



## The Sofia 2 LIS Interface Specification

### 1 The 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 either an industry standard ASTM interface or POCT1a interface for use over Ethernet or Wi-Fi<sup>1</sup> networks. The interface is designed to support unidirectional (ASTM) or bidirectional (POCT1a) communications with Laboratory Information Systems (LIS) or Point-of-Care (POC) Middleware. The LIS interface is built into the Sofia 2 instrument and requires minimal User configuration to use. Throughout this document, both interfaces may generally be referred to as an LIS Interface.

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

#### 1.1 Unidirectional (ASTM)

Sofia 2 may be setup for unidirectional 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 unidirectional interface requires one (1) interface to be setup;

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

<sup>1</sup> Wi-Fi networking supported as of Firmware 1.12.31 or later.

## 1.2 Bidirectional (POCT1a)

The bidirectional use of the Instrument interface means that the Sofia Instrument can send test results to a Point-of-Care (POC) system and also receive Date/Time and Operator List updates from the POC System. The POCT1a interface is compliant with version POCT1-A2 of the Clinical and Laboratory Standards Institute (CLSI) standard for electronic data exchange.

Implementation of a bidirectional interface requires one (1) interface to be setup;

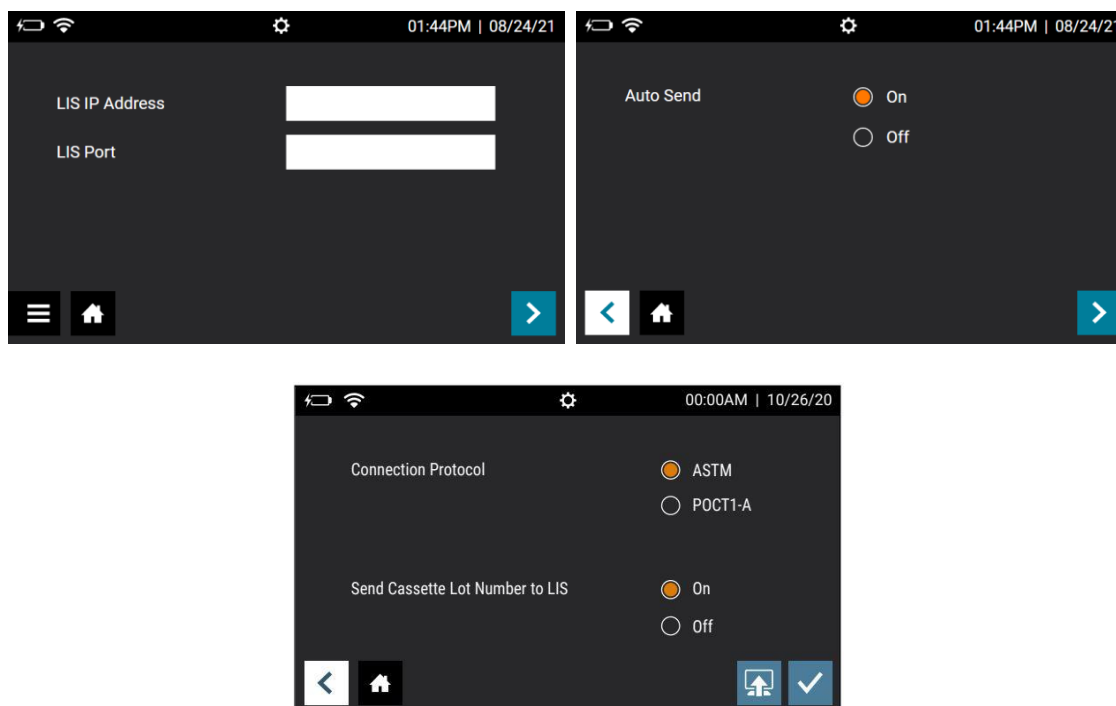
<b>Sofia Instrument</b>	<b>POC System</b>
<b>Bidirectional Interface</b> ↔ Configured to request Date/Time updates, Operator List management, and send Test Results to the LIS at the LIS IP Address and Port number that is listening for the POCT1a interface.	<b>Bidirectional Interface</b> ↔ The POC System listens for the Sofia request for Date/Time updates, Operator List management, and Test Results on its IP Address and designated Port number.

## 2 Table of Contents

<b>1</b>	<b>THE INSTRUMENT INTERFACE SPECIFICATION OVERVIEW .....</b>	<b>1</b>
1.1	UNIDIRECTIONAL (ASTM) .....	1
1.2	BIDIRECTIONAL (POCT1A) .....	2
<b>3</b>	<b>SOFIA 2 INTERFACE CONFIGURATION .....</b>	<b>4</b>
<b>4</b>	<b>THE UNIDIRECTIONAL (ASTM) RESULTS INTERFACE, FUNCTIONAL DESCRIPTION ...</b>	<b>5</b>
4.1	THE TEST RESULTS MESSAGE .....	6
4.1.1	<i>H: Message Header Record</i> .....	6
4.1.2	<i>P: Patient Identification Record</i> .....	7
4.1.3	<i>O: Order Record</i> .....	7
4.1.4	<i>C: Notes and Comments Record</i> .....	8
4.1.5	<i>R: Result Record</i> .....	8
4.1.6	<i>L: Terminator Record</i> .....	10
4.2	ASTM MESSAGE EXAMPLES .....	10
4.2.1	<i>Example A: Outgoing Result Message</i> .....	10
4.2.2	<i>Example B: Outgoing Result Message with Cassette Lot # and an additional R-Segment reporting the S/CO value</i> .....	10
4.2.3	<i>Example C: Outgoing Result Message with S/CO value reported in R-4.2</i> .....	10
4.2.4	<i>Example D: Outgoing QC Message</i> .....	11
4.2.5	<i>Example E: Outgoing Calibration Message</i> .....	11
4.2.6	<i>Example D: Result message Example A with low level characters</i> .....	11
4.2.7	<i>Example E: QC Result message Example B with low level characters</i> .....	11
4.2.8	<i>Example F: Calibration Result message Example C with low level characters</i> .....	12
4.2.9	<i>Example G: Multiple Result messages</i> .....	12
<b>5</b>	<b>THE BIDIRECTIONAL (POCT1A) INTERFACE, FUNCTIONAL DESCRIPTION .....</b>	<b>13</b>
5.1	THE INTRODUCTION PHASE .....	14
5.1.1	<i>HEL.R01 – Hello Message</i> .....	15
5.1.2	<i>ACK.R01 – Acknowledgement Message</i> .....	16
5.1.3	<i>DST.R01 – Device Status Message</i> .....	16
5.1.4	<i>DTV.R02 – Complex Directive Message</i> .....	17
5.1.5	<i>OPL.R01 – Operator List Message</i> .....	17
5.1.6	<i>EOT.R01 – End of Topic Message (at the end of the Operator List topic)</i> .....	18
5.1.7	<i>DTV.R01 – Basic Directive Message</i> .....	19
5.2	THE CONTINUOUS MODE .....	19
5.2.1	<i>OBS.R01 – Patient Test Observation Message</i> .....	19
5.2.2	<i>OBS.R02 – Non-Patient Test Observation Message</i> .....	21
5.2.3	<i>ACK.R01 – Acknowledgement Message</i> .....	22
5.2.4	<i>END.R01 – Terminate Message</i> .....	22
5.3	POCT1A MESSAGE EXAMPLES .....	23
5.3.1	<i>Example A: Sofia initiating the conversation with a POC System</i> .....	23
5.3.2	<i>Example B: Sofia sending status to a POC System</i> .....	23
5.3.3	<i>Example C: POC System sending DTV.R02 Set Time command to Sofia</i> .....	24
5.3.4	<i>Example D: POC System OPL.R01 Send Operator List of 2 Users and 1 Supervisor to Sofia</i> .....	24
5.3.5	<i>Example E: LIS DTV.R01 Start Continuous command to Sofia</i> .....	26
5.3.6	<i>Example F: OBS.R01 patient result and OBS.R02 calibration result to a POC System</i> .....	26
5.3.7	<i>Example G: OBS.R01 transmission of Quantitative Results from the C. difficile assay</i> .....	28
5.3.8	<i>Example H: OBS.R01 transmission of Results from the SARS IgG assay</i> .....	29
<b>6</b>	<b>RESULT ASSAY PANEL DEFINITION TABLE .....</b>	<b>30</b>
<b>7</b>	<b>QUIDELORTHO TECHNICAL SUPPORT .....</b>	<b>31</b>
<b>8</b>	<b>RELEASE AND REVISION HISTORY .....</b>	<b>31</b>

