QUIDEL®
Fluorescence

Technical Bulletin

Sofia™ Analyzer LIS Connectivity Software Developer's Notes

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1. **Summary**

This document provides the technical specifications for the implementation of host connectivity (LIS or Middleware) to the Quidel Sofia Analyzer. The Analyzer reads the Europium-based fluorescent lines developed on Quidel's assay test strips and is able to connect to a host for transfer of results.

This document is intended as an aid to software developers.

2. **Product Overview**

The Sofia platform consists of a small bench-top analyzer and separately a disposable test cartridge. A patient sample is collected, processed and deposited onto a test cassette. The cassette is then placed in the analyzer. Next, the Sofia Analyzer automatically measures the fluorescent signals, interprets the data and immediately displays the result on its screen, transmits it to an LIS, and prints out a hardcopy for the laboratory record.

The Sofia Analyzer may be set to two different development modes depending on the laboratory's desired workflow.

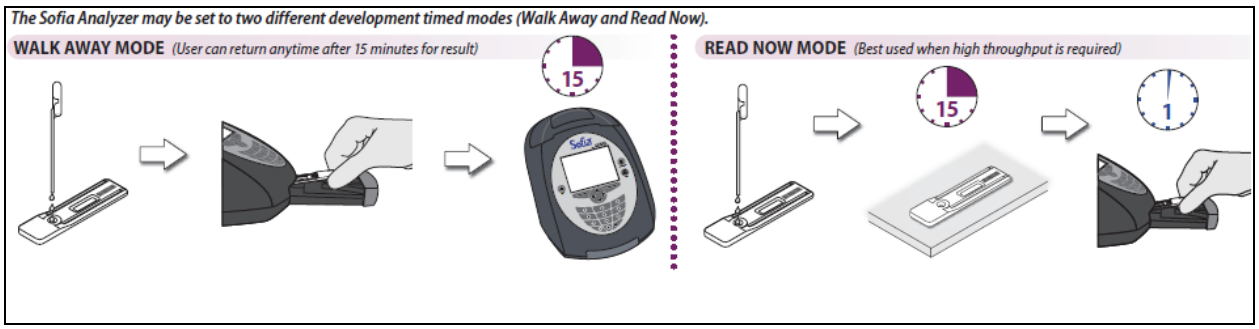
Walk Away Mode

Walk Away mode allows the user to walk away and essentially multi-task. The operator can return for the test results immediately or after an extended period of time. To run a test in this mode, the user adds the patient sample and inserts the cassette into the Analyzer, the Analyzer will automatically time the test development, scan, and display the test result in about fifteen (15) minutes.

Read Now Mode

Read Now Mode is a batch mode allowing the operator to run several tests in a shorter period of time. For example, running 10 tests in Walk Away Mode requires more than 150 minutes. In Read Now Mode, these same 10 tests can be run in less than 1 hour. To run a test in Read Now Mode, the user adds the patient sample to the cassette and places the cassette on the counter or bench top for fifteen (15) minutes (outside of the Analyzer). The user must manually time the development step. Once the development time is complete, the user immediately inserts the cassette into the Analyzer. The Analyzer will scan and display the test result within one (1) minute.

The following figure provides an illustration of the workflow in each mode.



The Sofia assay system utilizes a lateral flow assay design employing a Europium fluorescence detection system. The Analyzer scans the 2-D barcode on the cassette which determines a number of assay related attributes including assay type, cassette lot number and cassette serial number. Sofia then scans the test strip in the cassette and analyses the resultant fluorescent signal to generate a qualitative result. The combination of signals from these lines is used to determine the presence or absence of an analyte representing a disease state or health condition.

The Sofia configuration includes an LCD display, integrated thermal printer, Ethernet port (RJ45), SD memory card port, and PS2 port. The PS2 port accepts an external barcode scanner used for scanning patient and operator information.

The first assay to be released for use with Sofia in the U.S. and EU is the "Sofia Infuenza A+B Assay."

3. Applicable Standards

CLSI LIS01-A2 (formerly ASTM E-1381): Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems.

CLSI LIS2-A2 (formerly ASTM E-1394): Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems.

ISO 8859-1 1998 Information Technology 8-bit single-byte coded graphic character sets, Part 1: Latin Alphabet No 1.

