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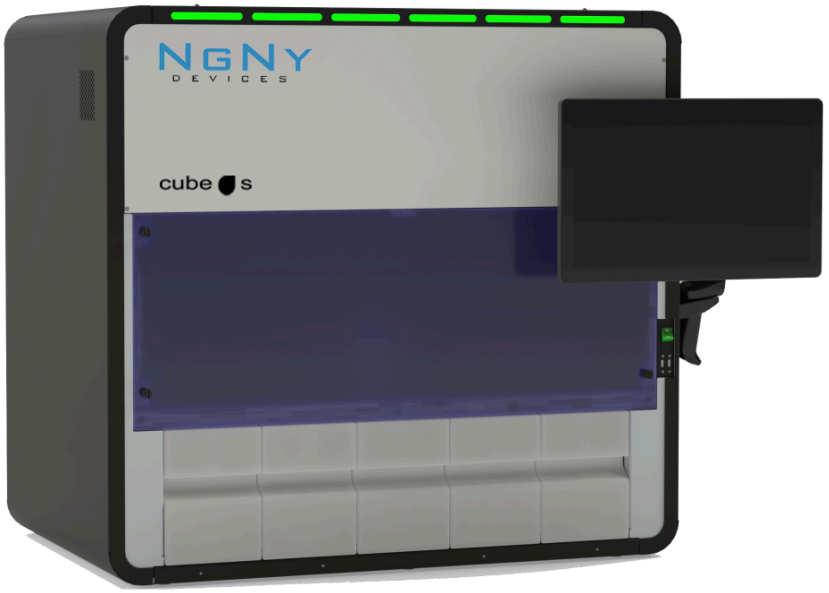
Service Manual: Technical Guide
LIS Communication Protocol



Original version

EN

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Document Versions

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Table of Contents

1. Prologue

This document is about the LIS Communication Protocol. This document is a product of NGNY Devices, SL (hereinafter “the manufacturer”).

Document Updates

The information and contents of this manual may be changed without notice. When a version of the application modifies the content of this manual, the manufacturer will publish a new version of this document in electronic format.

INFORMATION
This version of the *SM: LIS Communication Protocol* applies to software version 1.5.

Legal Information

Disclaimer

The information in this manual is meant to be read as a reference only, and it does not include or represent the warranty document of the product. Although this manual has been prepared with utmost care, the manufacturer is not liable for any loss or damage caused, or allegedly caused, directly or indirectly, in the event of non-performance of the instructions contained in this manual or the use of the software or hardware in a way different from that described in the labeling of the product. Should the operator perform any unauthorized work on the system, the warranty will be void.

Neither the manufacturer nor its subsidiaries assume any liability to the purchaser of this product or any third parties for damages, losses, costs or expenses incurred by the purchaser or third parties due to accident, misuse of the product or unapproved modifications, repairs or improvements to the instrument.

The system can only be used according to its intended use. Otherwise, the warranty will be void. In this case, the owner will assume all the risks and possible damages that may derive from the product.

The manufacturer assumes no liability for any errors, omissions or damages resulting from the use of the information contained in this manual.

Some events described in this manual might not be available in all products. There might be examples that do not apply to your device, please disregard them. For instance, there are examples that contain information about aliquots but, if your device does not perform aliquots, these examples can be ignored.

Trademarks

Throughout the manual, product names and registered trademarks are used for the sole purpose of identifying them. These products and trademarks are the exclusive property of their owners. If the trademark symbols are not included, it cannot be assumed that the name is an unregistered product name.

Illustrations

All images, especially screenshots and photographs, are intended only for illustration.

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Certifications

The system is designed and manufactured in accordance with the legal provisions and meets the requirements of the following standard certifications:

CE Compliance with the provisions of applicable EU directives

Manufacturer

The legal manufacturer of the system is NGNY Devices, SL, with address at:

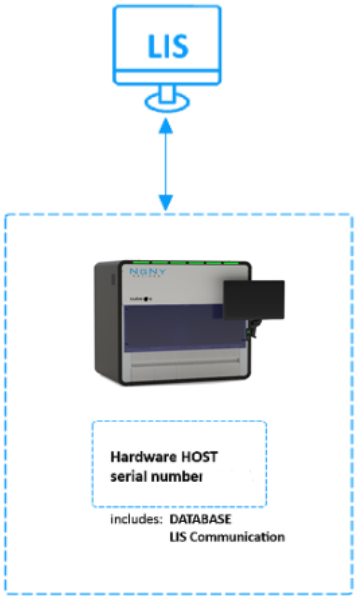
NGNY Devices, SL
Av. de Cornellà, 144
08950 Esplugues de Llobregat, Barcelona, Spain

2. Types of System Installation

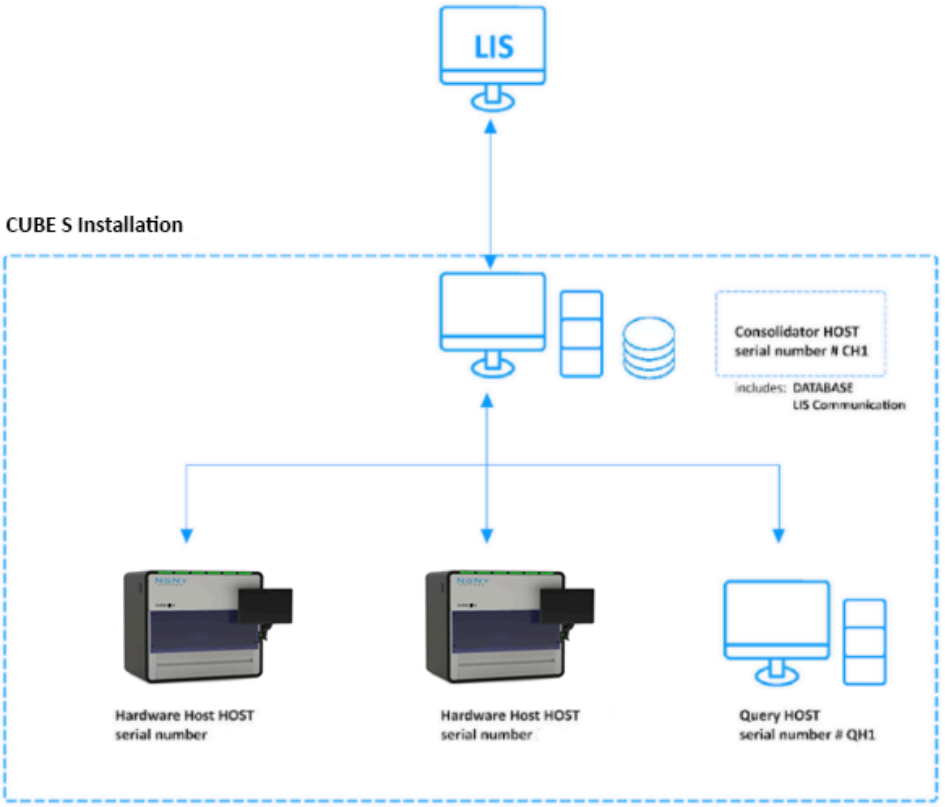
The system can be installed and configured depending on the needs of every lab. It can be a stand-alone installation, where only one machine deals with the samples arriving at the lab, or a multiple-system installation, where there is an internal network managed by the software of the system.

Regardless of the scenario, the interface with the LIS is centralized in one single host.

Stand-Alone Installation

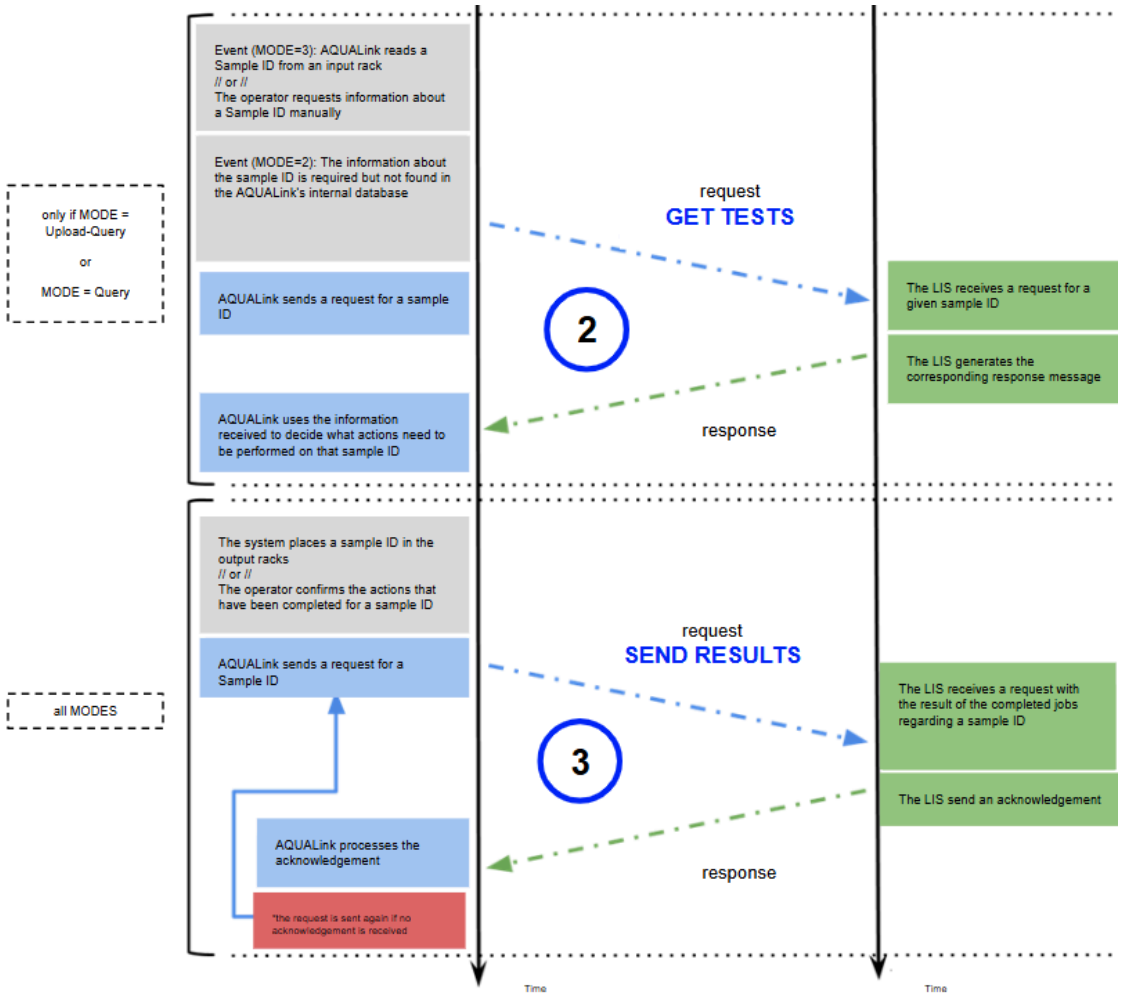


Multiple-System Installation



3. Communication Flow

The communication flow between the system software and the LIS follows this diagram:



When the software of the system fails to receive the confirmation of a sent message with information, the message is stored as “Pending” and it is retried every 10 minutes during the next 24 hours.