### 3 Sofia 2 Interface configuration

The 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 "Connection Protocol" setting is ASTM for Unidirectional or POCT1-A for Bidirectional as determined by the LIS System.

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> under the link there for "Product Documentation".

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, 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 LED

light next to the connector<sup>2</sup>. You may also see a blinking LED light which shows activity on the connection.

**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.

**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 another device on the network has the same IP address assigned.

**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.

## 4 The Unidirectional (ASTM) Results Interface, Functional Description

When a test completes, the 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
- Select the terminal send button in the lower right corner of the screen

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 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 have to be resent.

---

<sup>2</sup> 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.

## 4.1 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 in the R/O/N column, 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

### 4.1.1 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-digit Sofia 2 Serial Number	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	MASK	Firmware Version	This represents the current firmware version of the Sofia 2. Example: 1.12.2
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|20230829093015
```

#### 4.1.2 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	For firmware less than 1.12.31, the first 12 alphanumeric characters entered into the 20-character Patient ID field. Otherwise up to 20 characters.	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	For firmware less than 1.12.31 the first 15 alphanumeric characters entered into the Site Name field. Otherwise up to 30 characters.	Location	Location as configured by the user. Example: SITENAME

P Example

P|1|PAT1234|||||||||||||||||||SITENAME

#### 4.1.3 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	For firmware less than 1.12.31, the first 12 alphanumeric characters entered into the Order Number field. Otherwise up to 20 characters.	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	For firmware less than 1.12.31, the first 12 alphanumeric characters entered into the User ID field. Otherwise up to 20 characters.	Operator ID	The User ID when the sample was run. Example: 2142
O-12 through O-15	N	Empty	Not Used	Empty

Field	R/O/N	Qualified data	Name	Description
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

#### 4.1.4 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	<i>Empty</i>	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>

#### 4.1.5 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-3.4	R	Alphanumeric	Analyte Name	^^^analyte name Example: ^^^Flu A
R-4	R	Alphanumeric	Test Value	Result of test. Possible values are numeric, "positive", "negative" or "invalid" for patient results. "passed" or "failed" for Calibration and QC results. Example: positive
R-4.2	O	Alphanumeric	Concentration String	Starting in Firmware 15.1 and present for certain quantitative assays only. This represents the concentration string that is determined on an assay-to-assay basis. See <i>Table 1</i> below for assay details.
R-5	O	Alphanumeric	Test Units	Units used to measure result value. Empty for qualitative tests. May contain a number for a calculated result that has no associated units of measure. Unit of measure example: mg/mL



Field	R/O/N	Qualified data	Name	Description
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 Table 2 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	The date and time that the test was started. Example: 20230824153215
...	N			Not used

R Example

```
R|1|^^^Flu A|negative||||F|||20230824153215
R|2|^^^Flu B|negative||||F|||20230824153215
R|3|^^^Cassette Lot Number|121633||||F|||20230824153215
R|n| ...
```

Note 1: Beginning in firmware 15.1, the Instrument Administrator may elect to enable the sending of the Cassette Lot Number to LIS as a result string. If enabled, "Cassette Lot Number" will be sent in R-3.4. The Lot number will be sent in R-4. See example above.

Note 2: For some tests in some locales, the result may contain an additional R-segment that reports the Signal to Cutoff (S/CO) calculation for the assay. The format for the result value name in R-3.4 is "TestName\_VAL". R-4 will contain the value. R-4 values less than 1 correspond to a negative result. See the example in section 4.2.2.

Table 1 – Example Segment R-4.2 Characteristics

Assay	Analytes	ASTM Field R-4.2, Characteristic for quantitative assays
Sofia 2, C. difficile Assay Revision 57 (Not available in the U.S.)		Examples below contain partial result segments to illustrate R-4.2 and R-5 characteristics.
	GDH	GDH reports the value of the signal to cutoff ratio. Calculated values less than 1.0 are a negative result and segment R-4.2 will display <1.0 as the result value. Example: 5R 1 ^^^GDH negative^<1.0 <1.0 Segment R-5 will also report the R-4.2 value. Calculated values greater than 1.0 are positive and will report the calculated number up to two significant digits and one decimal place. The largest number will be 99.9. A reported 99.9 should be considered equal to or greater than 99.9. Example: 5R 1 ^^^GDH positive^99.9 99.9
	Toxins A and B	Tox A/B reports the positive or negative results based on the calculation of both analyte's signal to cutoff ratios. If the calculation for each analyte is less than 1.0, then the test is negative. If either or both analytes yield a result greater than 1.0, the test is positive and the values are reported. Example 1: 6R 2 ^^^Tox A/B negative^<1.0/<1.0 <1.0/<1.0 Example 2: 6R 2 ^^^Tox A/B positive^<1.0/78.8 <1.0/78.8 Example 3: 6R 2 ^^^Tox A/B positive^35.5/<1.0 <1.0/78.8 Example 4: 6R 2 ^^^Tox A/B positive^65.4/52.5 65.4/52.5

#### 4.1.6 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

## 4.2 ASTM Message Examples

### HIGH LEVEL ASTM MESSAGE EXAMPLES

#### 4.2.1 Example A: Outgoing Result Message

```
H|\^&|||Sofia^29000021|||||P|1.15.2|20230829093140
P|1|PAT1234|||||SITENAME
O|1|SAM1234||Flu A+B|||||2142||||P
C|1||Read-Now Mode
R|1|^^^Flu A|negative||||F|||20230829093015
R|2|^^^Flu B|negative||||F|||20230829093015
L|1|N
```

#### 4.2.2 Example B: Outgoing Result Message with Cassette Lot # and an additional R-Segment reporting the S/CO value<sup>3</sup>

```
H|\^&|||Sofia^20002815|||||P|1.15.2|20220620112327
P|1|PAT1234|||||SITENAME
O|1|7875421||Legion|||||2142||||P
C|1||Walk Away Mode
R|1|^^^Legion|negative||||F|||20220620111312
R|2|^^^Cassette Lot Number|156418||||F|||20220620111312
R|3|^^^Legion_VAL|0.23||||F|||20220620111312
L|1|N
```

#### 4.2.3 Example C: Outgoing Result Message with S/CO value reported in R-4.2<sup>4</sup>