4. Abbreviations

ASTM American Society for Testing and Materials
CLSI Clinical and Laboratory Standards Institute
LIS Laboratory Information System
ISO International Standards Organization

5. Network Connection

The Analyzer uses a TCP/IP connection over the network using a standard RJ45 connector. There is no serial port on the Analyzer.

Network and host connectivity is established using the Supervisor mode on the Sofia Analyzer:

- Network IP address may be set manually or using DHCP.
- Host connectivity requires manual entry of the host's IP address and entry of the assigned port number.

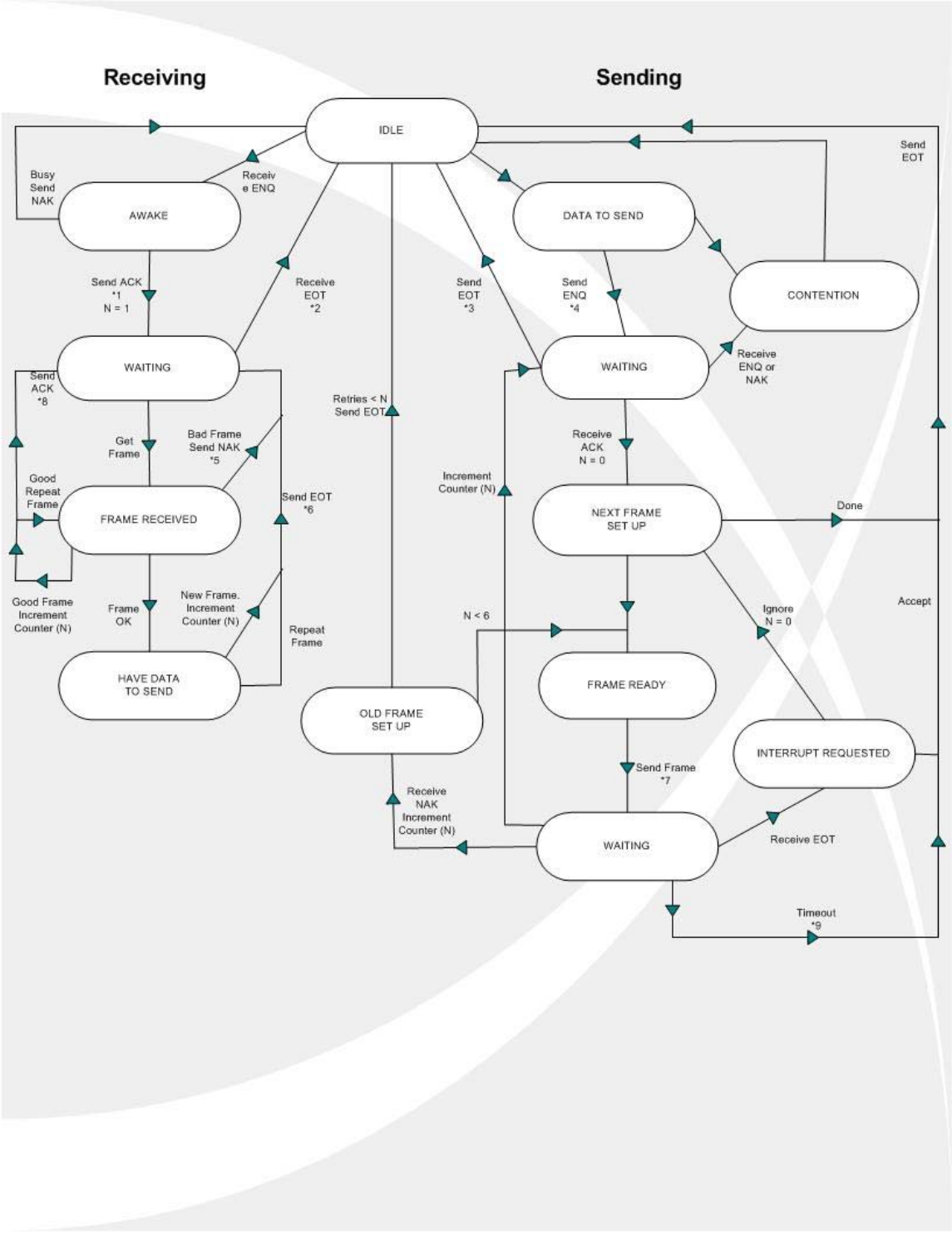
NOTE: The network module in the Analyzer is active only when the Analyzer initiates and conducts communication with the host. At all other times, this module is OFF and the Analyzer is not on the network.

