Technical Bulletin

LIS Interface Specification

1. Sofia 2 Instrument Interface Specification – Overview

The scope of this document is to provide detail on the capabilities and requirements for implementing a Systems Interface between the Sofia 2 Instrument and the LIS System.

The Sofia 2 Instrument implements an industry standard ASTM[1] interface for use over Ethernet networks. The interface is designed to support uni-directional (ASTM) communications with Laboratory Information Systems (LIS). The LIS interface is built into the Sofia 2 instrument and requires minimal configuration to use.

The physical instrument connection is via Ethernet and the transport is via the TCP/IP Protocol. The instrument has one standard Ethernet RJ-45 connector.

Uni-directional (ASTM)

Sofia 2 may be setup for uni-directional communication to send test results to the LIS. The ASTM interface is compliant with versions LIS1-A (formally ASTM E1381-91) and LIS2-A (formerly ASTM E1394-97) of the Clinical and Laboratory Standards Institute (CLSI) standard for electronic data exchange.

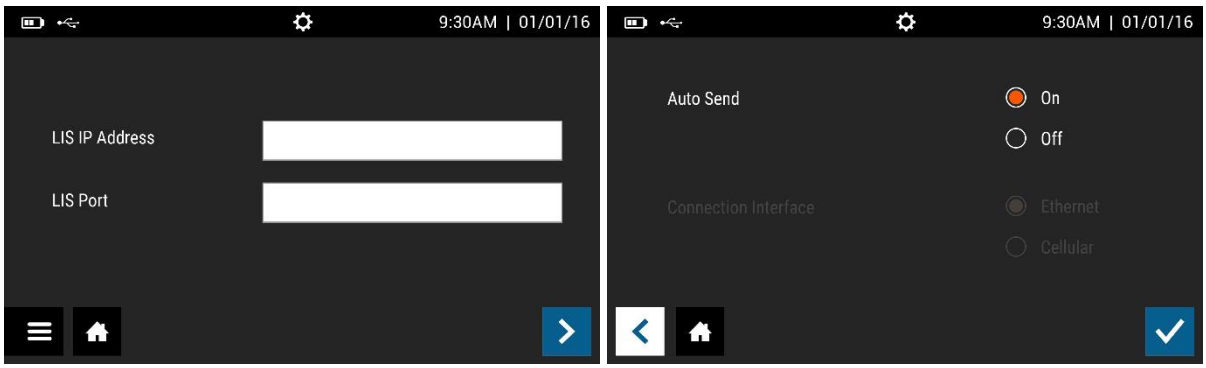
Implementation of a uni-directional interface requires one (1) interface be setup;

Sofia 2 Instrument	LIS System
Results Interface ➡ Configured to send Test Results to the LIS at the LIS IP Address and Port number that's listening for Test Results.	**Results Interface** ➡ LIS listens for Test Results on its IP Address and designated Port number.

[1] The Laboratory Information System (LIS) data transfer is implemented according to the following standards and documents: The Instrument Interface complies with legacy ASTM Interface Specifications maintained by the Clinical And Laboratory Standards Institute® (CLSI) and published as LIS1-A (formally ASTM E 1381-91) and LIS2-A (formally ASTM E1394-97).

1.1. LIS Interface configuration

LIS Interface setup screen in Sofia 2



After setting up the Sofia 2 with an IP address for its network connection, configure the LIS interface settings.

The example “LIS Settings” setup screen above is where the LIS interface is configured.

- The “LIS IP Address” field is for the IP address of the LIS server.
- The “LIS Port” is the port on which the LIS is listening for communication from the Sofia 2
- The “Auto Send” setting is set to On to have the LIS communication occur after the completion of each test.

The LIS administrator or LIS vendor support will advise on the correct IP address and port number for the LIS interface.