```
H|\^&|||Sofia^29000388|||||P|1.15.2|20230804103514
P|1|PAT1234|||||SITENAME
O|1|||C. Diff|||||1234||||P
C|1||Read-Now Mode
R|1|^^^GDH|positive^99.9|99.9||||F|||20230804103502
R|2|^^^Tox A/B|positive^<1.0/78.8|<1.0/78.8||||F|||20230804103502
L|1|N
```

<sup>3</sup> See Note 2 after *Table 1* in Section 4.1.5.

<sup>4</sup> See *Table 1* in Section 4.1.5 for more detail.

#### 4.2.4 Example D: 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|1.15.2|20230829093140
P|1|CASSER12|||||SITENAME
O|1|KITLOT12||Flu A+B|||||2142||||Q
C|1||Read-Now Mode
R|1|^ ^^POS|passed||||F|||20230829093015
L|1|N
```

```
H|\^&||Sofia^29000021|||||P|1.15.2|20230829093140
P|1|CASSER12|||||SITENAME
O|1|KITLOT12||Flu A+B|||||2142||||Q
C|1||Read-Now Mode
R|1|^ ^^NEG|passed||||F|||20230829093015
L|1|N
```

#### 4.2.5 Example E: Outgoing Calibration Message

```
H|\^&||Sofia^29000021|||||P|1.15.2|20230829093140
P|1|CASSER12|||||SITENAME
O|1|CASLOT12||CB Cass|||||2142||||C
R|1|^ ^^CB Cass|passed||||F|||20230829093015
L|1|N
```

### LOW LEVEL ASTM MESSAGE EXAMPLES

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

```
Sofia 2: <ENQ>
LIS: <ACK>
Sofia 2: <STX>1H|\^&||Sofia^29000021|||||P|1.15.2|20230829093140<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|||20230829093015<CR><ETX>9E<CR><LF>
LIS: <ACK>
Sofia 2: <STX>6R|2|^ ^^Flu B|negative||||F|||20230829093015<CR><ETX>A1<CR><LF>
LIS: <ACK>
Sofia 2: <STX>7L|1|N<CR><ETX>0A<CR><LF>
LIS: <ACK>
Sofia 2: <EOT>
```

#### 4.2.7 Example E: QC Result message Example B with low level characters.

```
Sofia 2: <ENQ>
LIS: <ACK>
Sofia 2: <STX>1H|\^&||Sofia^29000021|||||P|1.15.2|20230829093140<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|||20230829093015<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|1.15.2|20230829093145<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|||||20230829092912<CR><ETX>15<CR><LF>  
 LIS: <ACK>  
 Sofia 2: <STX>6L|1|N<CR><ETX>09<CR><LF>  
 LIS: <ACK>  
 Sofia 2: <EOT>

#### 4.2.8 Example F: Calibration Result message Example C with low level characters.

Sofia 2: <ENQ>  
 LIS: <ACK>  
 Sofia 2: <STX>1H|\^&||Sofia^29000021|||||P|1.15.2|20230829093140<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|||||20230829093015<CR><ETX>77<CR><LF>  
 LIS: <ACK>  
 Sofia 2: <STX>5L|1|N<CR><ETX>08<CR><LF>  
 LIS: <ACK>  
 Sofia 2: <EOT>

#### 4.2.9 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|1.15.2|20230829093140<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|||||20230829093015<CR><ETX>9E<CR><LF>  
 LIS: <ACK>  
 Sofia 2: <STX>6R|2|^ ^^Flu B|negative|||||F|||||20230829093015<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|1.15.2|20230829093142<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||||20230829092012<CR><ETX>A0<CR><LF>  
 LIS: <ACK>  
 Sofia 2: <STX>6R|2|^^^Flu B|negative||||F||||20230829092012<CR><ETX>A3<CR><LF>  
 LIS: <ACK>  
 Sofia 2: <STX>7L|1|N<CR><ETX>0A<CR><LF>  
 LIS: <ACK>  
 Sofia 2: <EOT>

## 5 The Bidirectional (POCT1a) Interface, Functional Description

When a test completes, the result is sent to the POC System. If the transmission fails, the result is saved 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
- Select the terminal send button in the lower right corner of the screen

After the connection has been established between the Sofia 2 and the POC System, a conversation starts with the Hello message and ends with the Terminate message. During the conversation, Sofia 2 and the LIS send messages to each other. Messages are always acknowledged by the other conversation participant. Messages are in xml format.

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

A communication session (conversation) is always initiated by the Sofia.

The conversation has two phases:

### 1. Introduction.

See below a successful introduction sequence:

Sofia 2	LIS
HEL The Sofia 2 initiates the conversation	
	ACK.R01
DST.R01 The Sofia 2 sends its status to the LIS (always 0 not transmitted results)	
	ACK.R01
	DTV.R02 Set time
ACK.R01 Sofia 2 sets the current time/date as sent by the DTV.R02 message	
	OPL.R01 Send Complete Operator List
ACK.R01 Sofia 2 deletes the User DB, inserts the default supervisor, and adds the operator list as sent by the OPL.R01 messages	
	EOT.R01 End Operator List
	DTV.R01

Sofia 2	LIS
	Start continuous.
ACK.R01 The Sofia 2 switches to LIS continuous phase.	

The introduction sequence starts if the Sofia 2 intends to send results.

Note that the Sofia 2 always declares a value of 0 not-transmitted results during the introduction and then switches to continuous mode.

## 2. The Continuous Phase.

During this phase the Sofia 2 will transmit, without any request from the POC System, new measurement results, or results stored in the Sofia 2.

Sofia 2	LIS
OBS.R01 The Sofia 2 sends a new/stored patient result to the POC System.	
	ACK.R01
OBS.R02 The Sofia 2 sends a new/stored non-patient result to the POC System.	
	ACK.R01
...	
	...
END.R01 The Sofia 2 ends the current conversation.	
	ACK.R01

The continuous phase will be terminated by any of the conversation participants by sending a termination message.

The Sofia 2 will send a termination message if the sending of the result/results is finished.

An Error Ack message is sent by the Sofia 2, if it gets invalid data. If the Sofia 2 receives an "error ack", it resends the message 3 times. If this also ends up in an error ack message:

- it sends a termination message and the conversation ends during the introduction phase.
- it does not change state during the continuous phase.

If any unexpected message is received by the Sofia 2, it transmits an ESC and an END message and disconnects from the LIS.

## 5.1 The Introduction Phase

The Introduction message phase is made up of the following xml messages.

Xml-Header	Always: <?xml version="1.0" encoding="UTF-8"?>
HEL.R01	Hello Message
ACK.R01	Acknowledgement Message
DST.R01	Device Status Message
DTV.R02	Complex Directive Message
OPL.R01	Operator List Message
EOT.R01	End of Topic Message (at the end of the Operator List topic)
DTV.R01	Basic Directive Message

Each of these message segments contain fields of data defined by the POCT1-A2 standard. The fields listed below are mandatory and sent. In the following tables defining the message segments, a description and example of each data field is presented.

### 5.1.1 HEL.R01 – Hello Message

Field	Description	Example
HDR.control_id	A string guaranteed to uniquely identify this message throughout the conversation. Sofia 2 implements this as an integer value.	"00001"
HDR.version_id	Version ID	Always: "POCT1"
HDR.creation_dttm	Sofia 2 date and time when the message was sent.	"2024-08-29T12:23:08+00:00"
DEV.device_id	Sofia 2 MAC Address	"00:20:4a:be:cf:a5"
DEV.serial_id	Sofia 2 Serial Number	"29028459"
DEV.manufacturer_name	The Sofia 2's corporate name.	Always: "QUIDEL"
DEV.hw_version	The version number for the Sofia 2 hardware.	"1.0"
DEV.sw_version	The version number for the Sofia 2 software.	"1.15.2"
DEV.device_name	The model name for the Sofia 2.	Always: "Sofia"
DCP.application_timeout	Sofia 2 application timeout in seconds.	Always: "100"
DSC.connection_profile_cd	CIC messaging profile that Sofia 2 supports.	Always: "CS"
DSC.topics_supported_cd	The message topics (beyond the minimum) supported.	Always: "DTV"
DSC.topics_supported_cd	The message topics (beyond the minimum) supported.	Always: "OP_LST_I"
DSC.directives_supported_cd	A Directive command that Sofia 2 supports.	Always: "SET_TIME"
DSC.directives_supported_cd	A Directive command that Sofia 2 supports.	Always: "START_CONTINUOUS"
DSC.max_message_sz	The max size message (in bytes) that Sofia can handle.	Always: "1000"

HEL.R01 Example