6. Sofia Implementation

At the applications layer, the Sofia Analyzer conducts one-way communication with the host. All communication is initiated and terminated by the Analyzer. The Analyzer does not service communications initiated by the host. Any such communication is handled in accordance with LIS01-A2 section 6.2.7, the Analyzer sends a <NAK>.

The Sofia Analyzer uses the CLSI/ASTM specifications listed in Section 3 when communicating with a host. All communication is limited to the ISO 8859-1 character set. The strings “positive,” “negative,” “invalid,” “passed,” “failed,” “Read-Now Mode,” “Walk Away Mode,” etc., will be sent in English regardless of language setting on the instrument.

ASTM LLP State Diagram



The **n* locations in the above figure represent settings which have been found to vary between host systems. These settings are defaulted to the standard ASTM timings. Some of the more frequently changed timings are:

Send Timeout – to be used when sending data such as in steps 4, 7 and 9 on the flowchart above. The default value is approximately 15 seconds.

Receive Timeout –The default value is approximately 30 seconds.

Linebid Timeout – how much time to wait when line bidding, i.e. the time between transmitting an ENQ and receiving an acknowledgement. The default value is approximately 500 ms.

Number of Tries – describes flowchart counter N variable. It defines how many times the record should try to be retransmitted in case of a timeout or Negative acknowledge. The default value is 5.

Checksums

A checksum is used for checking data integrity. As described in LIS01-A2 section 6.3.3, the checksum is computed by adding the binary values of the characters in the message, keeping the least significant 8 bits of the result. The first character used in computing the checksum is the frame number. Each character in the message text is added to the checksum (modulo 256). The calculation of the checksum does not include the STX, the checksum characters, or the trailing CR and LF (the ETX/ETB is included in the calculation). The checksum is converted to two ASCII characters of the hexadecimal representation. The two characters are transmitted as the checksum, with the most significant character first (C1).

Example 1: A checksum of 122 can be represented as 0x7A (0x stands for hexadecimal).

Example 2: In the L record below, the "**7L|1|N<CR><ETX>"** are the characters used to calculate the 0x0A checksum. The message is then *wrapped* and would be sent as follows:

<STX>7L|1|N<CR><ETX>0A<CR><LF>

Results

If the interface sends Results, the message format is defined as:

Results	**Results Message**
H	Message Header
{ [P]	Patient Identification
{ [O]	Order Record
{ [C] }	Notes and Comments
{ [R]	Result Record
}	
}	
}	
L	Terminator Record

INDIVIDUAL RECORD EXAMPLES

The Sofia Analyzer transmits three types of results: patient results, QC results, and calibration results. Each of the individual records is outlined below with example messages.

Header Record

Field Number	Field Name	Required Optional	Size / Type	Example	Description
1	Record Type	Required	1 Alpha	H	Record type
2	Encoding Characters (delimiters)	Required	4 Alpha	|\^&	In this order: | field separator \ repetition separator ^ component separator & escape character
5.1	Analyzer Name	Required	18 Alpha	"Sofia"	This is the textual description of the reader. The is not configured.
5.2	Serial Number	Required	8 Num	12345678	This is serial number of the device.
12	Processing ID	Required	1 Alpha	"P"	Free text. Always "P"
13	Firmware Version	Required	8 Num	1.0.2	This represents the current firmware version of the device.
14	Current Date and Time	Required	14 Date	20081229165023	This is the current Date and Time that the transmission was sent (yyyymmddhhmmss).

EXAMPLE:

```
H|\^&|||Sofia^12345678||||||P|1.0.2|20081229165023<CR>
```

Patient Record

The Patient record contains demographics and other information about the patient. This is a required record; therefore, it will be transmitted as an empty record if none of the user fields are populated.

Field Number	Field Name	Required Optional	Size / Type	Example	Description
1	Record Type	Required	1 Alpha	P	Record type
2	Sequence Number	Required	1 Num	1	Sequence Number for multiple P records
3	Patient ID	Required	12 Alpha	PID1234	Assigned Patient ID for patient result. For QC and Calibration this field will be the Cassette Serial Number.
26	Location	Optional	15Alpha	SITENAME	Location as configured by the user.

