoid interfering with software controls for devices

The restricted characters are: <SOH>, <STX>, <ETX>, <EOT>, <ENQ>, <ACK>, <DLE>, <NAK>, <SYN>, <ETB>, <LF>, <DC1>, <DC2>, <DC3> and <DC4>.

Checking channel status

To test the connection, the GEM 4000 transmits the ASCII <ENQ> transmission control character, decimal value 5. If the receiving system responds within fifteen seconds with one of the following:

- The ASCII <ACK> transmission control character, decimal value 6,
- The ASCII <NAK> transmission control character, decimal value 21, or
- <ENQ>.

The GEM 4000 enters the Termination phase and the result of the connection test is success. If the GEM 4000 does not receive one of the above responses within 15 seconds, the GEM 4000 enters the Termination phase and the result of the connection test is failure. See Volume 4a for a description of when connection test is performed.

12-4 High Level Protocol

Background

NCCLS LIS2-A (formerly ASTM E1394-97)

Background and Terminology

This protocol specifies the communication between clinical instruments and computers.

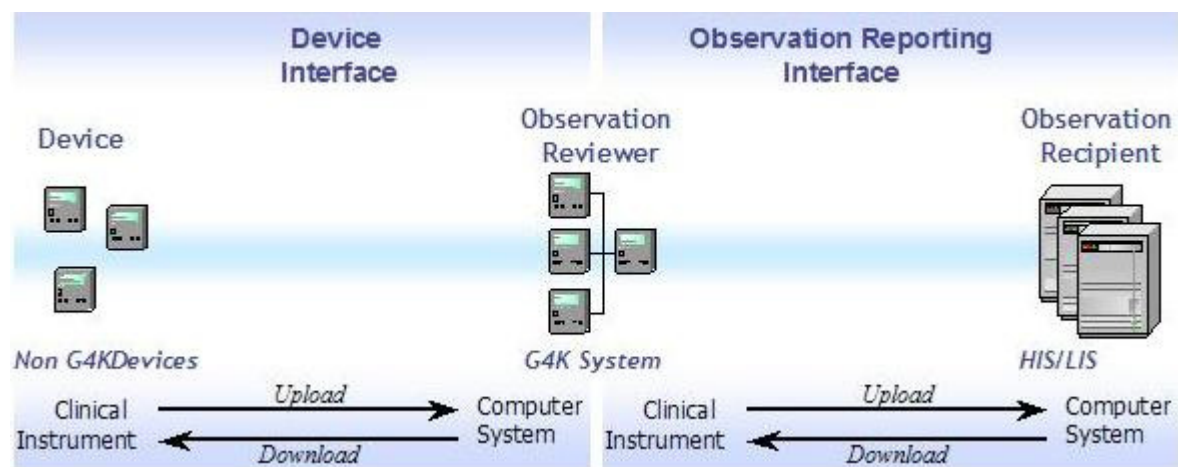
GEM 4000 uses the protocol to interchange information with non-G4K instruments and with the HIS/LIS:

- The Observation Reporting Interface (ORI), covers the communication between the GEM 4000 system and the HIS/LIS. In the ORI, the GEM 4000 plays the role of Clinical Instrument and the HIS/LIS plays the role of Computer System.
- The Device Interface (DI), covers the communication between the non-G4K devices and the GEM 4000 system. In the DI, the non-G4K devices play the role of Clinical Instrument and the GEM 4000 plays the role of Computer System.

Data transmitted from a computer system to a clinical instrument is called download.

Data transmitted from a clinical instrument to a computer system is called upload.

Figure 12-1 Clinical Instruments and Computer Systems



When describing the syntax of the protocol, the following conventions is used:

Table 12-3 Syntax

Convention	Meaning
x	1 Element X is required and can only appear once
{x}	1...* Element X is required and can appear more than once
[x]	0,1 Element X is not required and can only appear once
[{x}] = { [x] }	0...* Element X is not required and can appear more than once
+	And
 	Or

Each record is described by means of a table, with the following columns:

- Field, Field Name and Description. ASTM definitions for the field.
- Comp.: If the field has only one component, is empty. If the field has only one repeat, it indicates the component (1, 2, 3...). If it has more than one repeat, indicates repeat and component (1.1, 1.2, 1.3, 2.1, 2.2...).
- Max. Len.: A dash indicates that length is implicit in the field or has no maximum.
- Req.:
 - R: Required.
 - O: Optional.
 - X: Unused.
- Values Formats and Comments:
 - Quoted text appears exactly like this.
 - Elements in italics refer to one of the GEM 4000 database fields described in **Table 12-79**.

Table 12-4 ORI

	Field Name	Description	Comp	Max Len	Req	Values, formats and comments
1	Record Type ID	Identifies the record		1	R	"C"
2	Sequence Number	Defines the I'th occurrence of the associated record		1	R	"1"
3	Comment Source	Comment Origination Point		1	R	"I" (clinical instrument system)
4	Comment Text	Comment codes and text	1	1	R	Exception Code. See below
			2	?	R	Exception Description. See below
5	Comment Type	Comment type qualifier		1	R	"I" (instrument flags(s) comment)

Message Structure and contents

This standard specifies the conventions for structuring the content of the messages exchanged and for representing the data elements contained within those structures.

The standard specifies a message system in which messages are composed by a hierarchy of records that are defined using a positional convention. Each record describes one aspect of the complete message and can be of various types. Records are composed by an aggregate of fields, also defined using a positional convention.

Records

Table 3 details the records used by the GEM 4000.

Table 12-5 Record Fields

Record	First Character
Message Header Record	H
Patient Identifying Record	P
Test Order Record	O
Result Record	R
Comment Record	C
Request Information Record	Q
Manufacturer Information Record	M
Scientific Record (not used by GEM 4000)	S

The standard does not impose a maximum record length. Ingoing and outgoing messages can be of any size.

Fields

A field can be seen as a specific attribute of a record, which may contain aggregates of data elements further refining the basic attribute. There are two kinds of aggregates within a message, the repeat field and the component field:

- Repeat field: a single data element that expresses a duplication of the field definition. Each element of a repeat field is to be treated as having equal priority to associated repeat fields
- Component field: single data element or data elements that express a finer aggregate or extension of data elements, which precede it.

Example: A patient's name is recorded as last name, first name, and middle initial, each of which is separated by a component delimiter.

The standard does not impose a maximum field length, and assumes that all fields are variables in length. The GEM 4000 implementation restricts the maximum field length to a concrete value depending on the field, but never uses more characters than required by the given field value (according to the standard)

Maximum field lengths are specified in the different modes supported by the GEM 4000.

If the length of a received field is greater of the specified by the mode, the field is truncated and the event is traced (ex: if "Urruticoechea-Jiménez" is received as a last name in the GEM 3000 mode -which is 16 characters maximum- is truncated to "Urruticoechea-Ji").

The same consideration applies when sending fields.

Hierarchy

Message records are logically structured by levels:

- Records at level 0 contain information about the sender identification (Message Header Record) and the completion of the message (Message Terminator Record).
- Records at level 1 contain information about patients (Patient Information Record), queries (Request Information Record) or scientific records (Scientific Information Record). Scientific Records are not used by GEM 4000.
- Records at level 2 contain information about test order requests and specimens (Test Order Record). An order record may never appear without a preceding patient record.
- Records at level 3 contain information about test results (Result Record). A test result record may never appear without a preceding order record.
- Comments (Comment Record) and manufacturer records (Manufacture Information Record) may be inserted at any level in the hierarchy. These records relate to the immediately preceding it.

A sequence of records at one level is terminated by the appearance of a record type of same or higher level.

Character Codes

All data is represented as 8-bit, single-byte, coded graphic character values as defined in ISO 8859-1:1987. The allowed and disallowed characters are as follows:

Table 12-6 Character Codes

	Status	Comments
0-6	Disallowed	NUL (Null char.) SOH (Start of Header) STX (Start of Text) ETX (End of Text) EOT (End of Transmission) ENQ (Enquiry) ACK (Acknowledgment)
7	Allowed	BEL (Bell)
8	Disallowed	BS (Backspace)
9	Allowed	HT (Horizontal Tab)
10	Disallowed	LF (Line Feed)
11-13	Allowed	VT (Vertical Tab) FF (Form Feed) CR (Carriage Return)
14-31	Disallowed	SO (Shift Out) SI (Shift In) DLE (Data Link Escape) DC1 (XON) (Device Control 1) DC2 (Device Control 2) DC3 (XOFF) (Device Control 3) DC4 (Device Control 4) NAK (Negative Acknowledgement) SYN (Synchronous Idle) ETB (End of Trans. Block) CAN (Cancel) EM (End of Medium) SUB (Substitute) ESC (Escape) FS (File Separator) GS (Group Separator) RS (Request to Send)(Record Separator) US (Unit Separator)
32-126	Allowed	Space !"#\$%&'()*+,-./ 0 1 2 3 4 5 6 7 8 9 :;<=>?@ A B C D E F G H I J K L M N O P Q R S T U V W X Y Z [\]^_` a b c d e f g h i j k l m n o p q r s t u v w x y z { }~
127	Disallowed	DEL (Delete)
128-254	Allowed	Undefined by the standard. See description below
255	Disallowed	

The 8-bit values, within the range from 0 to 127 of ISO 8859-1:1987 correspond to the ASCII standard character set.

Values between 128 and 254 are undefined by standard. The standard states: "it is responsibility of the instrument vendor and computer system to understand the representation of any extended or alternate character set being used".

GEM 4000 uses the ISO-8859-1 (Latin-1) extended character set.

If a disallowed character is received in a field, the G4K processes the field, ignoring the disallowed character and tracing the event for debugging (ex: "S<BEL>mith" is processed as "Smith").

Delimiters

Delimiters are used to establish separate sections within a message. There are five different delimiters.

- **Record delimiter:** It signals the end of any of the defined record types. It is fixed to carriage return character Latin-1 (13) (ASCII 13).
- **Field delimiter:** It is used to separate adjacent fields. It is configurable, and is specified in the message header record. It is a single character excluding Latin-1 (13) (ASCII 13).
- **Repeat delimiter:** Used to separate variable number of descriptors for fields containing parts of equal members of the same set. It is configurable, and is specified in the message header record. It is a single character, excluding Latin-1 (13) (ASCII 13) and the value used by the field delimiter.
- **Component delimiter:** It is used to separate data elements of fields of a hierarchical or qualifier nature. It is configurable, and is specified in the message header record. It is a single character, excluding Latin-1 (13) (ASCII 13), the value used by the field delimiter and the value used by the repeat delimiter.
- **Escape delimiter:** Used within text fields to signify special case operations. It is configurable, and is specified in the message header record. It has a complex structure, but mainly use a single character. The chosen character is different from Latin-1 (13) (ASCII 13) and the field, repeat, and component delimiter values.

Alphanumeric characters should not be used as delimiters, according to the standard. GEM 4000 allows the use of the following characters as delimiters. (Boundary values are also included)

- Any value from ASCII (33) to ASCII (47)
- Any value from ASCII (58) to ASCII (64)
- Any value from ASCII (91) to ASCII (96)
- Any value from ASCII (123) to ASCII (126)

The default delimiters are the following set (these values depend on the mode, see the different modes description below in this document):

- | | | |
|--------------------------------------|-------------------------|-----------------------|
| • Record delimiter - carriage return | (represented as "<CR>") | (Latin 1 / ASCII 13) |
| • Field delimiter - vertical bar | (" ") | (Latin 1 / ASCII 124) |
| • Repeat delimiter - at | ("@") | (Latin 1 / ASCII 64) |
| • Component delimiter - caret | ("^") | (Latin 1 / ASCII 94) |
| • Escape delimiter - backslash | ("\") | (Latin 1 / ASCII 92) |

The escape delimiter may be used to signal certain special characteristics of portions of a text field (for example, imbedded delimiters, line feed, carriage return, etc). An escape sequence consists of the escape delimiter character followed by a single escape code ID (listed below), followed by zero or more data characters followed by another (closing) occurrence of the escape delimiter character.

No escape sequence contains a nested escape sequence.

The following predefined escape sequences are used by the GEM 4000 (assuming "\" as the escape delimiter, replace by the appropriate escape delimiter when different):

- \F\ Imbedded field delimiter character
- \S\ Imbedded component field delimiter character
- \R\ Imbedded repeat field delimiter character
- \E\ Imbedded escape delimiter character

The following predefined escape sequences are ignored by the GEM 4000.

- \H\ Start highlighting text (ignored by GEM 4000).
- \N\ Normal text (end highlighting) (ignored by GEM 4000).
- \Xhhhh\ Hexadecimal data. Any number of hexadecimal digits may follow. The escaping of ASTM disallowed characters happens when G4K wants to send a character that is not allowed in ASTM. Characters that can be escaped are the ASCII characters 10, 13, 127, 255. In this case, the character is escaped using the hexadecimal escaping. For example, if G4K wants to send the character 127 it is escaped to \X7F\.
- \Zcccc\ Local defined escape sequences, used to send characters not representable in the configured codepage. Local escape sequence is used to exchange characters not representable using the configured codepage. For example, if G4K wants to send a Japanese character (for example the Unicode character U+34C8) using the English codepage, the character would be lost in a normal transmission because it cannot be represented in that specific codepage. To avoid losing any character, characters not representable in the selected codepage are escaped using the local escape sequence. In that case, the Japanese character is sent in four hexadecimal digits as \Z34C8\.

(Note: Use of hexadecimal and local data is studied during implementation phase)

Fields are identified by their position, obtained by counting field delimiters from the front of the record. This position-sensitive identification procedure requires that when the contents of the field are null, its corresponding field delimiter is included in the record to ensure that the i'th field can be found by counting (i-1) delimiters. Delimiters are not included for trailing null fields.

Message Transmission Control

Storage

In order to ensure proper error logging and error recovery, the next rule is followed according to the standard. Since data content is structured in hierarchical fashion, any decreasing change in the hierarchical level triggers storage of all data transmitted prior to said level change, and not previously saved.

An example of the prior rule application is the following:

Record #	Record Type	Level	(level variation)	Storage action
1	Message Header	L0	(0)	
2	Patient1		L1 (+1)	
3	Order1		L2 (+1)	
4	Result1		L3 (+1)	
5	Order2		L2 (-1)	{Save 1 - 4}
6	Order3		L2 (0)	
7	Patient2		L1 (-1)	{Save 5 - 6}
8	Order1		L2 (+1)	
9	Comment1	L3	(+1)	
10	Result1		L3 (0)	
11	Comment1	L4	(+1)	
12	Result2		L3 (-1)	{Save 7 - 11}
13	Order2		L2 (-1)	{Save 12}
14	Patient3		L1 (-1)	{Save 13}
15	Order1		L2 (+1)	
16	Result1		L3 (+1)	
17	Message Terminator	L0	(-3)	{Save 14 - 16}

Note: Record # 17 is assumed as saved by virtue of the record type function

Error Recovery

If a transmission failure occurs, the protocol requires that transmission starts only at the last record not presumed saved as outlined the previous section (Storage). GEM 4000 transmits the complete message.

HL7

Background and conventions

This section defines the HL7 implementation used by the GEM 4000. This specification handles the communication of test result and ordering information between the GEM 4000 and the HIS/LIS.

This implementation is compliant with **version 2.4 of the Health Level Seven (HL7) Standard**.