```
<?xml version="1.0" encoding="UTF-8"?>
<HEL.R01>
  <HDR>
    <HDR.control_id V="00001"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2023-08-29T12:23:08+00:00"/>
  </HDR>
  <DEV>
    <DEV.device_id V="00:20:4a:be:cf:a5"/>
    <DEV.serial_id V="29028459"/>
    <DEV.manufacturer_name V="QUIDEL"/>
    <DEV.hw_version V="1.0"/>
    <DEV.sw_version V="1.15.2"/>
    <DEV.device_name V="Sofia"/>
  <DCP>
    <DCP.application_timeout V="100"/>
  </DCP>
</HEL.R01>
```

```

    <DSC>
      <DSC.connection_profile_cd V="CS"/>
      <DSC.topics_supported_cd V="DTV"/>
      <DSC.topics_supported_cd V="OP_LST_I"/>
      <DSC.directives_supported_cd V="SET_TIME"/>
      <DSC.directives_supported_cd V="START_CONTINUOUS"/>
      <DSC.max_message_sz V="1000"/>
    </DSC>
  </DEV>
</HEL.R01>

```

### 5.1.2 ACK.R01 – Acknowledgement Message

Field	Description	Example
HDR.control_id	A string guaranteed to uniquely identify this message throughout the conversation.	"4011"
HDR.version_id	Version ID	Always: "POCT1"
HDR.creation_dttm	LIS date and time when the message was sent.	"2023-08-29T12:23:10+00:00"
ACK.type_id	A code indicating whether the associated message was accepted (AA), in error (AE) or was rejected (AE).	"AA"
ACK.control_id	The control ID of the message that this message is in acknowledgement of.	"00001"

#### ACK.R01 Example

```

<?xml version="1.0" encoding="UTF-8"?>
<ACK.R01>
  <HDR>
    <HDR.control_id V="4011"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2020-09-18T15:23:18+00:00"/>
  </HDR>
  <ACK>
    <ACK.type_id V="AA"/>
    <ACK.control_id V="00001"/>
  </ACK>
</ACK.R01>

```

### 5.1.3 DST.R01 – Device Status Message

Field	Description	Example
HDR.control_id	A string guaranteed to uniquely identify this message throughout the conversation.	"00002"
HDR.version_id	Version ID	Always: "POCT1"
HDR.creation_dttm	Sofia 2 date and time when the message was sent.	"2023-08-29T12:23:15+00:00"
DST.status_dttm	The time from the Sofia 2 that this status was observed.	"2023-08-29T12:23:14+00:00"
DST.new_observations_qty	The number of observations that Sofia 2 has to report. In Introduction, this value is always 0.	Always: "0"
DST.condition_cd	The current level of readiness of the Sofia.	Always: "R"

#### DST.R01 Example

```

<?xml version="1.0" encoding="UTF-8"?>

```



```

<DST.R01>
  <HDR>
    <HDR.control_id V="00002" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2023-08-29T12:23:15+00:00" />
  </HDR>
  <DST>
    <DST.status_dttm V="2023-08-29T12:23:14+00:00" />
    <DST.new_observations_qty V="0" />
    <DST.condition_cd V="R" />
  </DST>
</DST.R01>

```

#### 5.1.4 DTV.R02 – Complex Directive Message

Field	Description	Example
HDR.control_id	A string guaranteed to uniquely identify this message throughout the conversation.	"4013"
HDR.version_id	Version ID	Always: "POCT1"
HDR.creation_dttm	LIS date and time when the message was sent.	"2023-08-29T12:24:15+00:00"
DTV.command_cd	The Directive commands that Sofia 2 supports to set the date and time, "SET_TIME".	Always: "SET_TIME"
TM.dttm	Observation Reviewer date-time stamp, conforming to the TS data type rules. Since Sofia 2 does not address time zone, the time zone offset is always "+00:00".	"2023-08-29T12:24:15+00:00"

#### DTV.R02 Example

```

<?xml version="1.0" encoding="UTF-8"?>
  <DTV.R02>
    <HDR>
      <HDR.control_id V="4013" />
      <HDR.version_id V="POCT1" />
      <HDR.creation_dttm V="2023-08-29T12:24:15+00:00"/>
    </HDR>
    <DTV>
      <DTV.command_cd V="SET_TIME" />
    </DTV>
    <TM>
      <TM.dttm V="2023-08-29T12:24:15+00:00" />
    </TM>
  </DTV.R02>

```

#### 5.1.5 OPL.R01 – Operator List Message

Field	Description	Example
HDR.control_id	A string guaranteed to uniquely identify this message throughout the conversation.	"4014"
HDR.version_id	Version ID	Always: "POCT1"
HDR.creation_dttm	Sofia 2 date and time when the message was sent.	"2023-08-29T12:24:15+00:00"
OPR.operator_id	The unique User ID for the operator.	"5010"
OPR.name	The name operator name associated with the User ID.	"Franklin Witt"

Field	Description	Example
ACC.method_cd	Sofia operators are granted permission to use all methods.	Always: "ALL"
ACC.permission_level_cd	The code that notates the Sofia 2 access level of the operator. 1 = SUPERVISOR, 4 = USER.	"1"
NTE.text	The Sofia value for operator to transmit as the Surveillance ID for Virena.	"20"

#### OPL.R01 Example

```
<?xml version="1.0" encoding="UTF-8"?>
<OPL.R01>
  <HDR>
    <HDR.control_id V="4014" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2023-08-29T12:24:15+00:00"/>
  </HDR>
  <OPR>
    <OPR.operator_id V="5010"/>
    <OPR.name V="Franklin Witt"/>
    <ACC>
      <ACC.method_cd V="ALL"/>
      <ACC.permission_level_cd V="1"/>
    </ACC>
    <NTE>
      <NTE.text V="20"/>
    </NTE>
  </OPR>
</OPL.R01>
```

#### 5.1.6 EOT.R01 – End of Topic Message (at the end of the Operator List topic)

Field	Description	Example
HDR.control_id	A string guaranteed to uniquely identify this message throughout the conversation.	"4015"
HDR.version_id	Version ID	Always: "POCT1"
HDR.creation_dttm	Sofia date and time when the message was sent.	"2023-08-29T12:24:15+00:00"
EOT.topic_cd	The code for the Topic that has just been completed.	Always: "OPL"

#### EOT.R01 Example

```
<?xml version="1.0" encoding="UTF-8"?>
<EOT.R01>
  <HDR>
    <HDR.control_id V="4015" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2023-08-29T12:24:23+00:00" />
  </HDR>
  <EOT>
    <EOT.topic_cd V="OPL" />
  </EOT>
</EOT.R01>
```

### 5.1.7 DTV.R01 – Basic Directive Message

Field	Description	Example
HDR.control_id	A string guaranteed to uniquely identify this message throughout the conversation.	"4016"
HDR.version_id	Version ID	Always: "POCT1"
HDR.creation_dttm	Sofia date and time when the message was sent.	"2023-08-29T12:24:15+00:00"
DTV.command_cd	The Directive commands that Sofia supports	"START_CONTINUOUS"

#### DTV.R01 Example