EXAMPLE:

P|1|PID1234||||||||||||||||||||||||SITENAME<CR>

Order Record

The O record segment is used for all results

Field Number	Field Name	Required Optional	Size / Type	Example	Description
1	Record Type	Required	1 Alpha	O	Record type
2	Sequence Number	Required	1 Num	1	Sequence Number for multiple O records
3	Order ID	Optional	12 Alpha	SAM1234	This is the Order Number as entered by the user For QC this will be the Kit Lot Number and for Calibration the Calibration Lot Number.
5	Test Type Name	Optional	0-8	Flu A+B	Test Type short Name for the cassette used
11	Operator ID	Optional	12 Num	987654	The user of the system when the sample was run.
16	Sample Type	Required	1 Alpha	P	This will be the sample type of the cassette, “P” for patient sample “Q” for a quality control sample, and “C” for calibration.

EXAMPLE:

0|1|SAM1234||Flu A+B||||||987654||||P<CR>

Comment Record

This record is optional and only sent when there is a sample comment that is available to be sent. This is not implemented on Sofia at this time. The format would be the following:

Field Number	Field Name	Required Optional	Size / Type	Example	Description
1	C	Required	1 Alpha	C	Record type
2	Sequence Number	Required	1 Num	1	Sequence Number for C record
4	Sample Comment	Required	18 Alpha	Read-Now Mode	Additional sample information: "Walk Away Mode" or "Read-Now Mode." Only transmitted on patient and QC results.

EXAMPLE:

C|1||Read-Now Mode<CR>

Result Record

Field Number	Field Name	Required Optional	Size / Type	Example	Description
1	Record Type	Required	1 Alpha	R	Record type
2	Sequence Number	Required	1 Num	1	Sequence Number for multiple R records
3	Test Name	Required	8 Alpha	^^^FLU A	^^^Test Name
4	Test Value	Required	8 Alpha	1.51	Result of test. Possible values are numeric values, positive, negative and invalid for patient results, passed and failed for Calibration and QC results.
5	Test Units	Optional	8 Alpha	mg/mL	Units used to measure result value
6	Reference Range	Optional	18 Alpha	0.5 - 1.5	Valid ranges for result
7	Test Flag	Optional	8 Alpha	H	Test Flag (See Chart Below)

9	Test Result Type	Required	1 Alpha	F	The value used are “F” – Final “R” – Retransmitted
13	Date/Time of Test Completion	Required	14 Date	20110414064534	The date and time that the test was completed

EXAMPLE:

```
R|1|^^^Flu A|negative|||||F||||20110414064534<CR>
R|2|^^^Flu B|negative|||||F||||20110414064534<CR>
…
R|n| …
```

Test Flag	Description
>	Below Measurable Range
<	Above Measurable Range
L	Below Normal
H	Above Normal
HH	Above Panic Normal
LL	Below Panic Normal
N	Normal
A	Abnormal

Terminator Record

Field Number	Field Name	Required Optional	Size / Type	Example	Description
1	L	Required	1 Alpha	L	Record type
2	Sequence Number	Required	1 Num	1	Sequence Number for the L record
3	N	Required	1 Alpha	N	N

EXAMPLE:

```
L|1|N<CR>
```

HIGH LEVEL ASTM MESSAGE EXAMPLES

Example A: ***Outgoing Result Message***

```
H|\^&|||Sofia^12345678|||||||P|1.0.2|20081229165023<CR>
P|1|PID1234||||||||||||||||||||||SITENAME<CR>
O|1|SAM1234||Flu A+B||||||JSmith|||||P<CR>
C|1||Read-Now Mode<CR>
R|1|^^^Flu A|negative|||||F||||20110414064534<CR>
R|2|^^^Flu B|negative|||||F||||20110414064534<CR>
L|1|N<CR>
```

Example B: ***Outgoing QC Message***

The QC result generates two results; one for positive QC and one for negative QC as two cartridges were run.

```
H|\^&|||Sofia^12345678|||||||P|1.0.2|20081229165023<CR>
P|1|CASSER12||||||||||||||||||||||SITENAME<CR>
O|1|KITLOT12||Flu A+B||||||987654|||||Q<CR>
C|1||Read-Now Mode<CR>
R|1|^^^POS|passed|||||F||||20110414064534<CR>
L|1|N<CR>

H|\^&|||Sofia^12345678|||||||P|1.0.2|20081229165023<CR>
P|1|CASSER12||||||||||||||||||||||SITENAME<CR>
O|1|KITLOT12||Flu A+B||||||987654|||||Q<CR>
C|1||Read-Now Mode<CR>
R|1|^^^NEG|passed|||||F||||20110414065486<CR>
L|1|N<CR>
```