The Sofia 2’s network address is configured and viewed under the “Network Settings\Ethernet Settings” settings screen in the Sofia 2. Additional configuration detail for both Sofia 2 network address and LIS server may be found in the Sofia 2 User Manual at:
http://www.quidel.com/immunoassays/sofia-tests-kits/sofia-2-analyzer

After configuring the instrument to communicate on the Ethernet network, use the network utility “Ping” to confirm the instrument is configured correctly for network communications.

When the Sofia 2 starts a communication session to send test results, it must receive an ACK response from LIS within 5 secs. If it does not receive an ACK response in time, then the Sofia 2 reports a “Send to LIS error”.

Troubleshooting a “Send to LIS error” condition
Step 1. LAN IP address – In consultation with your Network Administrator, confirm the Sofia 2 Ethernet Settings are entered properly in the Sofia 2.
Step 2. LIS IP address and port number – Confirm that you have entered the LIS IP address and LIS port number for the destination LIS Address into the Sofia 2 “LIS Settings” screen.
Step 3. Confirm a successful Ethernet connection – Examine the Ethernet connection socket on the back of the instrument and confirm your network cable is connected and that you see a solid green LED next to the connector[2].
Step 4. Sofia 2 Ping response – Have the Network Administrator Ping the Sofia 2 at the Sofia 2’s assigned IP address in the Ethernet Settings screen. Success will be verified by a successful Ping response.

[2] Lack of a green “Link Light” is an indication that you do not have a good connection to an Ethernet Network. Check your cable connections and if that does not resolve the condition, seek help from your Network Support resource.

Step 5. Confirm the Sofia 2 IP address is not shared – With the network cable unplugged from the Sofia 2, have the Network Administrator Ping the Sofia 2 at the Sofia 2's assigned IP address. Success will be verified by an unsuccessful Ping response showing that the IP address is not assigned to another device. If Ping receives a Ping response instead of "Request timed out", then have the Network Administrator resolve the IP conflict on your network as a Ping response here indicates this IP address is available on the network when the Sofia 2 is disconnected.
Step 6. Confirm LIS connectivity – Select "Send Data" from the Sofia 2 menu, select "Test Connection" and choose the LIS button at the bottom right of the screen. If Sofia 2 responds with "The Analyzer can be connected to LIS" then select "Send Last Result". If Sofia 2 responds with "Data were transmitted successfully.", then connectivity is resolved.
Step 7. LIS is unreachable or other network issues – Select "Send Data" from the Sofia 2 menu, select "Test Connection" and choose the LIS button at the bottom right of the screen. If Sofia 2 responds with "Test connection error." then notify the LIS support person to confirm that LIS is listening for the Sofia 2 connection at the LIS address and port number configured in the Sofia 2 "LIS Settings" screen. If the LIS is listening at the designated address and port number, then ask the Network Administrator to check and confirm that Sofia 2's connection path to LIS is not being blocked by network routing rules or network firewall settings.

2. The Uni-directional (ASTM) Results Interface – Functional Description

When the test completes, a result is sent to the LIS. If the transmission fails, the result is temporarily stored and can be resent. A Sofia 2 user may resend results when the connection to the LIS is reestablished through the following:
From the Main Menu,
select Send Data
select Last Result or All Results (Last 50)
select the terminal send button in the lower right corner.

The following information is sent with test results:

- Sofia 2 serial number
- Patient ID and/or order number
- Test identifier(s)
- Date and time of result reporting
- The analyte name and qualitative result(s)

After each segment of the result message is sent, the Sofia 2 expects an ACK message from the LIS, otherwise the transfer will report as failed and the results will need to be resent.

2.1. The Test Results Message

The Sofia 2 test results message is made up of the following ASTM message segments.

H	Message Header Record
P	Patient Identification Record
O	Order Record
C	Notes and Comments Record
R	Result Record
L	Terminator Record

Each of these message segments contain fields of data defined by the ASTM standard. Some fields of information are mandatory and sent, some are optional, and others are empty or not used. In the following tables defining the message segments, the abbreviations R, O and N indicate the status and use of a data field within the message segment.