The reporting of patient sample results to the HIS/LIS is compliant (as well as with HL7 v2.4) with the POCT1-A Standard:

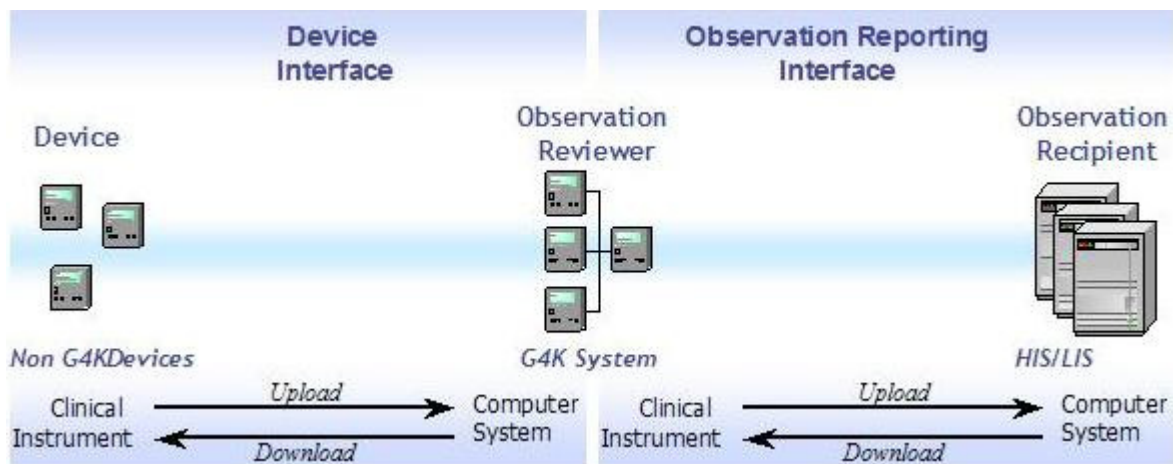
Point-Of-Care Connectivity; Approved Standard. NCCLS Document POCT1.A (ISBN 1-56238-450-3)
Appendix C: Observation Reporting Interface.

According to the POCT1-A Standard, the interface described in this chapter is the Observation Reporting Interface (Figure 2), where the GEM 4000 system plays the role of Observation Reviewer and the HIS/LIS plays the role of Observation Recipient.

Data transmitted from the HIS/LIS to the GEM 4000 is called download.

Data transmitted from the GEM 4000 to the HIS/LIS is called upload.

Figure 12-2 Observation Reporting Interface



When describing the syntax of the protocol, the following conventions are used:

Table 12-7 Protocol

	Meaning
X	1 Element X is required and can only appear once
{X}	1...* Element X is required and can appear more than once
[X]	0,1 Element X is not required and can only appear once
[{X}]=[X]	0...* Element X is not required and can appear more than once
+	And
 	Or

Message Structure and contents

This section defines the components of messages and provides the methodology for defining abstract messages that are used in later sections. A message is the atomic unit of data transferred between systems. It is comprised of a group of segments in a defined sequence. Each message has a message type that defines its purpose. For example the ADT Message type is used to transmit portions of a patient's Patient Administration (ADT) data from one system to another. A three-character code contained within each message identifies its type. Messages used by the GEM 4000 are listed in **Table 12-8**.

Table 12-8 Messages

	<i>Description</i>
ACK	General acknowledgement Message
ORU	Observation Result Unsolicited Message
OUL	Unsolicited Laboratory Observation Message

The real-world event that initiates an exchange of messages is called a trigger event. These events (a three letter code) represent values such as "A patient is admitted" or "An order event occurred". There is a one-to-many relationship between message types and trigger event codes. The same trigger event code may not be associated with more than one message type; however a message type may be associated with more than one trigger event. Triggers used by the GEM 4000 are listed in **Table 12-9**.

Table 12-9 Triggers

<i>Trigger</i>	<i>Description</i>	<i>Initiated by</i>
ORU^R31	New Observation. Search for an Order	G4K
ORU^R32	Preordered Observation	G4K
ACK^R33	Acknowledgement of ORU^R30/31/32,	HIS/LIS
OUL^R21	Update calibrations, QCs and CVP	G4K

Segments

A segment is a logical grouping of data fields. Segments of a message may be required or optional. They may occur only once in a message or they may be allowed to repeat. Each segment is given a name. For example, the ADT message may contain the following segments: Message Header (MSH), Event Type (EVN), Patient ID (PID), and Patient Visit (PV1).

Each segment is identified by a unique three-character code known as the Segment ID. Segments used by the GEM 4000 are listed in **Table 12-10**:

Table 12-10 HL7 Segments

<i>Segment</i>	<i>Description</i>
MSA	Message Acknowledgment Segment
MSH	Message Header Segment
NTE	Notes and Comments Segment
OBR	Observation Request Segment
OBX	Observation Segment

ORC	Common Order Segment
PID	Patient identification Segment
SAC	Specimen and Container Detail Segment

Fields

Definition: A field is a string of characters.

HL7 does not care how systems actually store data within an application. When fields are transmitted, they are sent as character strings. Except where noted, HL7 data fields may take on the null value. Sending the null value, which is transmitted as two double quote marks (""), is different from omitting an optional data field. The difference appears when the contents of a message is used to update a record in a database rather than create a new one. If no value is sent, (i.e., it is omitted) the old value should remain unchanged. If the null value is sent, the old value should be changed to null.

The various sections in §6 contain segment attribute tables. These tables list and describe the data fields in the segment and characteristics of their usage. In defining a segment, the following information is specified about each field:

- Field, Field Name and Description. HL7 definitions for the field.
- Comp.: If the field has only one component, is empty. If the field has only one repeat, it indicates the component (1, 2, 3...). If it has more than one repeat, indicates repeat and component (1.1, 1.2, 1.3, 2.1, 2.2...).
- Max. Len.: A dash indicates that length is implicit in the field or has no maximum.
- Req.:
 - R: Required.
 - RE: Required may be empty.
 - O: Optional.
 - X: Unused.
- Values Formats and Comments:
 - Quoted text appears exactly like this.
 - Elements in italics refer to one of the GEM 4000 database fields described in **Table 12-79**.

Character Codes

All data is represented as 8-bit, single-byte, coded graphic character values as defined in ISO 8859-1:1987. The allowed and disallowed characters are as follows:

Code	Status	Comments
32-126	Allowed	Space !"#\$%&'()*+,-./ 0123456789 ;;<=>?@ A B C D E F G H I J K L M N O P Q R S T U V W X Y Z [\] ^ _ ` a b c d e f g h i j k l m n o p q r s t u v w x y z { } ~
128-254	Allowed	ISO-8859-1 (Latin-1) extended character set.

GEM 4000 uses the ISO-8859-1 (Latin-1) extended character set.

If a disallowed character is received in a field, the G4K processes the field, ignoring the disallowed character and tracing the event for debugging (ex: "S<BEL>mith" is processed as "Smith").

The following predefined escape sequences are used by the GEM 4000 (being "\"the escape delimiter):

- \F\ Imbedded field delimiter character
- \S\ Imbedded component field delimiter character
- \R\ Imbedded repeat field delimiter character
- \T\ Imbedded subcomponent delimiter character
- \E\ Imbedded escape delimiter character

The following predefined escape sequences are ignored by the GEM 4000.

- \H\ Start highlighting text (ignored by GEM 4000).
 - \N\ Normal text (end highlighting) (ignored by GEM 4000).
 - \Xhhhh\ Hexadecimal data. Any number of hexadecimal digits may follow. The escaping of ASTM disallowed characters happens when G4K wants to send a character that is not allowed in ASTM. Characters that can be escaped are the ASCII characters 10, 13, 127, 255. In this case, the character is escaped using the hexadecimal escaping. For example, if G4K wants to send the character 127 it is escaped to \X7F\.
 - \Zcccc\ Local defined escape sequences, used to send characters not representable in the configured codepage. Local escape sequence is used to exchange characters not representable using the configured codepage. For example, if G4K wants to send a Japanese character (for example the Unicode character U+34C8) using the English codepage, the character would be lost in a normal transmission because it cannot be represented in that specific codepage. To avoid loosing any character, characters not representable in the selected codepage are escaped using the local escape sequence. In that case, the Japanese character is sent in four hexadecimal digits as \Z34C8\.
- Also note, that many non-representable codepage characters can be added in the same escape sequence.

Delimiters

In constructing a message, certain special characters are used. They are the segment terminator, the field separator, the component separator, subcomponent separator, repetition separator, and escape character.

The segment terminator is always a carriage return (in ASCII, a hex 0D). The other delimiters are defined in the MSH segment, with the field delimiter in the 4th character position, and the other delimiters occurring as in the field called Encoding Characters, which is the first field after the segment ID. The delimiter values used in the MSH segment are the delimiter values used throughout the entire message.

GEM 4000 always uses the suggested values by HL7, found in **Table 12-11**.

Table 12-11 HL7 Separators

	<i>Suggested Value</i>	<i>Usage</i>
Segment Terminator	<cr> (0x0D)	Terminates a segment record.
Field Separator		Separates two adjacent data fields within a segment. It also separates the segment ID from the first data field in each segment.
Component Separator	^	Separates adjacent components of data fields where allowed.
Subcomponent Separator	&	Separates adjacent subcomponents of data fields where allowed. If there are no subcomponents, this character may be omitted.
Repetition Separator	~	Separates multiple occurrences of a field where allowed.
Escape Character	\	Escape character for use with any field represented by an ST, TX or FT data type, or for use with the data (fourth) component of the ED data type. If no escape characters are used in a message, this character may be omitted. However, it must be present if subcomponents are used in the message.

Message Construction Rules

Construct the segments in the order defined for the message. Each message is constructed as follows:

1. The first three characters are the segment ID code.
2. Each data field in sequence is inserted in the segment in the following manner:
 - A field separator is placed in the segment.
 - If the value is not present, no further characters are required.
 - If the value is present, but null, the characters "" (two consecutive double quotation marks) are placed in the field.
 - Otherwise, place the characters of the value in the segment. As many characters can be included as the maximum defined for the data field. It is not necessary, and is undesirable, to pad fields to fixed lengths. Padding to fixed lengths is permitted.
 - If the field definition calls for a field to be broken into components, the following rules are used:
 - If more than one component is included they are separated by the component separator.
 - Components that are present but null are represented by the characters "".
 - Components that are not present are treated by including no characters in the component.

- Components that are not present at the end of a field need not be represented by component separators. For example, the two data fields are equivalent:

|ABC^DEF^^| and |ABC^DEF|.

- If the component definition calls for a component to be broken into subcomponents, the following rules are used:
 - If more than one subcomponent is included they are separated by the subcomponent separator.
 - Subcomponents that are present but null are represented by the characters "".
 - Subcomponents that are not present are treated by including no characters in the subcomponent.
 - Subcomponents that are not present at the end of a component need not be represented by subcomponent separators. For example, the two data components are equivalent:

^XXX&YYY&&^ and ^XXX&YYY^.

- If the field definition permits repetition of a field, the repetition separator is used only if more than one occurrence is transmitted. In such a case, the repetition separator is placed between occurrences. If three occurrences are transmitted, two repetition separators are used.) In the example below, two occurrences of telephone number are being sent:

|234-7120~599-1288B1234|

3. Repeat Step 1 while there are any fields present to be sent. If all the data fields remaining in the segment definition are not present there is no requirement to include any more delimiters.
4. End each segment with an ASCII carriage return character.

Repeat Steps 1 through 4 until all segments have been generated.

Message Processing Rules

The following rules apply to receiving HL7 messages and converting their contents to data values:

- a. Ignore segments, fields, components, subcomponents, and extra repetitions of a field that are present but were not expected.
- b. Treat segments that were expected but are not present as consisting entirely of fields that are not present.
- c. Treat fields and components that are expected but were not included in a segment as not present.

Message Transmission Control

Because the protocol describes an exchange of messages, it is described in terms of two entities, the initiating and responding systems. The GEM 4000 can play both roles.

Each is both a sender and receiver of messages. The initiating system sends first and then receives, while the responding system receives and then sends.

The HL7 protocols prescribe two kinds of acknowledge, original and enhanced. The GEM 4000 supports only the enhanced acknowledgement mode.

In overview this exchange proceeds as described in the following sections.

Initiation

The initiating application creates a message with data values as defined in the appropriate section of chapter 0, according to the rules described in §5.3.2.

The Message Header Segment (MSH) contain several fields that control the later message flow

- MSH-10 contains a unique identifier for the message. Acknowledgements refer to this ID.
- MSH-15 is set to AL, meaning that the message requires an accept acknowledgement
- MSH-16, depending on the nature of the message, can be set to
 - AL: The message requires an application acknowledgement
 - NE: The message does not require an application acknowledgement.

Response

The responding system returns a general acknowledgment message (ACK) with:

1. A commit accept (CA) in MSA-1-acknowledgment code if the message can be accepted for processing.
2. A commit reject (CR) in MSA-1-acknowledgment code if the one of the values of MSH-9-message type, MSH-12-version ID or MSH-11-processing ID is not acceptable to the receiving application.
3. A commit error (CE) in MSA-1-acknowledgment code if the message cannot be accepted for any other reason (e.g., sequence number error or a required field is not present).

The ACK message contain a NE in fields MSH-5 and MSH-6.

If the message header segment indicates that the initiating system also requires an application acknowledgment, this is returned as the initial message of a later exchange.

For this message, the receiving system acts as the initiator. Since the message it sends is application specific, the layouts of these application level response messages are defined in the relevant application-specific chapter. If needed, this application acknowledgment message can itself require (in MSH-15-accept acknowledgment type) an accept acknowledgment message (MSA). MSH-16-application acknowledgment type, however, is always null, since the protocol does not allow the application acknowledgment message to have an application acknowledgment.

At this point, the application acknowledgment portion of this message exchange is considered complete.

Error Recovery

Resend timeout

When GEM 4000 acting as the initiator, if the accept acknowledgement is not received in 60 seconds, the GEM 4000 resends the message until the acknowledgement is received or the transmission queue is cleared.

Non-expected message received

If the message does not required accept acknowledge, the SW takes no action

If the message requires accept acknowledge, the SW replies with a message having the structure defined in **Table 12-12**

Table 12-12 ORI HL7 Upload ACK of a Non-Expected Message

	Comments
MSH	See Table 12-13
MSA	See Table 12-14

Table 12-13 ORI HL7 Upload ACK of a Non-Expected Message MSH

Field	Field Name	Description	Comp	Len	Req	Values, formats and comments
1	Field Separator			1	R	" "
2	Encoding Characters			4	R	"^~\&"
3	Sending Application	Identifies the application (company, pg 273 of the specs, application and version)	1	180	RE	"IL"
			2			"GEM 4000"
						"1.0" (Data Format version)
4	Sending Facility		1	180	RE	AreaName
			2			Anl.Name
			3			Anl.Model
			4			Anl.SerialNumber
			5			Anl.CartSerial Number
			6			Anl.SWVersionNum
5	Receiving Application			180	RE	Null
6	Receiving Facility			180	RE	Null
7	Date/Time Of Message	Date time the message was generated (HL7/ASTM format).		26	R	YYYYMMDDHHMMSS
8	Security			40	X	
9	Message Type	ORU^R30, ORU^R31, ORU^R32, ACK^R33.		7	R	"ACK"
10	Message Control ID	Unique identifier for the message (32 bits PK).		20	R	0 - 4294967295
11	Processing ID	"T/D/P": Training/Debug/Production		3	R	"P"
12	Version ID			8	R	"2.4"
13	Sequence Number			15	X	
14	Continuation Pointer			180	X	
15	Accept Acknowledgement Type	All source messages should specify "AL"		2	R	"NE"
16	Application Acknowledgement Type	All ORU messages specify "AL"		2	R	"NE"
17	Country Code	Not used by GEM 4000		2	RE	Null

Table 12-14 ORI HL7 Upload ACK of a Non-Expected Message MSA

	Field Name	Description	Comp	Len	Req	Values, formats and comments
1	Acknowledgement Code	"CA," "CE," "CR," "AA," "AE," "AR"		2	R	"CR"
2	Message Control ID	From MSH-10 of the non expected message		20	R	0 – 4294967295
3	Text Message Note (2)			80	O	"Non Expected Message"
4	Expected Sequence Number			15	X	
5	Delayed Acknowledgement Type			1	X	
6	Error Condition	Coded Error		100	O	Null

12-5 ORI - HL7 Mode

General considerations

The HL7 mode uses the HL7 protocol. Considerations stated in "Upload Calibration Results to the HIS/LIS" on page 42 applies.

