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i 800 Automatic Chemiluminescence Analyzer LIS Communication Protocol

Version V1.0.00.221210

Maccura Medical Instrument Co., Ltd.

1. Standards for Hardware Interfaces of External Systems

1.1 Overview

The i 800 uses RS232 (serial port) as the system interface to communicate with the external system (usually referred to as LIS server), and can monitor the transmission data through third-party monitoring tools (such as AccessPort, etc.).

1.2 Pin Description

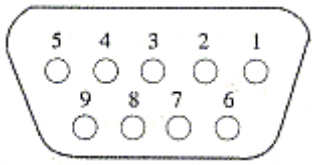
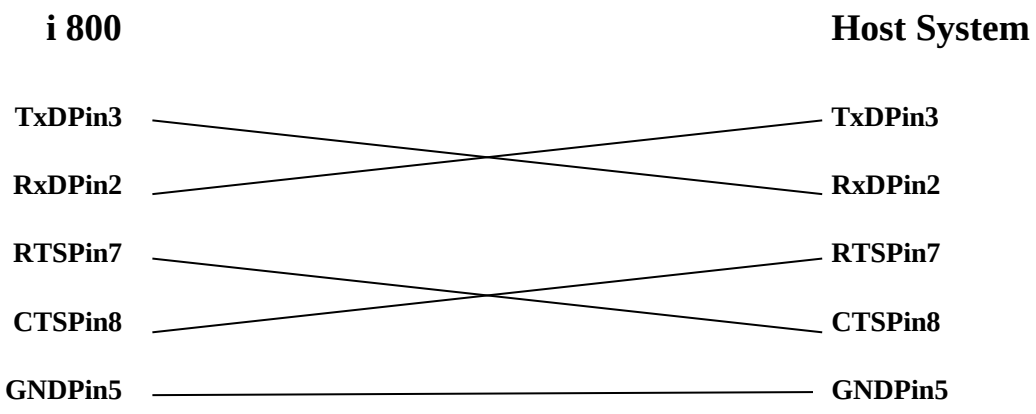


Fig.1.2 RS232 Serial Port Plug

S/N	Abbreviations	Full Name of Pin	Pin Description	Transmission Direction
1	DCD	DataCarrierDetect	Data carrier detection	Not used
2	RxD	ReceiveData	Serial port data input	i 800←HostSystem
3	TxD	TransmittedData	Serial port data output	i 800→HostSystem
4	DTR	DataTerminalReady	Data terminal ready	Not used
5	GND	SystemGround	Common grounding position	i 800—HostSystem
6	DSR	DataSetReady	Data sending ready	Not used
7	RTS	RequestToSend	Request for sending data	i 800→HostSystem

8	CTS	ClearToSend	Clear to send	i 800←HostSystem
9	RI	RingIndicator	Ring indicator	Not used

1.3 Connection Schematic Diagram



1.4 LIS Communication Configuration Description

RS232 serial port communication configuration is shown in Fig. 1.4 (Application - System -Settings):

The parts of the actual interface that you don't need to care about are covered in white

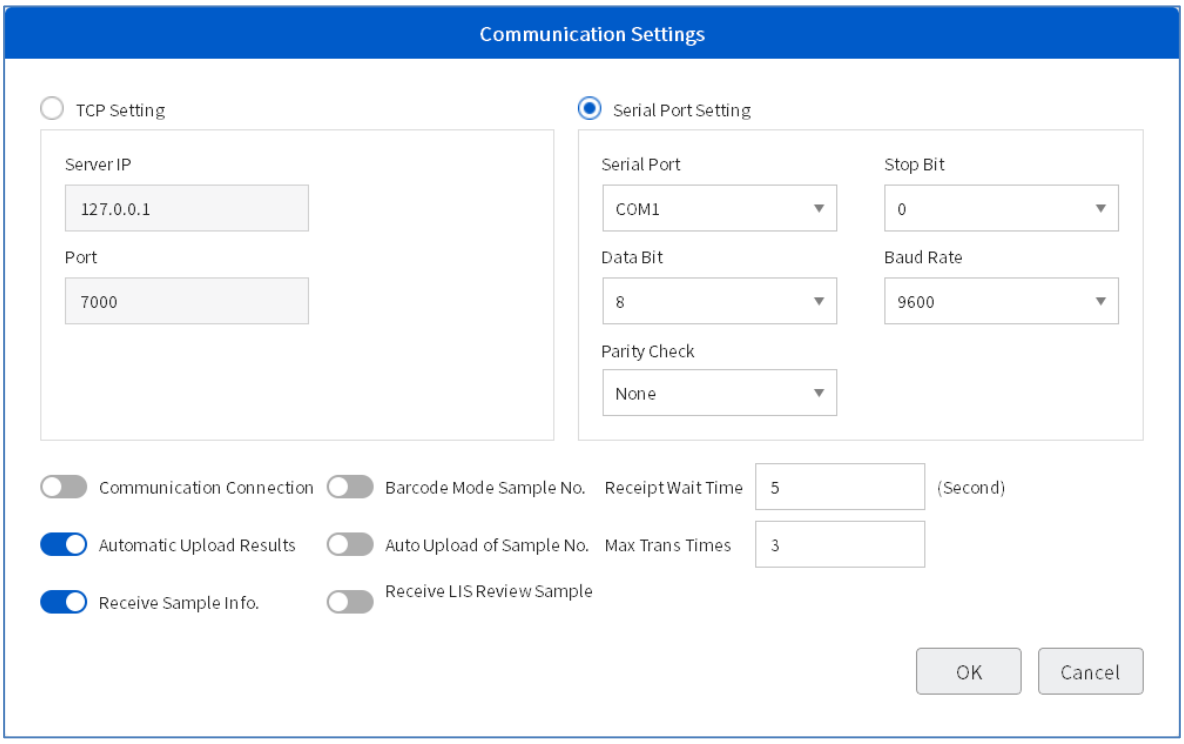


Fig. 1.4 Configuration Interface of LIS Communication in Serial Port Mode

Instructions:

The instrument should be in standby state and the "Communication connection" option is off before parameter configuration.

LIS communication settings through serial port include:

1. Communication Mode

- Communication mode: Select "Serial Port".

2. Serial Port Settings

- In the "Port No." drop-down list box, select the serial port number of i 800 computer host;
- In the "Data Bit" drop-down list box, select the data bit (consistent with that in the LIS server);
- In the "Stop Bit" drop-down list box, select the stop bit (consistent with that in the LIS server);
- In the "Baud Rate" drop-down list box, select the baud rate (consistent with that in the LIS server);
- In the "Parity Bit" drop-down list box, select the parity bit (consistent with that in the LIS server);

3. Automatically Upload Results

- Automatically Upload Results: Enable and Disable (check "Enable" if automatic upload of test results is required, otherwise check "Disable")

4. Receive specimen Information

- Receive specimen information: Enable and Disable (Check "Enable" if specimen information needs to be obtained from LIS, otherwise check "Disable")

5. Receiving Waiting Time

- Set according to the actual situation (the default value here is 5 seconds)

6. Maximum Number of Transmissions

- Set according to the actual situation (the default value here is 3)

7. Communication Connection

- Communication connection: Enable and Disable (tick "Enable" if LIS communication is required, otherwise tick "Disable")

After the above 1-7 settings are completed, click the "OK" button to save the configuration and exit.

Remarks:

- If LIS communication is required, click Start and make sure that "Host Communication" is turned on in the start interface
- LIS communication: In case of barcode mode, the specimen scanning mode is turned on (Application - System - Specimen Barcode Scanning); in case of serial number mode, the specimen scanning mode

is turned off (Application - System - Specimen Barcode Scanning)

- To upload the results or check the LIS connection, select the tested specimens in the "Data Browsing" interface and click "Manual Transmission" to check whether the LIS can receive the test results

2. Standards for Network Interfaces of External Systems

2.1 Overview

The i 800 uses TCP (Transmission Control Protocol) to communicate with external systems, and uses third-party tools (such as WireShark) to monitor transmission data.