Mode of Operation

The software communication can only be configured in Query mode. The system of the software sends to the LIS a query message for every Sample ID that it has picked at input racks or if an operator requires it manually. When samples and aliquots are being sorted, result messages are being sent to the LIS.

Retries to Send Information

When the system software fails to receive the confirmation of a message sent with information, the message is stored as “Pending” and retried every 10 minutes during the next 24 hours.

4. ASTM Communication Protocol: A9000P

Setup

The system software manages the information and communications between the systems (1 or more) and the Laboratory Information System (LIS). The system(s) and the LIS are connected via Ethernet TCP/IP.

This section describes the communication protocol between the system software and the LIS. The communication protocol used by the system is based on the following ASTM standard protocols:

- ASTM E1381-95 and NCCLS LIS01-A2 (low level protocol)
- ASTM E1394-97 and NCCLS LIS02-A2 (high level protocol)

The protocol is the following:

- ➢ The system software is the server and is listening for TCP connections at a given port.
- ➢ The LIS is the TCP client.

In the ASTM communication protocol, an application message consists of an ASTM Header Record, followed by any number of other ASTM Records, such as patient and order records, and ends with an ASTM termination record.

IP Addresses and Port

In a specific system installation, the computer with the system software has to be given an IP that is reachable from the LIS computer.

The system software will be listening for requests at a specific communications port.

Field Length Limitation

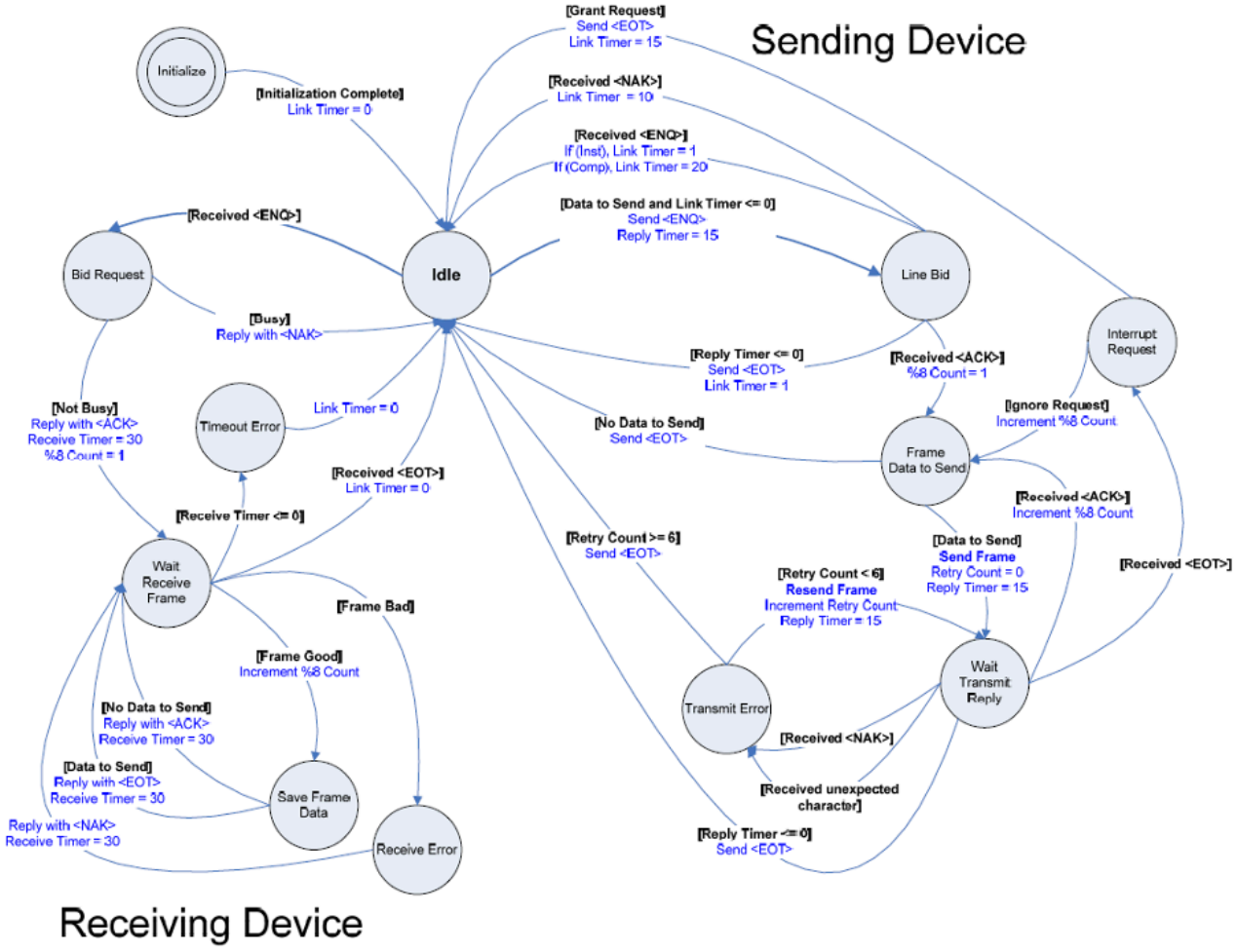
All text strings are stored in 128 byte fields in the system database. If longer texts are being sent by this protocol (for example, a test code returned by LIS), an error will be displayed.

Glossary

Name	Definition
ASTM-CI	ASTM Common Implementation software component
Device	Instrument or validation station
e.g.	Abbreviation of “for example” (“exempli gratia” in Latin)
Field	Unitary field, which is part of a record
Frame	One sequence of <STX>data<ETX>checksum<CR><LF>
i.e.	Abbreviation of “that is to say” (“id est” in Latin)
Message	The whole set of frames from H to L, both included
Record	The data part of a frame
UTF-8	A standard Transformation Format for encoding of universal characters

Principle

The principle is the receipt of requests for analysis, reporting of results and commands following the ASTM protocol on Ethernet media. The following figure, extracted from the *CLSI document LIS01-A2* document, shows the software states of a device communicating with the ASTM protocol.



The instrument should be in idle state after initialization. In this state, it will wait for data to send (from the instrument application), or for receiving data from the host.

Specifications of Low-Level Connection (LIS01-A2)

Physical Layer and Network Interface

The implementation of network-based communication is based on the TCP Socket standard. Refer to LIS01-A2. The socket client (the device) establishes a permanent session to the socket server. If, for any reason, the connection aborts, the device would attempt to re-establish the connection. The data transmitted between the client and the server takes the form of ASTM high level packets.

Communication Protocol

Control Characters

Notification and negotiation are performed using specific control characters. The control characters are the same for both Serial and Network Interfaces. Control characters not allowed to be received regarding the state of the device must be ignored.

The device must use the following control characters of the communication standard.

Control String	Hexadecimal Value
<ENQ>	$05
<ACK>	$06
<NAK>	$15
<STX>	$02
<ETX>	$03
<ETB>	$17
<CR>	$0D
<LF>	$0A
<EOT>	$04

When ready to send data, a device (instrument or host) should notify the other that he wants to send data. After being acknowledged by the receiving device, the emitting device should send data. Once the data sending has been completed, both devices should return to state “idle”.

a) Establishment phase from host

On reception of an <ENQ> control character from the host while in state “idle” (host requests to send data),

- if ready to receive a message, the ASTM-CI must send an <ACK> control character. The ASTM-CI should be set to state “waiting to receive the frame”.
- if not ready to receive a message, the ASTM-CI must send an <NAK> control character. The ASTM-CI should stay in state “idle”.

b) Establishment phase from device

To start the establishment phase (instrument request to send data), the ASTM-CI must send an <ENQ> control character to the host. The ASTM-CI should be set to state “line bid”.

The ASTM-CI must wait for a response from the host, or a timeout.

On reception of an <ACK> control character from the host while in state “line bid”, the ASTM-CI must start sending the message. The ASTM-CI should be set to state “frame data to send”.

c) Establishment phase timeout

When there has not been a response from the host while in state “line bid” state in 15 seconds,

- the ASTM-CI must send an <EOT> control character. The ASTM-CI should return to state “idle”.
- the ASTM-CI must wait at least 1 second before attempting a new establishment phase.

Device	**<>**	**Host**
<ENQ>	>	
	…	
Wait 15 seconds		
<EOT>	>	
Wait 1 second		

d) Establishment phase reject

On reception of an <NAK> control character from the host while in state “line bid”,

- the ASTM-CI should return to state “idle”.
- if an establishment phase request has been rejected (<NAK> received) less than 3 times, the ASTM-CI must wait 10 seconds, and then it must attempt an establishment phase retry.

Device	<>	Host
<ENQ>	>	
	<	<NAK>
Wait 10 seconds		
<ENQ>	>	
	<	<NAK>
Wait 10 seconds		
<ENQ>	>	
	<	<NAK>
Generate error log		

e) Establishment phase conflict

The selected behavior in conflict situations is that the device must remain the master of exchanges and decisions.

On reception of an <ENQ> control character from the host while in state “line bid” (contention phase),

- the ASTM-CI should return to state “idle”.
- if the establishment phase request has failed less than 3 consecutive times, the ASTM-CI must wait 1 second, then must attempt an establishment phase retry.

Device	<>	Host
<ENQ>	>	
	<	<ENQ>
Wait 1 second		Wait 20 seconds
<ENQ>	>	
	<	<ACK>
	…	
<EOT>	>	

f) Establishment phase invalid character

On reception of any control character outside <ACK>, <NAK> and <ENQ> while in state “line bid”, the ASTM-CI must ignore the received character. The ASTM-CI should stay in state “line bid”.

Sending Data Frames

The ASTM-CI should send data frames one by one. The ASTM-CI should be set to state “frame data to send”. Frame data format is described in the state diagram.

At each frame sent, the ASTM-CI must wait for a response from the host, or a timeout. The ASTM-CI should be set to state “waiting for a transmission reply”.

On reception of an <ACK> control character from the host while in state “waiting for a transmission reply”, the ASTM-CI should return to state “frame data to send” to send the next frame.

At the end of the data transmission (no more frame data is to send while in state “frame data to send”), the ASTM-CI must send the <EOT> control character. The ASTM-CI should be set to state “idle”.

Unexpected End of Transmission (EOT)

On reception of an <EOT> control character from the host while in state “waiting for a transmission reply”, the ASTM-CI should return to state “frame data to send” to send the next frame.

Sending Data Timeout

If there has not been a response from the host while in state “waiting for a transmission reply” in 15 seconds, the ASTM-CI must send an <EOT> control character. The ASTM-CI should return to state “idle”.

Device	**<>**	**Host**
<ENQ>	>	
	<	<ACK>
<STX>1...Data...<CR><ETX>xx<CR><LF>	>	
	...	
Wait 15 seconds		
<EOT>	>	

In case that the message delivery has been discarded due to no response from the host, the message should be re-sent later.