Example C: ***Outgoing Calibration Message***

```
H|\^&|||Sofia^12345678|||||||P|1.0.2|20081229165023<CR>
P|1|CASSER12||||||||||||||||||||||SITENAME<CR>
O|1|CASLOT12||CB Cass||||||987654|||||C<CR>
R|1|^^^CB Cass|passed|||||F||||20110414064534<CR>
L|1|N<CR>
```

LOW LEVEL ASTM MESSAGE EXAMPLES

Example D: Result message Example A with low level characters.

READER: <ENQ>
HOST: <**ACK**>
READER: <STX>1H|\^&|||Sofia^12345678|||||||P|1.0.2|20081229165023<CR><ETX>B1<CR><LF>
HOST: <**ACK**>
READER: <STX>2P|1|PID1234||||||||||||||||||||||SITENAME<CR><ETX>DC<CR><LF>
HOST: <**ACK**>
READER: <STX>3O|1|SAM1234||Flu A+B||||||987654|||||P<CR><ETX>46<CR><LF>
HOST: <**ACK**>
READER: <STX>4C|1||Read-Now Mode<CR><ETX>AE<CR><LF>
HOST: <**ACK**>

READER: <STX>5R|1|^^^Flu A|negative|||||F||||20110414064534<CR><ETX>96<CR><LF>
HOST: <**ACK**>
READER: <STX>6R|2|^^^Flu B|negative|||||F||||20110414064534<CR><ETX>99<CR><LF>
HOST: <**ACK**>
READER: <STX>7L|1|N<CR><ETX>0A<CR><LF>
HOST: <**ACK**>
READER: <EOT>

<u>Example E:</u> QC Result message Example B with low level characters.

READER: <ENQ>
HOST: <**ACK**>
READER: <STX>1H|\^&|||Sofia^12345678|||||||P|1.0.2|20081229165023<CR><ETX>B1<CR><LF>
HOST: <**ACK**>
READER: <STX>2P|1|CASSER12|||||||||||||||||||||SITENAME<CR><ETX>59<CR><LF>
HOST: <**ACK**>
READER: <STX>3O|1|KITLOT12||Flu A+B||||||987654|||||Q<CR><ETX>CE<CR><LF>
HOST: <**ACK**>
READER: <STX>4C|1||Read-Now Mode<CR><ETX>AE<CR><LF>
HOST: <**ACK**>
READER: <STX>5R|1|^^^POS|passed|||||F||||20110414064534<CR><ETX>2D<CR><LF>
HOST: <**ACK**>
READER: <STX>6L|1|N<CR><ETX>09<CR><LF>
HOST: <**ACK**>
READER: <EOT>

READER: <ENQ>
HOST: <**ACK**>
READER: <STX>1H|\^&|||Sofia^12345678|||||||P|1.0.2|20081229165023<CR><ETX>B1<CR><LF>
HOST: <**ACK**>
READER: <STX>2P|1|CASSER12|||||||||||||||||||||SITENAME<CR><ETX>59<CR><LF>
HOST: <**ACK**>
READER: <STX>3O|1|KITLOT12||Flu A+B||||||987654|||||Q<CR><ETX>CE<CR><LF>
HOST: <**ACK**>
READER: <STX>4C|1||Read-Now Mode<CR><ETX>AE<CR><LF>
HOST: <**ACK**>
READER: <STX>5R|1|^^^NEG|passed|||||F||||20110414064534<CR><ETX>1C<CR><LF>
HOST: <**ACK**>
READER: <STX>6L|1|N<CR><ETX>09<CR><LF>
HOST: <**ACK**>
READER: <EOT>

<u>Example F:</u> Calibration Result message Example C with low level characters.

READER: <ENQ>
HOST: <**ACK**>
READER: <STX>1H|\^&|||Sofia^12345678|||||||P|1.0.2|20081229165023<CR><ETX>B1<CR><LF>
HOST: <**ACK**>
READER: <STX>2P|1|CASSER12|||||||||||||||||||||SITENAME<CR><ETX>59<CR><LF>
HOST: <**ACK**>
READER: <STX>3O|1|CASLOT12||CB Cass||||||987654|||||C<CR><ETX>E9<CR><LF>
HOST: <**ACK**>
READER: STX>4R|1|^^^CB Cass|passed|||||F||||20110414064534<CR><ETX>69<CR><LF>
HOST: <**ACK**>
READER: <STX>5L|1|N<CR><ETX>08<CR><LF>
HOST: <**ACK**>
READER: <EOT>

<u>Example G</u>: Multiple Result messages.