2.2 Network Topology

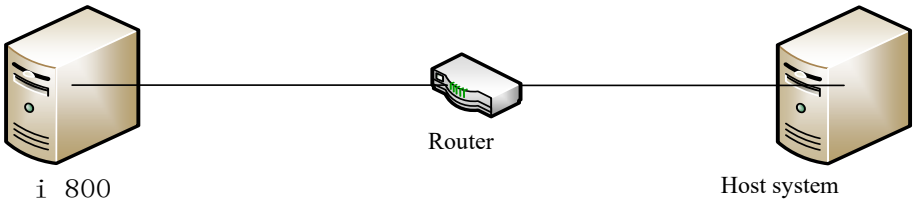


Fig. 2.2 Network Topology

When the i 800 device communicates with the host system through TCP, you can choose to directly connect through the network cable or communicate through routing.

2.3 LIS Communication Configuration Description

TCP communication configuration is shown in Fig. 2.3 (Application - System - Communication Settings):

The parts of the actual interface that you don't need to care about are covered in white

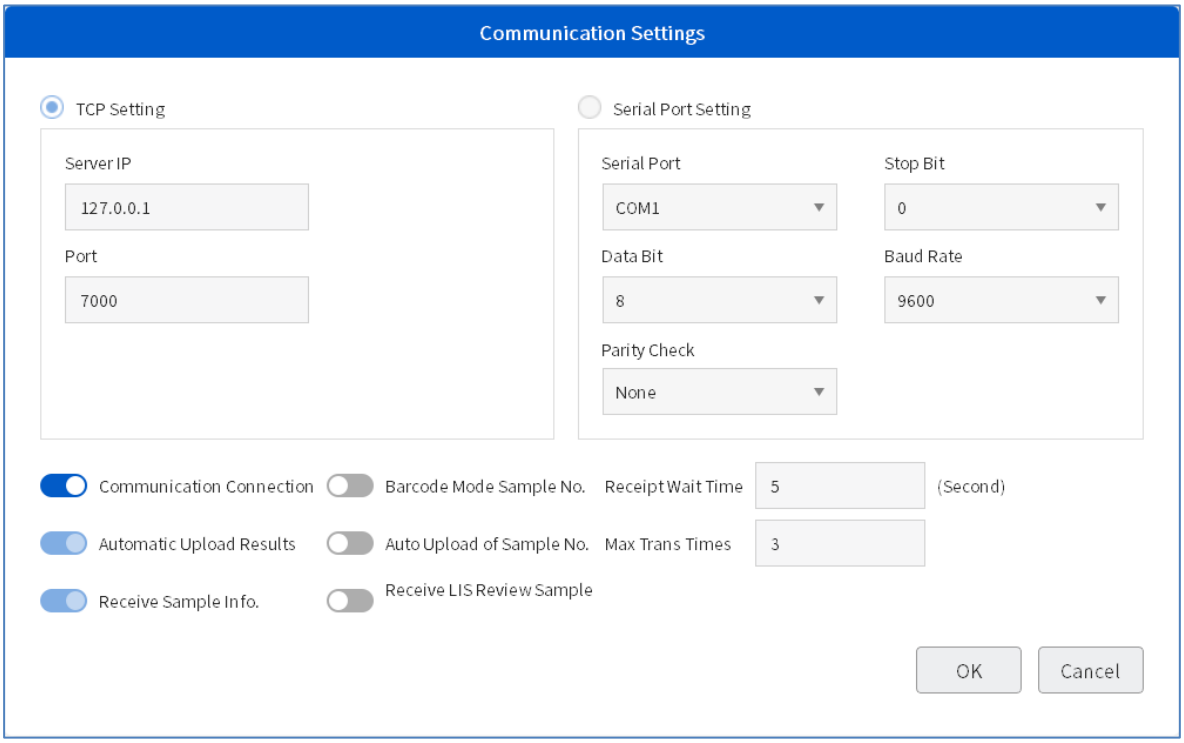


Fig. 2.3 Configuration Interface of LIS Communication in TCP Mode

说明：

Instructions:

LIS communication settings through TCP include:

The instrument should be in standby state and the "Communication connection" option is off before parameter configuration.

1. Communication Mode

- Communication mode: Select "TCP".

2. TCP Settings

- Server IP settings: Select the "Server IP" edit box and enter the IP address of the LIS server host;
- Port settings: Select the "Port" edit box and enter the LIS server port;

3. Automatically Upload Results

- Automatically Upload Results: Enable and Disable (check "Enable" if automatic upload of test results is required, otherwise check "Disable")

4. Receive specimen Information

- Receive specimen information: Enable and Disable (Check "Enable" if specimen information needs to be obtained from LIS during two-way communication, otherwise check "Disable")

5. Receiving Waiting Time

- Set according to the actual situation (the default value here is 5 seconds)

6. Maximum Number of Transmissions

- Set according to the actual situation (the default value here is 3)

7. Communication Connection

- Communication connection: Enable and Disable (tick "Enable" if LIS communication is required, otherwise tick "Disable")

After the above 1-5 settings are completed, click the "OK" button to save the configuration and exit.

Remarks:

- If LIS communication is required, click Start and make sure that "Host Communication" is turned on in the start interface
- LIS communication: In case of barcode mode, the specimen scanning mode is turned on (Application - System - Specimen Scanning); in case of serial number mode, the specimen scanning mode is turned off (Application - System - Specimen Scanning)
- To upload the results or check the LIS connection, select the tested specimens in the "Data Browsing" interface and click "Manual Transmission" to check whether the LIS can receive the test results

3. ASTM Protocol

3.1 Background

ASTM (American Society for Testing and Materials) has a communication standard between automatic analyzer and computer system, which is E1381-91 (lower layer protocol procedure for transmitting messages between clinical laboratory equipment and computer system) and E1394-91 (standard procedure for transmitting information between clinical equipment and computer system). The basic specifications of this standard are specified in X12 of ANSI.

The host communication interface of the i 800 fully meets the requirements of ASTM standards.

3.2 Communication Processing Layer

The communication processing between the instrument and the system host is divided into three layers as shown in the figure below. This document describes the processing and operation methods of the application layer.

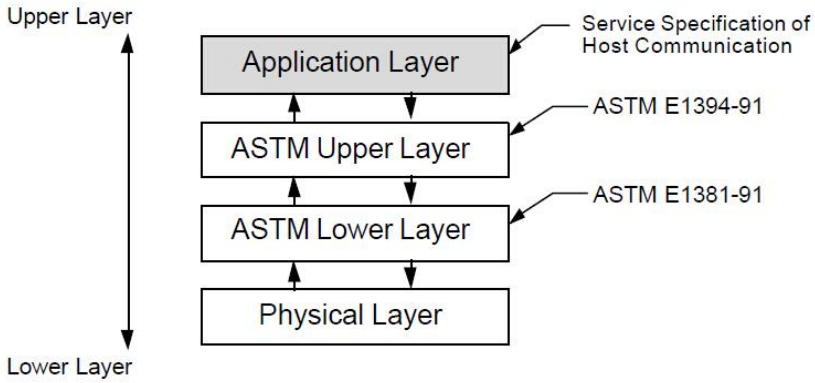


Fig. 3.2 Communication Processing Layer

ASTME1381-91 Lower-Layer Protocol

A lower-Layer protocol specification for the transmission of messages between clinical laboratory equipment and computer systems.

ASTME1394-91 Higher-layer Protocol

Standard specification for information transmission between clinical devices and computer systems.

3.3 ASTM Lower-Layer Protocol

The ASTM lower-layer protocol receives messages from higher-layer transmission requests, which are divided into multiple frame data and transmitted to other systems through communication media (such as RS232 serial port). The ASTM lower-layer protocol also reorganizes multiple frames received by the communication media into a complete message, and transmit them to the ASTM higher-layer protocol as new received messages. The configuration and communication process for sending and receiving frames is described in the following sections.