Negative Acknowledge of Frame Sent (NAK)

On reception of an <NAK> control character from the host while in state “waiting for a transmission reply”,

- if the sent frame has been sent 6 consecutive times (1 initial delivery plus 5 retries),
    - the ASTM-CI must send an <EOT> control character. The ASTM-CI should return to state “idle”.
    - The message to send must be discarded.
- if it is another case,
    - the ASTM-CI must retry sending the same frame.

Device	**<>**	**Host**
<ENQ>	>	
	<	<ACK>
<STX>1...Data...<CR><ETX>xx<CR><LF>	>	
	<	<NAK> #1
<STX>1...Data...<CR><ETX>xx<CR><LF>	>	
	<	<NAK> #2
<STX>1...Data...<CR><ETX>xx<CR><LF>	>	
	<	<NAK> #3
<STX>1...Data...<CR><ETX>xx<CR><LF>	>	
	<	<NAK> #4
<STX>1...Data...<CR><ETX>xx<CR><LF>	>	
	<	<NAK> #5
<STX>1...Data...<CR><ETX>xx<CR><LF>	>	
	<	<NAK> #6
<EOT**>**	>	

Unexpected Control Character

On reception of any control character outside <ACK>, <NAK> and <EOT> while in state “waiting for a transmission reply”,

- if the sent frame has been sent 6 consecutive times (1 initial delivery plus 5 retries),
    - the ASTM-CI must send an <EOT> control character. The ASTM-CI should return to state “idle”.
    - the message to send must be discarded.
- if it is another case, the ASTM-CI must retry sending the same frame.

While in state “waiting to receive the frame”, the ASTM-CI waits for a frame corresponding to the data format of ASTM frames specified in the state diagram, or for an <EOT> control character.

A frame must be recognized and considered by the sequence of the following consecutive or not control characters, in this order: STX, then ETB or ETX then CR and LF.

Characters received before the first STX character must be ignored.

At reception of a valid ASTM frame (i.e. without frame errors, cf. §1.1.1.1.1), the ASTM-CI must send an <ACK> control character to the host. The ASTM-CI should return to state “waiting to receive the frame”.

On reception of an <EOT> control character from the host while in state “waiting to receive the frame”, the ASTM-CI should return to state “idle”, and should manage the received ASTM frames regarding high-level content.

Received Frame Errors

If the received frame exceeds the 247 character length,

- the ASTM-CI must send an <NAK> control character. The ASTM-CI should return to state “waiting to receive the frame”.
- the erroneous frame must be ignored.

If a received frame has a valid length, but does not exactly fit with the required frame format (refer to requirement ASTM_CI_1.0.0_FRAME_FORMAT_1),

- the ASTM-CI must send an <NAK> control character. The ASTM-CI should return to state “waiting to receive the frame”.
- the erroneous frame must be ignored.

If the received frame has a valid length and structure, but contains an invalid frame number,

- the ASTM-CI must send an <NAK> control character. The ASTM-CI should return to state “waiting to receive the frame”.
- the erroneous frame must be ignored.

On receiving a frame with a valid length, structure and frame number, the ASTM-CI must compute the frame checksum.

If the computed frame checksum does not correspond to the checksum bytes of the received frame,

- the ASTM-CI must send an <NAK> control character. The ASTM-CI should return to “waiting to receive the frame” state.
- the erroneous frame must be ignored.

Receive Data Timeout

If no frame has been received from the host while in state “waiting to receive the frame” in 30 seconds,

- the ASTM-CI should return to state “idle”.

Device	<>	Host
	<	<ENQ>
<ACK>	>	
	<	<STX>1...Data...<CR><ETX>xx<CR><LF>
<ACK>	>	
	...	
Waits 30 seconds		
Returns to state “idle”		

Data Format of ASTM Frames

A frame must be sent or received according to the table below.

ASTM Field	Definition	Transmitted Data	# of bytes	Comments
0	STX	$02	1	
1	Frame Number	1 ($31) To 7 ($37)	1	Frame number is set to 1 and incremented by 1 for each frame up to 7, and then returns to 0
2	Data Record		1..240	One of the managed ASTM Records
3	ETB or ETX		1	ETB if it is the end of the intermediate data record text ETX if it is the end of the data record text
4	Checksum		2	
5	CRLF	$0D $0A	2	

All transmitted data must be coded in ASCII.

Frame length must not exceed 247 characters, i.e. 240 data-record characters. The data record whose length is greater than 240 characters must be communicated into 2 or more frames. Intermediate frames must use the ETB character and the last frame must use the ETX character.

The “data record” part of an ending frame (a frame with ETX) must end in the CR character, i.e. the data record has a maximum of 239 useful characters plus one <CR>.

<STX>1[DATA_1**]<CR><ETX>[**ChkSum**]<CR><LF>**

<STX>2[DATA_2 first part**]<ETB>[**ChkSum**]<CR><LF>**

<STX>3[DATA_2 last part**]<CR><ETX>[**ChkSum**]<CR><LF>**

A sequential number must be inserted in each frame.

By default, the frame number must be equal to 1. This number must be incremented by 1 for all the frames properly acquired until the 7th, before returning to 1.

The frame number is thus used to distinguish the new frames from frame retransmissions. In fact, in case of a frame retransmission (after a negative <NAK> response has been received), the frame number should not be incremented.

According to the LIS01-A2 ASTM format, the frame checksum must be calculated as the sum modulo 256 of all ASCII values between the character “STX” (not included) and the character ETX (included).

Example: <STX>4R|8|^^^EOS#^711-2|0.26|||||F<CR><ETX>34<CR><LF>

Character values taken into account.

34: Calculated Checksum.

Nominal Communication Types between Device and Host

The following table shows a typical dialogue between device and host with 2 frames less than or equal to 247 characters:

Device	**<>**	**Host**
<ENQ>	>	
	<	<ACK>
<STX>1...Data...<CR><ETX>xx<CR><LF>	>	
	<	<ACK>
<STX>2...Data...<CR><ETX>xx<CR><LF>	>	
	<	<ACK>
<EOT>	>	

The following table shows a typical dialogue between host and device with 2 frames less than or equal to 247 characters:

Device	**<>**	**Host**
	<	<ENQ>
<ACK>	>	
	<	<STX>1...Data...<CR><ETX>xx<CR><LF>
<ACK>	>	
	<	<STX>2...Data...<CR><ETX>xx<CR><LF>
<ACK>	>	
	<	<EOT>

The following table shows a typical dialogue between device and host with 1 frame of more than 247 characters (240 useful data characters):

Device	<>	Host
<ENQ>	>	
	<	<ACK>
<STX>1...Data(240) ...<ETB>xx<CR><LF>	>	
	<	<ACK>
<STX>2...Data(10)...<CR><ETX>xx<CR><LF>	>	
	<	<ACK>
<EOT>	>	

The following table shows a typical dialogue between host and device with 1 frame of more than 247 characters (240 useful data characters):

Device	<>	Host
	<	<ENQ>
<ACK>	>	
	<	<STX>1...Data(240)...<ETB>xx<CR><LF>
<ACK>	>	
	<	<STX>2...Data(10)...<CR><ETX>xx<CR><LF>
<ACK>	>	
	<	<EOT>

Timeouts and Maximum Numbers of Rebroadcasts

The table below summarizes the different timeout to be observed in all cases that can happen during a communication between host and device:

Description	**Timeout (sec)**	**Max. Number of Retries**
No response from the host for an “ENQ”	15	n/a
Connection Link request after a communication ended by ENQ timeout	1	0
“ENQ/ENQ” conflict	1 (device) / 20 (host)	2
“ENQ/NAK” conflict	10	2
No response from the host on a data frame	15	0
No data received from the host	30	0
Negative acknowledgement of a data frame	0	5
Host end of transmission	n/a	n/a

High-Level Communication Records (LIS2-A2)

ASTM Records

The ASTM-CI must manage messages with the following types of records:

Record ID	Record Level	ASTM Definition
H	1	Header
P	2	Patient
O	2 or 3	Order
R	4	Result
C	3, 4 or 5	Comment
Q	2	Request Information (Query) Order
M	2 or 4	Manufacturer Information
L	1	Terminator Record

Other record types must be ignored if received from a host.

The level of a record is used to associate it with previous ones. Consecutive records of level N or more are all associated with the latest level N-1 record.

In the following sections, the level of records is represented as shown below:

```
X (Level 1 record)

---------- X (Level 2 record)

---------- X (Level 3 record)

---------- X (Level 4 record)

---------- X (Level 5 record)
```

The ASTM-CI must ignore a record of level N (with N > 1) if no record of level N-1 has been received previously (e.g. a Result Record of level 4 is received without a previous Order Record of level 3). In this case, the ASTM-CI must also ignore all following records of the same or higher level until a new record of a lower level is received.

Header Record

The ASTM-CI must start sending a message by a Header Record.

H (Header)

The ASTM-CI must ignore all records received before a Header Record.

Patient Record

The ASTM-CI should not send Patient Records without Order Records associated with them.

A single Patient Record is expected in every GetTest request.

H (Header)

----------P (Patient)

Order Record

The ASTM-CI must send Order Records in a message of the following form.

H (Header)

----------P (Patient)

----------O (Order)

In the case of the reception of several Order Records with the same Sample ID associated with the same Patient Record, at least the last Order Record should be taken into account by the application.

In the case of the reception of several Order Records with different Sample IDs, all Order Records should be taken into account by the application.

Result Record

The ASTM-CI must send Result Records in a message of the following form.

The ASTM-CI must manage received Result Records if the message form corresponds with the following form.

H (Header)

----------P (Patient)

----------O (Order)

----------R (Result)

----------R (Result)

If a received Result Record does not correspond with the expected message forms, ASTM-CI must ignore the Result Record.

Comment Record

If a received Comment Record does not correspond with the following expected message forms, the ASTM-CI must ignore the Comment Record.

Request Information Record

The ASTM-CI must send Request Information Records in a message with the following format:

H (Header)

----------Q (Request Information)

The ASTM-CI does not manage multiple samples in one Request Information Record (authorized by LIS2-A2 standard).

The ASTM-CI must send one Request Information Record per sample.

The ASTM-CI must ignore received Request Information Records.

Terminator Record

All messages should be terminated by a Terminator Record.

The ASTM-CI must end sending a message by a Terminator Record.

```
----------

----------

----------

L (Terminator)
```

The A9000 protocol will ignore messages that do not end with a Terminator Record.

Manufacturer Record

Manufacturer records are not used in this A9000 protocol.

Detailed Description of ASTM Records

ASTM Record Contents

Only the fields defined in the following tables are interpreted on the device. “Not used” means “not filled by the device or discarded when coming from the host”.