Upload Patient Sample Results to the HIS/LIS

This specification is compliant with HL7 v2.4 and NCCLS POCT1-A

Point-of-care workflow for measurement and ordering is quite complex, dynamic, and flexible. However, most scenarios may be reduced to three use cases:

1. A test is performed without an order and the Observation Recipient should place an order.
2. A test is performed which may or may not have an order previously placed.
3. A test is performed that was previously ordered.

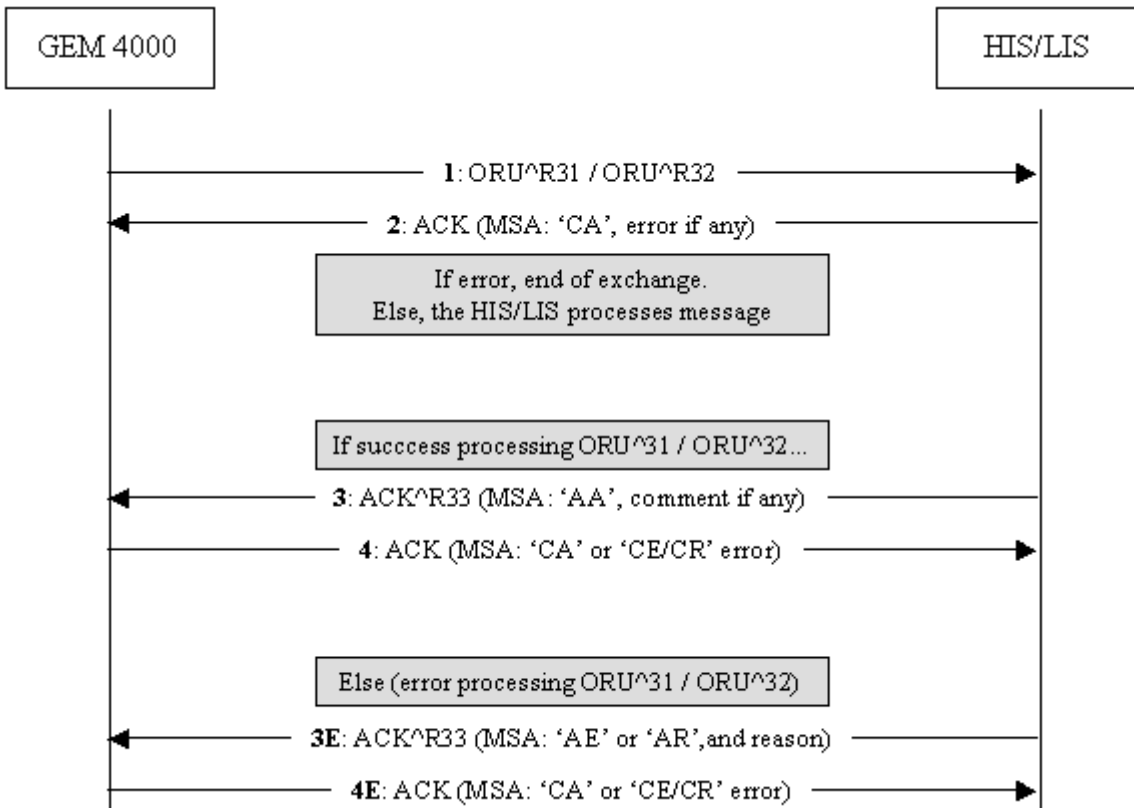
These three use cases all rely on the ORU message to communicate the appropriate mix of result and order information. Currently, the ORU message has no trigger event appropriate for the common POC Use Cases. Four new trigger events are required to distinguish between the ORU messages that support these three use cases. The HL7 organization has issued an Authoritative Use Statement (Section 4.1.6) permitting the use of the new triggers: R30, R31 and R32, in advance of being balloted by HL7 for a future version of the standard.

The GEM 4000 uses only use cases 2 and 3:

- Use case #2. Search for an Order:
- Use case #3. Preordered Observation:

The message flow of both use case is described in **Figure 12-3 "Upload Patient Sample Results to the HIS/LIS"**. The following sections describe these triggers and their use in more detail.

Figure 12-3 Upload Patient Sample Results to the HIS/LIS



Message 1: ORU^R32 (uploading)

This message is an uploading message and has the structure defined in **Table 12-15**.

Table 12-15 ORI. NCCLS POCT1-A

	<i>Comments</i>
MSH	See "Message Header Segment - MSH"
PID	See "Patient Identification Segment - PID"
ORC	See "Common Order Segment - ORC"
OBR	See "Observation Request Segment - OBR"
[NTE]	See "Notes and Comment Segment (related to message) - NTE (MSG)"
OBX	See "Observation Result Segment - OBX"
[NTE]	See "Observation Result Segment - OBX"

Message Header Segment - MSH

Table 12-16 ORI. NCCLS POCT1-A MSH

	Field Name	Description	Comp	Len	Req	Values, formats and comments
1	Field Separator			1	R	" "
2	Encoding Characters			4	R	"^~\&"
3	Sending Application	Identifies the application (company, pg 273 of the specs, application and version)	1	180	RE	"IL"
			2			"GEM 4000"
			3			"1.0" (Data Format version)
4	Sending Facility		1	180	RE	AreaName
			2			Anl.Name
			3			Anl.Model
			4			Anl.SerialNumber
			5			Anl.CartSerial Number
			6			Anl.SWVersionNum
5	Receiving Application			180	RE	Null
6	Receiving Facility			180	RE	Null
7	Date/Time Of Message	Date time the message was generated (HL7/ASTM format).		26	R	YYYYMMDDHHMSS
8	Security			40	X	
9	Message Type	ORU^R30, ORU^R31, ORU^R32, ACK^R33.		7	R	ORU^R32/ ORU^R31: See note below
10	Message Control ID	Unique identifier for the message (32 bits PK).		20	R	0 - 4294967295
11	Processing ID	"T/D/P": Training/Debug/ Production		3	R	"P"
12	Version ID			8	R	"2.4"
13	Sequence Number			15	X	
14	Continuation Pointer			180	X	
15	Accept Acknowledgement Type	All source messages should specify "AL"		2	R	"AL"
16	Application Acknowledgement Type	All ORU messages specify "AL"		2	R	"AL"
17	Country Code	Not used by GEM 4000		2	RE	Null

MSH-9: Possible values are:

- ORU^R32: indicates that this is a ORU^R32 trigger ("preordered observation"), the use case #3 in the POCT1-A standard.
- ORU^R31: indicates that this is a ORU^R31 trigger ("search for an order"), the use case #2 in the POCT1-A standard.

Comments (informative only):

- OBX-15 is set to "AL" (always), so the message requires acknowledge at accept level (which is message 2).
- OBX-16 is set to "AL" (always), so the message requires acknowledge at application level (which is message 4).

Patient Identification Segment - PID

Table 12-17 ORI. NCCLS POCT1-A PID

Field	Field Name	Description	Comp	Len	Req	Values, formats and comments
1	Set ID - Patient ID Optional. Set ID Sequence Number.			4	O	"1"
2	Patient ID			20	X	
3	Patient Identifier List Use Case #1, #2 Patient ID required.	G4K always considers this fields as optional.		20	O	Pat.ID
4	Alternate Patient ID – PID			20	X	
5	Patient Name	Extension to the standard	1	48	O	Pat.LastName
			2		O	Pat.FirstName
			3		O	Pat.MiddleInitial
6	Mother's Maiden Name			48	X	
7	Date/Time of Birth	Extension to the standard		26	O	Pat.BirthDate (YYYYMMDDHHM MSS)
8	Administrative Sex	Extension to the standard		1	R	"M"/"F"/"U"
9	Patient Alias			48	X	
10	Race			1	X	
11	Patient Address			106	X	
12	Country Code Empty for USA.			4	RE	Null
13	Phone Number – Home			40	X	
14	Phone Number – Business			40	X	

15	Primary Language			60	X	
16	Marital Status			1	X	
17	Religion			3	X	
18	Patient Account Number	Account number, if available.		20	O	Null
19	SSN Number – Patient			16	X	
20	Driver's License Number - Patient			25	X	
21	Mother's Identifier			250	X	
22	Ethnic Group			250	X	
23	Birth Place			250	X	
24	Multiple Birth Indicator			1	X	
25	Birth Order			2	X	
26	Citizenship			250	X	
27	Veterans Military Status			250	X	
28	Nationality			250	X	
29	Patient Death Date and Time			26	X	
30	Patient Death Indicator			1	X	
31	Identity Unknown Indicator			1	X	
32	Identity Reliability Code			20	X	
33	Last Update Date/Time			26	X	
34	Last Update Facility			40	X	
35	Species Code			250	X	
36	Breed Code			250	X	
37	Strain			80	X	
38	Production Class Code			250	X	

Comments (informative only):

- OBX-2 and OBX-4 are deprecated fields.
- PID-5, PIC-7 and PID-8 are HL7 valid extensions to the POCT1-A standard.

Common Order Segment - ORC

Table 12-18 ORI. NCCLS POCT1-A ORC

	Field Name	Description	Comp	Len	Req	Values, formats and comments
1	Order Control	Use Case #1, #2: iNW.i Use Case #3: iRE.i		2	R	"RE": Preordered Observation "NW": Search for an order
2	Placer Order Number.	Use Case #3 Only: Order ID		22	X/R	Null: Search for an Order Order ID: Preordered observation.
3	Filler Order Number	External identifier for these results in the Observation Reviewer.		22	O	Sample ID
4	Placer Group Number			22	X	
5	Order Status			2	X	
6	Response Flag			1	X	
7	Quantity/Timing			200	X	
8	Parent			200	X	
9	Date/Time of Transaction			26	X	
10	Entered By			120	X	
11	Verified By			120	X	
12	Ordering Provider			120	X	
13	Enterer's Location			80	X	
14	Call Back Phone Number			40	X	
15	Order Effective Date/ Time			26	X	
16	Order Control Code Reason			200	X	
17	Entering Organization			60	X	
18	Entering Device			60	X	

Observation Request Segment - OBR

Table 12-19 ORI. NCCLS POCT1-A OBR

Field	Field Name	Description	Comp	Len	Req	Values, formats and comments
1	Set ID – OBR Optional. Set ID Sequence Number			4	R	1
2	Placer Order Number See ORC-2			75	X	
3	Filler Order Number See ORC-3			75	X	
4	Universal Service ID	e.g., 1-2345^GLU^LN for single valued result.		200	R	TBD. I propose a blank
5	Priority			2	X	
6	Requested Date/Time			26	X	
7	Observation Date/Time			26	X	
8	Observation End Date/Time			26	X	
9	Collection Volume	Extension to the standard	1	20	R	“150” (Normal Sample) “75” (micro sample)
			2		R	“ml”
10	Collector Identifier			60	X	
11	Specimen Action Code	!OI (Specimen obtained by service other than Lab)		1	R	“O”
12	Danger Code			60	X	
13	Relevant Clinical Info.			300	X	
14	Specimen Received Date/Time			26	X	

15	Specimen Source. e.g., BLDA^^^LLFA^^^P (Patient test from arterial blood taken from left lower forearm). Optional in the spec	The specimen source name	1	300	R	Patient Sample types are described in Table 12-78 .
		Free text additives to the specimen such as Heparin, EDTA, or Oxlate, when applicable.	2		X	
		Free text component describing the method of collection	3		R	"N" (Normal size) "M" (Micro Sample)
		Body site from which the specimen was obtained.	4		X	
		Site modifier. For example, the site could be antecubital fossa, and the site modifier 1right.1	5		X	
		Indicates whether the specimen is frozen as part of the collection method. If the component is blank, the specimen is assumed to be at room temperature.	6		X	
		Sample Role.	7		R	"P"
16	Ordering Provider e.g., Smith^John^J^Dr - Note -4		1	80	O	OrderingClin.LastN ame
			2		O	OrderingClin.FirstN ame
			3		O	OrderingClin. MidInitial
17	Order Callback Phone Number			40	X	
18	Placer Field 1			60	X	
19	Placer Field 2			60	X	
20	Filler Field 1			60	X	
21	Filler Field 2			60	X	
22	Results Rpt/Status Chng – Date/Time			26	X	
23	Charge to Practice			40	X	
24	Diagnostic Serv Sect ID			10	X	
25	Result Status			1	X	
26	Parent Result			400	X	
27	Quantity/Timing			200	X	
28	Result Copies To			150	X	
29	Parent			150	X	
30	Transportation Mode			20	X	
31	Reason for Study			300	X	

32	Principal Result Interpreter			200	X	
33	Assistant Result Interpreter			200	X	
34	Technician			200	X	
35	Transcriptionist			200	X	
36	Scheduled Date/Time			26	X	

Notes and Comment Segment (related to message) - NTE (MSG)

Table 12-20 ORI. NCCLS POCT1-NTE (MSG)

	Field Name	Description	Comp	Len	Req	Values, formats and comments
1	Set ID – NTE			4	X	
2	Source of Comment			8	X	
3	Comment			64k	RE	See Below

The comment record is used send several pieces of information, separated by the separator character:

1. Draw Date and Time:

Component	Required	Contents
1	R	"FIELD"
2	R	"DrawDateTime"
3	R	<i>DrawDateTime</i> in YYYYMMDDHHMMSS format.

Example: "FIELD^DrawDateTime^20121222123456"

2. Patient Age:

Component	Required	Contents
1	R	"FIELD"
2	R	"Pat.Age"
3	R	Pat.Age
4	R	Units. Units for age are described in §A.5

Example: "FIELD^Pat.Age^99^YR"

3. User-defined patient and sample demographics fields. Format is described is as follows:

Component	Required	Contents
1	R	"FIELD"
2	R	Field Name. name assigned in configuration (ex, if user creates a "Número de SS", the entered text is sent in the Field Name field).
3	R	Pat.Age
4	R	Units. Units for age are described in §A.5

Example: "FIELD^Número de SS^12345"

Field Name is the name assigned in configuration (ex, if user creates a "Número de SS", the entered text is sent in the Field Name field).

4. Operator comments to the sample. Format is as follows:

	Required	Contents
1	R	"COMMENT"
2	R	Date Time the comment was performed, in YYYYMMDDHHMMSS format.
3	R	Op.Id
4	R	Op.LastName
5	R	Op.FirstName
6	R	Op.MiddleInitial
7	R	Comment Text

Example: "COMMENT^20053112173456^ggalilei^Galilei^Galileo^^Eppur si muove"

5. Indicate which fields have been edited after the sample has been accepted. Format is as follows:

Component	Required	Contents
1	R	"EDIT"
2	R	Field Name or Analyte Name
3	R	Old Value
4	R	New Value
5	O	Units
6	R	Date time the edit was performed
7	R	OpID
8	R	OpLastName
9	R	OpFirstName
10	R	OpMiddleInitial

Example: "EDIT^Temperature^37.2^38.2^C^20053112173456^lordkelvin^Thompson^William"

Fields without value are not be sent.

Field names for non-user defined fields are always sent in English.

For user defined fields the user entered name is sent (ex, if user enters "Número de SS" for Pat.2, the entered text is sent in the Field Name field).