ASTM Bottom Communication Protocol Table:

Item	Mode	Statement
Frame configuration	Intermediate frame <STX>FN text <ETB>C1 C2 <CR><LF> End frame <STX>FN text <ETX>C1 C2	● Control characters (characters in <>) <STX>is a control character (0x02) (0x represents hexadecimal, the same below) <ETB>is a control character (0x17) <CR>is a control character (0x0D) <LF>is a control character (0x0A) <ETX>is a control character (0x03) ● FN: FN is a single ASCII number. FN indicates the frame number (modulus of frame

	<CR><LF>	number and 8). Single transmitted frames are numbered continuously from 1, so FN is from 1 to 7, then 0, 1, and so on. ● Text: data content of the frame (240 characters at most). Records are divided into frames of 240 or fewer characters, with Text being part of the split message. ● C1 and C2: The first byte is taken out of the cumulative sum of each byte. For the intermediate frame, it is added from FN to <ETB>, and for the end frame, it is added from FN to <ETX>, expressed in hexadecimal, with high byte as C1 and low byte as C0. The characters are '0' to '9' or 'A' to 'F'.
Text characters for frame configuration	Other characters: <SOH><STX><ETX> <EOT><ENQ><ACK> <DLE><NAK><SYN> <ETB><CR><LF> <DC1><DC2><DC3> <DC4>	<SOH>is a control character (0x01) <EOT>is a control character (0x04) <ENQ>is a control character (0x05) <ACK>is a control character (0x06) <DLE>is a control character (0x10) <NAK>is a control character (0x15) <SYN>is a control character (0x16) <DC1>~<DC4>are control characters (0x11~0x14)
Maximum frame length	247 characters	For a frame, the maximum length is 240 text characters and 7 control characters. If the message is less than or equal to 240 characters, it will eventually be transmitted as a frame. If the message is larger than 240 characters, it will be divided into different frames according to the limit of 240 characters. The only last remaining frame becomes the end frame and is represented by <ETX>. All other intermediate frames are represented by<ETB>

3.4 ASTM Syntax

According to the communication rules of ASTM, the sentence structure to be transmitted is described in this chapter. A series of data such as test requests and results are transmitted back and forth

between the analyzer and the computer system. All these data conforms to the following syntax.

3.4.1 Definition

Message	A message consists of several records. It is the smallest unit that transfers information between the i 800 and the external system (usually referred to as LIS). The message starts from the "Message Start Record" to indicate the beginning of the message and ends at the "Message End Record" to indicate the end of the message.
Record	A record consists of several fields and expresses a single purpose (for example, whether to specify a result or a test request). A record may be used repeatedly or once in a message. The code used to indicate the purpose of the record is marked with the first character of the record.
Field	A field is the smallest element that constructs ASTM information. Field attributes (such as: name, format and meaning) are defined in the record unit.

3.4.2 Message Coding Rules

This section describes the coding rules and special characters of messages, such as separators, which are provided by fields and records to form messages.

3.4.2.1 End Character of Record

The ASCII CR character (0x0D) is always used to indicate the end of the record.

3.4.2.2 Field Separator=Vertical Bar '|'

The field separator is a character used to separate adjacent fields in a record. It is also the separator between the first record ID (the character displayed at the beginning of the record) and the adjacent field. According to the second character appearing in the message header record (the record displayed in front of the message), the field separator can be defined as an optional character through the message header record; in any case, the recommended vertical bar '|' is used.

3.4.2.3 Repetition Separator=Backslash '\'

Duplicate fields are involved when a field consists of the same data repeated several times. The separator between the repeating items in the repeating field is called the repetition separator. Repetition characters can be defined as optional characters in the message header record. In any case, it is recommended that the backslash '\' be used.

3.4.2.4 Component Separator=Caret '^'

When a field is composed of multiple elements, it involves component fields. The separator between these elements is the component separator. The component separator can be defined as an optional character in the message header record. In any case, it is recommended that the caret '^' be used.

3.4.2.5 Escape Character=Ampersand '&'

Escape characters are used to indicate separators in fields that contain generic text. When an escape character appears in a related field, the character immediately following it contains a special meaning (see the following discussion). Escape characters can be defined as optional characters in the message header record. In any case, it is recommended that the ampersand '&' be used.

3.4.2.6 Expression of Special Characters Accompanied by Escape Characters

The following escape sequence (starting with & and ending with &) is defined. When these sequences appear in a field, they are converted to other corresponding characters. These escape sequences are skipped and treated as NULL values.

&F&	indicates the field separator
&S&	indicates the component separator
&R&	indicates the repetition separator
&E&	indicates escape

3.4.3 Message Transmission Stage

In order to establish a link between the sending system and the receiving system, and to ensure good coordination of the behavior of the sender and receiver, the transmitted information is divided into three distinct stages:

1. Establishment Phase
2. Transfer Phase
3. Termination Phase

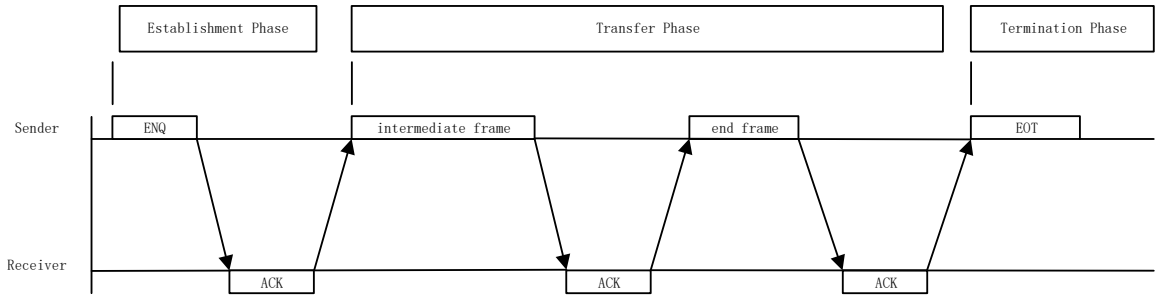


Fig. 3.4.3 Schematic Diagram of Message Transmission Process

Sender, i 800

Receiver

Sender	Sender, i 800
Receiver	Receiver, which refers to the host system, i.e., LIS
ENQ	Request message, which contains only one character 0x05
ACK	Acknowledgement message, which contains only one character 0x06
intermediate frame	Intermediate frame; there may be 0 or more in a complete message delivery process
end frame	End frame
EOT	End message, which contains only one character 0x04. This message does not require the LIS to give an ACK. It is used to indicate that the complete transmission of a message has been completed

In the transmission phase, in order to increase the speed, all records of related messages are grouped into long frames. These records are separated by the [CR] character. Therefore, in order to get a complete ASTM record again, the receiver must wait for the [EOT] character to connect all frames. Then, finally, it can process these frames and separate them into different frames with [CR] as the separator.

3.4.4 Checksum Calculation of Message Frames

Intermediate frame

【STX】	FN	Character 1... Character N	【ETB】	CH	CL	【CR】	【LF】

End frame

【STX】	FN	Character 1... Character N	【ETX】	CH	CL	【CR】	【LF】

Instructions:

- The characters contained by [ ] are control characters, that is, invisible characters, which are displayed as garbled characters in ordinary text tools, and the characters not contained by [ ] are visible characters;
- If the length of a complete message is less than 240 characters, only the last frame of data is available. If its length is greater than 240 characters, it contains at least one intermediate frame and one last frame;
- The length of the control character (the part of the frame other than the frame data Text) is 7 characters.

[STX]	Frame start bit, ASCII code 2 (0x02), indicating the start of transmission of a frame.
FN	Frame number, whose value is modulo with 8. In a complete message transfer phase, its frame number is consecutively from 1, so after modulus calculation with 8, FN's value will go from 1 to 7, then from 0, 1,... 7, 0... and so on. FN uses the characters '0' (0x30) to '7' (0x37) to indicate the calculated moduli 0 to 7.
Text	Frame data: The frame data in a frame contains a maximum of 240 characters. When a record is longer than 240 characters, it is divided into intermediate frames of 240 characters. The intermediate frame indicates the end position of the frame data with [ETB]; the end frame indicates the end position of the frame data with [ETX] for the

	final frame data remaining up to 240 characters. For different records, such as the detection results of two different specimens, different frames must be used for transmission.
[ETB]	Frame data **end flag** of **intermediate frame**, ASCII code 23 (0x17), used to indicate the end of frame data (Text) of an intermediate frame
[ETX]	Frame data **end flag** of the **last frame**, ASCII code 3 (0x03), indicating the end of the frame data (Text) of the last frame
CH,CL	They represent the upper 4 bits and the lower 4 bits of the 8-bit checksum respectively. CH and CL are represented as two digit hexadecimal digits. The checksum starts from 'FN' (including 'FN') and successively accumulates to the sum of ASCII values of [ETB] and [ETX] (including [ETB] and [ETX]), and then modulo 256; the obtained value is converted into hexadecimal data, and the hexadecimal data is converted into two ASCII character strings. For example, if 0xD6 is converted into an ASCII character string, the values are 'D' and '6' respectively.
CR,LF	CR is the carriage return character, ASCII code 13 (0x0D), LF is the line feed character, ASCII code 10 (0x0A), used to identify the end position of each frame

Example of Checksum Calculation

【STX】1Test【ETX】

Character	Value (HEX)	Cumulative sum (HEX)
【STX】	0x02	0x00 [STX] Not included in cumulative sum
'1'	0x31	0x31
'T'	0x54	0x85
'e'	0x65	0xEA
's'	0x73	0x015D
't'	0x74	0x01D1
【ETX】	0x03	0x01D4
	= 0x01D4 % 0x0100 = 0xD4	

Transferred as:

【STX】1Test【ETX】D4【CR】【LF】

3.4.5 Text Content Transfer

3.4.5.1 Record Level

The following table shows the types and levels of standard records (see ASTME1394-91 Chapter 5, 'Information Requirements in Clinical Testing')

Level	Record Name (English)	Identifier
0	Message Header Record	H
1	Patient Information Record	P
2	Test Order Record	O
3	Result Record	R
1…3	Comment Record	C
1…3	Manufacturer Information Record	M
0	Message Termination Record	L
1	Request Information Record	Q

3.4.5.2 Messages Involved in Transmission

All messages are displayed in the following table. The following sections will describe the contents of these messages in detail.