The table below shows how inputs are defined:

Fixed	Only the fixed value is allowed
Closed list	Value from a fixed list of values defined in the ASTM specification or in this document
Open list	Value from a list of predefined values in the device specification or free text if no predefined value exists
Alpha-numeric	Free text
Numeric	Numerical positive data
Date and time	Date and time data in “yyyymmddhhmmss” format
Date	Date in “yyyymmddhhmmss” format

The ASTM-CI must use UTF-8 encoding for alpha-numeric fields.

Records to Send

The ASTM-CI has to control all record’s fields before sending a message.

Fields values of a record to send must have values in accordance with the specified input types.

The field length of a record to send must not exceed the specified maximum allowed length for the associated field.

Fields of a record to send must not contain repeat delimiter if not allowed for the associated field.

The ASTM-CI must send a record with all mandatory fields filled with valid values.

When sending records, the ASTM-CI must send all fields defined for the record. Non-used fields must be sent empty.

When sending records, the ASTM-CI must send only non-empty components, i.e. without component delimiters for the last empty components of the field.

Example: For a field composed of 4 components with only the second one filled:
<^123> should be sent instead of **<^123^^>**

Received Records

If a field value of a received record does not contain a valid value or does not correspond to the required input type, the ASTM-CI must ignore the corresponding record.

The ASTM-CI must ignore all other field errors for this record.

If a field value of a received record with an allowed repeat delimiter contains a repeat delimiter, the ASTM-CI must ignore the corresponding record.

The ASTM-CI must ignore all other field errors for this record.

When managing received records, if a field length exceed the maximum allowed length, the ASTM-CI must

- truncate the field and manage the record for non mandatory field, or
- ignore the record for a mandatory field.

The ASTM-CI must ignore all other field errors for this record.

If a field of a received record contains more component values than allowed, the ASTM-CI must manage the record (with additional component values ignored).

If a record is ignored, all following records of the higher level must be ignored, until a new record of the same level is received.

The ASTM-CI must be able to manage incomplete received records (missing fields or missing components).

In this case, the ASTM-CI must see all non-received fields or components as empty.

Requests from the System Software to the LIS

When the system software sends a request to the LIS, the timeout to receive a response is 30 seconds. If the response time exceeds 3 seconds, the communication will affect the system's performance.

There are two types of payloads (high level communication records):

- Get Tests
- Send Results

"Get Tests" Request

This message is sent from the system software to the LIS for two possible reasons:

1. A system has picked a sample from an input rack and has read the Sample ID's barcode.
2. An operator has requested the information manually and has performed manually the actions related to a Sample ID's code from the interface of the system software.

"Get Tests" Request Message

The request message is composed by the following records:

1. Header
2. Query
3. Termination

Header Record

The ASTM-CI must send a Header Record to the host with the following fields:

Field	ASTM Definition	Value	Max. Length	Input Type	Repeat Delimiter	Man-datory
6.1	Record Type ID	H	1	Fixed	N	Y
6.2	Delimiter Definition	|\^& Description: | Field Delimiter \ Repeat Delimiter ^ Component Delimiter & Escape Delimiter	4	Fixed	N	Y
6.3	Message Control ID	Not used				
6.4	Access Password	Not used				
6.5	Sender Name or ID	A9000P	32 (5^15^10)	Alpha-numeric^ Alpha-numeric^ Alpha-numeric	N	N
6.6	Sender Address	Not used				
6.7	Reserved Field	Not used				
6.8	Sender Telephone Nb	Not used				
6.9	Characteristic of Sender	Not used				
6.10	Receiver Name or ID	LIS	32	Alpha-numeric	N	N

6.11	Comment or Special Instruction	Not used				
6.12	Processing ID	“P” for a Production, “Q” for a QC, “D” for debugging. A9000P will always send “P”.	1	Closed list	N	N
6.13	Version Number	Always 1	10	Fixed	N	N
6.14	Date and Time of Message	yyyymmddhhmmss	14	Date and time	N	N

No Field Delimiter should be inserted between fields 6.1 and 6.2. The first character of field 6.2 (“|”) is considered a separator from the previous field (“H”).

The Header Record is always the first record in an application message. It contains general information about the sender and the receiver. The A9000 protocol will just check for the Header Record type.

Query Record

The Query Record is used to request data from remote systems.

The Query Record structure is as follows:

Q|SEQUENCE_NUMBER|^TUBE_ID^RACK_ID^HOLE_ID|||||||||O

The ASTM-CI must send a Request Information record to the host with the following fields:

Field	ASTM Definition	Device Definition	Value	Max. Length	Input Type	Repeat Delimiter	Man-datory
11.1	Record Type ID		Q	1	Fixed	N	Y
11.2	Sequence Number	Sequence of Request Record	Always 1. The system always ends an application message before transmitting another query record.	2	Numeric	N	Y
11.3	Starting Range ID Number	^SampleID^RackID^HoleID	For rack: e.g.: ^01234567^001DIF 10^08 The RackID and HoleID position might be empty if a manual request is used.	^64^64^3	^Alpha-numeric ^Alpha-numeric ^Alpha-numeric	N	^Y^N ^N^N
11.4	Enf of Identifier List	Not used	Not used				
11.5	Universal Test ID	Not used	Not used	3	Fixed	N	N
11.6	Time limits	Not used	Not used				
11.7	Max. Time Limits	Not used	Not used				
11.8	Min. Time Limits	Not used	Not used				
11.9	Physician Name	Not used	Not used				
11.10	Telephone Number	Not used	Not used				
11.11	Reserved for User	Not used	Not used				
11.12	Reserved for User	Not used	Not used				
11.13	Request Information Status Codes	Request Information Status	“O” request for information	1	Fixed	N	Y

The Request information record must not be sent if the Sample ID is empty and at least one of the following are empty: Rack Loading Nb, Rack ID or Rack Position.

Variable	Description	Example Value	Comments
SAMPLE_ID	Identifier of the primary tube as read on the barcode	312011223344	The maximum length of this field is 64 characters.
RACK_ID	Identifier of the rack from which the tube has been picked	InputRack1	- It can be left empty. - The maximum length of this field is 128 characters (counting “RACK_ID” + “rack model”).
HOLE_ID	Coordinates in the rack from which the tube has been picked	C6	- It can be left empty. - The maximum length of this field is 3 characters.

When manually operated requests are sent, the RACK_ID and HOLE_ID can be left blank.

Termination Record:
The Termination Record is the last record of a message and closes the message. It provides an explanation for ending the message.

The Termination Record structure is as follows:

L| SEQUENCE_NUMBER |TERMINATION_CODE

The ASTM-CI must send a Message Terminator Record to the host with the following fields:

Field	ASTM Definition	Device Definition	Value	Max. Length	Input Type	Repeat Delimiter	Man-datory
12.1	Record Type ID		L	1	Fixed	N	Y
12.2	Sequence Number	Sequence of Terminator Record	1	1	Fixed	N	Y
12.3	Termination Code		“N” - Normal	1	Fixed	N	Y

By default, the response from the LIS should only include the list of pending tests (or virtual tests*).

***Note:** The system software calculates what actions to perform (sorting primary destination, decapping, aliquots, volumes of aliquots…) with the list of tests received. The tests can be real analytic determinations that are pending in the LIS database, or can be virtual tests that are agreed with the LIS and are configured during installation and start-up. For example, one virtual test per each possible aliquot type can be used. The volume and properties of the aliquot are configured in the database of the system software.

The response message is composed by:

HeaderRecord + PatientRecord + OrderRecord + TerminationRecord

Header Record

The Header Record is always the first record in an application message. It contains general information about the sender and the receiver. It is already described in the previous section.

Outgoing Patient Record

The Patient Record is used to supply patient demographic information for Order and Result Records that follow it.

The Patient Record structure is as follows:

P|SEQUENCE_NUMBER|PATIENT_ID|||FAMILY_NAME^FIRST_NAME^MIDDLE_NAME||BIRTH_DATE|PATIENT_SEX|||||PHYSICIAN|||||||||||LOCATION

The ASTM-CI must send a Patient Record to the host with the following fields:

Field	ASTM Definition	Device Definition	Value	Max. Length	Input Type	Repeat Delimiter	Man-datory
7.1	Record Type		P	1	Fixed	N	Y
7.2	Sequence Number	Sequence of Patient Record	1	2	Numeric	N	Y
7.3	Practice Assigned Patient ID	PatientID	477XXXXX12	25	Alpha-numeric	N	Y
7.4	Laboratory Assigned Patient ID	Not used	Not used				
7.5	Patient ID N°3	Not used	Not used				
7.6	Patient Name	Last Name^First Name	Last Name^First Name	41 (20^20)	Alpha-numeric	N	N
7.7	Mother’s Maiden Name	Not used	Not used				
7.8	Birthdate	Birth Date^Age^Age unit	YYYYMMDD^AGE^U U: “Y” - year “M” - month “D” - day	14 (8^3^1)	Date^ numeric^Closed List	N	N

7.9	Patient Sex	Gender	"M" - male "F" - female "U" - unknown	1	Closed list	N	N
7.10	Patient Race-Ethnic Origin	Not used	Not used	20	Alpha-numeric	N	N
7.11	Patient Address	Not used	Not used				
7.12	Reserved Field	Not used	Not used				
7.13	Custom Field 1	Can be used		64	Alpha-numeric	N	N
7.14	Attending Physician ID	PhysicianID^PhysicianName	PhysicianID^Physician Name	51 (20^30)	Alpha-numeric^ Alpha-numeric	N	N^N
7.15	Special Field 1	Not used	Not used				
7.16	Custom Field 2	Can be used		64	Alpha-numeric	N	N
7.17	Custom Field 3	Can be used		64	Alpha-numeric	N	N
7.18	Custom Field 4	Can be used		64	Alpha-numeric	N	N
7.19	Custom Field 5	Can be used		64	Alpha-numeric	N	N
7.20	Custom Field 6	Can be used		64	Alpha-numeric	N	N
7.21	Custom Field 7	Can be used		64	Alpha-numeric	N	N
7.22	Custom Field 8	Can be used		64	Alpha-numeric	N	N
7.23	Custom Field 9	Can be used		64	Alpha-numeric	N	N
7.24	Custom Field 10	Can be used		64	Alpha-numeric	N	N
7.25	Admission Status	Not used	Not used				
7.26	Location	Department	e.g.: Emergency	64	Alpha-numeric	N	N
7.27	Extraction Center	Can be used		64	Alpha-numeric	N	N
7.28	Alternative Diag. Code and Class	Not used	Not used				
7.29	Patient Religion	Not used	Not used				
7.30	Marital Status	Not used	Not used				
7.31	Isolation Status	Not used	Not used				
7.32	Language	Not used	Not used				
7.33	Hospital Service	Not used	Not used				
7.34	Sample Source Service	Can be used		64	Alpha-numeric	N	N
7.35	Sample Source Section	Can be used		64	Alpha-numeric	N	N

The following table gives more detailed information about this structure:

Variable	Description	Example Value	Comments
PATIENT_ID	ID of the patient	2233667744B	The maximum length is 32 characters
FAMILY_NAME	Family name of the patient	Smith	
FIRST_NAME	First name of the patient	John	
MIDDLE_NAME	Middle name of the patient	Levin	
BIRTHDATE	Birthdate of the patient (“yyyymmdd” format)	1975/03/18	
PATIENT_SEX	Sex of the patient	Male	This field is text. Values are not forced.
PHYSICIAN	Name of the doctor	Conrad	
LOCATION	Set to the Location field of worklist entry or result	ER1	

Outgoing Order Record

The Order Record is used to supply information on a specific sample's test requests. This information is necessary either for ordering tests on a specific sample or for reporting results for tests on a specific sample.