```
<?xml version="1.0" encoding="UTF-8"?>
  <DTV.R01>
    <HDR>
      <HDR.control_id V="4016" />
      <HDR.version_id V="POCT1" />
      <HDR.creation_dttm V="2023-08-29T12:34:00+00:00" />
    </HDR>
    <DTV>
      <DTV.command_cd V="START_CONTINUOUS" />
    </DTV>
  </DTV.R01>
```

## 5.2 The Continuous Mode

The Continuous message phase is made up of the following xml messages.

Xml-Header    Always: <?xml version="1.0" encoding="UTF-8"?>  
 OBS.R01        Patient Test Observation Message  
 OBS.R02        Non-Patient Test Observation Message  
 ACK.R01        Acknowledgement Message  
 END.R01        Terminate Message

Each of these message segments contain fields of data defined by the POCT1-A2 standard. The fields listed below are mandatory and sent. In the following tables defining the message segments, a description and example of each data field is presented.

### 5.2.1 OBS.R01 – Patient Test Observation Message

Field	Description	Example
HDR.control_id	A string guaranteed to uniquely identify this message throughout the conversation. Sofia 2 implements this as an integer value.	"00027"
HDR.version_id	Version ID	Always: "POCT1"
HDR.creation_dttm	Sofia 2 date and time when the message was sent.	"2023-08-29T12:24:15+00:00"
SVC.role_cd	For a patient test, this value is always "OBS".	Always: "OBS"
SVC.observation_dttm	Sofia 2 date and time when the test completed.	"2023-08-29T12:24:10+00:00"
SVC.reason_cd	Is the observation NEW or RES for resend?	"NEW"
PT.patient_id	The Sofia 2 patient id entry.	"Y B1232"

Field	Description	Example
OBS.observation_id	The analyte name from the Test Type File.	"Flu A"
OBS.qualitative_value	The qualitative result value from Sofia 2.	"negative"
OBS.method_cd	Sofia 2 value determination, Measured "M", not Calculated "C".	Always: "M"
OBS.value	Select tests may send measured values in addition to Pos / Neg results and send them as additional OBS.observations. See example in section 5.3.8	"<OBS.value U="None" V="11.78" />"
OBS.concentration_value	For quantitative tests only. The concentration value.	Values like "99.9" or "<1.0" See examples in 5.3.7
OPR.operator_id	Sofia 2 "User ID"	"5010"
OPR.name	Name associated with the User ID	"Franklin Witt"
ORD.universal_service_id	The assay long name from the Test Type File.	"Sofia Flu A+B"
ORD.order_id	Order Number from the Sofia 2.	"1232Y B"
RGT.name	The assay long name from the Test Type File.	"Sofia Flu A+B"
RGT.lot_number	The cassette lot number.	"140403"
RGT.expiration_date	The cassette expiration date in format YYYY-MM-DD.	"2024-01-17"

#### OBS.R01 Example

```
<?xml version="1.0" encoding="UTF-8"?>
```

```
<OBS.R01>
```

```
  <HDR>
```

```
    <HDR.control_id V="00027"/>
```

```
    <HDR.version_id V="POCT1"/>
```

```
    <HDR.creation_dttm V="2023-08-29T12:24:15+00:00"/>
```

```
  </HDR>
```

```
  <SVC>
```

```
    <SVC.role_cd V="OBS"/>
```

```
    <SVC.observation_dttm V="2023-08-29T12:24:10+00:00"/>
```

```
    <SVC.reason_cd V="NEW"/>
```

```
  <PT>
```

```
    <PT.patient_id V="Y B1232"/>
```

```
    <OBS>
```

```
      <OBS.observation_id V="Flu A" SN="QUIDEL"/>
```

```
      <OBS.qualitative_value V="negative"/>
```

```
      <OBS.method_cd V="M"/>
```

```
    </OBS>
```

```
    <OBS>
```

```
      <OBS.observation_id V="Flu B" SN="QUIDEL"/>
```

```
      <OBS.qualitative_value V="negative"/>
```

```
      <OBS.method_cd V="M"/>
```

```
    </OBS>
```

```
  </PT>
```

```
  <OPR>
```

```
    <OPR.operator_id V="5010"/>
```

```
    <OPR.name V="Franklin Witt"/>
```

```
  </OPR>
```

```
  <ORD>
```

```
    <ORD.universal_service_id V="Sofia Flu A+B"/>
```

```
    <ORD.order_id V="1232Y B" SN="QUIDEL"/>
```

```
  </ORD>
```

```
</RGT>
```

```

    <RGT.name V="Sofia Flu A+B"/>
    <RGT.lot_number V="140403"/>
    <RGT.expiration_date V="2024-01-17"/>
  </RGT>
</SVC>
</OBS.R01>

```

### 5.2.2 OBS.R02 – Non-Patient Test Observation Message

Field	Description	Example
HDR.control_id	A string guaranteed to uniquely identify this message throughout the conversation. Sofia implements this as an integer value.	"00027"
HDR.version_id	Version ID	Always: "POCT1"
HDR.creation_dttm	Sofia date and time when the message was sent.	"2023-08-29T12:27:15+00:00"
SVC.role_cd	For a Calibration test "CAL" and for a QC test "LQC".	"CAL"
SVC.observation_dttm	Sofia date and time when the test completed.	"2023-08-29T12:27:10+00:00"
SVC.reason_cd	The observation is NEW or RES for resend.	"NEW"
CTC.name	For a Calibration test, "Calibration Result". For a QC test, "QC Result".	"Calibration Result"
CTC.lot_number	The cassette lot number for a Calibration test. The kit lot number for a QC test.	"103533"
CTC.expiration_date	The expiration date of the QC kit in format YYYY-MM-DD.	"2020-06-30"
CTC.level_cd	For a QC test either "Positive Control" or "Negative Control". For a Calibration this field is omitted.	"Positive Control"
OBS.observation_id	The analyte name from the Test Type File.	"Overall Result"
OBS.qualitative_value	The qualitative result value from Sofia.	"passed" or "failed" for Calibration and QC results.
OBS.method_cd	Sofia value determination, Measured "M", not Calculated "C".	Always: "M"
OPR.operator_id	Sofia 2 "User ID"	"5010"
OPR.name	The name associated with the User ID.	"Franklin Witt"
RGT.name	For a QC test, the assay long name from the Test Type File.	"Sofia Flu A+B"
RGT.lot_number	For a QC test, the cassette lot number.	"140403"
RGT.expiration_date	For a QC test, the cassette expiration date in format YYYY-MM-DD.	"2024-01-17"

#### OBS.R02 Example

```

<?xml version="1.0" encoding="UTF-8"?>
<OBS.R02>
  <HDR>
    <HDR.control_id V="00018"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2023-08-29T12:27:15+00:00"/>
  </HDR>
  <SVC>
    <SVC.role_cd V="OBS"/>

```

```

<SVC.observation_dttm V="2023-08-29T12:27:10+00:00"/>
<SVC.reason_cd V="RES"/>
<CTC>
  <CTC.name V="Calibration Result"/>
  <CTC.lot_number V="103533"/>
</CTC>
  <OBS>
    <OBS.observation_id V="Overall Result" SN="QUIDEL"/>
    <OBS.qualitative_value V="passed"/>
    <OBS.method_cd V="M"/>
  </OBS>
</CTC>
<OPR>
  <OPR.operator_id V="5010"/>
  <OPR.name V="Franklin Witt" />
</OPR>
</SVC>
</OBS.R01>

```

### 5.2.3 ACK.R01 – Acknowledgement Message

Field	Description	Example
HDR.control_id	A string guaranteed to uniquely identify this message throughout the conversation.	"4011"
HDR.version_id	Version ID	Always: "POCT1"
HDR.creation_dttm	Sofia date and time when the message was sent.	"2023-08-29T12:45:15+00:00"
ACK.type_id	A code indicating whether the associated message was accepted (AA), in error (AE) or was rejected (AE).	"AA"
ACK.control_id	The control ID of the message that this message is in acknowledgement of.	"1"

#### ACK.R01 Example