Abbreviation	Meaning	Description	
		LIS → Instrument	Instrument → LIS
R	Required	Is required and analyzed	Is always present
O	Optional	If present, will be evaluated	Sometimes present
N	Not used	Ignored	Not filled

2.1.1. H: Message Header Record

Field	R/O/N	Qualified data	Name	Description
H-1	R	H	Record Type	Always: H
H-2	R	|\^&	Encoding Characters (delimiters)	Always: |\^& | field separator \ repetition separator ^ component separator & escape character
H-3	R	*Empty*	Message Control ID	Empty
H-4	R	*Empty*	Access Password	Empty
H-5.1	R	Sofia	Analyzer Name	Always: Sofia
H-5.2	R	8 digits with 29 as the 2 left most digits.	Serial Number	The Sofia 2's serial number. Example: 29000021
H-6 through H-11	R	*Empty*	Not Used	Empty
H-12	R	P	Processing ID	Always: P
H-13	R	1 digit . 1 digit . 1 digit	Firmware Version	This represents the current firmware version of the Sofia 2. Example: 1.7.0
H-14	R	14 digits YYYYMMDDHHMMSS	Current Date and Time	Timestamp when the message has been created. Format: YYYYMMDDHHMMSS

H Example

H|\^&|||Sofia^29000021|||||||P|1.7.0|20191010092111<CR>

2.1.2. P: Patient Identification Record

Field	R/O/N	Qualified data	Name	Description
P-1	R	P	Record Type	Always: P
P-2	R	1	Sequence Number	Always: 1
P-3	R	First 12 alphanumeric characters entered into the 20 character Patient ID field.	Patient ID	Assigned patient ID for patient result. For QC and Calibration result transmissions, this field will be the cassette serial number. Example: PAT1234
P-4 through P-25	N	*Empty*	Not Used	Empty
P-26	O	First 15 alphanumeric characters entered	Location	Location as configured by the user. Example: SITENAME

		into the 20 character Site Name field.		

P Example

P|1|PAT1234||||||||||||||||||||||||SITENAME<CR>

2.1.3. O: Order Record

Field	R/O/N	Qualified data	Name	Description
O-1	R	O	Record Type	Always: O
O-2	R	1	Sequence Number	Sequence number for multiple O records.
O-3	O	First 12 alphanumeric characters entered into the 20 character Order Number field.	Order ID	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.
O-4	N	*Empty*	Not Used	Empty
O-5	O	Cassette Test Type name.	Test Type Name	Test type short name for the cassette used. Example: Flu A+B
O-6 through O-10	N	*Empty*	Not Used	Empty
O-11	O	First 12 alphanumeric characters entered into the 20 character User ID field.	Operator ID	The User ID when the sample was run. Example: 2142
O-12 through O-15	N	*Empty*	Not Used	Empty
O-16	R	Single character representing the sample type of the cassette.	Sample Type	This will be the sample type of the cassette, “P” for patient sample “Q” for a quality control sample, and “C” for calibration.
...	N			Not used

Field	R/O/N	Qualified data	Name	Description
O-1	R	O	Record Type	Always: O
O-2	R	1	Sequence Number	Sequence number for multiple O records.

Field	R/O/N	Qualified data	Name	Description	
O-3	O	First 12 alphanumeric characters entered into the 20 character Order Number field.		Order ID	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.
O-4	N	Empty		Not Used	Empty
O-5	O	Cassette Test Type name.		Test Type Name	Test type short name for the cassette used. Example: Flu A+B
O-6 through O-10	N	Empty		Not Used	Empty
O-11	O	First 12 alphanumeric characters entered into the 20 character User ID field.		Operator ID	The User ID when the sample was run. Example: 2142
O-12 through O-15	N	Empty		Not Used	Empty
O-16	R	Single character representing the sample type of the cassette.		Sample Type	This will be the sample type of the cassette, “P” for patient sample “Q” for a quality control sample, and “C” for calibration.
...	N				Not used