The Order Record structure is as follows:

O|SEQUENCE_NUMBER|TUBE_ID^RACK_ID^HOLE_ID||UNIVERAL_TEST_ID|PRIORITY|||||ACTION_CODE|||||||||||||REPORT_TYPE

The ASTM-CI must manage an Order Record from the host if the fields contents matches with the table below:

Field	ASTM Definition	Device Definition	Value	Max. Length	Input Type	Repeat Delimiter	Man-datory
8.1	Record Type ID		O	1	Fixed	N	Y
8.2	Sequence Number	Sequence of Order Record	1	2	Numeric	N	Y
8.3	Specimen ID	SampleID^ ^RackID^ Rack Position	For rack: e.g.: 0123456789^001DIF10^08 For open tube: e.g.: 0123456789^^^	64^64^3	Alpha-numeric^ Alpha-numeric^ Alpha-numeric	N	Y^N^N
8.4	Device Specimen ID	Not used	Not used				
8.5	Universal Test ID	Tests	^^^Test\1^^^Test2	19 (^^^10^5^3)	^^^Open list^ Numeric^ Closed list	Y	^^^N^N^N
8.6	Priority	Emergency	"R" - for routine "S" - for STAT	1	Closed list	N	N
8.7	Requested / Ordered Date/Time	Not used	Not used				
8.8	Specimen Collection Date/Time	Not used	Not used				
8.9	Collection End Time	Not used	Not used				
8.10	Collection Volume	Not used	Not used				
8.11	Collector ID	Not used	Not used				
8.12	Action Code	Not used	Not used				
8.13	Danger Code	Not used	Not used				
8.14	Relevant Clinical Information	Not used	Not used				
8.15	Date and Time of the Received Specimen	Not used	Not used				

8.16	Specimen Descriptor	Not used	Not used				
8.17	Ordering Physician	Not used	Not used				
8.18	Physician Phone NB	Not used	Not used				
8.19	User Field 1	Not used	Not used				
8.20	User Field 2	Not used	Not used				
8.21	Laboratory Field 1	Not used	Not used				
8.22	Laboratory Field 2	Not used	Not used				
8.23	Date and Time of the Reported Result	Not used	Not used				
8.24	Instrument Charge to Computer System	Not used	Not used				
8.25	Device Section ID	Not used	Not used				
8.26	Report Types	Report Types	“Z” - unknown order “Y” - closed order “S” - opened order “C” - cancelled orden	1	Closed list	N	Y
8.27	Reserved Field	Not used	Not used				
8.28	Location or Ward	Not used	Not used				
8.29	Nosocomial Service	Not used	Not used				
8.30	Specimen Service	Not used	Not used				
8.31	Specimen Institution	Not used	Not used				

The following table gives more detailed information about this structure:

Variable	Description	Example Value	Comments
TUBE_ID	Identifier of the primary tube as read on the barcode	312011223344	The system's barcode reader can only read up to 18 characters
RACK_ID	Identifier of the rack from which the tube has been picked	InputRack1	This field can be empty on order download
HOLE_ID	Coordinates in the rack from which the tube has been picked	C6	
UNIVERSAL_TEST_ID	List of tests	^^^T4\^^^HCG\^^^P1234	
PRIORITY	Value determined by the stat flag in the worklist entry. - If the stat flag is "Yes", the "PRIORITY" field is set to "S" (Stat). - If the stat flag is "No", the "PRIORITY" field is set to "R" (Routine).	S	"S" (Stat) or "R" (Routine) Receiving this value in the Order Record from the LIS is supported. "R" is accepted for routine and "S" is accepted for urgent.
REPORT_TYPE	If the outgoing message contains rejected incoming worklist or result data, or the test is not resulted, the "REPORT_TYPE" field contains "X (Work Cannot Be Done)". If the outgoing message contains worklist data, the "REPORT_TYPE" field contains "O (Order)". If the outgoing message contains result data, the "REPORT_TYPE" field contains "F (Final Results)". If the outgoing message contains data in response to a query, the "REPORT_TYPE" field contains "Q (Response to a Query)".	Q	The system does not support answering queries from the LIS.

“Send Results” Request

This message is sent from the system software to the LIS for two possible reasons:

1. A system hardware has placed a sample in an output rack (it has finished its actions) and sends the results of every requested test.
2. An operator has performed manually some actions related to a Sample ID’s code and confirms the result of them from the interface of a system software.

The “Send Results” request is composed by the following records:

- **Header Record**
- **Patient Record**
- **Order Record**
- **Primary Result Record**
- **Test Result Records**
- **Secondary Samples Result Records**
- **TerminationRecord**

This behavior can be defined using the **Host configuration** parameter:
a9000p.send.results.confirmation.expected. There are two possible values:

- **Enabled**: The behavior will remain as in the previous version, expecting a Header and a Termination record within 6 seconds.
- **Disabled**: No high-level confirmation will be expected, as the low-level ASTM protocol has already accepted the information. This is the default value.

Header Record
The Header Record is always the first record in an application message. It contains general information about the sender and the receiver.

Patient Record
Only the used fields described in the Patient Record table will be reported back when the results of a sample are sent to the LIS.

Order Record
The Order Record is used to supply information about the primary sample and about in which output rack and hole it was placed. The fields that are used are the following.

The following table gives more detailed information about this structure:

Variable	Description	Example Value	Comments
SEQUENCE_NUMBER	Equal to the nth occurrence of a Patient Record within the current outgoing application message. Used for validating the integrity of the application message by ensuring that the message contains all records.	1	
TUBE_ID	Identifier of the primary tube as read on the barcode	312011223344	The maximum length is 64 characters.
RACK_ID	Identifier of the rack from which the tube has been placed	OutputRack1	
HOLE_ID	Coordinates in the rack from which the tube has been placed	C6	The maximum length is 10 characters.
UNIVERSAL_TEST_ID	List of tests	^^^T4\^^^HCG\^^^P1234	
PRIORITY	Value determined by the stat flag in the worklist entry. - If the stat flag is “Yes”, the “PRIORITY” field is set to “S” (Stat). - If the stat flag is “No”, the “PRIORITY” field is set to “R” (Routine).	R	S (Stat) or R (Routine)
REPORT_TYPE	Always sent as “F” (Final Results).	F	F (Final Results)

Example:

O|1|312011223344^OutputRack1^C6||^^^T4\^^^HCG\^^^P1234|S||||||||||||||||||||F

Primary Result Record

A virtual Result Record is used to inform LIS if the primary sample was sorted correctly.

The following table gives more detailed information about this structure:

Variable	Description	Example Value	Comments
SEQUENCE_NUMBER	Equal to the nth occurrence of a Result Record since the last Order Record. Used to verify the integrity of an application message by ensuring that the message contains all records.	1	
UNIVERSAL_TEST_ID	ID of the virtual test	PRIMARY_T	
FLAGS	Status of the primary sample	Success Failure	
RESULT_STATUS	Location of the primary sample	InputRack1_G1	
DATE	Date in “yyyymmddhhmmss” format		

Test Result Record

For all the tests provided by LIS during the “get tests” operation, a test record is generated with the following structure:

Variable	Description	Example Value	Comments
SEQUENCE_NUMBER	Equal to the nth occurrence of a Result Record since the last Order Record. Used to verify the integrity of an application message by ensuring that the message contains all records.	1	
UNIVERSAL_TEST_ID	ID of the virtual test	PRIMARY_T	
FLAGS	Status of the primary sample	Success Failure	
RESULT_STATUS	Location of the primary sample	InputRack1_G1	
DATE	Date in “yyyymmddhhmmss” format		

Aliquot Result Record

Virtual tests starting with "SECONDARY_T_" and ending with the sequence index of the aliquot are used to inform the LIS that a secondary aliquot has been created and sorted.

Variable	Description	Example Value	Comments
SEQUENCE_NUMBER	Equal to the nth occurrence of a Result Record since the last Order Record. Used to verify the integrity of an application message by ensuring that the message contains all records.	1	
UNIVERSAL_TEST_ID	ID of the virtual test	SECONDARY_T_1 SECONDARY_T2 SECONDARY_T3 …	
FLAGS	Status of the aliquot sample	Success Failure	
RESULT_STATUS	Location of the secondary sample	InputRack1_G1	
DATE	Date in "yyyymmddhhmmss" format		

"Frame Separation"

To provide backwards compatibility with existing installations, the A9000P protocol allows sending the payload compacted into ASTM frames, therefore not expecting an ACK for each frame. This can be disabled by setting the host configuration parameter **a9000.separate_frames=1**. In this case, the payload is divided into frames (H, Q, R, L) and each of those is sent independently, waiting for an ACK.

"Keep-Alive" Connection

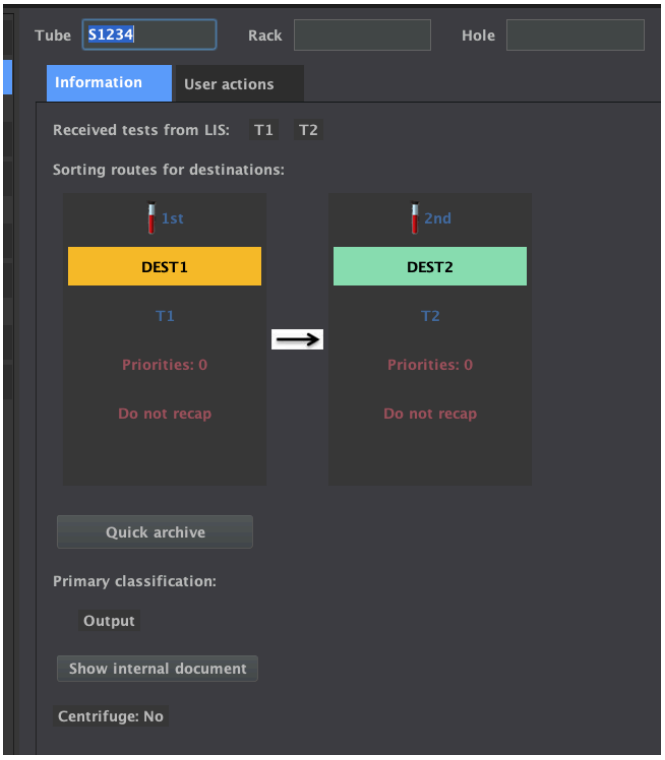
Some networks close the TCP connection if no information has been sent during a given time period. In order to prevent this, it is possible to configure a keep-alive connection mode as a legacy parameter in host configuration, with the name **a9000p.keep.alive**.