Observation Result Segment - OBX

Table 12-21 ORI. NCCLS POCT1-A OBX

Field	Field Name	Description	Comp	Len	Req	Values, formats and comments
1	Set ID Optional.	Provided by some Devices.		10	R	Sequence number 1,2, 3...
2	Value Type	All POCT1 values are iST† (string).		2	R	"ST"
3	Observation Identifier e.g., ^^^AaDpO2,T&E - a mnemonic identifying the parameter along with a subcomponent specifying the type of observation, in this case [E]stimated).		1	590	X	
			2		X	
			3		X	
			4		R	Parameter Name See description below
			5		X	
			6		X	
4	Observation Sub-ID			20	X	
5	Observation Value	E.g., i150,† i<50,† iHI,† iLO†		655 36	CE	Parameter Value. See description below
6	Unitsmg/dL† or similar			60	CE	Parameter Units. See description below
7	References Range	70^mg/dl-105^mg/dl		10	O	See note below.
8	Abnormal Flags.			40	RE	See note below.
9	Probability			5	X	
10	Nature of Abnormal Test			2	X	
11	Result Status			1	R	"F" (valid result) or "X" (result has an error)
12	Date Last Observed Normal Values			26	X	
13	User Defined Access Checks			20	X	
14	Date/Time of the Observation	Format is CCYYMMDDHHMMSS		26	O	Date and time the instrument completed the test
15	Producer's ID			60	X	

16	Responsible Observer POC User ID^optional Last^First name	Operator who performed the analysis	1	80	O	<i>OpRun.ID</i> (only the first result)
			2		O	<i>OpRun.LastName</i> (only the first result)
			3		O	<i>OpRun.FirstName</i> (only the first result)
			4		O	<i>OpRun.MidIntial</i> (only the first result)
17	Observation Method			60	O	Null
18	Equipment Instance Identifier IEEE EUI-64 format.			22	O	Serial number of the instrument that performed the test or the calculation
19	Date/Time of Analysis	The timestamp when the Device performed the test. Format is CCYYMMDDHHMMSS		26	O	Date and time the instrument completed the test

A result record is transmitted for a parameter if the parameter is part of the test panel selected for the sample. If the parameter is not part of the test panel that was selected for the sample, no Result record is transmitted for that parameter.

Results are always sent using the format defined in Volume 2a.

Decimal separator is always the default (1234.56).

Note that the standard does not specify that Result records be transmitted in a particular order.

OBX-3: Field OBX-3.4 contains one of the parameter names listed in **Table 12-77**, in the G4K column

OBX-6: Parameter units (OBX-6) are sent in the display units configured in the system. Available units are described in Volume 2.

OBX-7: The reference range values (OBX-7) are encoded using the following scheme:

- If both lower (lo) and upper (hi) limit are known:
lo_value^lo_units-hi_value^hi_units (e.g., 70^mg/dl-105^mg/dl)
- If only the lower limit is known:
>lo_value^lo_units (e.g., >70^mg/dl)
- If only the upper limit is known:
<hi_value^hi_units (e.g., <105^mg/dl)

OBX-8: Possible values are:

- Null: Reference ranges are unknown or result has an error.
- "LL": Below lower panic limits
- "L": Below low normal
- "N": Inside Normal limits.
- "H": Above high normal
- "HH": Above upper panic limits

Exceptions are handled according Table 18:

Table 12-22 ORI. NCCLS POCT1-A OBX Exception Handling

	<i>Field contents</i>			
	OBX-5	OBX-7, OBX-8	OBX-11	NTE-3
None	Actual Value	Yes, when available	"F"	No NTE segment
C	Null	No	"X"	"C^Incalculable"
>	High reportable range	No	"X"	">^Higher than reportable range"
<	Low reportable range	No	"X"	"<^Lower than reportable range"
A	Actual Value	No	"X"	"A^Above Linearity Range"
I	Actual Value	Yes, when available	"X"	"I^Interference detected"
T	Actual Value	Yes, when available	"X"	"T^Micro clot"
M	Actual Value	Yes, when available	"X"	"M^Reference Shift Error"
S	Actual Value	Yes, when available	"X"	"S^SHb detected"
B	Actual Value	Yes, when available	"X"	"B^Turbidity detected"
X	Null	No	"X"	"X^Unknown Exception"

Note: Errors A and X are reserved for external instruments.

Notes and Comment Segment (related to Observation) - NTE (OBX)

Table 12-23 ORI. NCCLS POCT1-A (OBX)

<i>Field</i>	<i>Field Name</i>	<i>Description</i>	<i>Comp</i>	<i>Len</i>	<i>Req</i>	<i>Values, formats and comments</i>
1	Set ID – NTE			4	X	
2	Source of Comment			8	X	
3	Comment			64k	RE	See Table 18.

Message 2: ACK (downloading)

This message is a downloading message and has the structure defined in **Table 12-24**.

Table 12-24 ORI. NCCLS POCT1-A ACK Message 2

<i>Message</i>	<i>Comments</i>
MSH	See " Message Header Segment - MSH "
MSA	See " General Acknowledgement Segment - MSA "

Message Header Segment - MSH**Table 12-25** ORI. NCCLS POCT1-A MSH Message 2

	Field Name	Description	Comp	Len	Req	Values, formats and comments
1	Field Separator			1	R	" "
2	Encoding Characters			4	R	"^~\&"
3	Sending Application	Identifies the application (company, pg 273 of the specs, application and version)		180	RE	Ignored by the GEM 4000
4	Sending Facility			180	RE	Ignored by the GEM 4000
5	Receiving Application			180	RE	Ignored by the GEM 4000
6	Receiving Facility			180	RE	Ignored by the GEM 4000
7	Date/Time Of Message	Date time the message was generated (HL7/ASTM format).		26	R	YYYYMMDDHHM MSS
8	Security			40	X	
9	Message Type			7	R	"ACK"
10	Message Control ID	Unique identifier for the message (32 bits PK).		20	R	0 - 4294967295
11	Processing ID	"T/D/P": Training/Debug/Production		3	R	"P". Ignored by the GEM 4000
12	Version ID			8	R	"2.4". Ignored by the GEM 4000
13	Sequence Number			15	X	
14	Continuation Pointer			180	X	
15	Accept Acknowledgement Type	All source messages should specify "AL"		2	R	"NE"
16	Application Acknowledgement Type	All ORU messages specify "AL"		2	R	"NE"
17	Country Code	Not used by GEM 4000		2	RE	Ignored by the GEM 4000

General Acknowledgement Segment - MSA**Table 12-26** ORI. NCCLS POCT1-A MSA Message 2

Field	Field Name	Description	Comp	Len	Req	Values, formats and comments
1	Acknowledgement Code	"CA," "CE," "CR," "AA," "AE," "AR"		2	R	"CA" / "CE" / "CR"
2	Message Control ID	From MSH-10 of associated message		20	R	0 – 4294967295
3	Text Message			80	O	Text description. Empty if "CA"

4	Expected Sequence Number			15	X	
5	Delayed Acknowledgement Type			1	X	
6	Error Condition	Coded Error		100	O	Coded Error

Notes:

MSA-1: Possible values are:

- "CA": Message accepted.
- "CE": Error (message not accepted).
- "CR": Rejection (message not accepted).

Upon reception of the message, the GEM 4000 removes the record from the transmission queue. If the message has not been accepted, the SW the event as traced indicating the contents of MSA-3 and MSA-6.

Message 3/3E: ACK^R33 (downloading)

This message is a downloading message. Once the HIS/LIS has processed the message, it returns the result of the processing using the message defined in **Table 12-27**.

Table 12-27 ORI. NCCLS POCT1-A Message 3/3E: ACK^R33

	Comments
MSH	See "Message Header Segment - MSH"
MSA	See "General Acknowledgement Segment - MSA"

Message Header Segment - MSH

Table 12-28 ORI. NCCLS POCT1-A MSH Message 3

Field	Field Name	Description	Comp	Len	Req	Values, formats and comments
1	Field Separator			1	R	" "
2	Encoding Characters			4	R	"^~\&"
3	Sending Application	Identifies the application (company, pg 273 of the specs, application and version)		180	RE	Ignored by the GEM 4000
4	Sending Facility			180	RE	Ignored by the GEM 4000
5	Receiving Application			180	RE	Ignored by the GEM 4000
6	Receiving Facility			180	RE	Ignored by the GEM 4000
7	Date/Time Of Message	Date time the message was generated (HL7/ASTM format).		26	R	YYYYMMDDHHM MSS
8	Security			40	X	

9	Message Type	ORU^R30, ORU^R31, ORU^R32, ACK^R33.		7	R	"ACK^R33"
10	Message Control ID	Unique identifier for the message (32 bits PK).		20	R	0 - 4294967295
11	Processing ID	"T/D/P": Training/Debug/ Production		3	R	"P". Ignored by the GEM 4000
12	Version ID			8	R	"2.4". Ignored by the GEM 4000
13	Sequence Number			15	X	
14	Continuation Pointer			180	X	
15	Accept Acknowledgement Type	All source messages should specify "AL"		2	R	"AL" (always)
16	Application Acknowledgement Type	All ORU messages specify "AL"		2	R	"NE" (never)
17	Country Code	Not used by GEM 4000		2	RE	Ignored by the GEM 4000

General Acknowledgement Segment - MSA

Table 12-29 ORI. NCCLS POCT1-A MSA Message 3

	Field Name	Description	Comp	Len	Req	Values, formats and comments
1	Acknowledgement Code	"CA," "CE," "CR," "AA," "AE," "AR"		2	R	"AA" / "AE" / "AR"
2	Message Control ID	From MSH-10 of associated message		20	R	0 – 4294967295
3	Text Message Note (2)			80	O	Text description
4	Expected Sequence Number			15	X	
5	Delayed Acknowledgement Type			1	X	
6	Error Condition	Coded Error		100	O	Coded Error

Notes:

MSA-1: Possible values are:

- "AA": Message accepted.
- "AE": Error (message not accepted).
- "AR": Rejection (message not accepted).

If the message has not been accepted, the SW the event is traced indicating the contents of MSA-3 and MSA-6.

Note (Informative only): This message is used in the future to receive "returned orders".

Message 4/4E: ACK (uploading)

This message is an uploading message and has the structure defined in the following table.

Table 12-30 ORI. NCCLS POCT1-A Message 4/4E: ACK

Message	Comments
MSH	See " Message Header Segment - MSH "
MSA	See " General Acknowledgement Segment - MSA "

Message Header Segment - MSH

Table 12-31 ORI. NCCLS POCT1-A MSH Message 4

Field	Field Name	Description	Comp	Len	Req	Values, formats and comments
1	Field Separator			1	R	" "
2	Encoding Characters			4	R	"^~\&"
3	Sending Application	Identifies the application (company, pg 273 of the specs, application and version)	1	180	RE	"IL"
			2			"GEM 4000"
						"1.0" (Data Format version)
4	Sending Facility		1	180	RE	AreaName
			2			Anl.Name
			3			Anl.Model
			4			Anl.SerialNumber
			5			Anl.CartSerial Number
			6			Anl.SWVersionNum
5	Receiving Application			180	RE	Null
6	Receiving Facility			180	RE	Null
7	Date/Time Of Message	Date time the message was generated (HL7/ASTM format).		26	R	YYYYMMDDHHM MSS
8	Security			40	X	
9	Message Type	ORU^R30, ORU^R31, ORU^R32, ACK^R33.		7	R	"ACK"
10	Message Control ID	Unique identifier for the message (32 bits PK).		20	R	0 - 4294967295
11	Processing ID	"T/D/P": Training/Debug/ Production		3	R	"P"
12	Version ID			8	R	"2.4"
13	Sequence Number			15	X	

14	Continuation Pointer			180	X	
15	Accept Acknowledgement Type	All source messages should specify "AL"		2	R	"NE"
16	Application Acknowledgement Type	All ORU messages specify "AL"		2	R	"NE"
17	Country Code	Not used by GEM 4000		2	RE	Null

General Acknowledgement Segment - MSA

Table 12-32 ORI. NCCLS POCT1-A MSA Message 4

	Field Name	Description	Comp	Len	Req	Values, formats and comments
1	Acknowledgement Code	"CA," "CE," "CR," "AA," "AE," "AR"		2	R	"CA"
2	Message Control ID	From MSH-10 of associated message		20	R	0 – 4294967295
3	Text Message Note (2)			80	O	Null
4	Expected Sequence Number			15	X	
5	Delayed Acknowledgement Type			1	X	
6	Error Condition	Coded Error		100	O	Null

Transmission examples

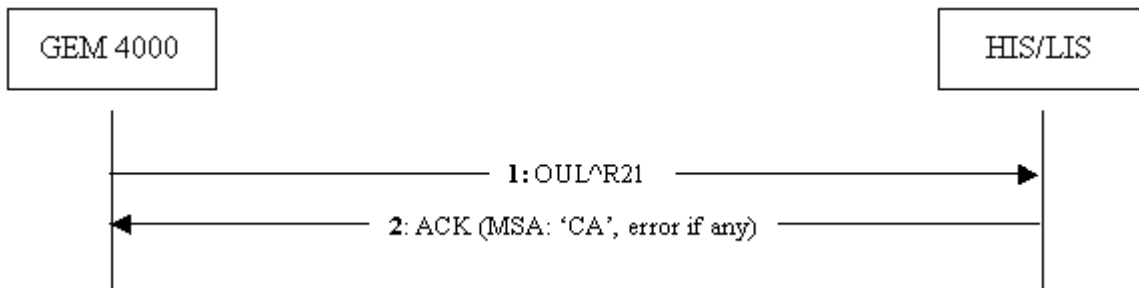
Successful upload

HILS/LIS rejects GEM 4000 message

HIS/LIS fails to process transmission

Upload Calibration Results to the HIS/LIS

The message flow is described in Figure 4.

Figure 12-4 Upload Calibration Results to the HIS/LIS**Message 1: OUL^R21 (uploading)**

This message is an uploading message and has the structure defined in **Table 12-33**.

Table 12-33 ORI. HL7 Message 1 OUL^R21

	<i>Comments</i>
MSH	See “Message Header Segment - MSH” on page 44
SAC	See “Specimen and Container Detail Segment - SAC” on page 45
OBR	See “Observation Request Segment - OBR” on page 47
{OBX}	See “Observation Result Segment - OBX” on page 49

Note (informative only): This spec follows HL7 v2.4, section 13.5, about QC usage.

Use the 7th component of OBR-15-specimen source or SAC-6 -specimen source to indicate that this is a control specimen. Use SAC-3-container identifier for the identification of a control specimen container. The SID segment appended to this SAC segment specifies the manufacturer, lot identifiers, etc. for the control specimen.

The identification of the instrument performing the QC measurement, should be transferred with the OBX-18-equipment instance identifier), the measurement data/time with the OBX-19 date/time of the analysis.

```

MSH|^~\&|INSTPROG|AUTINST|LASPROG|LASSYS|19980630080040|SECURITY
|OUL^R21|MSG00001|P|2.4|<cr>
SAC|||Q092321^LAS|||SER^^^^^Q |19980620080037|R^PROCESS COMPLETED<cr>
SID|01230^Na|ABCDE-01234567890||04^RD<cr>
ORC|RE|5212498721A|||||^^^^^R<CR>
OBR|1|5212498721A||2951-2^SODIUM^LN|||199807240826||||||SER^^^^^Q<CR>
OBX|1|NM|2951-2^SODIUM^LN||24.3|ug/g||N<CR>
  
```

Message Header Segment - MSH

Table 12-34 ORI. HL7 Message 1 MSH

	Field Name	Description	Comp	Len	Req	Values, formats and comments
1	Field Separator			1	R	" "
2	Encoding Characters			4	R	"^~\&"
3	Sending Application	Identifies the application (company, pg 273 of the specs, application and version)	1	180	RE	"IL"
			2			"GEM 4000"
			3			"1.0" (Data Format version)
4	Sending Facility		1	180	RE	AreaName
			2			Anl.Name
			3			Anl.Model
			4			Anl.SerialNumber
			5			Anl.CartSerial Number
			6			Anl.SWVersionNum
5	Receiving Application			180	RE	Null
6	Receiving Facility			180	RE	Null
7	Date/Time Of Message	Date time the message was generated (HL7/ASTM format).		26	R	YYYYMMDDHHMMSS
8	Security			40	X	
9	Message Type			7	R	OUL^R21
10	Message Control ID	Unique identifier for the message (32 bits PK).		20	R	0 - 4294967295
11	Processing ID	"T/D/P": Training/Debug/Production		3	R	"P"
12	Version ID			8	R	"2.4"
13	Sequence Number			15	X	
14	Continuation Pointer			180	X	
15	Accept Acknowledgement Type	All source messages should specify "AL"		2	R	"AL"
16	Application Acknowledgement Type	All ORU messages specify "AL"		2	R	"NE"
17	Country Code	Not used by GEM 4000		2	RE	Null

Comments (informative only):

- OBX-15 is set to "AL" (always), so the message requires acknowledge at accept level (which is message 2).
- OBX-16 is set to "NE" (never), so the message does not require acknowledge at application level.