O Example

O|1|SAM1234||Flu A+B||||||2142|||||P<CR>

2.1.4. C: Notes and Comments Record

Field	R/O/N	Qualified data	Name	Description
C-1	R	C	Record Type	Always: C
C-2	R	1	Sequence Number	Always: 1
C-3	N	*Empty*	Not Used	Empty
C-4	R	Test Mode	Sample Comment	Additional sample information: “Walk Away Mode” or “Read-Now Mode” Only transmitted on patient and QC results. Example: Read-Now Mode

C Example

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

2.1.5. R: Result Record

Field	R/O/N	Qualified data	Name	Description
R-1	R	R	Record Type	Always: R

R-2	R	Number	Sequence Number	Sequence number for multiple R records.
R-3	R	Alphanumeric	Analyte Name	^^^analyte name Example: ^^^Flu A
R-4	R	Alphanumeric	Test Value	Result of test. Possible values are numeric values, positive, negative and invalid for patient results, passed and failed for Calibration and QC results. Example: positive
R-5	O	Alphanumeric	Test Units	Units used to measure result value. Empty for qualitative tests. Example: mg/mL
R-6	O	Alphanumeric	Reference Range	Valid ranges for result. Empty for qualitative tests. Example: 0.5 – 1.5
R-7	O	Alphanumeric	Test Flag	Test Flag (See Chart Below). Not applicable for some tests. Example: H
R-8	N	*Empty*	Not Used	Empty
R-9	R	F	Test Result Type	The values used are "F" – Final "R" – Retransmitted
R-10 through R-12	R	*Empty*	Not Used	Empty
R-13	R	14 digits YYYYMMDDHHMMSS	Date/time of Test Completion	The date and time that the test was completed Example: 20190414064534
…	N			Not used

R Example

R|1|^^^Flu A|negative|||||F||||20191010092059<CR>
R|2|^^^Flu B|negative|||||F||||20191010092059<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

2.1.6. L: Terminator Record

Field	R/O/N	Qualified data	Name	Description
L-1	R	L	Record Type	Always: L
L-2	R	1	Sequence Number	Always: 1
L-3	R	N	N	Always: N

L Example

L|1|N <CR>

2.2 ASTM Message Examples

HIGH LEVEL ASTM MESSAGE EXAMPLES

Example A: Outgoing Result Message

H|\^&|||Sofia^29000021|||||||P|1.7.0|20190414065327<CR>
P|1|PAT1234||||||||||||||||||||||||SITENAME<CR>
O|1|SAM1234||Flu A+B||||||2142|||||P<CR>
C|1||Read-Now Mode<CR>
R|1|^^^Flu A|negative|||||F||||20190414064534<CR>
R|2|^^^Flu B|negative|||||F||||20190414064534<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^29000021|||||||P|1.7.0|20190414065327<CR>
P|1|CASSER12||||||||||||||||||||||||SITENAME<CR>
O|1|KITLOT12||Flu A+B||||||2142|||||Q<CR>
C|1||Read-Now Mode<CR>
R|1|^^^POS|passed|||||F||||20190414061543<CR>
L|1|N<CR>

H|\^&|||Sofia^29000021|||||||P|1.7.0|20190414065739<CR>
P|1|CASSER12||||||||||||||||||||||||SITENAME<CR>
O|1|KITLOT12||Flu A+B||||||2142|||||Q<CR>
C|1||Read-Now Mode<CR>
R|1|^^^NEG|passed|||||F||||20190414062123<CR>
L|1|N<CR>

Example C: Outgoing Calibration Message

H|\^&|||Sofia^29000021|||||||P|1.7.0|20190414070819<CR>
P|1|CASSER12||||||||||||||||||||||||SITENAME<CR>
O|1|CASLOT12||CB Cass||||||2142|||||C<CR>
R|1|^^^CB Cass|passed|||||F||||20190414062839<CR>
L|1|N<CR>