```

<?xml version="1.0" encoding="UTF-8"?>
<ACK.R01>
  <HDR>
    <HDR.control_id V="00019"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2023-08-29T12:45:15+00:00"/>
  </HDR>
  <ACK>
    <ACK.type_id V="AA"/>
    <ACK.control_id V="4310"/>
  </ACK>
</ACK.R01>

```

### 5.2.4 END.R01 – Terminate Message

Field	Description	Example
HDR.control_id	A string guaranteed to uniquely identify this message throughout the conversation.	"00002"
HDR.version_id	Version ID	Always: "POCT1"
HDR.creation_dttm	Sofia date and time when the message was sent.	"2023-08-29T12:55:25+00:00"

TRM.reason_cd	The reason for terminating the conversation.	Always: "USR"
---------------	--	---------------

DST.R01 Example

```
<?xml version="1.0" encoding="UTF-8"?>
<END.R01>
  <HDR>
    <HDR.control_id V="00020" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2023-08-29T12:55:25+00:00" />
  </HDR>
  <TRM>
    <TRM.reason_cd V="USR" />
  </TRM>
</END.R01>
```

## 5.3 POCT1a Message Examples

### 5.3.1 Example A: Sofia initiating the conversation with a POC System.

Sofia: <?xml version="1.0" encoding="UTF-8"?>

```
<HEL.R01>
  <HDR>
    <HDR.control_id V="00001"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2023-08-29T12:24:15+00:00"/>
  </HDR>
  <DEV>
    <DEV.device_id V="00:20:4a:be:cf:a5"/>
    <DEV.serial_id V="29028459"/>
    <DEV.manufacturer_name V="QUIDEL"/>
    <DEV.hw_version V="1.0"/>
    <DEV.sw_version V="1.15.2"/>
    <DEV.device_name V="Sofia"/>
    <DCP>
      <DCP.application_timeout V="100"/>
    </DCP>
    <DSC>
      <DSC.connection_profile_cd V="CS"/>
      <DSC.topics_supported_cd V="DTV"/>
      <DSC.topics_supported_cd V="OP_LST_I"/>
      <DSC.directives_supported_cd V="SET_TIME"/>
      <DSC.directives_supported_cd V="START_CONTINUOUS"/>
      <DSC.max_message_sz V="1000"/>
    </DSC>
  </DEV>
</HEL.R01>
```

LIS: <?xml version="1.0" encoding="UTF-8"?>

```
<ACK.R01>
  <HDR>
    <HDR.control_id V="4011"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2023-08-29T12:24:17+00:00"/>
  </HDR>
  <ACK>
    <ACK.type_id V="AA"/>
    <ACK.control_id V="00001"/>
  </ACK>
</ACK.R01>
```

### 5.3.2 Example B: Sofia sending status to a POC System.

Sofia: <?xml version="1.0" encoding="UTF-8"?>

```

<DST.R01>
  <HDR>
    <HDR.control_id V="00002" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2023-08-29T12:24:15+00:00" />
  </HDR>
  <DST>
    <DST.status_dttm V="2023-08-29T12:24:15+00:00" />
    <DST.new_observations_qty V="0" />
    <DST.condition_cd V="R" />
  </DST>
</DST.R01>

```

```

LIS:  <?xml version="1.0" encoding="UTF-8"?>
<ACK.R01>
  <HDR>
    <HDR.control_id V="4012"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2023-08-29T12:24:16+00:00"/>
  </HDR>
  <ACK>
    <ACK.type_id V="AA"/>
    <ACK.control_id V="00002"/>
  </ACK>
</ACK.R01>

```

### 5.3.3 Example C: POC System sending DTV.R02 Set Time command to Sofia.

```

LIS:  <?xml version="1.0" encoding="UTF-8"?>
<DTV.R02>
  <HDR>
    <HDR.control_id V="4012" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2023-08-29T12:45:15+00:00" />
  </HDR>
  <DTV>
    <DTV.command_cd V="SET_TIME" />
  </DTV>
  <TM>
    <TM.dttm V="2023-08-29T12:45:15+00:00" />
  </TM>
</DTV.R02>

```

```

Sofia: <?xml version="1.0" encoding="UTF-8"?>
<ACK.R01>
  <HDR>
    <HDR.control_id V="00004"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2023-08-29T12:45:16+00:00"/>
  </HDR>
  <ACK>
    <ACK.type_cd V="AA"/>
    <ACK.ack_control_id V="4012"/>
  </ACK>
</ACK.R01>

```

### 5.3.4 Example D: POC System OPL.R01 Send Operator List of 2 Users and 1 Supervisor to Sofia.

```

LIS:  <?xml version="1.0" encoding="UTF-8"?>
<OPL.R01>
  <HDR>
    <HDR.control_id V="4013"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2023-08-29T12:45:25+00:00"/>
  </HDR>

```



```

</HDR>
<OPR>
  <OPR.operator_id V="5010"/>
  <OPR.name V="Franklin Witt"/>
  <ACC>
    <ACC.method_cd V="ALL"/>
    <ACC.permission_level_cd V="1"/>
  </ACC>
  <NTE>
    <NTE.text V="10"/>
  </NTE>
</OPR>
<OPR>
  <OPR.operator_id V="5001"/>
  <OPR.name V="Majors"/>
  <ACC>
    <ACC.method_cd V="ALL"/>
    <ACC.permission_level_cd V="4"/>
  </ACC>
  <NTE>
    <NTE.text V="11"/>
  </NTE>
</OPR>
<OPR>
  <OPR.operator_id V="5002"/>
  <OPR.name V="Snowden"/>
  <ACC>
    <ACC.method_cd V="ALL"/>
    <ACC.permission_level_cd V="4"/>
  </ACC>
  <NTE>
    <NTE.text V="12"/>
  </NTE>
</OPR>
</OPL.R01>

```

Sofia: <?xml version="1.0" encoding="UTF-8"?>

```

<ACK.R01>
  <HDR>
    <HDR.control_id V="00005" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2023-08-29T12:45:27+00:00" />
  </HDR>
  <ACK>
    <ACK.type_cd V="AA" />
    <ACK.ack_control_id V="4013" />
    <ACK.error_detail_cd V="0" />
  </ACK>
</ACK.R01>

```

LIS: <?xml version="1.0" encoding="UTF-8"?>

```

<EOT.R01>
  <HDR>
    <HDR.control_id V="4014"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2023-08-29T12:45:28+00:00"/>
  </HDR>
  <EOT>
    <EOT.topic_cd V="OPL"/>
  </EOT>
</EOT.R01>

```

### 5.3.5 Example E: LIS DTV.R01 Start Continuous command to Sofia.