Specimen and Container Detail Segment - SAC

Table 12-35 ORI. HL7 Message 1 SAC

Field	Field Name	Description	Comp	Len	Req	Values, formats and comments
1	External Accession Identifier			80	X	
2	Accession Identifier			80	X	
3	Container Identifier			80	X	
4	Primary (parent) Container Identifier			80	X	
5	Equipment Container Identifier			80	X	
6	Specimen Source. e.g., BLDA^^^LLFA^^^P (Patient test from arterial blood taken from left lower forearm). Optional in the spec	The specimen source name	1	300	X	“C”
		Free text additives to the specimen such as Heparin, EDTA, or Oxlate, when applicable.	2		X	
		Free text component describing the method of collection	3		X	
		Body site from which the specimen was obtained.	4		X	
		Site modifier. For example, the site could be antecubital fossa, and the site modifier right.	5		X	
		Indicates whether the specimen is frozen as part of the collection method. If the component is blank, the specimen is assumed to be at room temperature.	6		X	
		Sample Role.	7		R	
7	Registration Date/Time			26	X	
8	Container Status			250	X	
9	Carrier Type			250	X	
10	Carrier Identifier			80	X	
11	Position in Carrier			80	X	
12	Tray Type - SAC			250	X	
13	Tray Identifier			80	X	
14	Position in Tray			80	X	
15	Location			250	X	
16	Container Height			20	X	
17	Container Diameter			20	X	

18	Barrier Delta			20	X	
19	Bottom Delta			20	X	
20	Container Height/ Diameter/Delta Units			250	X	
21	Container Volume			20	X	
22	Available Volume			20	X	
23	Initial Specimen Volume			20	X	
24	Volume Units			250	X	
25	Separator Type			250	X	
26	Cap Type			250	X	
27	Additive			250	X	
28	Specimen Component			250	X	
29	Dilution Factor			20	X	
30	Treatment			250	X	
31	Temperature			20	X	
32	Hemolysis Index			20	X	
33	Hemolysis Index Units			250	X	
34	Lipemia Index			20	X	
35	Lipemia Index Units			250	X	
36	Icterus Index			20	X	
37	Icterus Index Units			250	X	
38	Fibrin Index			20	X	
39	Fibrin Index Units			250	X	
40	System Induced Contaminants			250	X	
41	Drug Interference			250	X	
42	Artificial Blood			250	X	
43	Special Handling Considerations			250	X	
44	Other Environmental Factors			250	X	

Observation Request Segment - OBR

Table 12-36 ORI. HL7 Message 1 OBR

Field	Field Name	Description	Comp	Len	Req	Values, formats and comments
1	Set ID – OBR Optional. Set ID Sequence Number			4	R	1
2	Placer Order Number See ORC-2			75	X	
3	Filler Order Number See ORC-3			75	X	
4	Universal Service ID		1	590	X	
			2		X	
			3		X	
			4		R	Calibration Type. See Table 12-56
			5		X	
			6		X	
5	Priority			2	X	
6	Requested Date/Time			26	X	
7	Observation Date/Time			26	X	
8	Observation End Date/Time			26	X	
9	Collection Volume			20	X	
10	Collector Identifier			60	X	
11	Specimen Action Code			1	X	
12	Danger Code			60	X	
13	Relevant Clinical Info.			300	X	
14	Specimen Received Date/Time			26	X	

15	Specimen Source.	The specimen source name	1	300	X	“C”
		Free text additives to the specimen such as Heparin, EDTA, or Oxlate, when applicable.	2		X	
		Free text component describing the method of collection	3		X	
		Body site from which the specimen was obtained.	4		X	
		Site modifier. For example, the site could be antecubital fossa, and the site modifier 'right.'	5		X	
		Indicates whether the specimen is frozen as part of the collection method. If the component is blank, the specimen is assumed to be at room temperature.	6		X	
		Sample Role.	7		R	
16	Ordering Provider			80	X	
17	Order Callback Phone Number			40	X	
18	Placer Field 1			60	X	
19	Placer Field 2			60	X	
20	Filler Field 1			60	X	
21	Filler Field 2			60	X	
22	Results Rpt/Status Chng – Date/Time			26	X	
23	Charge to Practice			40	X	
24	Diagnostic Serv Sect ID			10	X	
25	Result Status			1	X	
26	Parent Result			400	X	
27	Quantity/Timing			200	X	
28	Result Copies To			150	X	
29	Parent			150	X	
30	Transportation Mode			20	X	
31	Reason for Study			300	X	
32	Principal Result Interpreter			200	X	
33	Assistant Result Interpreter			200	X	
34	Technician			200	X	
35	Transcriptionist			200	X	
36	Scheduled Date/Time			26	X	

Observation Result Segment - OBX

Table 12-37 ORI. HL7 Message 1 OBX

	Field Name	Description	Comp	Len	Req	Values, formats and comments
1	Set ID Optional.	Provided by some Devices.		10	R	Sequence number 1,2, 3...
2	Value Type	All POCT1 values are iSTi (string).		2	R	"ST"
3	Observation Identifier e.g., ^^^AaDpO2,T&E - a mnemonic identifying the parameter along with a subcomponent specifying the type of observation, in this case [E]stimated).		1	590	X	
			2		X	
			3		X	
			4		R	One of the calibration records See below
			5		X	
			6		X	
4	Observation Sub-ID			20	X	
5	Observation Value			655 36	CE	Calibration result. Null if incalculable
6	UnitsdL or similar			60	CE	Calibration Units. See description below
7	References Range	70^mg/dl-105^mg/dl		10	X	
8	Abnormal Flags.			40	X	
9	Probability			5	X	
10	Nature of Abnormal Test			2	X	
11	Result Status			1	R	"F" (valid result) or "X" (calibration failure)
12	Date Last Observed Normal Values			26	X	
13	User Defined Access Checks			20	X	
14	Date/Time of the Observation	Format is CCYYMMDDHHMMSS		26	O	Date and time the instrument completed the calibration
15	Producer's ID			60	X	
16	Responsible Observer POC User ID^optional Last^First name			80	X	
17	Observation Method			60	X	
18	Equipment Instance Identifier IEEE EUI-64 format.			22	O	Serial number of the instrument that performed the calibration
19	Date/Time of Analysis	The timestamp when the Device performed the test. Format is CCYYMMDDHHMMSS		26	O	Date and time the instrument completed the calibration

A Result record is transmitted if the record is reported for a calibration. Otherwise, no record is transmitted for that parameter

Note that the standard does not specify that Result records be transmitted in a particular order.

Results are always sent using the format defined in Volume 2a.

Decimal separator is always the default (1234.56).

Parameter units are sent in the default units. Default units are described in Volume 2.

The available calibration records are described in Table 70 and Table 71.

Records transmitted for each calibration type are described in Volume 6 (see section 4.2: Calibration Data File: Format).

Message 2: ACK (downloading)

This section is identical to “Message 2: ACK (downloading)” on page 37

Transmission examples

One point calibration

Three point calibration

Low oxygen calibration

Upload iQM-CVP Results to the HIS/LIS

Not currently available.

Upload iQM-CAR Reports to the HIS/LIS

Not currently available.

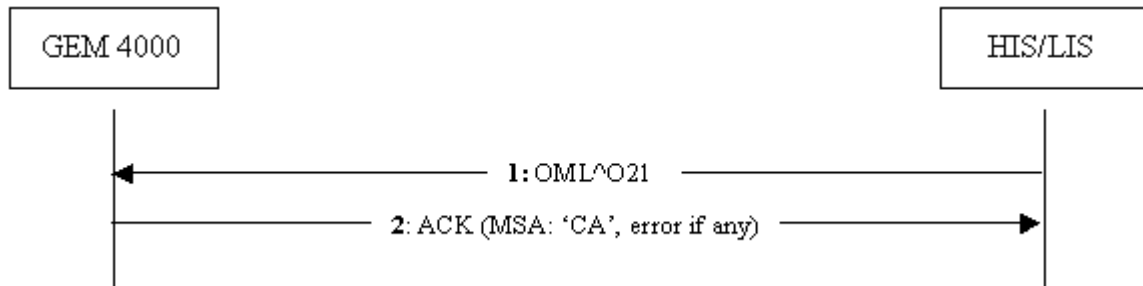
Upload iQM-Delta Charts to the HIS/LIS

Not currently available.

Download test orders from the HIS/LIS

The message flow is described in **Figure 12-5 "Download Test Orders from the HIS/LIS"**.

Figure 12-5 Download Test Orders from the HIS/LIS



Message 1: OML^O21 (downloading)

This message is a downloading message and has the structure defined in the following table.

Table 12-38 Download Test Orders from the HIS/LIS Message 1

	<i>Comments</i>

Message 2: ACK (uploading)

This message is a downloading message and has the structure defined in the following table.

Table 12-39 Download Test Orders from the HIS/LIS Message 2

	<i>Comments</i>
MSH	See §
MSA	See §

12-6 ORI - LIS2-A Native Mode

General considerations

The ORI-LIS-2A mode uses the NCCLS LIS2-A protocol. Considerations stated in “Upload Patient Sample Results to the HIS/LIS” on page 25 apply.

Comments are used for many purposes. Table 36 summarizes the usage of comments.

Table 12-40 ORI. LIS-2A NATIVE MODE. USAGE OF COMMENTS

	<i>Description</i>	
Sending analyte error information, as a comment to a result record.	Source	“I” (clinical instrument)
	Text	Instrument Error Code + “^”+ Error Text
	Type	“I” (Instrument flag(s) comments)
	Example	C 1 I^Microclot Detected I
Sending Demographic fields, as a comment to a Patient Information Record or a Test Order Record	Source	“P” (practice)
	Text	“FIELD” + “^”+ Field Name + “^”+ Field Value + “^”+ Field Units
	Type	“G” (generic/free text comment)
	Example	C 1 P FIELD^SSNumber^12-34-567 G
Sending Operator Comments, as a comment to a Test Order Record	Source	“P” (practice)
	Text	“COMMENT” + “^”+ Comment Text + “^”+ Date Time+ “^”+ OPID+ “^”+ OpName
	Type	“G” (generic/free text comment)
	Example	C 1 P COMMENT^Hello World^20031222131512^pdirac^Dirac^Paul^M G
Indicating that sample has been edited: Which field, old and new value, who did it and when	Source	“P” (practice)
	Text	“EDIT” + “^”+ Field Name + “^”+ Old Value + “^”+ New Value+ “^”+ Units+ “^”+ Date Time+ “^”+ OPID+ “^”+ OpName
	Type	“G” (generic/free text comment)
	Example	C 1 P EDIT^Temp^37.4^38.2^°C^20041231185555^pdirac^Dirac^Paul^M G

Fields without value are not sent.

Field names for non-user defined fields are always sent in English.

For user defined fields the user entered name is sent (ex, if user enters "Número de SS" for Pat.2, the entered text is sent in the Field Name field).

Upload Patient Sample Results to the HIS/LIS

This conversation is initiated by the G4K and allows the G4K to send the results of one sample for an individual patient to the HIS/LIS.

Uploading message

The uploading message has the structure defined in the following table.

Table 12-41 ORI. LIS-2A Uploading Message

					Comments
0	1	2	3	4	
H					1 Master Header Record
P					1 Patient Information Record
{C}					0 or more Comments associated to the patient
{O}					1 or 2 Test Order Records (2 only when AV-Pair)
{C}					0 or more Comments associated to the order
{R}					1 or more results
[C]					0 or 1 Comments associated to the result
L					1 Message Termination Record

Message Header Record (H)

Table 12-42 ORI. LIS-2A MHR

Field	Field Name	Description	Comp	Max Len	Req	Values, formats and comments
1	Record Type ID	Identifies the record		1	R	"H"
2	Delimiter Definition	Define the delimiters to be used throughout the subsequent records of the message		4	R	" @^\"
5	Sender Name or ID	Defines the manufacturer/ instrument specific to this line. May use the repeat or component delimiter to reflect software revisions or firmware revisions, multiple instruments available on this line, etc.	1	8	R	"GEM 4000"
			2	-	R	"1.0" (Data Format version)
			3	10	R	AreaName

			4	10	R	Anl.Name
			5	10	R	Anl.Model
			6	10	R	Anl.SerialNumber
			7	24	R	Anl.CartSerial Number
			8	20	R	Anl.SWVersionNu m
12	Processing ID	Indicates how this message is to be processed		1	R	"P" (Production)
13	Version No.	Version level of the specification.		6	R	"LIS2-A"
14	Date and Time of Message	The date and time that the message was generated.		14	R	ASTM date format

See **Table 12-79** for details on the fields.

Comment Record associated to a Patient Information Record (C)

The comment records are used for

- Sending the following fields (Table 40):
 - Patient Demographics User defined fields. The user is able to define additional patient demographic fields (see Volume 4b). Defined fields are sent.
 - Patient Age.

See **Table 12-79** for details.

- Indicating which patient demographic fields have been edited after the sample has been accepted. Format is described in Table 41.

The Units component is only used in conjunction with the PatAge field. Units for age are described in §A.5.

Table 12-43 ORI. LIS-2A CMR Associated to a PIR

	Field Name	Description	Comp	Max Len	Req	Values, formats and comments
1	Record Type ID	Identifies the record		1	R	"C"
2	Sequence Number	Defines the i'th occurrence of the associated record		?	R	[1,+inf[
3	Comment Source	Comment Origination Point		1	R	"P" (practice)
4	Comment Text	Comment codes and text	1	5	R	"FIELD" (Comment type is field)
			2	24	R	Field Name
			3	24	R	Value
			4	10	O	Units
5	Comment Type	Comment type qualifier		1	R	"G" (generic/free text comment)

Table 12-44 ORI. LIS-2A CMR Associated to a TOR or PIR

	Field Name	Description	Comp	Max Len	Req	Values, formats and comments
1	Record Type ID	Identifies the record		1	R	"C"
2	Sequence Number	Defines the i'th occurrence of the associated record		-	R	[0,+inf[
3	Comment Source	Comment Origination Point		1	R	"P" (practice)
4	Comment Text	Comment codes and text	1	5	R	"EDIT" (Comment type is field)
			2	24	R	Field Name or Analyte Name
			3	24	R	Old Value
			4	24	R	New Value
			5	10	O	Units
			6	14	R	Date time
			7	24	R	OpID
			8	24	R	OpLastName
			9	24	R	OpFirstName
			10	1	R	OpMiddleInitial
5	Comment Type	Comment type qualifier		1	R	"G" (generic/free text comment)

Test Order Record (O)**Table 12-45** ORI. LIS-2A TOR

Field	Field Name	Description	Comp	Max Len	Req	Values, formats and comments
1	Record Type ID	Identifies the record as TOR		1	R	"O"
2	Sequence Number	Defines the i'th occurrence of the associated record		1	R	A-V Pair. Arterial: "1". Venous: "2". Non A-V Pairs: "1"
3	Specimen ID	A unique id. for the specimen assigned by the HOST		24	O	OrderNumber
4	Instrument Specimen ID	A unique ID for the specimen assigned by G4K		24	O	Sample Number
7	Requested/Ordered Date and Time	Date and time the order was received or recorded		-	U	Ordered Date Time (phase 2)
8	Specimen Collection Date and Time	Date and time the specimen was collected or obtained		14	O	DrawnDateTime
15	Date/Time Specimen Received	Date and time the specimen was approved/saved		-	U	-
16	Specimen Descriptor	Sample type		2	R	SampleType. See below
17	Ordering Physician	Name of the ordering physician	1	24	O	OrderingPhID

			2	24	O	OrderingPhLastName
			3	24	O	OrderingPhFirstName
			4	1	O	OrderingPhMiddleInitial
23	Date/Time Results Reported or Last Modified	Date and time of the results		14	R	SentDateTime
26	Report Type			1	R	"F" (Final results) / "C" (correction of previously transmitted)
28	Location			-	U	-

See **Table 12-79** for details on the fields.