LOW LEVEL ASTM MESSAGE EXAMPLES

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

Sofia 2: <ENQ>
LIS: <ACK>
Sofia 2: <STX>1H|\^&|||Sofia^29000021|||||||P|1.7.0|20190414065327<CR><ETX>A3<CR><LF>
LIS: <ACK>
Sofia 2: <STX>2P|1|PAT1234||||||||||||||||||||||||SITENAME<CR><ETX>E4<CR><LF>
LIS: <ACK>
Sofia 2: <STX>3O|1|SAM1234||Flu A+B||||||2142|||||P<CR><ETX>C0<CR><LF>
LIS: <ACK>
Sofia 2: <STX>4C|1||Read-Now Mode<CR><ETX>AE<CR><LF>
LIS: <ACK>
Sofia 2: <STX>5R|1|^^^Flu A|negative|||||F||||20190414064534<CR><ETX>9E<CR><LF>
LIS: <ACK>
Sofia 2: <STX>6R|2|^^^Flu B|negative|||||F||||20190414064534<CR><ETX>A1<CR><LF>
LIS: <ACK>
Sofia 2: <STX>7L|1|N<CR><ETX>0A<CR><LF>

LIS: <ACK>
Sofia 2: <EOT>

Example E: QC Result message Example B with low level characters.
Sofia 2: <ENQ>
LIS: <ACK>
Sofia 2: <STX>1H|\^&|||Sofia^29000021|||||||P|1.7.0|20190414065327<CR><ETX>A3<CR><LF>
LIS: <ACK>
Sofia 2: <STX>2P|1|CASSER12||||||||||||||||||||||SITENAME<CR><ETX>59<CR><LF>
LIS: <ACK>
Sofia 2: <STX>3O|1|KITLOT12||Flu A+B||||||2142|||||Q<CR><ETX>50<CR><LF>
LIS: <ACK>
Sofia 2: <STX>4C|1||Read-Now Mode<CR><ETX>AE<CR><LF>
LIS: <ACK>
Sofia 2: <STX>5R|1|^^^POS|passed|||||F||||20190414061543<CR><ETX>32<CR><LF>
LIS: <ACK>
Sofia 2: <STX>6L|1|N<CR><ETX>09<CR><LF>
LIS: <ACK>
Sofia 2: <EOT>
Sofia 2: <ENQ>
LIS: <ACK>
Sofia 2: <STX>1H|\^&|||Sofia^29000021|||||||P|1.7.0|20190414065739<CR><ETX>AA<CR><LF>
LIS: <ACK>
Sofia 2: <STX>2P|1|CASSER12||||||||||||||||||||||SITENAME<CR><ETX>59<CR><LF>
LIS: <ACK>
Sofia 2: <STX>3O|1|KITLOT12||Flu A+B||||||2142|||||Q<CR><ETX>50<CR><LF>
LIS: <ACK>
Sofia 2: <STX>4C|1||Read-Now Mode<CR><ETX>AE<CR><LF>
LIS: <ACK>
Sofia 2: <STX>5R|1|^^^NEG|passed|||||F||||20190414062123<CR><ETX>15<CR><LF>
LIS: <ACK>
Sofia 2: <STX>6L|1|N<CR><ETX>09<CR><LF>
LIS: <ACK>
Sofia 2: <EOT>

Example F: Calibration Result message Example C with low level characters.
Sofia 2: <ENQ>
LIS: <ACK>
Sofia 2: <STX>1H|\^&|||Sofia^29000021|||||||P|1.7.0|20190414070819<CR><ETX>A5<CR><LF>
LIS: <ACK>
Sofia 2: <STX>2P|1|CASSER12||||||||||||||||||||||SITENAME<CR><ETX>59<CR><LF>
LIS: <ACK>
Sofia 2: <STX>3O|1|CASLOT12||CB Cass||||||2142|||||C<CR><ETX>6B<CR><LF>
LIS: <ACK>
Sofia 2: STX>4R|1|^^^CB Cass|passed|||||F||||20190414062839<CR><ETX>77<CR><LF>
LIS: <ACK>
Sofia 2: <STX>5L|1|N<CR><ETX>08<CR><LF>
LIS: <ACK>
Sofia 2: <EOT>