It can have the following values:

- Low-level: A9000P driver sends a minimal ASTM ping. The A9000P sends an ENQ, the LIS must respond with an ACK and the A9000P will send an ETX. This will happen every 90 seconds, and this is the default value.
- High-level: A9000P driver sends one full ASTM frame pair containing H and L frame types every 90 seconds, like this one:

    - H|\^&|||A9000P|||||LIS||P|LIS2-A2|<CR>
    - L|1|N
- Disabled: Keep-alive is disabled.

This section shows a communication example using parameter **a9000p.separate_frames=1**.



The system sends a request for tests for sample SS1234. The LIS answers with the patient information and tests T1 and T2: This will sort the sample to destination DEST1.

The request is sent to LIS.

```
2025/06/12 11:56:28.844 #### A9000P-CLIENT   W <EOT>
2025/06/12 11:56:34.529 #### A9000P-CLIENT   W <ENQ>
2025/06/12 11:56:34.530 #### A9000P-CLIENT   R <ACK>
2025/06/12 11:56:34.530 #### A9000P-CLIENT   W <STX>1H|\^&|||A9000P|||||LIS||P|LIS2-A2|<CR><ETX>01<CR><LF>
2025/06/12 11:56:34.531 #### A9000P-CLIENT   R <ACK>
2025/06/12 11:56:34.531 #### A9000P-CLIENT   W <STX>2Q|1|^S1234^^^0|||||||||O<CR><ETX>A8<CR><LF>
2025/06/12 11:56:34.532 #### A9000P-CLIENT   R <ACK>
2025/06/12 11:56:34.532 #### A9000P-CLIENT   W <STX>3L|1|N<CR><ETX>06<CR><LF>
2025/06/12 11:56:34.532 #### A9000P-CLIENT   R <ACK>
2025/06/12 11:56:34.533 #### A9000P-CLIENT   W <EOT>
```

The response is received from LIS.

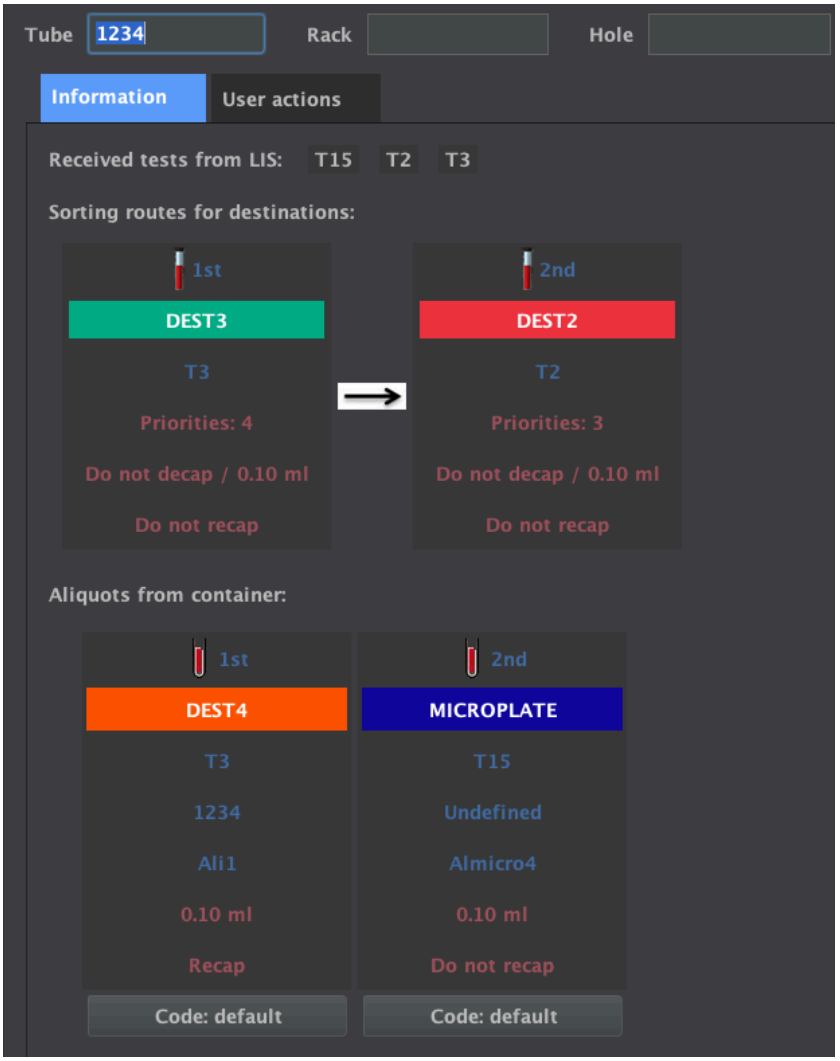
```
2025/06/12 11:56:36.553 #### A9000P-CLIENT   R <ENQ>
2025/06/12 11:56:36.553 #### A9000P-CLIENT   W <ACK>
2025/06/12 11:56:36.554 #### A9000P-CLIENT   R <STX>
2025/06/12 11:56:36.554 #### A9000P-CLIENT   R 1H|\^&|||SERVER|||||A9000P||P|LIS2-A2|<CR><ETX>F6<CR><LF>
2025/06/12 11:56:36.554 #### A9000P-CLIENT   W <ACK>
2025/06/12 11:56:36.555 #### A9000P-CLIENT   R <STX>
2025/06/12 11:56:36.555 #### A9000P-CLIENT   R 2P|1||PATIENT_1||ISAACNEWTON^^|||||||||||||||||||<CR><ETX>7C<CR><LF>
2025/06/12 11:56:36.555 #### A9000P-CLIENT   W <ACK>
2025/06/12 11:56:36.556 #### A9000P-CLIENT   R <STX>
2025/06/12 11:56:36.556 #### A9000P-CLIENT   R 3O|2|^S1234^^^0||^^^T1\^^^T2|null||||||null|||||||||||||Q<CR><ETX>07<CR><LF>
2025/06/12 11:56:36.556 #### A9000P-CLIENT   W <ACK>
2025/06/12 11:56:36.556 #### A9000P-CLIENT   R <STX>
2025/06/12 11:56:36.557 #### A9000P-CLIENT   R 4L|1|F<CR><ETX>FF<CR><LF>
```

2025/06/12 11:56:36.557 #### A9000P-CLIENT W <ACK>
2025/06/12 11:56:36.557 #### A9000P-CLIENT R <EOT>

When the system sorts the sample to its destination, it sends this ASTM payload.

2025/06/12 12:03:04.234 #### A9000P-CLIENT W <ENQ>
2025/06/12 12:03:04.239 #### A9000P-CLIENT R <ACK>
2025/06/12 12:03:04.240 #### A9000P-CLIENT W <STX>1H|\^&|||A9000P|||||LIS||P|LIS2-A2|<CR><ETX>01<CR><LF>
2025/06/12 12:03:04.241 #### A9000P-CLIENT R <ACK>
2025/06/12 12:03:04.241 #### A9000P-CLIENT W <STX>2P|1||PATIENT_1||ISAACNEWTON^^|||||||||||||||||||||<CR><ETX>7C<CR><LF>
2025/06/12 12:03:04.242 #### A9000P-CLIENT R <ACK>
2025/06/12 12:03:04.243 #### A9000P-CLIENT
W <STX>3O|2|S1234^^RACK1^B1||^^^PRIMARY_T\^^^T1\^^^T2|R|||||||||||||||||||F<CR><ETX>5C<CR><LF>
2025/06/12 12:03:04.243 #### A9000P-CLIENT R <ACK>
2025/06/12 12:03:04.244 #### A9000P-CLIENT W <STX>4R|3|^^^PRIMARY_T^^^^|RACK1_B1|||||SUCCESS||||20250612120304<CR><ETX>FB<CR><LF>
2025/06/12 12:03:04.245 #### A9000P-CLIENT R <ACK>
2025/06/12 12:03:04.245 #### A9000P-CLIENT W <STX>5R|4|^^^T1^^^^|OK|||||F||||20250612120304<CR><ETX>4E<CR><LF>
2025/06/12 12:03:04.246 #### A9000P-CLIENT R <ACK>
2025/06/12 12:03:04.246 #### A9000P-CLIENT W <STX>6R|5|^^^T2^^^^|ERROR|||||F||||20250612120304<CR><ETX>41<CR><LF>
2025/06/12 12:03:04.247 #### A9000P-CLIENT R <ACK>
2025/06/12 12:03:04.247 #### A9000P-CLIENT W <STX>7L|1|N<CR><ETX>0A<CR><LF>
2025/06/12 12:03:04.248 #### A9000P-CLIENT R <ACK>
2025/06/12 12:03:04.248 #### A9000P-CLIENT W <EOT>

This section shows a communication example where frames are not divided:



The system sends a request for tests for sample 1234:

2023-12-05 19:03:12.567 W <ENQ>

2023-12-05 19:03:12.567 R <ACK>

2023-12-05 19:03:12.567 W <STX>1H|\^&|||A9000P|||||LIS||P|LIS2-A2|<CR>

2023-12-05 19:03:12.567 W Q|1|^1234^^||||||||||O<CR>

2023-12-05 19:03:12.567 W L|1|N<CR>

2023-12-05 19:03:12.587 W <ETX>63<CR>

2023-12-05 19:03:12.587 W <LF>

2023-12-05 19:03:12.587 R <ACK>

2023-12-05 19:03:12.587 W <EOT>

The LIS answers with the patient information and tests T2, T15 and T3: This will sort the sample to destination DEST3, since it has a higher priority than destination DEST2. A secondary sample will be generated with 0.10ml and a microplate aliquot will be performed.