Transmission Content	Transmission Direction
Request Information Record	i 800→host system
Test Order Record	Host system→ i 800
Result Record	i 800→host system

Note: Other transmission contents not listed in the above table can exist in two-way communication, that is, the i 800 or the host system can send to the other party.

3.4.5.3 Messages Actively Transmitted by i 800

The messages transmitted by the i 800 (messages received by the host system) are shown in the following table, where the message's purpose is indicated by the remarks or the identifier of the special instruction field in the record message header.

Message	Syntax/Record	Remarks or Special Instructions	Reason
Query the information of specimen items to be tested	H Q L	TSREQ^REAL	After the barcode reader scans the specimen barcode, it requests LIS for the test items that the specimen needs to perform
Report results	H P O C {R C}n L n=0~160	RSUPL^REAL	After i 800 completes the specimen testing and calculates the result, it is uploaded to the LIS system

3.4.5.4 Messages Actively Transmitted by Host System (LIS)

The messages actively transmitted by the host system (i 800 as the receiver) are shown in the following table:

Message	Syntax/Record	Remarks or Special Instructions	Reason
Respond to specimen test item requests	H P O C L	TSDWN^REAL	LIS receives "Request Information Record" sent by i 800 - real-time response when querying the item information of the specimen to be tested

3.4.6 Record Description

3.4.6.1 Message Header Record

The attribute types of fields are shown in the following table:

S/N	Attributes	Description
1	Field Name	Full name of the field
2	Reference	Field location. The display order of related fields in the record.
3	Format	Field formats are as follows: ST: String: character string TX: Text: A group of strings that can be printed or displayed by terminals (such as computer monitors and printers). This is optional. Note that different terminals may display different special escape and control characters NM: Numeric: numerical value; A positive number (+) or a negative number (-) is displayed before a number as an indicator. If no indicator is specified, the value is a positive number (+) by default. If there is no decimal point, the value is an integer by default, and the first and last consecutive '0' will be ignored. For example, "00040.006040" is equal to "40.00604". DT: Date: The year is a 4-digit number in the format of YYYYMMDD (YYYY is a 4-digit year, MM is a month, and DD is a date). For example, October 8, 2011 is denoted as 20111008 TM: Time: 24 hour system time. The format is HHMMSS (HH is hour, MM is minute, and SS is second). For example, 4:10:35 in the afternoon is 161035 TS: TimeStamp: the combination of the date and time, format YYYYMMDDHHMMSS CM: Combination: a field consisting of multiple data separated by component separators, such as ^ and /
4	Maximum Length	Maximum length of a valid character in the relevant field, except for the escape separator
5	Remarks (Data Content)	Containing field contents and related field remarks Note: Although the message field marked "Field does not contain content" on the column is defined by ASTM, the receiver can ignore the content of this

		field after receiving the data

3.4.6.2 Message Header Record

This record is at the beginning of the message and is used to indicate the purpose of the message, such as sender and receiver.

H|\^&|||I800|||||host|RSUPL^REAL|P|1|

Note: The field whose name ends with "*" in the following table is mandatory. "-" in the remarks indicates that the field does not contain data, the same below.

Field Name	Format	Maximum Length	Remarks (Data Content)
Record Type ID (H)	ST	1	'H'
Delimiter Definition	ST	4	Define four characters: field separator, repetition separator, component separator and escape character. The field separator defined by the first character and the corresponding record type ID field separator. 4 characters specified in i 800 are: |\^&
Message Control ID			—
Access Password			—
Sender Name or ID	CM	36	Name of the instrument that sent this message, such as "i 800". When sending this message from i 800 to LIS, the version number of the communication protocol will be transmitted together, such as i 800^1
Sender Street Address			—
Reserved Field			—
Sender Telephone Number			—
Characteristics of Sender			—

Receiver ID	ST	30	Name of the device receiving this message. When sending this message from the i 800 to the LIS, this value must be "host"; when i 800 receives this message from LIS, this value should be the same as the original "sender name or ID", but i 800 does not check this value
Comment or Special Instructions	CM	11	When i 800 is the sender, the possible values are TSREQ^REAL, RSUPL^REAL, etc. The first component element indicates the purpose of the message: TSREQ: Test specimen Request RSUPL: Results Report The second component element specifies the cause of the message. REAL: Real time/manual message sending, which means that i 800 automatically/manually sends messages to LIS. When i 800 is the receiver, the possible value is: TSDWN^REAL The first component element indicates the purpose of the message. TSDWN Test Request Information The second component element specifies the cause of the message. REAL: real time message sent by LIS
Processing ID	ST	1	Indicating the processing method of the message, currently fixed as the character 'P'
Version No.	NM	1	Version number of a communication program, currently fixed as the character '1'.
Date and Time of Message			—

3.4.6.3 Message Termination Record

This record appears at the end of the message to indicate the end of the message.

L|1|N

Field Name	Format	Maximum Length	Remarks (Data Content)
Record Type ID (L)	ST	1	'L'
Sequence Number	NM	1	'1'
Termination Code	ST	1	N: normal termination T: forced end by the sender R: forced end by the receiver E: system error Q: last received request error (request rejected) I: the last requested reply message is not received F: the previous request is being processed

3.4.6.4 Patient Information Record

This record is used to transmit patient information (such as gender, age, etc.) between i 800 and LIS (follow the test specimen message), which is included in the "test message" when sent to i 800; when this message is sent to LIS, it is included in the "result message".

P|1||||||U|||||||||||||||||||||||||

Field Name	Format	Maximum Length	Remarks (Data Content)
Record Type ID (P) *	ST	1	'P'
Sequence Number*	NM	6	Serial number, starting from '1'.
Practice Assigned Patient ID			—
Laboratory Assigned			When i 800 transmits it to the host system,

Patient ID			this field does not contain data; when the host system transmits to the Analyzer, this field is the medical record number
Patient ID No.3			—
Patient Name			—
Mother's Maiden Name			—
Date of Birth	DT	8	YYYYMMDD
Patient Sex	ST	1	M: Male; F: Female; U: Unknown
Patient Race-Ethnic Origin			—
Patient Address			—
Reserved Field			—
Patient Telephone Number			—
Attending Physician ID			—
Special Field 1	CM		Format: <age>^<age unit> Element Maximal length Format The maximum length of age is 3, the format type is NM, and the valid range is 1-200. The maximum length of the age unit is 1. The format is ST, and the age unit is represented by 'Y', 'M' or 'D'. 'Y' is the year, 'M' is the month, and 'D' is the day.
Special Field 2			—
Patient Height (in cm)			—
Patient Weight(in kg)			—
Patient's Known or Suspected Diagnosis			—
Patient Active Medications			—
Patient's Diet			—
Practice Field No.1			—
Practice Field No.2			—

Admission and Discharge Dates			—
Admission Status			—
Location			—
Nature of Alternative Diagnostic Code and Classifiers			—
Alternative Diagnostic Code and Classification			—
Patient Religion			—
Marital Status			—
Isolation Status			—
Language			—
Hospital Service			—
Hospital Institution			—
Dosage Category			—

3.4.6.5 Test Order Record

This record saves the analysis request information and specimen information to the Analyzer (a sub-message in the test selection message) or to the host system (following the result message).

```
O|1|2589631478975|0^5003^1^^S1^SC|^^^1001^1\^^^1013^1|R||||||N||||1|||||||||||||||
```

Field Name	Format	Maximum Length	Remarks (Data Content)
Record Type ID (O)*	ST	1	'O'
Sequence Number*	NM	6	Serial number; this record is located after the patient information record, and when a new patient information record appears, the serial number is set to 1. For each occurrence of this record, this value is consecutively numbered as 1, 2, 3, etc.
Specimen ID*	ST	22	Specimen barcode or sequence number. i 800 identifies the specimen only according to this

<table>
<tr><td></td><td></td><td></td><td>field.