The reader is capable of sending multiple messages during one communication phase. A low level example of sending two messages during one session is shown below. Note how the reader has to request the line for each result transmission.

READER: <ENQ>
HOST: <ACK>
READER: <STX>1H|\^&|||Sofia^12345678|||||||P|1.0.2|20081229165023<CR><ETX>B1<CR><LF>
HOST: <ACK>
READER: <STX>2P|1|PID1234||||||||||||||||||||||SITENAME<CR><ETX>DC<CR><LF>
HOST: <ACK>
READER: <STX>3O|1|SAM1234||Flu A+B||||||987654|||||P<CR><ETX>46<CR><LF>
HOST: <ACK>
READER: <STX>4C|1||Read-Now Mode<CR><ETX>AE<CR><LF>
HOST: <ACK>
READER: <STX>5R|1|^^^Flu A|negative|||||F||||20110414064534<CR><ETX>96<CR><LF>
HOST: <ACK>
READER: <STX>6R|2|^^^Flu B|negative|||||F||||20110414064534<CR><ETX>99<CR><LF>
HOST: <ACK>
READER: <STX>7L|1|N<CR><ETX>0A<CR><LF>
HOST: <ACK>
READER: <EOT>
READER: <ENQ>
HOST: <ACK>
READER: <STX>1H|\^&|||Sofia^12345678|||||||P|1.0.2|20081229167023<CR><ETX>B3<CR><LF>
HOST: <ACK>
READER: <STX>2P|1|PID1236||||||||||||||||||||||SITENAME<CR><ETX>DE<CR><LF>
HOST: <ACK>
READER: <STX>3O|1|SAM1236||Flu A+B||||||987654|||||P<CR><ETX>48<CR><LF>
HOST: <ACK>
READER: <STX>4C|1||Read-Now Mode<CR><ETX>AE<CR><LF>
HOST: <ACK>
READER: <STX>5R|1|^^^Flu A|negative|||||F||||20110414064534<CR><ETX>96<CR><LF>
HOST: <ACK>
READER: <STX>6R|2|^^^Flu B|negative|||||F||||20110414064534<CR><ETX>99<CR><LF>
HOST: <ACK>
READER: <STX>7L|1|N<CR><ETX>0A<CR><LF>
HOST: <ACK>
READER: <EOT>

<u>Example H</u>: Establishing a Connection with the Host.

In the previous examples the host is always listening and immediately responds with an <ACK>. If the host is not listening, then the Analyzer will attempt to connect multiple times before going back to "sleep." The timeout between transmissions will be a minimum of five seconds.

For example:
READER wakes up and has results to send. It waits 200 milliseconds before trying to establish communication.

READER: <ENQ> (waits 400 ms)
READER: <EOT> (this is sent to notify the LIS the reader has given up)
READER: <ENQ> (waits 400 ms)
READER: <EOT> (this is sent to notify the LIS the reader has given up)
READER: <ENQ> (waits 350 ms)
READER: <EOT> (this is sent to notify the LIS the reader has given up)
READER goes back to sleep for 5-15 minutes

READER wakes up and tries from the beginning again by sending the <ENQ>
READER: <ENQ>
HOST: **<ACK>**
READER:
<STX>1H|\^&|||Sofia^12345678||||||P|1.0.2|20081229165023<CR><ETX>B1<CR><LF>
HOST: **<ACK>**

…. (Example continues as listed in Example D)

Please call Quidel Technical Support at 800-874-1517 (USA only), 858-552-1100 or technicalsupport@quidel.com if you have any questions regarding the Quidel Sofia Analyzer or any other Quidel Product. Our hours of operation are Monday-Friday, 7:00 a.m.-5:00 p.m. Pacific Time.

You may also visit our website at **quidel.com** for information on Quidel's line of Rapid Diagnostics and Specialty Product Group (Bone Health and Autoimmune & Complement). Other product information available on our website includes: CPT codes, CLSI procedure guides, MSDS, and package inserts.