Patient Sample types are described in **Table 12-78**.

Comment Record associated to a Test Order Record (C)

The comment records is used for three purposes:

1. Sending those sample demographics fields that are not sent in the TOR. Those are the user-defined fields. See **Table 12-79**. Format is described in Table 43. Field Name is the name assigned in configuration (ex: SSNum or whatever).
2. Sending Operator comments to the sample. Format is described in Table 44.
3. Indicating which patient demographic fields have been edited after the sample has been accepted. Format is described in Table 41

Table 12-46 ORI.LIS-2A CMR Associated to a TOR Demographic Fields

	Field Name	Description	Comp	Max Len	Req	Values, formats and comments
1	Record Type ID	Identifies the record		1	R	"C"
2	Sequence Number	Defines the i'th occurrence of the associated record		-	R	[0,+inf[
3	Comment Source	Comment Origination Point		1	R	"P" (practice)
4	Comment Text	Comment codes and text	1	5	R	"FIELD" (Comment type is field)
			2	24	R	Field Name
			3	24	R	Value
			4	10	O	Units
5	Comment Type	Comment type qualifier		1	R	"G" (generic/free text comment)

Table 12-47 ORI. CMR Associated to a TOR Operator Comments

	Field Name	Description	Comp	Max Len	Req	Values, formats and comments
1	Record Type ID	Identifies the record		1	R	"C"
2	Sequence Number	Defines the i'th occurrence of the associated record		1	R	[1,42]
3	Comment Source	Comment Origination Point		1	R	"P" (practice)
4	Comment Text	Comment codes and text	1	7	R	"COMMENT" (Comment type is comment)
			2	80	R	Comment Text
			3	14	R	Date time
			4	24	R	OpID
			5	24	R	OpLastName
			6	24	R	OpFirstName
			7	1	R	OpMiddleInitial
5	Comment Type	Comment type qualifier		1	R	"G" (generic/free text comment)

Result Record (R)**Table 12-48** ORI. LIS2-A RSR

Field	Field Name	Description	Comp	Max Len	Req	Values, formats and comments
1	Record Type ID	Identifies the record		1	R	"R"
2	Sequence Number	Defines the i'th occurrence of the associated record		?	R	[1,+inf[
3	Universal Test ID	Universal Test ID Part 1	1	-	U	-
		Universal Test ID Part 2	2	-	U	-
		Universal Test ID Part 3	3	-	U	-
		Universal Test ID Part 4	4	16	R	Parameter Name See description below
		Part 5 (allowed by ASTM)		-	U	-
4	Data or Measurement Value	Observed, calculated or implied result value		10	R	Parameter Value. See description below
5	Units	Abbreviation of units for numerical results		10	R	Parameter Units. See description below

6	Reference Ranges	When available reports the reference ranges		-	O	RefLow + " to " + RefHigh -If both ranges defined: "2.34 to 3.15". -If only Min range defined: "2.34 to". -If only Max range defined: "to 3.15". -If no ranges defined: "" (null).
7	Result Abnormal Flags			2	O	"LL", "L", "N", "H", "HH"
8	Nature of Abnormality Testing	Normal testing performed by Age, Sex, Race or Generic		2	O	"N" (Generic ranges) or "AS" (based on age and sex)
9	Result Status			1	R	"F" (valid result) or "X" (result has an error)
11		Identifies the instrument operator and the verifier for the test	1.1	24	O	<i>OpRun.ID</i> (only the first result)
			1.2	24	O	<i>OpRun.LastName</i> (only the first result)
			1.3	24	O	<i>OpRun.FirstName</i> (only the first result)
			1.4	1	O	<i>OpRun.MidInitial</i> (only the first result)
			2.1	24	O	<i>OpAccept.ID</i> (only the first result)
			2.2	24	O	<i>OpAccept.LastName</i> (only the first result)
			2.3	24	O	<i>OpAccept.FirstName</i> (only the first result)
			2.4	1	O	<i>OpAccept.MidInitial</i> (only the first result)
13	Date Time Test Completed	Date and time the instrument completed the test		14	O	<i>RunDateTime</i> (only the first result)
14	Instrument Identification	Identifies the instrument that performed this measurement		TBD	O	<i>Anl.SerialNum</i> (only first result and when different than G4K)

A Result record is transmitted for a parameter if the parameter is part of the test panel selected for the sample. If the parameter is not part of the test panel that was selected for the sample, no Result record is transmitted for that parameter.

Note that the standard does not specify that Result records be transmitted in a particular order.

Field RSR.3.4 contains one of the parameter names listed in **Table 12-77**, in the G4K column

Results are always sent using the format defined in Volume 2a.

Decimal separator is always the default (1234.56).

Parameter units are sent in the display units configured in the system. Available units are described in Volume 2.

Exceptions are handled according **Table 12-49**:

Table 12-49 ORI. LIS2-A Exception Handling

<i>Contents of the ASTM field</i>				
		R.6, R.7, R.8	R.9	C.4
None	Actual Value	Yes, when available	"F"	No comment record
C	Null	No	"X"	"C^Incalculable"
>	High reportable range	No	"X"	">^Higher than reportable range but inside measurable range"
<	Low reportable range	No	"X"	"<^Lower than reportable range but inside measurable range"
A	Actual Value	No	"X"	"A^Above Linearity Range"
I	Actual Value	Yes, when available	"X"	"I^Interference detected"
T	Actual Value	Yes, when available	"X"	"T^Micro clot"
M	Actual Value	Yes, when available	"X"	"M^Reference Shift Error"
S	Actual Value	Yes, when available	"X"	"S^SHb detected"
B	Actual Value	Yes, when available	"X"	"B^Turbidity detected"
X	Null	No	"X"	"X^Unknown Exception"

Note: Errors A and X are reserved for external instruments.

CMR associated to a RSR

Table 12-50 ORI. LIS-2A CMR Associated to a RSR

<i>Field</i>	<i>Field Name</i>	<i>Description</i>	<i>Comp</i>	<i>Max Len</i>	<i>Req</i>	<i>Values, formats and comments</i>
1	Record Type ID	Identifies the record		1	R	"C"
2	Sequence Number	Defines the i'th occurrence of the associated record		1	R	"1"
3	Comment Source	Comment Origination Point		1	R	"I" (clinical instrument system)
4	Comment Text	Comment codes and text	1	1	R	Exception Code. See below
			2	128	R	Exception Description. See below
5	Comment Type	Comment type qualifier		1	R	"I" (instrument flags(s) comment)

This record is used to report an exception. **Table 12-49** describes the contents of field 4 in the event of an analyte exception.

Message Terminator Record (L)

Table 12-51 ORI. GEM 3000 Mode MTR

	Field Name	Description	Comp	Max Len	Req	Values, formats and comments
1	Record Type ID	Identifies the record		1	R	"L"
2	Sequence Number	Defines the i'th occurrence of the associated record		1	R	"1"
3	Termination code	Provides explanation of end of session		1	R	"N" (Normal Termination)

Expected responses

None

Transmission examples

Table 12-52 Transmission Example ORI. Native Mode Sample to HIS/LIS

	<i>Records</i>
0	H @^ 1.0^ICU^ANL1^GEM 4000^123^334^R3.1 CERNER P LIS2-A 20030922142358<CR>
1	P 1 1234567890 L BLAKE01 BLAKE^LINDSEY 19221123 U<CR>
2	C 1 P FIELD^Billing Number^235634 G<CR>
2	O 1 99999 123 A<CR>
3	C 1 P FIELD^Priority^High G<CR>
3	C 2 P COMMENT^What a wonderful day^20030922141516^fdyson^Dyson^Freeman G<CR>
3	R 1 ^^^pH 7.22 F 123456789 20030922142357<CR>
3	R 2 ^^^pCO2 62 mmHg F<CR>
3	R 3 ^^^pO2 81 mmHg F<CR>
3	R 4 ^^^Na+ 131.1 mmol/L F<CR>
3	R 5 ^^^K+ 5.14 mmol/L F<CR>
3	R 6 ^^^Ca++ mmol/L X<CR>
4	C 1 >^Higher than reportable range <CR>
3	R 7 ^^^Hct 65% > F<CR>
3	R 8 ^^^Ca++(7.4) 1.14 mmol/L F<CR>
3	R 9 ^^^HCO3- 25.3 mmol/L F<CR>
3	R 10 ^^^HCO3std 25.3 mmol/L F<CR>
3	R 11 ^^^TCO2 27.2 mmol/L F<CR>
3	R 15 ^^^%FiO2 100% F<CR>
0	L 1 N<CR>

Upload Calibration Results to the HIS/LIS

This conversation is initiated by the G4K and allows the G4K to send the results of one calibration to the HIS/LIS.

Uploading message

The uploading message structure is defined in the following table.

Table 12-53 ORI. LIS-2A Native Mode. Upload Calibration Results to the HIS-LIS

					Comments
0	1	2	3	4	
H					1 Master Header Record
	P				1 Patient Information Record
		O			1 Test Order Records
			{R}		1 or more results
L					1 Message Termination Record

Message Header Record (H)

This section is identical to §7.2.1.1 (Upload Patient Sample, ORI LIS-2A Native Mode).

Patient Information Record (P)

Table 12-54 ORI. LIS2-A PIR

Field	Field Name	Description	Comp	Max Len	Req	Values, formats and comments
1	Record Type ID	Identifies the record		1	R	"P"
2	Sequence Number	Defines the i'th occurrence of the associated record		1	R	"1"

Test Order Record (O)

Table 12-55 ORI. LIS2-A TOR

Field	Field Name	Description	Comp	Max Len	Req	Values, formats and comments
1	Record Type ID	Identifies the record as TOR		1	R	"O"
2	Sequence Number	Defines the i'th occurrence of the associated record		1	R	"1"
16	Specimen Descriptor	Sample type			R	Calibration type. See table below

Test Order field 16 contains one of the following character strings to indicate the calibration type:

Table 12-56 Calibration Types

Character String	Description
LOCal	Low Oxygen Calibration
1PtCal	1 Point Calibration
3PtCal	3 Point Calibration

Note: 2Ptcal is needed when interfacing GEM 3000

Result Record (R)**Table 12-57** ORI. LIS2-A RSR

	Field Name	Description	Comp	Max Len	Req	Values, formats and comments
1	Record Type ID	Identifies the record		1	R	"R"
2	Sequence Number	Defines the i'th occurrence of the associated record			R	[1, Infinity]
3	Universal Test ID	Universal Test ID Part 1	1	-	U	-
		Universal Test ID Part 2	2	-	U	-
		Universal Test ID Part 3	3	-	U	-
		Universal Test ID Part 4	4	16	R	One of the calibration records See below
		Part 5 (allowed by ASTM)	5	-	U	-
4	Data or Measurement Value	Observed, calculated or implied result value		10	O	Calibration result. Null if incalculable
5	Units	Abbreviation of units for numerical results		10	R	Parameter Units. See description below
7	Result Abnormal Flags			-	U	-
9	Result Status			1	R	"F" (valid result) or "X" (calibration failure)
13	Date Time Test Completed	Date and time the instrument completed the test		14	O	ASTM date time (only the first result)
14	Instrument Identification	Identifies the instrument that performed this measurement		-	U	Identification of the instrument if different than GEM 4000- Phase 2

A Result record is transmitted if the record is reported for a calibration. Otherwise, no record is transmitted for that parameter

Note that the standard does not specify that Result records be transmitted in a particular order.

Results are always sent using the format defined in Volume 2a.

Decimal separator is always the default (1234.56).

Parameter units are sent in the default units. Default units are described in Volume 2.

The available calibration records are described in **Table 12-58** and **Table 12-59**.

Records transmitted for each calibration type are described in Volume 6 (see section 4.2: Calibration Data File: Format).

Table 12-58 ORI. LIS2-A Calibration Records (Table 1/2)

	Slope	DriftA	MeasuredA	DriftB	MeasuredB	DriftC
pH	pHSlope	pHDriftA	pHMeasuredA	pHDriftB	pHMeasuredB	pHDriftC
PCO2	PCO2Slope	PCO2DriftA	PCO2Measure dA	PCO2DriftB	PCO2Measure dB	PCO2Drift C
PO2	PO2Slope	PO2DriftA	PO2MeasuredA	PO2DriftB	PO2Measured B	PO2DriftC
Na+	Na+Slope	Na+DriftA	Na+MeasuredA	Na+DriftB	Na+Measured B	
K+	K+Slope	K+DriftA	K+MeasuredA	K+DriftB	K+MeasuredB	
Cl-	Cl-Slope	Cl-DriftA	Cl-MeasuredA	Cl-DriftB	Cl-MeasuredB	
HCO3-	HCO3-Slope	HCO3-DriftA	HCO3- MeasuredA	HCO3-DriftB	HCO3- MeasuredB	
Ca++	Ca++Slope	Ca++DriftA	Ca++Measured A	Ca++DriftB	Ca++Measured B	
Hct	HctSlope	HctDriftA	HctMeasuredA	HctDriftB	HctMeasuredB	
Glu	GluSlope	GluDriftA	GluMeasuredA	GluDriftB	GluMeasuredB	
Lac	LacSlope	LacDriftA	LacMeasuredA	LacDriftB	LacMeasuredB	
BUN	BUNSlope	BUNDriftA	BUNMeasured A	BUNDriftB	BUNMeasured B	BUNDriftC
Cr	CrSlope	CrDriftA	CrMeasuredA	CrDriftB	CrMeasuredB	
Creat	CreatSlope	CreatDriftA	CreatMeasured A	CreatDriftB	CreatMeasured B	
tHb	tHbSlope	tHbDriftA	tHbMeasuredA	tHbDriftB	tHbMeasuredB	

Table 12-59 ORI. LIS2-A Calibration Records (Table 2/2)

	MeasuredC	SlopeC	DriftD	MeasuredD	Slope2
pH	pHMeasuredC	pHSlopeC			
PCO2	PCO2Measured C	PCO2SlopeC	PCO2DriftD	PCO2MeasuredD	
PO2	PO2MeasuredC				
Na+			Na+DriftD	Na+MeasuredD	
K+			K+DriftD	K+MeasuredD	
Cl-			Cl-DriftD	Cl-MeasuredD	
HCO3-			HCO3-DriftD	HCO3- MeasuredD	
Ca++			Ca++DriftD	Ca++MeasuredD	
Hct					
Glu			GluDriftD	GluMeasuredD	
Lac			LacDriftD	LacMeasuredD	
BUN	BUNMeasuredC		BUNDriftD	BUNMeasuredD	BUNSlope2
Cr			CrDriftD	CrMeasuredD	
Creat			CreatDriftD	CreatMeasuredD	CreatSlope2
tHb			tHbDriftD	tHbMeasuredD	

Message Terminator Record (L)

This section is identical to §7.2.1.8 (Upload Patient Sample, ORI LIS-2A Native Mode).