2023-12-05 19:03:14.927 R <ENQ>

2023-12-05 19:03:14.927 W <ACK>

2023-12-05 19:03:14.947 R <STX>1H|\^&|||LIS|||||A9000P||P|LIS2-A2|<CR>

2023-12-05 19:03:14.947 R P|1||||^^||||||||||||||||||||<CR>

2023-12-05 19:03:14.947 R O|2|^1234^^^^||^^^T2\^^^T15\^^^T3|||20231205190314||||||||||||||||<CR>

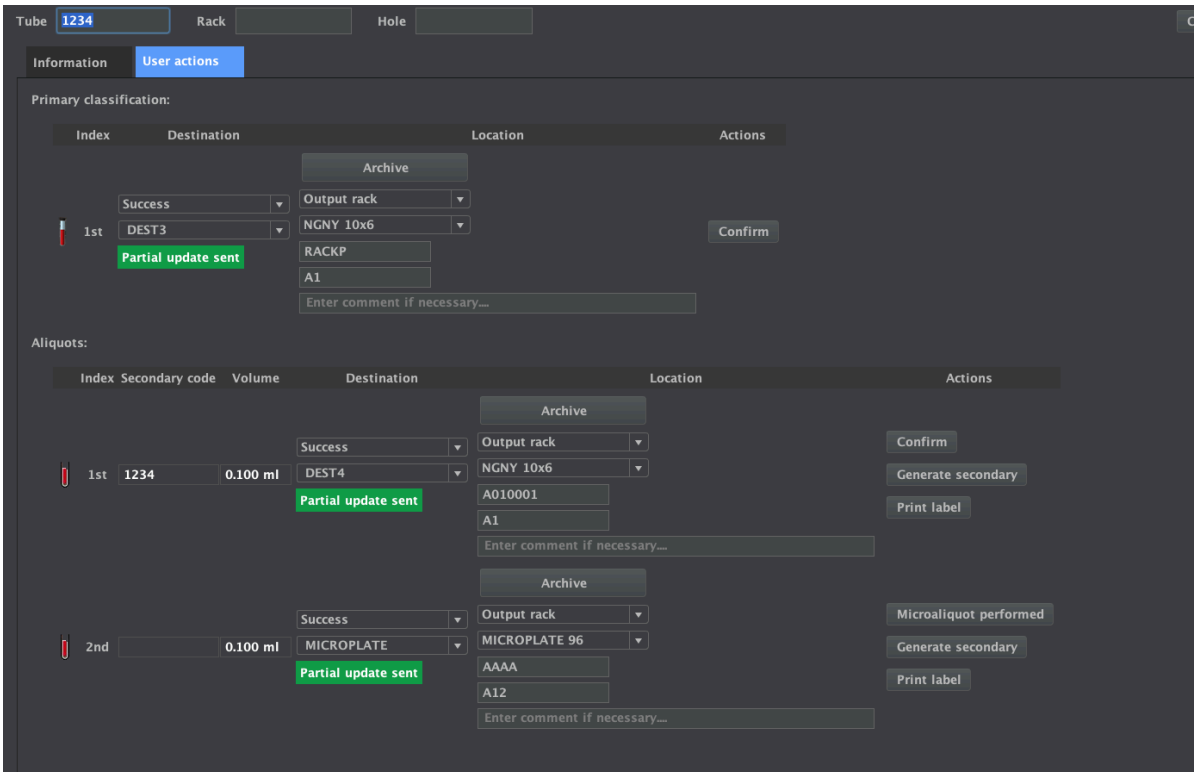
2023-12-05 19:03:14.967 R L|1|F<CR>

2023-12-05 19:03:14.967 R <ETX>07<CR>

2023-12-05 19:03:14.967 R <LF>

2023-12-05 19:03:14.967 W <ACK>

The actions are executed and the system sends the results:



The results are the following:

- T15 is performed correctly (*2T15^^^^|OK|*):
  - An aliquot has been performed and dispensed into the microplate. The rack ID is *AAAA12* and the aliquot has been placed in position A12 (*^^^SECONDARY_T_2^^^^|AAAA12_A12*). The microtube tube will be labeled *AAAA12*.
- T3 is performed correctly (*^^^T3^^^^|OK*):
  - The primary tube has been sorted into DEST3. The rack ID is *RACKP* and the primary tube has been placed in position A1 (*^^^PRIMARY_T^^^^|RACKP_A1*).
  - An aliquot has been performed and sorted into DEST4. The rack ID is *A010001* and the aliquot has been placed in position A1 (*^^^SECONDARY_T_1^^^^|A010001_A1*).
- T2 is not performed (*^^^T2^^^^|ERROR*). The reason is that T3 requires sorting into DEST3 and T2 requires sorting into DEST2. The tube can only have one destination and the tube has been sorted into T3's destination (DEST3), so T2 fails.

2023-12-05 19:03:14.967 R <EOT>

2023-12-05 19:33:51.327 W <ENQ>

2023-12-05 19:33:51.327 R <ACK>

2023-12-05 19:33:51.347 W <STX>1H|\^&|||A9000P|||||LIS||P|LIS2-A2|<CR>

2023-12-05 19:33:51.347 W P|1||||^^|||||||||||||||||||||<CR>

2023-12-05 19:33:51.347 W O|2|1234^RACKP^A1||^^^PRIMARY_T\^^^T15\^^^T2\^^^T3\^^^SECONDARY_T_1\^^^SECONDARY_T_2|R|||||||||||||||||||F<CR>

2023-12-05 19:33:51.347 W R|3|^^^PRIMARY_T^^^^|RACKP_A1|||||SUCCESS||||20231205073351<CR>

2023-12-05 19:33:51.347 W R|4|^^^<ETB>83<CR>

2023-12-05 19:33:51.367 W <LF>

2023-12-05 19:33:51.367 R <ACK>

2023-12-05 19:33:51.367 W <STX>2T15^^^^|OK|||||F||||20231205073351<CR>

2023-12-05 19:33:51.367 W R|5|^^^T2^^^^|ERROR|||||F||||20231205073351<CR>

2023-12-05 19:33:51.367 W R|6|^^^T3^^^^|OK|||||F||||20231205073351<CR>

2023-12-05 19:33:51.367 W R|7|^^^SECONDARY_T_1^^^^|A010001_A1|||||SUCCESS||||20231205073351<CR>

2023-12-05 19:33:51.367 W R|8|^^^SECONDARY_T_2^^^^|AAAA12_A12|||||SUCCESS||||20231<ETB>87<CR>

2023-12-05 19:33:51.407 W <LF>

2023-12-05 19:33:51.407 R <ACK>

2023-12-05 19:33:51.407 W <STX>3205073351<CR>

2023-12-05 19:33:51.407 W L|1|N<CR>

2023-12-05 19:33:51.407 W <ETX>DD<CR>

2023-12-05 19:33:51.427 W <LF>

2023-12-05 19:33:51.427 R <ACK>

2023-12-05 19:33:51.427 W <EOT>

The LIS will confirm that results have been received in the application layer by sending H and L frames:

2023-12-05 19:33:51.767 R <ENQ>

2023-12-05 19:33:51.767 W <ACK>

2023-12-05 19:33:51.787 R <STX>1H|\^&|||LIS|||||A9000P||P|LIS2-A2|<CR>

2023-12-05 19:33:51.787 R L|1|F<CR>

2023-12-05 19:33:51.787 R <ETX>C9<CR>

2023-12-05 19:33:51.787 R <LF>

2023-12-05 19:33:51.787 W <ACK>

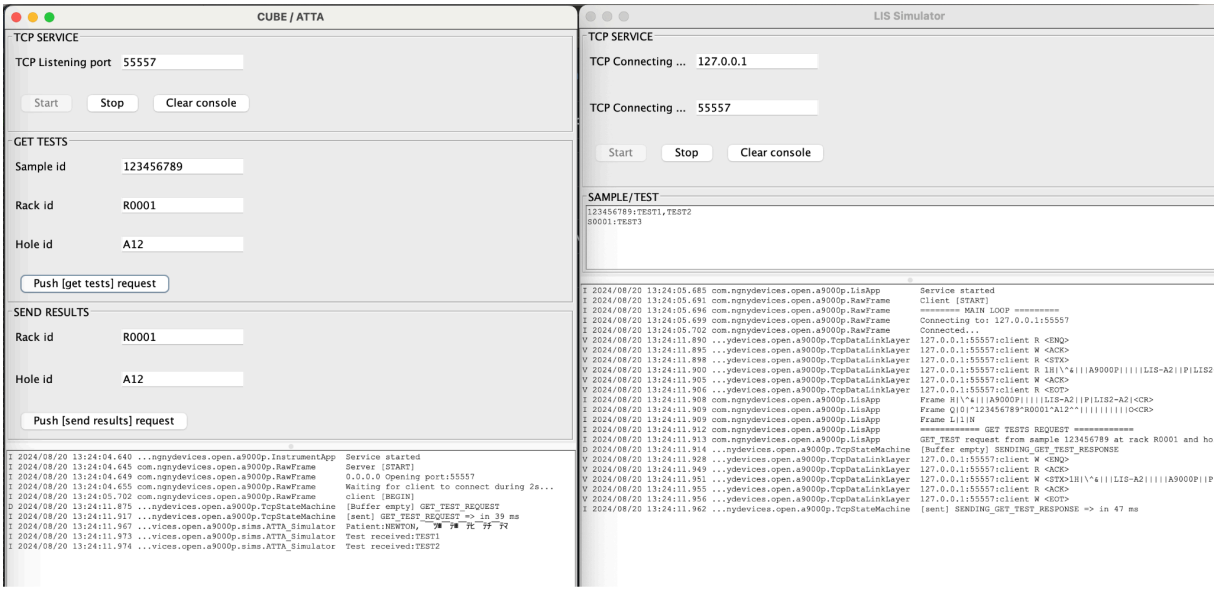
2023-12-05 19:33:51.787 R <EOT>

In order to facilitate integration, the following repository contains a simulator of both the LIS and the instrument, including the source code of the implementation. This source is distributed freely from any license and can be used as a starting point for new implementations.

https://github.com/ngny/AQUALink-sample

The following file contains a readme with the instructions.

https://github.com/ngny/AQUALink-sample/tree/master/a9000p/app



The test procedure would use the instrument simulator against the newly developed LIS application. Please remember that in the A9000P protocol, the LIS instrument is the TCP client while the system is the TCP server, which listens for TCP connections from the LIS.

5. WSDL XML Communication Protocol: AquaLIS v3.0

Communication Configuration

The system software manages the information and communications between the system (1 or more) and the Laboratory Information System (LIS).

This section describes the communication protocol between the system software and the LIS.

- ➢ The LIS is the server. It will deploy an HTTP SOAP XML Web service over TCP/IP.
- ➢ The system software is the client. It will send HTTP SOAP XML requests and will wait for the response from the server.
- ➢ The LIS should be able to handle multiple concurrent requests from the client.

A WSDL (Web Service Description Language) document describes this web service. It specifies the location of the service and the methods.

WSDL of Communication

In this link, you can find the document describing the web service and examples. You can also find a code to test using a curl command from a terminal.

https://raw.githubusercontent.com/ngny/AQUALink-sample/master/aqualis_3.07_wsdl.xml

Future versions of the system software might include new optional fields that will be described in future WSDL releases. LIS implementation should ignore optional fields even if not defined in the WSDL at the time the LIS was implemented.

IP Addresses

In a specific system installation, the computer with the system software has to be given an IP that is reachable from the LIS computer.

LIS Port

The LIS must be listening for requests at a specific communication port.

Requests from the System Software to the LIS

The LIS module must be listening at a given TCP port for incoming HTTP SOAP/XML requests.

The system software (in this case, the client) sends requests to the LIS (in this case, the server) and waits for a response. The timeout to receive a response is 30 seconds. If the response time exceeds 3 seconds, the communication will affect the system's performance.

There are two types of payloads:

- ➢ Get Tests
- ➢ Send Results

Get Tests

This message is sent from the system to the LIS for two possible reasons:

- A hardware has picked a sample from an input rack and has read the Sample ID's barcode.
- An operator has requested manually the information and the actions related to a Sample ID's code from the interface of a system software.