Specimen ID: when it is a barcode, the ID is the barcode number on the specimen tube. i 800 scans the barcode label through the barcode reader and the maximum effective length contains 22 characters; if it is a sequence number, the ID is the specimen number. i 800 numbers the specimens in sequence according to the specimens of starting and ending positions as well as the starting sequence number.</td></tr>
<tr><td>Instrument Specimen ID*</td><td>ST</td><td>2</td><td>Format: <specimen No.>^<Rack No.>^< Position No.>^^<specimen Type>^<Vessel Type>

<table>
<tr><td>Element</td><td>Maximum Length</td><td>Format</td></tr>
<tr><td>Specimen No.</td><td>12</td><td>NM</td></tr>
<tr><td>Rack No.</td><td>4</td><td>NM</td></tr>
<tr><td>Position No.</td><td>2</td><td>NM</td></tr>
<tr><td>Specimen Type</td><td>2</td><td>ST</td></tr>
<tr><td>Vessel Type</td><td>5</td><td></td></tr>
</table>
<table>
<tr><td>Element</td><td>Description</td></tr>
<tr><td>Specimen No.</td><td>The number formed by sequentially numbering the specimens according to the input sequence. The range is 1-999999999, and the serial number is 0 in barcode mode.</td></tr>
<tr><td>Rack No.</td><td>Specimen rack number; 10 specimen positions can be placed in a single specimen rack; the range of specimen rack is 5001-5999 for conventional rack, 3001-3999 for QC rack, 2001-2999 for calibration rack and 8001-8999 for recheck rack.</td></tr>
<tr><td>Position No.</td><td>The position of the specimen</td></tr>
</table></td></tr>
</table>

<table>
<tr><td></td><td></td><td></td><td>in the rack begins from 1 and ends at 10, the range is from 1 to 10.

Vessel Type SC: regular cup (tube)

MC: micro cup (tube)</td></tr>
<tr><td>Universal Test ID*</td><td>CM</td><td>10</td><td>Repeating field (such as ^^^1001^1\^^^1002^1\^^^1003^1) is used to assign test request.

Format:

^^^<Item channel number>^<Dilution multiple>

^^^<Application Code>^<Dilution>

If there are more than one test, use the separator "\" to combine the tests and there can be 160 test items at most.

<table>
<tr><th>Element</th><th>Maximum Length</th><th>Format</th></tr>
<tr><td>Item channel number</td><td>4</td><td>NM</td></tr>
<tr><td>Dilution multiple</td><td>12</td><td>ST</td></tr>
</table>

<table>
<tr><th>Element</th><th>Description</th></tr>
<tr><td>Item channel number</td><td>i 800 system and LIS system should number each test item coordinately and uniformly. The item number in the i 800 system should be the same with that in the LIS system. (See the appendix for the detailed meaning of channel number.)</td></tr>
<tr><td>Dilution multiple</td><td>In the test, if the specimen doesn't need to be diluted, the dilution multiple is 1. If the specimen needs to be diluted, the dilution multiple is 5, 10, 20, 100 etc.</td></tr>
</table>
</td></tr>
</table>

Priority*	ST	1	Indicate the priority sequence of patients' specimen and the values are as follows: Field value — Description R — Regular specimen S — STAT specimen
Requested/Ordered Date and Time			—
Specimen Collection Date and Time	TS	14	As to the date and time of specimen collection, they should be in this format: YYYYMMDDHHMMSS
Collection End Time			—
Collection Volume			—
Collector ID			—
Action Code*	ST	1	If the indication is QC bottle or patients' specimens, the detailed information is as follows: Field value — Sender — Description Q — i 800 — Control N — i 800 — Regular specimen A — LIS — Add test items to some specimen C — LIS — Cancel some test item
Danger Code			—
Relevant Clinical Information			—
Date/Time Specimen Received			—
Specimen Descriptor*	NM	1	The type of indication specimen for the field is as follows: Field value — Description 1 — Serum 2 — Urine

			3 Whole blood 4 Plasma 5 Others
Ordering Physician			—
Physician's Telephone Number			—
User Field No. 1			—
User Field No. 2			—
Laboratory Field No. 1			—
Laboratory Field No. 2			—
Date/Time Results Reported or Last Modified	TS	14	As to the date and time of getting the result, LIS system doesn't set any value for the field.
Instrument Charge to Computer System			—
Instrument Section ID			—
Report Types*	ST	1	The transfer types are as follows in detail: Field value Description O The information is sent by LIS system; the response is for the test item requested by i 800. F i 800 sends the information and transfers the data of analysis result.
Reserved Field			Obtain the specimen number (small size) of the test request, which supports English+numbers.
Location or Ward of Specimen Collection			—
Nosocomial Infection Flag			—
Specimen Service			—
Specimen Institution			—

3.4.6.6 Comment Record

Transfer the record of patients' comment data, and this record is after the test order record. This record is transferred by LIS system (included in the test item message) and i 800 (included in the test result message).

C|1|L|^^^^|G

Field Name	Format	Maximum Length	Remarks (Data Content)
Record Type ID(C)*	ST	1	'C'
Sequence Number*	NM	6	Sequence number. When there is a new test request record, its sequence number is set as 1 and other new records are numbered consecutively in the sequence of 1, 2, 3, 4.
Comment Source	ST	1	Indicate the sender of this comment record. 'I': it means the record is sent by i 800. 'L': it means the record is sent by LIS.
Comment Text	CM	104	Format: <Comment 1>^<Comment 2>^<Comment 3>^<Comment 4>^<Comment 5> Component / Maximum Length / Format Comment 1 / 30 / ST Comment 2 / 25 / ST Comment 3 / 20 / ST Comment 4 / 15 / ST Comment 5 / 10 / ST
Comment Type	ST	1	'G' or 'I'

3.4.6.7 Result Record

i 800 transmits record of analysis result data to LIS.

R|1|^^^1001/1/not|0.9278|IU/mL||||F|||||

Field Name	Format	Maximum Length	Remarks (Data Content)
Record Type ID(R) *	ST	1	'R'
Sequence Number*	NM	6	Sequence number. When there is a new test request record, its sequence number is set as 1 and other new records are numbered consecutively in the sequence of 1, 2, 3, 4.
Universal Test ID	CM	22	Such as: ^^^1001/1/not indicates test request. Format: ^^^<Item channel number>/<Dilution multiple>/<Pre-dilution> ^^^<Application Code>/<Dilution>/<Pre-Dil.> Component / Maximum Length / Format Item channel number / 4 / NM Dilution multiple / 12 / ST Pre-dilution / 5 / ST Component: Description Item channel number: Each item has the only sequence number for identification. Dilution multiple: If the item doesn't need dilution, then the dilution multiple is 1. Pre-dilution: It is always 'not'.
Data or Measurement Value	ST	12	Test result with decimal point. If the test result is higher than the upper limit of the test range, the symbol '>' will appear before the numerical value; if the test result is less than the lower limit of the test range, the symbol '<' will appear before the numerical value.

Units	ST	6	Unit of the test result data
Reference Ranges			—
Result Abnormal Flags	ST	2	It indicates that the test result is abnormal (blank as i 800 does not upload by default) Field value — Description LL — Below the lower limit of the re-test range HH — Higher than the upper limit of the re-test range L — Lower than normal value H — Higher than normal A — Abnormal value N — Normal value
Nature of Abnormality Testing			—
Result Status	ST	1	It represents the times of test for analyzing results Field value — Description F — Data of the first test C — Data of the re-test
Date of Change in Instrument Normative Values Units			—
Operator Identification	ST	6	The instrument operator number is not used at present.
Date/Time Test Started			—
Date/Time Test Completed			—
Instrument Identification	ST	4	It indicates the identification of the Analyzer module (i 800 uploads M1 by default) Field value — Description Empty — Not enabled M1 — Module 1

3.4.6.8 Request Information Record

Request information record sent from the instrument. This record is sent by the instrument (as part of the test item request information).