```
LIS:  <?xml version="1.0" encoding="UTF-8"?>
      <DTV.R01>
        <HDR>
          <HDR.control_id V="4015"/>
          <HDR.version_id V="POCT1"/>
          <HDR.creation_dttm V=" 2023-08-29T12:53:10+00:00"/>
        </HDR>
        <DTV>
          <DTV.command_cd V="START_CONTINUOUS"/>
        </DTV>
      </DTV.R01>
```

```
Sofia: <?xml version="1.0" encoding="UTF-8"?>
       <ACK.R01>
         <HDR>
           <HDR.control_id V="00006" />
           <HDR.version_id V="POCT1" />
           <HDR.creation_dttm V=" 2023-08-29T12:53:12+00:00" />
         </HDR>
         <ACK>
           <ACK.type_cd V="AA" />
           <ACK.ack_control_id V="4015" />
           <ACK.error_detail_cd V="0" />
         </ACK>
       </ACK.R01>
```

### 5.3.6 Example F: OBS.R01 patient result and OBS.R02 calibration result to a POC System.

```
Sofia: <?xml version="1.0" encoding="UTF-8"?>
       <OBS.R01>
         <HDR>
           <HDR.control_id V="00007"/>
           <HDR.version_id V="POCT1"/>
           <HDR.creation_dttm V=" 2023-08-29T12:45:25+00:00"/>
         </HDR>
         <SVC>
           <SVC.role_cd V="OBS"/>
           <SVC.observation_dttm V=" 2023-08-29T12:45:10+00:00"/>
           <SVC.reason_cd V="RES"/>
           <PT>
             <PT.patient_id V="218223"/>
             <OBS>
               <OBS.observation_id V="IgM" SN="QUIDEL"/>
               <OBS.qualitative_value V="negative"/>
               <OBS.method_cd V="M"/>
             </OBS>
             <OBS>
               <OBS.observation_id V="IgG" SN="QUIDEL"/>
               <OBS.qualitative_value V="negative"/>
               <OBS.method_cd V="M"/>
             </OBS>
           </PT>
           <OPR>
             <OPR.operator_id V="1234"/>
             <OPR.name V="Supervisor"/>
           </OPR>
           <ORD>
             <ORD.universal_service_id V="Sofia Lyme"/>
             <ORD.order_id V="225" SN="QUIDEL"/>
           </ORD>
         </SVC>
       </OBS.R01>
```

```

        <RGT.name V="Sofia Lyme"/>
        <RGT.lot_number V="129826"/>
        <RGT.expiration_date V="2024-01-17"/>
    </RGT>
</SVC>
</OBS.R01>

LIS: <?xml version="1.0" encoding="UTF-8"?>
<ACK.R01>
    <HDR>
        <HDR.control_id V="4216"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2023-08-29T12:45:27+00:00"/>
    </HDR>
    <ACK>
        <ACK.type_cd V="AA"/>
        <ACK.ack_control_id V="00007"/>
    </ACK>
</ACK.R01>

Sofia: <?xml version="1.0" encoding="UTF-8"?>
<OBS.R02>
    <HDR>
        <HDR.control_id V="00008"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2023-08-29T12:45:28+00:00"/>
    </HDR>
    <SVC>
        <SVC.role_cd V="CAL"/>
        <SVC.observation_dttm V="2023-08-29T12:05:15+00:00"/>
        <SVC.reason_cd V="RES"/>
    <CTC>
        <CTC.name V="Calibration Result"/>
        <CTC.lot_number V="103324"/>
    <OBS>
        <OBS.observation_id V="Overall Result" SN="QUIDEL"/>
        <OBS.qualitative_value V="passed"/>
        <OBS.method_cd V="M"/>
    </OBS>
</CTC>
<OPR>
    <OPR.operator_id V="5010"/>
    <OPR.name V="Franklin Witt"/>
</OPR>
</SVC>
</OBS.R02>

LIS: <?xml version="1.0" encoding="UTF-8"?>
<ACK.R01>
    <HDR>
        <HDR.control_id V="4217"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2023-08-29T12:45:30+00:00"/>
    </HDR>
    <ACK>
        <ACK.type_cd V="AA"/>
        <ACK.ack_control_id V="00008"/>
    </ACK>
</ACK.R01>

Sofia: <?xml version="1.0" encoding="UTF-8"?>
<END.R01>
    <HDR>

```

```

        <HDR.control_id V="00009" />
        <HDR.version_id V="POCT1" />
        <HDR.creation_dttm V="2023-08-29T12:45:32+00:00" />
    </HDR>
    <TRM>
        <TRM.reason_cd V="USR" />
    </TRM>
</END.R01>

```

```

LIS: <?xml version="1.0" encoding="UTF-8"?>
    <ACK.R01>
        <HDR>
            <HDR.control_id V="4218"/>
            <HDR.version_id V="POCT1"/>
            <HDR.creation_dttm V="2023-08-29T12:45:33+00:00"/>
        </HDR>
        <ACK>
            <ACK.type_cd V="AA"/>
            <ACK.ack_control_id V="00009"/>
        </ACK>
    </ACK.R01>

```

### 5.3.7 Example G: OBS.R01 transmission of Quantitative Results from the C. difficile assay

....

```

<OBS.R01>
    <HDR>
        <HDR.control_id V="00016" />
        <HDR.version_id V="POCT1" />
        <HDR.creation_dttm V="2023-08-29T12:24:15+00:00" />
    </HDR>
    <SVC>
        <SVC.role_cd V="OBS" />
        <SVC.observation_dttm V="2023-08-29T12:24:11+00:00" />
        <SVC.reason_cd V="NEW" />
        <PT>
            <PT.patient_id V="" />
        <OBS>
            <OBS.observation_id SN="QUIDEL" V="GDH" />
            <OBS.qualitative_value V="positive" />
            <OBS.method_cd V="M" />
            <OBS.concentration V="99.9" />
            <OBS.units V="99.9" />
        </OBS>
        <OBS>
            <OBS.observation_id SN="QUIDEL" V="Tox A/B" />
            <OBS.qualitative_value V="positive" />
            <OBS.method_cd V="M" />
            <OBS.concentration V="&lt;1.0/78.3" />
            <OBS.units V="&lt;1.0/78.3" />
        </OBS>
    </PT>
    <OPR>
        <OPR.operator_id V="9872" />
        <OPR.name V="Wally Nitman" />
    </OPR>
    <ORD>
        <ORD.universal_service_id V="C. Diff" />
    </ORD>
    <RGT>
        <RGT.name V="C. Diff" />
        <RGT.lot_number V="152998" />
        <RGT.expiration_date V="2024-01-17" />
    </RGT>

```

```
</SVC>
</OBS.R01>
```

**Note:** See *Table 1*, Page 9 for information on the characteristics of the values shown here in 5.3.7. The OBS.Concentration and OBS.units fields for this C.difficile transmission example. The "less than" character "<" is escaped in the HTML format as "&lt;" in accordance with HTML rules for reserved characters.

### 5.3.8 Example H: OBS.R01 transmission of Results from the SARS IgG assay