Example G: Multiple Result messages.
The Sofia 2 can send multiple messages during one communication phase. A low-level example of sending two messages during one session is shown below. Note how the Sofia 2 must initiate each result transmission.

Sofia 2: <ENQ>
LIS: <ACK>
Sofia 2: <STX>1H|\^&|||Sofia^29000021|||||||P|1.7.0|20190414071031<CR><ETX>98<CR><LF>
LIS: <ACK>
Sofia 2: <STX>2P|1|PAT1234||||||||||||||||||||||SITENAME<CR><ETX>E4<CR><LF>
LIS: <ACK>
Sofia 2: <STX>3O|1|SAM1234||Flu A+B||||||2142|||||P<CR><ETX>C0<CR><LF>
LIS: <ACK>
Sofia 2: <STX>4C|1||Read-Now Mode<CR><ETX>AE<CR><LF>
LIS: <ACK>
Sofia 2: <STX>5R|1|^^^Flu A|negative|||||F||||20190414064534<CR><ETX>9E<CR><LF>
LIS: <ACK>
Sofia 2: <STX>6R|2|^^^Flu B|negative|||||F||||20190414064534<CR><ETX>A1<CR><LF>
LIS: <ACK>
Sofia 2: <STX>7L|1|N<CR><ETX>0A<CR><LF>
LIS: <ACK>
Sofia 2: <EOT>
Sofia 2: <ENQ>
LIS: <ACK>
Sofia 2: <STX>1H|\^&|||Sofia^29000021|||||||P|1.7.0|20190414071231<CR><ETX>9A<CR><LF>
LIS: <ACK>
Sofia 2: <STX>2P|1|PAT1236||||||||||||||||||||||SITENAME<CR><ETX>E4<CR><LF>
LIS: <ACK>
Sofia 2: <STX>3O|1|SAM1236||Flu A+B||||||2142|||||P<CR><ETX>C0<CR><LF>
LIS: <ACK>
Sofia 2: <STX>4C|1||Read-Now Mode<CR><ETX>AE<CR><LF>
LIS: <ACK>
Sofia 2: <STX>5R|1|^^^Flu A|negative|||||F||||20190414064734<CR><ETX>A0<CR><LF>
LIS: <ACK>
Sofia 2: <STX>6R|2|^^^Flu B|negative|||||F||||20190414064734<CR><ETX>A3<CR><LF>
LIS: <ACK>
Sofia 2: <STX>7L|1|N<CR><ETX>0A<CR><LF>
LIS: <ACK>
Sofia 2: <EOT>

4. Result Assay Panel Definition Table

The table below outlines what assay panel information will be used test name field (O-5 ASTM) and the analyte name field (R-3 ASTM). The Short Name is used in the test name field and the Analyte Name is used in the observation id (analyte name) field.

Long Name	Short Name	Analyte Name	Lower Limit	Upper Limit	Scale	Observation Values
Sofia Flu A+B	Flu A+B	Flu A				Invalid, Negative, Positive
Sofia Flu A+B	Flu A+B	Flu B				Invalid, Negative, Positive
Sofia Lyme	Lyme	IgG				Invalid, Negative, Positive
Sofia Lyme	Lyme	IgM				Invalid, Negative, Positive
Sofia SARS Antigen	SARS	SARS				Invalid, Negative, Positive
Sofia RSV	RSV	RSV				Invalid, Negative, Positive
Sofia Strep A+	Strep A+	Strep A+				Invalid, Negative, Positive

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