Q|1|^^2589631478975^0^5003^1^^S1^R||ALL||||||||O

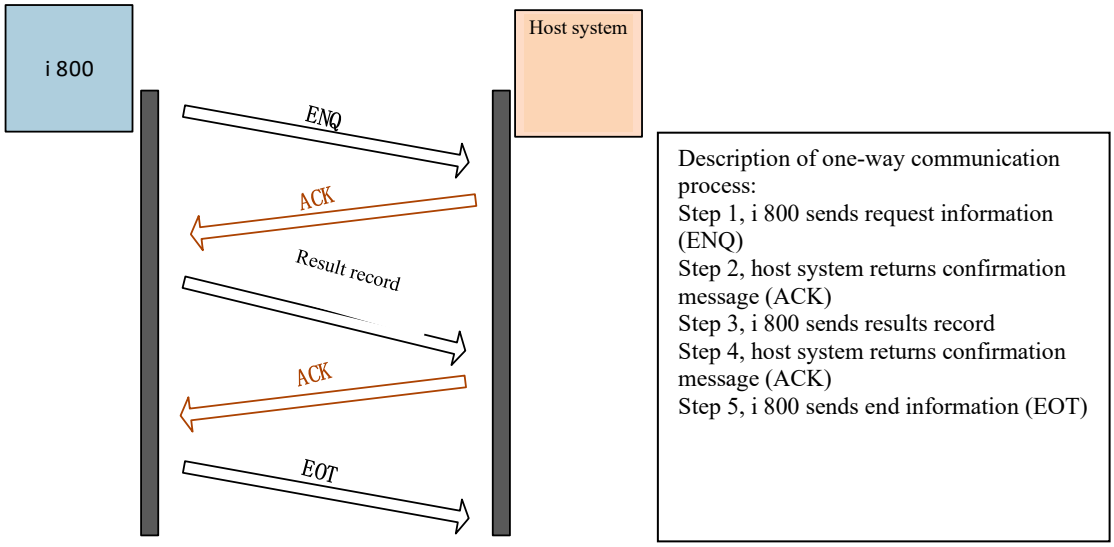
Field Name	Format	Maximum Length	Remarks (Data Content)
Record Type ID(R) *	ST	1	'Q'
Sequence Number*	NM	6	Sequence number. When there is a new test request record, its sequence number is set as 1 and other new records are numbered consecutively in the sequence of 1, 2, 3, 4.
Starting Range ID Number	CM	39	Format: ^^<specimen ID>^<specimen No.>^<rack No.>^<position No.>^^<specimen type>^<specimen priority> Element / Maximum Length / Format Specimen ID / 22 / ST Specimen No. / 12 / NM Rack No. / 4 / NM Position No. / 2 / NM Specimen Type / 2 / ST Specimen priority / 1 / ST Component / Description Specimen ID / Specimen barcode or sequence number. i 800 identifies the specimen only according to this field. Specimen ID: when it is a barcode, the ID is the

				barcode number on the specimen tube. i 800 scans the barcode label through the barcode reader and the maximum effective length contains 22 characters; if it is a sequence number, the ID is the specimen number. i 800 numbers the specimens in sequence according to the specimens of starting and ending positions as well as the starting sequence number.
			Specimen No.	The number formed by sequentially numbering the specimens according to the input sequence. The range is 1-999999999, and the serial number is 0 in barcode mode.
			Rack No.	Specimen rack number; 10 specimen positions can be placed in a single specimen rack; the range of specimen rack is 5001-5999 for conventional rack, 3001-3999 for QC rack, 2001-2999 for calibration rack and 8001-8999 for recheck rack.
			Position No.	The position of the specimen in the rack begins from 1 and ends at 10, the range is from 1 to 10.
			Specimen Type	S1 represents serum; S2 represents urine; S3 represents whole blood; S4 represents plasma;

			S5 indicates others Specimen priority: R means regular specimen; S means STAT specimen.
Ending Range ID Number			—
Universal Test ID			'ALL'
Nature of Request Time Limits			—
Beginning Request Results Date and Time			—
Ending Request Results Date and Time			—
Requesting Physician Name			—
Requesting Physician Telephone Number			—
User Field No. 1			—
User Field No. 2			—
Request Information Status Codes			'O' means this record is sent by the instrument to the host system.

3.5 One-way Communication

In one-way communication, rules in the protocol of result record are used. One-way communication should conform with the following process:



Example 1

Data flow	Process	Content	Data	Comment
1	i 800 sends to the host system	ENQ	#5’	0x05
2	Host system replies	ACK	#6’	0x06
3	i 800 sends to the host system	Result record	#2'1H|\^&|||I800||||host|RSUPL^REAL|P|1|#13'P|1|||||U|||||

	replies			
7	i 800 sends to the host system	EOT	#4’	0x04

[Note**]** Each data flow has a time-out period. Please reply the data in time when using serial port or Network Associate for debugging.

[Note] As to the record of results, if a single specimen has so many test items that one frame data can't hold them, i 800 will separate the data into different frames. When receiving data of each frame, host system should reply ACK and host system (LIS) should pay attention to the framing status when analyzing the data (see instructions in section 3.4.4 for details).

In this example: frame 1: #2'1H……#23' B8#13'#10'; frame 2: #2'2/not……#3' FE#13'#10'.

In this example, #2'1, #2' represents frame starting position (**STX**), and 1 represents frame sequence number; #2'2, #2' represents the frame starting position (**STX**), and 2 represents the frame sequence number.

Brief description of example 1

Name	Content	Corresponding data (contents marked in red)
Specimen barcode	2589631478975	#2'1H|\^&|||I800|||||host|RSUPL^REAL|P|1|#13'P|1|||||U|||||

Test item	1013	#2'1H|\^&|||I800||||host|RSUPL^REAL|P|1|#13'P|1|||||U|||||

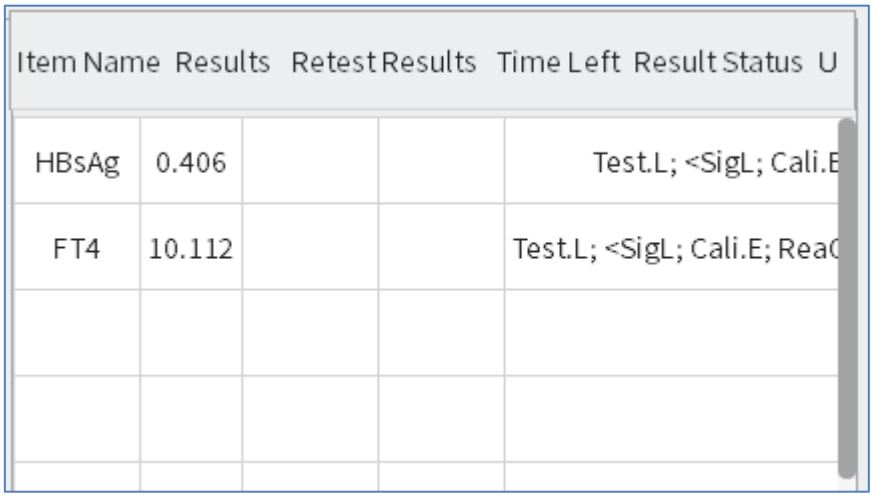


Fig. 3.5.1 Example 1 Software Interface Display Content

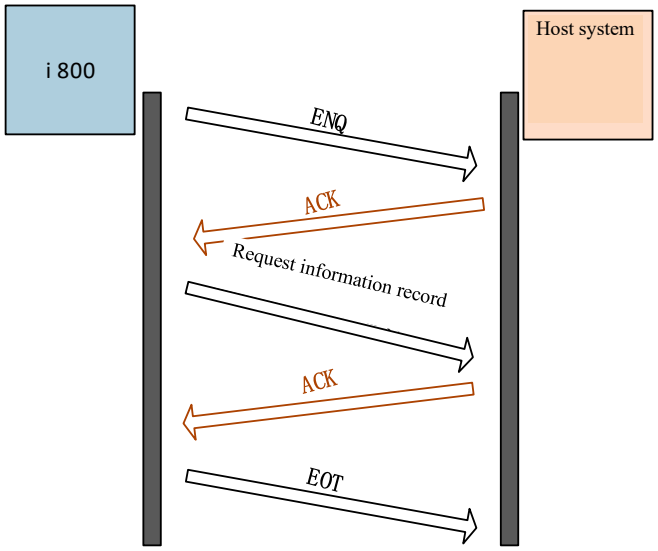
3.6 Two-way Communication

Two-way communication finishes in three steps and it uses the rules inrequest information record, test order recordand result record. **In the first step and the second step, test order is got and in the third step, the order result record is uploaded.**

- Step 1: i 800 sends request to get test order;
- In the second step, host system sends order data;
- Step 3: i 800 sends order result record.