Expected responses

None

Transmission examples**Table 12-60** 1 Point Calibration

	Records
0	H @^ ^1.0^ICU^ANL1^GEM 4000^123^334^R3.1 CERNER P LIS2-A 20050922142358<CR>
1	P 1<CR>
2	O 1 1PtCal<CR>
3	R 1 ^^pHDriftB 0.00 20050922142350<CR>
3	R 2 ^^PCO2DriftB 0 mmHg F<CR>
3	R 3 ^^PO2DriftB 0 mmHg F<CR>
3	R 4 ^^Na+DriftB 0.0 mmol/L F<CR>
3	R 5 ^^K+DriftB 0.00 mmol/L F<CR>
3	R 6 ^^Ca++DriftB 0.25 mmol/L X<CR>
3	R 7 ^^HctDriftB 0 % F<CR>
3	R 8 ^^pHMeasuredB 7.41 F<CR>
3	R 9 ^^PCO2MeasuredB 35 mmHg F<CR>
3	R 10 ^^PO2MeasuredB 199 mmHg F<CR>
3	R 11 ^^Na+MeasuredB 136.0 mmol/L F<CR>
3	R 12 ^^K+MeasuredB 6.00 mmol/L F<CR>
3	R 13 ^^Ca++MeasuredB 2.07 mmol/L F<CR>
3	R 14 ^^HctMeasuredB 11 % F<CR>
0	L 1 N<CR>

Table 12-61 3 point Calibration

Level	Records
0	H @^ ^1.0^ICU^ANL1^GEM 4000^123^334^R3.1 CERNER P LIS2-A 20050922142358<CR>
1	P 1<CR>
2	O 1 3PtCal<CR>
3	R 1 ^^pHSlope 62 mV/dec 19980825133636<CR>
3	R 2 ^^PCO2Slope 54 mV/dec F<CR>
3	R 3 ^^PO2Slope 8 mV/dec F<CR>
3	R 4 ^^Na+Slope 64 mV/dec F<CR>

3	R 5 ^^^K+Slope 58 mV/dec F<CR>
3	R 6 ^^^Ca++Slope 24 mV/dec F<CR>
3	R 7 ^^^HctSlope 38 mV/mho F<CR>
3	R 8 ^^^pHDriftA 0.01 F<CR><CR>
3	R 9 ^^^PCO2DriftA 0 mmHg F<CR>
3	R 10 ^^^PO2DriftA 0 mmHg F<CR>
3	R 11 ^^^Na+DriftA 0.01 mmol/L F<CR>
3	R 12 ^^^K+DriftA -0.01 mmol/L F<CR>
3	R 13 ^^^Ca++DriftA 0.25 F mmol/L F<CR>
3	R 14 ^^^pHMeasuredA 6.93 F<CR>
3	R 15 ^^^PCO2MeasuredA 63 mmHg F<CR>
3	R 16 ^^^PO2MeasuredA 0 mmHg F<CR>
3	R 17 ^^^Na+MeasuredA 154.0 mmol/L F<CR>
3	R 18 ^^^K+MeasuredA 1.89 mmol/L F<CR>
3	R 19 ^^^Ca++MeasuredA 0.19 mmol/L F<CR>
3	R 20 ^^^pHDriftB 0.00 F<CR>
3	R 21 ^^^PCO2DriftB 0 mmHg F<CR>
3	R 22 ^^^PO2DriftB 0 mmHg F<CR>
3	R 23 ^^^Na+DriftB 0.0 mmol/L F<CR>
3	R 24 ^^^K+DriftB 0.00 mmol/L F<CR>
3	R 25 ^^^Ca++DriftB 0.00 mmol/L F<CR>
3	R 26 ^^^HctDriftB 0 % F<CR>
3	R 27 ^^^pHMeasuredB 7.41 F<CR>
3	R 28 ^^^PCO2MeasuredB 35 mmHg F<CR>
3	R 29 ^^^PO2MeasuredB 199 mmHg F<CR>
3	R 30 ^^^Na+MeasuredB 136.0 mmol/L F<CR>
3	R 31 ^^^K+MeasuredB 6.00 mmol/L F<CR>
3	R 32 ^^^Ca++MeasuredB 2.07 mmol/L F<CR>
3	R 33 ^^^HctMeasuredB 11 % F<CR>
3	R 34 ^^^K+DriftD 0.00 mmol/L F<CR>
3	R 35 ^^^Ca++DriftD 0.00 mmol/L F<CR>
3	R 36 ^^^HctDriftD 0 % F<CR>
3	R 37 ^^^Na+MeasuredD 136.0 mmol/L F<CR>
3	R 38 ^^^K+MeasuredD 6.00 mmol/L F<CR>
3	R 39 ^^^Ca++MeasuredD 2.07 mmol/L F<CR>
0	L 1 N<CR>

12-7 ORI-GEM 3000 Mode

General considerations

The ORI-GEM 3000 mode uses the NCCLS LIS2-A protocol.

Upload Patient Sample Results to the HIS/LIS

This conversation is initiated by the G4K and allows the G4K to send the results of one sample for an individual patient to the HIS/LIS.

Uploading message

The uploading message structure is defined in the following table.

Table 12-62 ORI. GEM 3000 Mode HIS/LIS Upload Message

					<i>Comments</i>
0	1	2	3	4	
H					1 Master Header Record
	P				1 Patient Information Record
		{O}			1 or 2 Test Order Records (2 only when AV-Pair)
			[[C]]		0 or more Comments associated to the order
			{R}		1 or more results
L					1 Message Termination Record

Message Header Record (H)

Table 12-63 ORI. GEM 3000 Mode MHR

	Field Name	Description	Comp	Max Len	Req	Values, formats and comments
1	Record Type ID	Identifies the record		1	R	"H"
2	Delimiter Definition	Define the delimiters to be used throughout the subsequent records of the message		4	R	" \\^&"
5	Sender Name or ID	Defines the manufacturer/ instrument specific to this line. May use the repeat or component delimiter to reflect software revisions or firmware revisions, multiple instruments available on this line, etc.	1	8	R	Instrument Model
			2	20	R	Anl.SWVersionNum
			3	10	R	InstrumentSerialNumber
			4	13	O	InstrumentName
			5	6	R	CartridgeSerialNumber
			6	3	R	"3.0" (Data Format version)
10	Receiver ID	Text value includes name or other ID of the receiver. Used to verify that the transmission is indeed for the receiver		-	U	-
12	Processing ID	Indicates how this message is to be processed		-	U	-
13	Version No.	Version level of the specification.		-	U	-
14	Date and Time of Message	The date and time that the message was generated.		14	R	ASTM date format

Patient Information Record (P)

Table 12-64 ORI. GEM 3000 Mode PIR

Field	Field Name	Description	Comp	Max Len	Req	Values, formats and comments
1	Record Type ID	Identifies the record		1	R	"P"
2	Sequence Number	Defines the i'th occurrence of the associated record		1	R	"1"
3	Practice Assigned PatientID			10	R	PatientPK
4	Laboratory Assigned Patient ID	"True" patient ID		16	O	PatientID
5	Patient ID No. 3	Social Security Account No.		-	U	-

6	Patient Name	The patient's name	1	20	O	PatLastName
			2	20	O	PatFirstName
			3	1	O	PatMiddleInitial
8	Birthdate			8	O	PatDOB in ASTM format
9	Patient Sex			1	R	"M", "F" or "U"
15	Special Field 1	Used by IMPACT to receive the patient Billing Number		-	U	-
16	Special Field 2	Used By Impact to receive the Medical Number		-	U	-
26	Location	Room/Bed of patient		-	U	-

See **Table 12-79** for details on the fields.

Test Order Record (O)

Table 12-65 ORI. GEM 3000 Mode TOR

	Field Name	Description	Comp	Max Len	Req	Values, formats and comments
1	Record Type ID	Identifies the record as TOR		1	R	
2	Sequence Number	Defines the i'th occurrence of the associated record		1	R	A-V Pair. Arterial: "1". Venous: "2". Non A-V Pairs: "1"
3	Specimen ID	A unique id. for the specimen assigned by the HOST		16	O	OrderNumber
4	Instrument Specimen ID	A unique ID for the specimen assigned by G4K		10	O	Sample Number
7	Requested/Ordered Date and Time	Date and time the order was received or recorded		-	U	-
8	Specimen Collection Date and Time	Date and time the specimen was collected or obtained		14	O	DrawnDateTime
15	Date/Time Specimen Received	Date and time the specimen was approved/saved by IMPACT		-	U	-
16	Specimen Descriptor	Sample type		2	R	SampleType
17	Ordering Physician	Name of the ordering physician	1	-	U	-
			2	-	U	-
			3	-	U	-
			4	-	U	-
23	Date/Time Results Reported or Last Modified	Date and time of the results		-	U	-
26	Report Type			-	U	-
28	Location	Area Drawn		-	U	-

See **Table 12-79** for details on the fields.

Patient Sample types are described in **Table 12-78**.

CMR associated to TOR

Table 12-66 ORI. GEM 3000 Mode CMR associated to TOR

	Field Name	Description	Comp	Max Len	Req	Values, formats and comments
1	Record Type ID	Identifies the record		1	R	"C"
2	Sequence Number	Defines the i'th occurrence of the associated record		1	R	[1,Infinity]
3	Comment Source	Comment Origination Point		1	R	"I" (clinical instrument)
4	Comment Text	Comment codes and text	1	48	R	Comment text (see description below)
			2	-	U	-
			3	-	U	-
5	Comment Type	Comment type qualifier		1	R	"G" (generic/free text comment)

The comment text contains the date and time of the comment, the Operator ID of the person that did the comment and the comment text itself, separated by blanks: "YYYYMMDD OperatorID Comment"

See **Table 12-79** for details on the fields OperatorID and Comment.

The field is truncated to 48 characters.

Result Record (R)

Table 12-67 ORI. GEM 3000 Mode RSR

Field	Field Name	Description	Comp	Max Len	Req	Values, formats and comments
1	Record Type ID	Identifies the record		1	R	"R"
2	Sequence Number	Defines the i'th occurrence of the associated record		-	R	[1, Infinity]
3	Universal Test ID	Universal Test ID Part 1	1	-	U	-
		Universal Test ID Part 2	2	-	U	-
		Universal Test ID Part 3	3	-	U	-
		Universal Test ID Part 4	4	16	R	ParamName
		Part 5 (allowed by ASTM)	5	-	U	-
4	Data or Measurement Value	Observed, calculated or implied result value		10	R	Parameter Value. See description below
5	Units	Abbreviation of units for numerical results		10	R	Parameter Units. See description below
6	Reference Ranges	When available reports the reference ranges		10	O	Ranges. See description below

7	Result Abnormal Flags			2	O	Error or abnormal flag. See description below
8	Nature of Abnormality Testing	Normal testing performed by Age and Sex		-	U	-
9	Result Status			-	U	-
11	Operator Identification	Identifies the instrument operator and the verifier for the test		16	O	<i>OperatorID</i> (only the first result)
13	Date Time Test Completed	Date and time the instrument completed the test		14	O	ASTM date time (only the first result)
14	Instrument Identification	Identifies the instrument that performed this measurement		-	U	Identification of the instrument if different than GEM 4000 (phase 2)

A Result record is transmitted for a parameter if the parameter is part of the test panel selected for the sample. If the parameter is not part of the test panel that was selected for the sample, no Result record is transmitted for that parameter.

Field RSR.3.4 contains one of the parameter names listed in **Table 12-77**.

Note that the standard does not specify that Result records be transmitted in a particular order.

Results are always sent using the format defined in Volume 2a.

Decimal separator is always the default (1234.56).

Parameter units are sent in the display units configured in the system. Available units are described in Volume 2.

Table 12-68 defines the contents of fields RSR.4, RSR.6 and RSR.7.

The format of field RSR.6 (Reference Ranges) is the two ranges separated by a blank:

- If both ranges defined: "2.34 3.15".
- If only Min range defined: "2.34 ".
- If only Max range defined: " 3.15".
- If no ranges are defined: "" (null).

Note that the GEM 3000 mode does not allow flag results for patient results with an exception.

Table 12-68 ORI. GEM 3000 Mode Uploading RSR Fields 4, 6 and 7

Exception on Analyte	Contents of the ASTM field		
	RSR.4	RSR.7	RSR.6
None	Actual value	Null	Null
C (Incalculable)	Null	C	Null
> (Higher than reportable range)	Reportable Range – High	>	Null
< (Lower than reportable range)	Reportable Range – Low	<	Null
A (Above Linearity Range)	Actual value	A	Null
I (Interference detected)	Actual value	I	Null

T (Micro clot)	Actual value	T	Null
M (Reference Shift Error)	Actual value	M	Null
S (SHb detected)	Actual value	S	Null
B (Turbidity detected)	Actual value	B	Null
X (Unknown Exception)	Actual value or blank	X	Null
Outside Critical Limits	Actual value	P	Critical Ranges “Low High”
Outside Reference Range	Actual value	N	Critical Ranges “Low High”

Note: Errors A and X are reserved for external instruments.

Message Terminator Record (L)

Table 12-69 ORI. GEM 3000 Mode MTR

	Field Name	Description	Comp	Max Len	Req	Values, formats and comments
1	Record Type ID	Identifies the record		1	R	"L"
2	Sequence Number	Defines the i'th occurrence of the associated record		1	R	"1"
3	Termination code	Provides explanation of end of session		-	U	-

Expected responses

None

Transmission examples

Table 12-70 ORI. GEM 3000 Mode Transmission Example

GEM 4000 uploads a sample to the HIS/LIS	
Level	Records
0	H ^& GEM 4000^V1.0r2^7040^999^123456^1.00 20030922142358<CR>
1	P 1 1234567812345678 ^BLAKE^LINDSEY<CR>
2	O 1 99999 123 A<CR>
3	R 1 ^^^pH 7.22 123456789 20030922142357<CR>
3	R 2 ^^^pCO2 62 mmHg<CR>
3	R 3 ^^^pO2 81 mmHg<CR>
3	R 4 ^^^Na+ 131.1 mmol/L<CR>
3	R 5 ^^^K+ 5.14 mmol/L<CR>
3	R 6 ^^^Ca++ 1.14 mmol/L<CR>
3	R 7 ^^^Hct 65 % ><CR>
3	R 8 ^^^Ca++(7.4) 1.14 mmol/L<CR>
3	R 9 ^^^HCO3- 25.3 mmol/L<CR>

3	R 10 ^^HCO3std 25.3 mmol/L<CR>
3	R 11 ^^TCO2 27.2 mmol/L<CR>
3	R 12 ^^BEcf C<CR>
3	R 13 ^^BE(B) C<CR>
3	R 14 ^^SO2c C<CR>
3	R 15 ^^%FiO2 100 %<CR>
0	L 1<CR>

Upload Calibration Results to the HIS/LIS

This conversation is initiated by the G4K and allows the G4K to send the results of one calibration to the HIS/LIS.

Uploading message

The uploading message structure is defined in the following table.

Table 12-71 ORI. GEM 3000 Mode Upload Calibration Results

					Comments
0	1	2	3	4	
H					1 Master Header Record
	P				1 Patient Information Record
		O			1 Test Order Records
			{R}		1 or more results
L					1 Message Termination Record

Message Header Record (H)

This section is identical to “Message Header Record (H)” on page 68 (Upload Patient Sample, ORI GEM 3000 Mode).

Patient Information Record (P)

This section is identical to “Patient Information Record (P)” on page 62 (Upload Calibration Sample, ORI Native Mode).

Test Order Record (O)

This section is identical to “Test Order Record (O)” on page 62 (Upload Calibration Sample, ORI Native Mode).