```
....
<OBS.R01>
  <HDR>
    <HDR.control_id V="00021"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2023-09-12T18:19:46+00:00"/>
  </HDR>
  <SVC>
    <SVC.role_cd V="OBS"/>
    <SVC.observation_dttm V="2022-09-02T17:11:56+00:00"/>
    <SVC.reason_cd V="RES"/>
    <PT>
      <PT.patient_id V="NITMAN"/>
      <OBS>
        <OBS.observation_id SN="QUIDEL" V="N"/>
        <OBS.qualitative_value V="negative"/>
        <OBS.method_cd V="M"/>
      </OBS>
      <OBS>
        <OBS.observation_id SN="QUIDEL" V="S1"/>
        <OBS.qualitative_value V="positive"/>
        <OBS.method_cd V="M"/>
      </OBS>
      <OBS>
        <OBS.observation_id SN="QUIDEL" V="S2"/>
        <OBS.qualitative_value V="negative"/>
        <OBS.method_cd V="M"/>
      </OBS>
      <OBS>
        <OBS.observation_id SN="QUIDEL" V="N_VAL"/>
        <OBS.value U="None" V="0.42"/>
        <OBS.method_cd V="M"/>
      </OBS>
      <OBS>
        <OBS.observation_id SN="QUIDEL" V="S1_VAL"/>
        <OBS.value U="None" V="11.78"/>
        <OBS.method_cd V="M"/>
      </OBS>
      <OBS>
        <OBS.observation_id SN="QUIDEL" V="S2_VAL"/>
        <OBS.value U="None" V="0.96"/>
        <OBS.method_cd V="M"/>
      </OBS>
    </PT>
    <OPR>
      <OPR.operator_id V="1234"/>
      <OPR.name V="Penelope"/>
    </OPR>
    <ORD>
      <ORD.universal_service_id V="SARS IgG"/>
    </ORD>
    <RGT>
      <RGT.name V="SARS IgG"/>
      <RGT.lot_number V="210197"/>
    </RGT>
  </SVC>
</OBS.R01>
```

```

</RGT.expiration_date V="2023-05-07"/>
</RGT>
</SVC>
</OBS.R01>

```

## 6 Result Assay Panel Definition Table

The table below outlines what assay and analyte names are sent by the LIS interfaces. The text in the "short name" column is the assay name. The text in the "analyte name" column are the individual analyte names.

For ASTM, they assay name (short name) is sent on O-5. The analyte name is sent in R-3.4. For POCT1a, the assay name is sent as "ORD.universal\_service\_id" and also in "RGT.name". The analyte name is sent as "OBS.observation\_id".

Long Name	Short Name	Analyte Name	Lower Limit	Upper Limit	Scale	Obs Values
Sofia 2 Campylobacter	Campy	Campy				invalid, negative, positive
Sofia 2 Lyme	Lyme	IgG, IGM				invalid, negative, positive
Sofia 2 Lyme+ (Not available in the U.S.)	Lyme	IgM, IgG				invalid, negative, positive
Sofia 2 SARS Antigen	SARS	SARS				invalid, negative, positive
Sofia 2 SARS Plus	SARS+	SARS				invalid, negative, positive
Sofia 2 SARS-CoV-2 Antibody IgG (Not available in the U.S.)	SARS IgG	N, S1, S2				invalid, negative, positive
Sofia 2, C. difficile (Not available in the U.S.)	C.Diff	GDH, Toxin A, Toxin B	<1.0	99.9	signal/cutoff	invalid, negative, positive
Sofia Flu + SARS Antigen	Flu+SARS	SARS, Flu A, Flu B				invalid, negative, positive
Sofia Flu A+B	Flu A+B	Flu A, Flu B				invalid, negative, positive
Sofia Legionella	Legion	Legion				invalid, negative, positive
Sofia RSV	RSV	RSV				invalid, negative, positive
Sofia S. Pneumo (Not available in the U.S.)	S. Pneumo	S. Pneumo				invalid, negative, positive
Sofia Strep A+	Strep A+	Strep A+				invalid, negative, positive

## 7 QuidelOrtho Technical Support

If you have any questions regarding the use of this product or to report a problem, please contact QuidelOrtho Technical Support at 1.800.874.1517 (in the U.S.) or [technicalsupport@quidelortho.com](mailto:technicalsupport@quidelortho.com). If outside the U.S., further information can be obtained from your distributor, or directly from Quidel at one of the numbers listed below. Reference **quidelortho.com** to see more options for Support.

Country	Phone	E-Mail Address
Europe, Middle East and Africa	+353 (91) 412 474 (main) 0 1800 200441 (toll free)	<a href="mailto:emeatechnicalsupport@quidelortho.com">emeatechnicalsupport@quidelortho.com</a>
Austria	+43 316 231239	
Belgium	+32 (2) 793 0180	
France	0 (805) 371674	
Germany	+49 (0) 7154 1593912	
Netherlands	0 800 0224198	
Switzerland	0 800 554864	
United Kingdom	0 800 3688248	
Ireland	+353 (91) 412 474	
Italy	+39 (800) 620 549	
North America, Asia-Pacific, Latin America	858.552.1100	<a href="mailto:technicalsupport@quidelortho.com">technicalsupport@quidelortho.com</a>
Canada	437.266.1704 (main) 888.415.8764 (toll free)	<a href="mailto:technicalsupport@quidelortho.com">technicalsupport@quidelortho.com</a>
China	0400 920 9366 or +86 021 3217 8300	<a href="mailto:chinatechnicalservice@quidelortho.com">chinatechnicalservice@quidelortho.com</a>

You may also visit our website at [quidelortho.com](http://quidelortho.com) for information on QuidelOrtho's line of Rapid Diagnostics, Molecular Diagnostics, Cell Culture and Specialty Products (Bone Health and Autoimmune & Complement). Other product information available on our website includes CPT codes, CLSI procedure guides, SDS, and Package Inserts.

## 8 Release and Revision History

Revision	Change Summary
E Current Revision	This revision from the D revision of the Sofia 2 interface specification is applicable to Sofia 2 Firmware release 1.15.1 or greater. The Specification is updated to include detail in table 5.2.1 for the element OBS.value. This field contains a measured value that is sent with select tests that report a quantitative (positive / negative) result as well as a measured result. An example SARS IgG transmission is in section 5.3.8. In table 5.2.1, the attribute name "OBS.concentration" is now correct. In the prior release it was listed as "OBS.concentration_value".

Revision	Change Summary
D Prior Revision	This revision from the C revision of the Sofia 2 interface specification is applicable to Sofia 2 Firmware release 1.15.1 or greater. Sofia 2 may optionally send the Cassette Lot Number as a result segment via ASTM. See the example following section 4.1.5. For a quantitative test result only, Sofia will send test result characteristics that differ from qualitative results. Examples may be found in ASTM section 4.1.5 (R-4.2) and POCT1A section 5.2.7. Table 1 on page 9 has more detail on reporting qualitative results characteristics. POCT1a examples have been updated to show the correct detail for transmission of OPR.operator_ID and OPR.name data. Document has been reformatted to include a table of contents

Revision	Change Summary
C Prior Revision	This revision from B Revision of the Sofia 2 interface specification is applicable to Sofia 2 Firmware release 1.12.2x or greater. The "Result Assay Panel Definition Table" has been updated to include all the available Sofia 2 tests as of September 2022.

	<p>References to Wi-Fi added. Wi-Fi support became available with the release of 1.12 firmware. As of 1.12 firmware, data sent for the fields for Patient ID, Order ID and Site Name will no longer be truncated in the LIS transmission. As of this revision, the currently available firmware version is 1.14.2. Please update Sofia 2 to the most current revision of Firmware before interfacing. Sofia updates are available at <a href="http://www.MyQuidel.com">www.MyQuidel.com</a> or via Automatic Update if the instrument has firmware 1.12 or later. See <a href="https://connectme.quidel.com/docs/updates/">https://connectme.quidel.com/docs/updates/</a> for Information on Automatic Updates.</p>
--	---

Revision	Change Summary
B Prior Revision	<p>This revision from the original Sofia 2 interface specification is applicable to Sofia 2 Firmware release 1.12.2x or greater. New to this specification is the ability of Sofia 2 to communicate using the POCT1a standard. Sofia 2 prior to firmware release 1.12 does not support POCT1a communications. The "Result Assay Panel Definition Table", has been updated to include all the available Sofia 2 tests as of September 2021</p>

TB20299905EN00 (01/24)