3.6.1 Step 1: i 800 sends request to get test order;

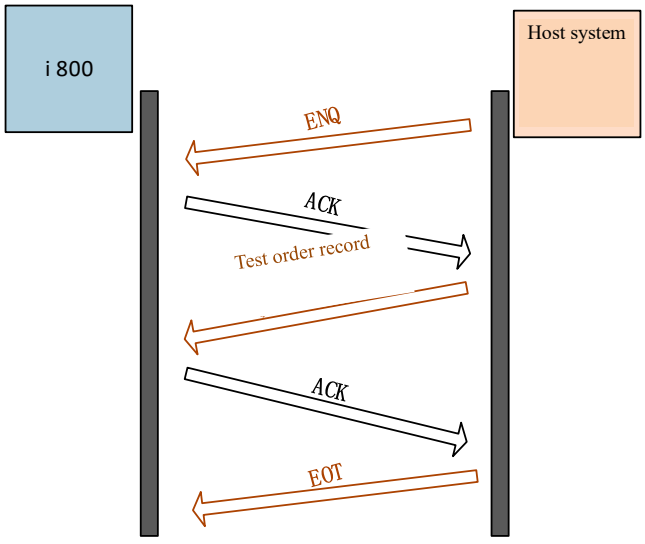
I 800 sends specimen information to the host system (LIS) as a request information record



Description of communication process of sending request information record:
Step 1, i 800 sends request information (ENQ)
Step 2, host system returns confirmation message (ACK)
Step 3, i 800 sends request information record
Step 4, host system returns confirmation message (ACK)
Step 5, i 800 sends end information (EOT)

3.6.2 Step 2, the host system sends test order

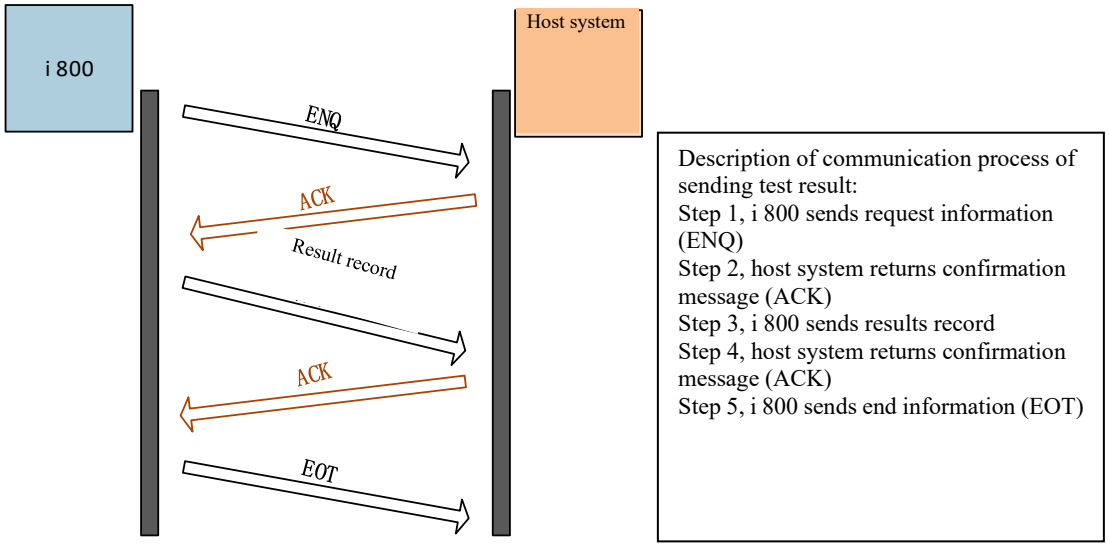
The host system (LIS) sends order data to i 800 as test order result.



Description of communication process of LIS sending test order record:
Step 1, host system (LIS) sends request information (ENQ)
Step 2, i 800 returns confirmation information (ACK)
Step 3, host system sends test order information record
Step 4, i 800 returns confirmation information (ACK)
Step 5, host system sends end information (EOT)

3.6.3 Step 3, i 800 sends order result record

After finishing the test, i 800 sends the test result to LIS system and this step is similar to one-way communication.



Example 2

- **Step 1: i 800 sends request to get test order**

Data flow	Process	Content	Data	Comment
1	i 800 sends to the host system	ENQ	#5’	0x05
2	Host system replies	ACK	#6’	0x06
3	i 800 sends to the host system	Request information record	#2'1H|\^&|||I800|||||host|TSREQ^REAL|P|1|#13'Q|1|^^21598745632493745^0^5003^2^^S1^R||ALL|||||||O#13'L|1|N#13'#3'DA#13'#10'	
4	Host system replies	ACK	#6’	0x06
5	i 800 sends to the host system	EOT	#4’	0x04

[Note**]** Each data flow has a time-out period. Please reply the data in time when using serial port or Network Associate for debugging.

Brief Description

Name	**Content**	**Corresponding data (contents marked in red)**
Specimen barcode	21598745632493745	#2'1H|\^&|||I800|||||host|TSREQ^REAL|P|1|#13'Q|1|^^21598745632493745^0^5003^2^^S1^R||ALL|||||||O#13'L|1|N#13'#3'DA#13'#10'
Specimen S/N		#2'1H|\^&|||I800|||||host|TSREQ^REAL|P|1|#13'Q|1|^^21598745632493745^0^5003^2^^S1^R||ALL|||||||O#13'L|1|N#13'#3'DA#13'#10'
Rack No.	5003	#2'1H|\^&|||I800|||||host|TSREQ^REAL|P|1|#13'Q|1|^^21598745632493745^0^5003^2^^S1^R||ALL|||||||O#13'L|1|N#13'#3'DA#13'#10'
Position No.	2	#2'1H|\^&|||I800|||||host|TSREQ^REAL|P|1|#13'Q|1|^^21598745632493745^0^5003^2^^S1^R||ALL|||||||O#13'L|1|N#13'#3'DA#13'#10'
Specimen Type	Serum	#2'1H|\^&|||I800|||||host|TSREQ^REAL|P|1|#13'Q|1|^^21598745632493745^0^5003^2^^S1^R||ALL|||||||O#13'L|1|N#13'#3'DA#13'#10'

- **Step 2: host system sends test order**

Data flow	Process	Content	Data	Comment
1	Host system	ENQ	#5’	0x05

	sending			
2	i 800 replying	ACK	#6’	0x06
3	Host system sending	Test order record	#2'1H|\^&|||I800|||||host|TSDWN^REAL|P|1|#13'P|1|||||||U||||||||||||||||||||||#13'O|1|21598745632493745|0^5003^2^^S1^R|^^^1001^1\^^^1013^1|R||||||||||0||||||||||||||#13'C|1|L|^^^^|I#13'L|1|N#13'#3'47#13'#10'	
4	i 800 replying	ACK	#6’	0x06
5	Host system sending	EOT	#4’	0x04

[Note**]** Each data flow has a time-out period. Please reply the data in time when using serial port or Network Associate for debugging.