Result Record (R)**Table 12-72** ORI. GEM 3000 Mode RSR

	Field Name	Description	Comp	Max Len	Req	Values, formats and comments
1	Record Type ID	Identifies the record		1	R	"R"
2	Sequence Number	Defines the i'th occurrence of the associated record			R	[1, Infinity]
3	Universal Test ID	Universal Test ID Part 1	1	-	U	-
		Universal Test ID Part 2	2	-	U	-
		Universal Test ID Part 3	3	-	U	-
		Universal Test ID Part 4	4	16	R	One of the calibration records See below
		Part 5 (allowed by ASTM)	5	-	U	-
4	Data or Measurement Value	Observed, calculated or implied result value		10	O	Calibration result. Null if incalculable
5	Units	Abbreviation of units for numerical results		10	R	Parameter Units. See description below
7	Result Abnormal Flags			1	O	"F" if calibration failure. Null otherwise
9	Result Status			-	U	-
13	Date Time Test Completed	Date and time the instrument completed the test		14	O	ASTM date time (only the first result)
14	Instrument Identification	Identifies the instrument that performed this measurement		-	U	Identification of the instrument if different than GEM 4000. Phase 2

A Result record is transmitted if the record is reported for a calibration. Otherwise, no record is transmitted for that parameter. Note that the standard does not specify that Result records be transmitted in a particular order.

Results are always sent using the format defined in Volume 2a.

Decimal separator is always the default (1234.56).

Parameter units are sent in the default units. Default units are described in Volume 2.

Notice that if the parameter is unitless (ex: pH), the field is empty.

Notice, that the only difference with the Native Mode is the usage of fields 7 and 9. The native mode uses field 9 to indicate a failure (following the standard), while the GEM 3000 uses incorrectly the field 7.

The available calibration records are described in **Table 12-73** and **Table 12-74**.

Notice that the only differences with the records in the native mode are the PCO2, PO2 and tHB names.

Table 12-73 ORI. GEM 3000 Mode Calibration Records (Table 1/2)

	Slope	DriftA	MeasuredA	DriftB	MeasuredB	DriftC
pH	pHSlope	pHDriftA	pHMeasuredA	pHDriftB	pHMeasuredB	pHDriftC
PCO2	pCO2Slope	pCO2DriftA	pCO2MeasuredA	pCO2DriftB	pCO2MeasuredB	pCO2DriftC
PO2	pO2Slope	pO2DriftA	pO2MeasuredA	pO2DriftB	pO2MeasuredB	pO2DriftC
Na+	Na+Slope	Na+DriftA	Na+MeasuredA	Na+DriftB	Na+MeasuredB	
K+	K+Slope	K+DriftA	K+MeasuredA	K+DriftB	K+MeasuredB	
Cl-	Cl-Slope	Cl-DriftA	Cl-MeasuredA	Cl-DriftB	Cl-MeasuredB	
HCO3-	HCO3-Slope	HCO3-DriftA	HCO3-MeasuredA	HCO3-DriftB	HCO3-MeasuredB	
Ca++	Ca++Slope	Ca++DriftA	Ca++MeasuredA	Ca++DriftB	Ca++MeasuredB	
Hct	HctSlope	HctDriftA	HctMeasuredA	HctDriftB	HctMeasuredB	
Glu	GluSlope	GluDriftA	GluMeasuredA	GluDriftB	GluMeasuredB	
Lac	LacSlope	LacDriftA	LacMeasuredA	LacDriftB	LacMeasuredB	
BUN	BUNSlope	BUNDriftA	BUNMeasuredA	BUNDriftB	BUNMeasuredB	BUNDriftC
Cr	CrSlope	CrDriftA	CrMeasuredA	CrDriftB	CrMeasuredB	
Creat	CreatSlope	CreatDriftA	CreatMeasuredA	CreatDriftB	CreatMeasuredB	
tHb	THbSlope	THbDriftA	THbMeasuredA	THbDriftB	THbMeasuredB	

Table 12-74 ORI. GEM 3000 Mode Calibration Records (Table 2/2)

	MeasuredC	SlopeC	DriftD	MeasuredD	Slope2
pH	pHMeasuredC	pHSlopeC			
PCO2	pCO2MeasuredC	pCO2SlopeC	pCO2DriftD	pCO2MeasuredD	
PO2	pO2MeasuredC				
Na+			Na+DriftD	Na+MeasuredD	
K+			K+DriftD	K+MeasuredD	
Cl-			Cl-DriftD	Cl-MeasuredD	
HCO3-			HCO3-DriftD	HCO3-MeasuredD	
Ca++			Ca++DriftD	Ca++MeasuredD	
Hct					
Glu			GluDriftD	GluMeasuredD	
Lac			LacDriftD	LacMeasuredD	
BUN	BUNMeasuredC		BUNDriftD	BUNMeasuredD	BUNSlope2
Cr			CrDriftD	CrMeasuredD	
Creat			CreatDriftD	CreatMeasuredD	CreatSlope2
tHb				THbMeasuredD	

Transmission examples

Table 12-75 1 Point Calibration

Ca++ has a drift error. ORI. GEM 3000 Mode. Upload Calibration Results to HIS/LIS. Uploading Message.	
Level	Records
0	H ^& GEM 4000^V1.0r2^7040^999^123456^1.00 20050922142358<CR>
1	P 1<CR>
2	O 1 1PtCal<CR>
3	R 1 ^pHDriftB 0.00 20050922142350<CR>
3	R 2 ^pCO2DriftB 0 mmHg<CR>
3	R 3 ^pO2DriftB 0 mmHg<CR>
3	R 4 ^Na+DriftB 0.0 mmol/L<CR>
3	R 5 ^K+DriftB 0.00 mmol/L<CR>
3	R 6 ^Ca++DriftB 0.25 mmol/L F<CR>
3	R 7 ^HctDriftB 0 %<CR>
3	R 8 ^pHMeasuredB 7.41<CR>
3	R 9 ^pCO2MeasuredB 35 mmHg<CR>
3	R 10 ^pO2MeasuredB 199 mmHg<CR>
3	R 11 ^Na+MeasuredB 136.0 mmol/L<CR>
3	R 12 ^K+MeasuredB 6.00 mmol/L<CR>
3	R 13 ^Ca++MeasuredB 2.07 mmol/L<CR>
3	R 14 ^HctMeasuredB 11 %<CR>
0	L 1<CR>

Table 12-76 3 Point Calibration

Ca++ has a DRIFTA ERROR. ORI. GEM 3000 Mode. Upload Calibration Results to HIS/LIS. Uploading Message.	
Level	Records
0	H ^& GEM 4000^V1.0r2^7040^999^123456^1.00 20030922142358<CR>
1	P 1<CR>
2	O 1 3PtCal<CR>
3	R 1 ^pHSlope 62 mV/dec 19980825133636<CR>
3	R 2 ^pCO2Slope 54 mV/dec<CR>
3	R 3 ^pO2Slope 8 mV/dec<CR>
3	R 4 ^Na+Slope 64 mV/dec<CR>
3	R 5 ^K+Slope 58 mV/dec<CR>
3	R 6 ^Ca++Slope 24 mV/dec<CR>
3	R 7 ^HctSlope 38 mV/mho<CR>
3	R 8 ^pHDriftA 0.01<CR>
3	R 9 ^pCO2DriftA 0 mmHg<CR>

3	R 10 ^^^pO2DriftA 0 mmHg<CR>
3	R 11 ^^^Na+DriftA 0.01 mmol/L<CR>
3	R 12 ^^^K+DriftA -0.01 mmol/L<CR>
3	R 13 ^^^Ca++DriftA 0.25 mmol/L F<CR>
3	R 14 ^^^pHMeasuredA 6.93<CR>
3	R 15 ^^^pCO2MeasuredA 63 mmHg<CR>
3	R 16 ^^^pO2MeasuredA 0 mmHg<CR>
3	R 17 ^^^Na+MeasuredA 154.0 mmol/L<CR>
3	R 18 ^^^K+MeasuredA 1.89 mmol/L<CR>
3	R 19 ^^^Ca++MeasuredA 0.19 mmol/L<CR>
3	R 20 ^^^pHDriftB 0.00<CR>
3	R 21 ^^^pCO2DriftB 0 mmHg<CR>
3	R 22 ^^^pO2DriftB 0 mmHg<CR>
3	R 23 ^^^Na+DriftB 0.0 mmol/L<CR>
3	R 24 ^^^K+DriftB 0.00 mmol/L<CR>
3	R 25 ^^^Ca++DriftB 0.00 mmol/L<CR>
3	R 26 ^^^HctDriftB 0 %<CR>
3	R 27 ^^^pHMeasuredB 7.41<CR>
3	R 28 ^^^pCO2MeasuredB 35 mmHg<CR>
3	R 29 ^^^pO2MeasuredB 199 mmHg<CR>
3	R 30 ^^^Na+MeasuredB 136.0 mmol/L<CR>
3	R 31 ^^^K+MeasuredB 6.00 mmol/L<CR>
3	R 32 ^^^Ca++MeasuredB 2.07 mmol/L<CR>
3	R 33 ^^^HctMeasuredB 11 %<CR>
3	R 34 ^^^K+DriftD 0.00 mmol/L<CR>
3	R 35 ^^^Ca++DriftD 0.00 mmol/L<CR>
3	R 36 ^^^HctDriftD 0 %<CR>
3	R 37 ^^^Na+MeasuredD 136.0 mmol/L<CR>
3	R 38 ^^^K+MeasuredD 6.00 mmol/L<CR>
3	R 39 ^^^Ca++MeasuredD 2.07 mmol/L<CR>
0	L 1<CR>

12-8 Tables

Analyte names

The following table contains the conversion table between the GEM 4000 notation and the several modes for the factory default ones. User defined analytes are always sent with the name defined in configuration in all the modes. Results are always sent using the format defined in Volume 2a. Decimal separator are always the default (1234.56).

If temperature is not entered, temperature corrected parameters contain the value at 37.0°C.

NOTE: Items marked with (N) are not present in the GEM 3000 analyzer. G4K sends those analytes in G3K mode.

Table 12-77 Factory Default Analyte Names

G4K	G3K	ICC		Syn
		Code	Name	
pH	pH			
PCO2	pCO2			
PO2	pO2			
Na+	Na+			
K+	K+			
Cl-	Cl- (N)			
HCO3-	HCO3-			
Ca++	Ca++			
Hct	Hct			
Glu	Glu			
Lac	Lac			
BUN	BUN (N)			
Urea	Urea (N)			
Creat	Creat (N)			
tHb	THb			
O2Hb	O2Hb			
COHb	COHb			
MetHb	MetHb			
HHb	HHb			
SO2	SO2			
pH(T)	pH(T)			
PCO2(T)	pCO2(T)			
PO2(T)	pO2(T)			
Ca++(7.4)	Ca++(7.4)			
HCO3std	HCO3std			
TCO2	TCO2			
BEecf	BEecf			
BE(B)	BE(B)			

SO2c	SO2c			
tHbc	THbc			
O2ct	O2ct			
O2cap	O2cap			
A-aDO2	A-aDO2			
pAO2	pAO2			
paO2/pAO2	paO2/pAO2			
RI	RI			
CaO2	CaO2			
CvO2	CvO2			
CcO2	CcO2			
a-vDO2	a-vDO2			
Qsp/Qt	Qsp/Qt			
P50	P50			
AG	AG (N)			
Osm	Osm (N)			
BUN/Creat	BUN/Creat (N)			
Urea/Creat	Urea/Creat (N)			
P/F Ratio	P/F Ratio (N)			
Temp	Temp			
BP	BP			
O2	O2			
%FiO2	%FiO2			
Mech VT	Mech VT			
Spont VT	Spont VT			
O2 Device #1	O2 Device #1			
O2 Device #2	O2 Device #2			
Mech Rate (bpm)	Mech Rate (bpm)			
Mech Rate (Hz)	Mech Rate (Hz)			
Spont Rate (bpm)	Spont Rate (bpm)			
Spont Rate (Hz)	Spont Rate (Hz)			
Peak Press	Peak Press			
MAP	MAP			
Itime(sec)	Itime(sec)			
Itime(%)	Itime(%)			
PEEP	PEEP			
CPAP	CPAP			
BIPAP(I)	BIPAP(I)			
BIPAP(E)	BIPAP(E)			
PS	PS			
PC	PC			
Pulse Ox	Pulse Ox			
Flow	Flow			

Patient Sample Types

Table 12-78 Patient Sample Types

	<i>G4K</i>	<i>G3K</i>	<i>HL7</i>	<i>ICC</i>	<i>Synthesi s</i>
Arterial	A	A	BLDA	4	4
Venous	V	V	BLDV	5	5
Capillary	C	C	BLDC	6	6
Mixed Venous	M	M	BLMV	TBD	TBD
Other	O	O	BLDO	9	9
Arterial - Micro sample	AM	AM	BLDA	4	4
Venous – Micro sample	VM	VM	BLDV	5	5
Capillary – Micro sample	CM	CM	BLDC	6	6
Mixed Venous – Micro sample	MM	MM	BLMV	TBD	TBD
Other - Micro sample	OM	OM	BLDO	9	9

Notes on POCT1-A:

- Other" is not defined in HL7, so a new code (BLDO) has been created
- Remind that sample size is reported in fields OBR-9 and OBR-15.3.

Database Fields

The communication standards do not impose maximum field or record lengths, allowing the instrument and computer system vendors to agree on.

The following table describes the maximum lengths for data fields

Table 12-79 Database Fields

Category	Field	Max. Length	Format	Description
Patient	Pat.ID	24	Text	Patient ID
	Pat.PK	10	0- 4294967295	Unique internal G4K identifier for the patient (32 bits primary key).
	Pat.LastName	24	Text	Patient's last name
	Pat.FirstName	24	Text	Patient's first name
	Pat.MidInitial	1	Text	Patient's middle initial
	Pat.DOB	14	ASTM Date Time	Patient's birthdate
	Pat.Gender	1	"M", "F" or "U"	Patien's sex
	Pat.Age	3	Numeric	Patien's Age when the sample is done
	Pat.1 to Pat.N	20	Text	User defined patient demographics (no limit)

Sample	OrderNum	24	Text	Order Number (a.k.a. Accession ID)
	SampleNum	24		
	SamplePK	10	0- 4294967295	Unique internal G4K identifier for the sample patient (32 bits primary key).
	SampleType		See Table 12-78	Sample Type
	AnalysisDateTime	14	ASTM Date Time	Date and time of instrument completed the test
	SampleComment	80?	Text	Sample comments
	SentDateTime	14	ASTM Date Time	Date the sample was sent to the LIS. Empty in a first transmission.
	OrderingClin.ID	24		Ordering Clinician
	OrderingClin.LastNa me	24		
	OrderingClin.FirstNa me	24		
	OrderingClin. MidInitial	1		
	OpRun.ID	24		Operator that ran the sample
	OpRun.LastName	24		
	OpRun.FirstName	24		
	OpRun.FMidInitial	1		
	OpAccept.ID	24		Operator that accepted the sample
	OpAccept.LastName	24		
	OpAccept.FirstNam e	24		
	OpAccept.FMidInitial	1		
	AcceptDateTime	14	ASTM Date Time	Date and time of sample was accepted
	Sample.1 to Sample.N	20	Text	User defined sample demographics (no limit)
Analyzer	Anl.Model	10	Text	Analyzer model. "GEM 4000" is used
	Anl.SWVersionNum	20		Analyzer Operating SW version.
	Anl.SerialNum	10		Analyzer serial numbe.
	Anl.Name	10		Analyzer Name
	Aml.CartSerialNum	24		Cartridge Serial Number
	AreaName	10		Area Name
Other	Field Name	24		Patient or sample Demographics field name
	Field Value	24		Patient or sample Demographics field value
	Analyte Name	16		Enterd/O2Vent maximum length
	Value	10		
	Units	10		

Age Units

The units for age use the HL7 convention, described in **Table 12-80**.

Table 12-80 Units for Age

	<i>Description</i>
D	Days
WK	Weeks
MO	Months
YR	Years

The SW chooses the appropriate units (i.e 3 days instead of 0.082 years) according to the rules specified in Volume 1, so the transmitted units match the units displayed in the UI.

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