Brief Description

Name	**Content**	**Corresponding data (contents marked in red)**
Specimen barcode	21598745632493745	#2'1H|\^&|||I800|||||host|TSDWN^REAL|P|1|#13'P|1|||||||U||||||||||||||||||||||#13'O|1|21598745632493745|0^5003^2^^S1^R|^^^1001^1\^^^1013^1|R||||||||||0||||||||||||||#13'C|1|L|^^^^|I#13'L|1|N#13'#3'47#13'#10'
Specimen S/N		#2'1H|\^&|||I800|||||host|TSDWN^REAL|P|1|#13'P|1|||||||U||||||||||||||||||||||#13'O|1|21598745632493745|0^5003^2^^S1^R|^^^1001^1\^^^1013^1|R||||||||||0||||||||||||||#13'C|1|L|^^^^|I#13'L|1|N#13'#3'47#13'#10'
Rack No.	5003	#2'1H|\^&|||I800|||||host|TSDWN^REAL|P|1|#13'P|1|||||||U||||||||||||||||||||||#13'O|1|21598745632493745|0^5003^2^^S1^R|^^^1001^1\^^^1013^1|R||||||||||0||||||||||||||#13'C|1|L|^^^^|I#13'L|1|N#13'#3'47#13'#10'
Position No.	2	#2'1H|\^&|||I800|||||host|TSDWN^REAL|P|1|#13'P|1|||||||U||||||||||||||||||||||#13'O|1|21598745632493745|0^5003^2^^S1^R|^^^1001^1\^^^1013^1|R||||||||||0||||||||||||||#13'C|1|L|^^^^|I#13'L|1|N#13'#3'47#13'#10'
Specimen Type	Serum	#2'1H|\^&|||I800|||||host|TSDWN^REAL|P|1|#13'P|1|||||||U||||||||||||||||||||||#13'O|1|21598745632493745|0^5003^2^^S1^R|^^^1001^1\^^^1013^1|R||||||||||0||||||||||||||#13'C|1|L|^^^^|I#13'L|1|N#13'#3'47#13'#10'
Test item	1001	#2'1H|\^&|||I800|||||host|TSDWN^REAL|P|1|#13'P|1|||||||U||||||||||||||||||||||#13'O|1|21598745632493745|0^5003^2^^S1^R|^^^1001^1\^^^1013^1|R||||||||||0||||||||||||||#13'C|1|L|^^^^|I#13'L|1|N#13'#3'47#13'#10'
Test item	1013	#2'1H|\^&|||I800|||||host|TSDWN^REAL|P|1|#13'P|1|||||||U||||||||||||||||||||||#13'O|1|21598745632493745|0^5003^2^^S1^R|^^^1001^1\^^^101

		3^1|R||||||||||0|||||||||||||||#13'C|1|L|^^^^|I#13'L|1|N#13'#3'47#13'#10'

- **Step 3: i 800 sends order result record**

Data flow	Process	Content	Data	Comment
1	i 800 sends to the host system	ENQ	#5’	0x05
2	Host system replies	ACK	#6’	0x06
3	i 800 sends to the host system	Result record	#2'1H|\^&|||I800|||||host|RSUPL^REAL|P|1|#13'P|1||||||U|||||||||||||||

Brief description of example 2

Name	Content	Corresponding data (contents marked in red)
Specimen barcode	21598745632493745	#2'1H|\^&|||I800|||||host|RSUPL^REAL|P|1|#13'P|1||||||U||||||

Test item	1013	#2'1H|\^&|||I800||||host|RSUPL^REAL|P|1|#13'P|1|||||U|||||

4. Appendixes

4.1 Item Channel Number and Item Correspondence Table

Item channel number	Item name
1001	HBsAg
1002	HBsAb
1003	HBeAg
1004	HBeAb
1005	HBcAb
1007	HBV preS1-Ag
1028	HIV Ag/Ab
1029	Anti-HCV
1030	Anti-TP
1011	TSH
1012	FT3
1013	FT4
1014	TT3
1015	TT4
1016	Anti-TG
1017	Anti-TPO
1055	Tg
1018	AFP
1019	CEA
1020	CA 125
1021	CA 15-3
1022	CA 19-9
1023	fPSA
1024	tPSA
1050	NSE
1051	CYFRA21-1
1054	proGRP
1052	CA50
1053	SCC
1099	CA72-4
1100	HE4
1031	cTnI
1032	MYO
1034	CK-MB
1033	NT-proBNP
1044	INS

1045	C-P
1457	2019-nCoV IgG
1458	2019-nCoV IgM
1047	PCT
1075	IL-6
1042	CT
1046	25-OH VD
1048	iPTH
1049	Anti-CCP
1025	Ferr
1065	Anti-CENP-B
1063	Anti-Jo-1
1066	Anti-Nuc
1058	Anti-Sm
1057	Anti-Sm/RNP
1059	Anti-SSA(Ro60)
1061	Anti-SSB(La)
1056	Anti-dsDNA
1070	AMA-M2
1060	Anti-SSA(Ro52)
1062	Anti-Scl-70
1064	Anti-Rib-P
1067	Anti-His
1068	Anti-PM-Scl
1069	Anti-PCNA
1161	PG Ⅰ
1162	PG Ⅱ
1036	LH
1035	FSH
1037	PRL
1038	Prog
1041	β-HCG
1040	E2
1039	Tes
1081	AMH
1043	hGH

If the channel number changes, please refer to the actual status.

4.2 Frequently Asked Questions

Question 1: Two-way LIS can't get test order.

Problem description	One-way communication can operate, but two-way LIS can't get specimen test information.
Solutions	1. Check whether there is check digit in the serial port setting; 2. Check whether the timing sequence is right when LIS interacts with i 800; 3. Check whether the format of the content data transferred by LIS is correct.
Problem description	Two-way LIS can't get the specimen test information. LIS sends the order, but the instrument doesn't reply.
Solutions	1. Check whether the timing sequence is right when LIS interacts with i 800; 2. Check section by section if the "O" field of data transferred by LIS is right when it is compared with examples; (section 3.6) 3. Check if the check digit is right; (section 3.4.4) 4. Check if the frame terminators are understood consistently.
Problem description	As to two-way LIS, when LIS sends information, whether the patient information is filled in or not.
Solutions	1. The field content should be encapsulated according to actual status. Please refer to the examples (i 800 of the current version doesn't analyze patient information).

Question 2: How to distinguish the QC results

Problem description	How does LIS identify the QC result?
Solutions	1. If the QC is tested in the form of regular specimen testing, deal with the problem according to the actual status on the site; 2. Test the controls in the way of instrument QC testing, identify the Action Code (Action Code*) field in the test order record. Q: indication of QC result (section 3.4.6.5).
Problem description	How does LIS identify the QC results of different modules?

Solutions	1. If the QC is tested in the form of regular specimen testing, deal with the problem according to the actual status on the site; 2. Test in the way of instrument QC and distinguish according to position set in the interface; 3. Test in the way instrument QC and identify the instrument identification in the result field. See details in the description of result field. (i 800 only supports a single module, and the instrument identification field is M1) (Chapter 3.4.6.7)

Question 3: Communication can't be conducted.

Problem description	LIS end can't receive the data sent by the instrument.
Solutions	1. Check the host communication settings; 2. Check whether the way of communication of LIS is consistent with that of the instrument; check whether the setting of serial port parameters or TCP network segments of the two are consistent; 3. Check whether the physical serial cable or the network cable is connected well.

Question 4: Result

Problem description	The result unit is unreadable code.
Solutions	1. If the result unit of some items contains special characters, LIS should convert these characters when analyzing them. For example: the unit "μm"; 2. Unit of system direct integration items.
Problem description	The result received by LIS is different from that displayed on the local interface.
Solutions	1. Pay attention to the framing status and frame sequence number. Combine the frames and extract the content parsing and pay attention to the intermediate frame termination identification, the end frame termination identification and the communication termination identification. (Section 3.4.4).
Problem description	Results received by LIS/ simulation tool are not complete.
Solutions	1. When there are more than 2 test results (the frame data contains more than 240 characters) and data sends the framing status, the intermediate frame LIS should replay ACK after receiving it. Then, i 800 continues to send data of the next frame. Pay attention to the intermediate frame termination identification, the end frame termination identification and the communication termination identification. (Section 3.4.4).

Question 5: Check

Problem description	How to calculate the check digit
Solutions	1. Calculation reference (section 3.4.4) 2. Note: there are two check digits, CH and CL. If the check digit is 0x0E, then CH='0', CL='E'

Question 6: In two-way communication, the specimen number can't be displayed.

Problem description	In barcode two-way communication, the specimen number can't be displayed.
Solutions	1. Place the specimen number in the "Reserved Field" of test order record (section 3.4.6.5); 2. Specimen number is suggested to contain no more than 10 characters and only figures and letters can be used (Chinese and special characters can't be used). The client software displays the specimen number in the position of specimen number. In this way, it is convenient for customers to search the label and recheck it as well as other operation; 3. In two-way communication, the interaction is conducted with the specimen ID as the only identification.