Request Message

```
<?xml version="1.0" encoding="UTF-8"?>
<S:Envelope xmlns:S="http://schemas.xmlsoap.org/soap/envelope/">
   <S:Body>
      <GetTests xmlns="http://www.ngnydevices.tech/aqualis/3-0">
         <ClientId>CLIENT_ID</ClientId>
         <PrimaryTube>
            <Id>TUBE_ID</Id>
            <Location>
               <RackId>RACK_ID</RackId>
               <HoleId>HOLE_ID</HoleId>
            </Location>
            <TubeContainers>
               <TubeContainer>
                  <Name>CONTAINER_NAME</Name>
               </TubeContainer>
            </TubeContainers>
         </PrimaryTube>
      </GetTests>
   </S:Body>
</S:Envelope>
```

The following table gives more detailed information about this structure:

Variable	Description	Example Value	Usage
CLIENT_ID	Installation identifier (it is usually the serial number of the system hardware where the operation is performed)	S403100	Mandatory
TUBE_ID	Identifier of the primary tube as read on the barcode	312011223344	Mandatory
RACK_ID	Identifier of the rack from which the tube has been picked	InputRack1	Mandatory
HOLE_ID	Coordinates in the rack from which the tube has been picked	C6	Mandatory
CONTAINER_NAME	Name of the container in the container list as defined in the database	SERUM	Optional

When manually-operated, the **Location** field is optional.

Response Message

By default, the response from the LIS should include only the list of pending tests*. However, if there are special requirements for sorting and aliquoting, it is possible to send the complete list of tests, and it is possible to specify the state of each test.

***Note**: The system software calculates what actions to perform (sorting primary destination, decapping, aliquots, volumes of aliquots…) with the list of tests received. The tests can be real analytic determinations that are pending in the LIS database, or can be virtual tests that are agreed with the LIS and are configured during installation and start-up. For example, one virtual test per each possible aliquot type can be used. The volume and properties of the aliquot are configured in the database of the system software.

You can see an example of a response message below:

```
<?xml version="1.0" encoding="UTF-8"?>
<S:Envelope xmlns:S="http://schemas.xmlsoap.org/soap/envelope/">
   <S:Body>
      <GetTestsResponse xmlns="http://www.ngnydevices.tech/aqualis/3-0">
         <Result>LIS_RESULT</Result>
         <PrimaryTube>
            <Id>TUBE_ID</Id>
            <Location>
               <RackId>RACK_ID</RackId>
               <HoleId>HOLE_ID</HoleId>
               <TubeContainers>
                  <TubeContainer>
                     <Name>CONTAINER_NAME</Name>
                  </TubeContainer>
               </TubeContainers>
            </Location>
         </PrimaryTube>
```

```
            <Order>
               <Status>ORDER_STATUS</Status>
               <Priority>ORDER_PRIORITY</Priority>
               <Id>ORDER_ID</Id>
            </Order>
            <SampleSource>
               <ExtractionCenter>EXTRACTION_CENTER</ExtractionCenter>
               <Service>SERVICE</Service>
               <Section>SECTION</Section>
            </SampleSource>
            <Patient>
               <Id>PATIENT_ID</Id>
               <FamilyName>FAMILY_NAME</FamilyName>
               <FirstName>FIRST_NAME</FirstName>
               <MiddleName>MIDDLE_NAME</MiddleName>
               <Sex>PATIENT_SEX</Sex>
               <Physician>PHYSICIAN</Physician>
               <Type>PATIENT_TYPE</Type>
               <BirthDate>BIRTHDATE</BirthDate>
            </Patient>
            <CustomFields>
               <CF1>CF1_VALUE</CF1>
               <CF2>CF2_VALUE</CF2>
               <CF3>CF3_VALUE</CF3>
               <CF4>CF4_VALUE</CF4>
               <CF5>CF5_VALUE</CF5>
               <CF6>CF6_VALUE</CF6>
               <CF7>CF7_VALUE</CF7>
               <CF8>CF8_VALUE</CF8>
               <CF9>CF9_VALUE</CF9>
               <CF10>CF10_VALUE</CF10>
            </CustomFields>
            <Tests>
               <Test>
                  <Id>TEST1</Id>
                  <Status>TEST_STATUS</Status>
                  <SecondaryTubeId>SEC_TUBE_ID1</SecondaryTubeId>
                  <SecondaryVoluL>SEC_VOLUME</SecondaryVoluL>
                  <SecondaryDestination>SEC_DESTINATION</SecondaryDestination>
                  <SecondaryName>SEC_NAME</SecondaryName>
               </Test>
               <Test>
                  <Id>TEST2</Id>
                  <Status>TEST_STATUS</Status>
                  <SecondaryTubeId>SEC_TUBE_ID2</SecondaryTubeId>
               </Test>
               <Test>
                  <PrimaryTubeDestination>PRIMARY_TUBE_DEST</PrimaryTubeDestination>
                  <PrimaryTubePriority>PRIMARY_TUBE_PRIORITY</PrimaryTubePriority>
                  <Id>TEST_PRIM</Id>
                  <Status>Pending</Status>
               </Test>
            </Tests>
         </GetTestsResponse>
      </S:Body>
   </S:Envelope>
```

The following table gives more detailed information about this structure:

Variable	Description	Example Value	Usage
LIS_RESULT	Result of the internal query of the LIS. **Valid values**: Success PrimaryTubeNotFound InternalError	Success	Mandatory
TUBE_ID	Identifier of the primary tube	312011223344	Mandatory
RACK_ID	Identifier of the rack from which the tube was picked	InputRack1	Mandatory
HOLE_ID	Coordinates in the rack from which the tube was picked	C6	Mandatory
ORDER_ID	Order identifier for the current Sample ID	11223344	Optional
ORDER_STATUS	Status of the order for the current Sample ID	Opened	Optional
ORDER_PRIORITY	Priority of the order for the current Sample ID	Routine	Optional
EXTRACTION_CENTER	Identifier of the extraction center where the Sample ID is coming from	12345	Optional
SERVICE	Identifier of the service demanding the current order for the current Sample ID	AAA	Optional
SECTION	Identifier of the section of the laboratory in charge of the current Sample ID	BBB	Optional
PATIENT_ID	ID of the patient	2233667744B	Optional
PATIENT_TYPE	Type of patient	Human	Optional
PATIENT_SEX	Sex of patient	Male	Optional
FAMILY_NAME	Family name of patient	Smith	Optional
FIRST_NAME	First name of patient	John	Optional
MIDDLE_NAME	Middle name of patient	Levin	Optional
PHYSICIAN	Name of the doctor	Conrad	Optional
BIRTHDATE	Birthdate of the patient (“yyyymmdd” format)	1975/18/03	Optional
CF1_VALUE	Custom field #1 value		Optional

CF2_VALUE	Custom field #2 value		Optional
CF3_VALUE	Custom field #3 value		Optional
CF4_VALUE	Custom field #4 value		Optional
CF5_VALUE	Custom field #5 value		Optional
CF6_VALUE	Custom field #6 value		Optional
CF7_VALUE	Custom field #7 value		Optional
CF8_VALUE	Custom field #8 value		Optional
CF9_VALUE	Custom field #9 value		Optional
CF10_VALUE	Custom field #10 value		Optional
TEST1..N	Identifiers of the tests linked to a Sample ID	GLU	Mandatory*
TEST_STATUS	Status of the current test for the Sample ID. **Valid values:** Validated Done Pending Cancel	Pending	Mandatory
SEC_TUBE_ID1..N	ID to be printed in the generated aliquot tube according to each test. If not used, the standard rules to generate aliquot IDs will be used.	12300001	Optional
SEC_VOLUME	Volume (in uL) to be dispensed in the aliquot tube. If not used, the standard rules to calculate the aliquot volume will be used.	300	Optional
SEC_DESTINATION	Destination where the aliquot tube has to be sorted. If not used, the standard rules to determine the aliquot's sorting destination will be used.	IMMUNO	Optional
SEC_NAME	Name of the aliquot tube to be printed in the label. If not used, the standard rules to determine the aliquot's name will be used.	ENA	Optional

CONTAINER_NAME	Name of the container in the container list as defined in the database	SERUM	Optional
PRIMARY_TUBE_DEST	The LIS can use this field to select the sorting destination of the primary sample.	DEST1	Optional
PRIMARY_TUBE_PRIORITY	This priority can be used to find the destination with higher priority.	1	Optional

* If there are no tests for a Sample ID, the response will include an empty test list.

Send Results

This message is sent from the system software to the LIS for two possible reasons:

1. A hardware has placed a sample at an output rack (actions finished) and sends the results for every requested test.
2. An operator has manually performed some actions related to a Sample ID code and confirms the result of them.

Request Message

```
<?xml version="1.0" encoding="UTF-8"?>
<S:Envelope xmlns:S="http://schemas.xmlsoap.org/soap/envelope/">
   <S:Body>
      <SendResults xmlns="http://www.ngnydevices.tech/aqualis/3-0">
         <ClientId>CLIENT_ID</ClientId>
         <ProcessedPrimaryTube>
            <Id>TUBE_ID</Id>
            <Status>PRIMARY_STATUS</Status>
            <Location>
               <RackId>RACK_ID</RackId>
               <HoleId>HOLE_ID</HoleId>
            </Location>
            <VisualAnalysis>
               <Width>PRIMARY_WIDTH</Width>
               <Height>PRIMARY_HEIGHT</Height>
               <VolumeEstimation>VOLUME_ESTIMATION</VolumeEstimation>
               <CapType>CAP_TYPE</CapType>
               <HValue>H_VALUE</HValue>
               <IValue>I_VALUE</IValue>
               <LValue>L_VALUE</LValue>
               <PictureUrl>PICTURE_URL</PictureUrl>
            </VisualAnalysis>
            <Comment>PRIMARY_COMMENT</Comment>
            <TubeContainers>
               <TubeContainer>
                  <Name>CONTAINER_NAME</Name>
               </TubeContainer>
            </TubeContainers>
         </ProcessedPrimaryTube>
         <TestResults>
            <Test>
               <Id>TEST1</Id>
               <Status>TEST_ACTION_RESULT</Status>
            </Test>
            <Test>
               <Id>TESTN</Id>
               <Status>TEST_ACTION_RESULT</Status>
            </Test>
         </TestResults>
         <GeneratedSecondaryTubes>
            <SecondaryTube>
               <Id>SEC_TUBE_ID</Id>
               <Location>
                  <RackId>RACK_ID</RackId>
                  <HoleId>HOLE_ID</HoleId>
               </Location>
               <Comment>SECONDARY_COMMENT</Comment>
               <VolumeMl>SECONDARY_VOLUME</VolumeMl>
               <Status>SECONDARY_STATUS</Status>
            </SecondaryTube>
         </GeneratedSecondaryTubes>
      </SendResults>
   </S:Body>
</S:Envelope>
```

The following table gives more detailed information about this structure:

Variable	Description	Example Value	Usage
CLIENT_ID	Installation identifier (it is usually the serial number of the hardware where the operation is performed)	S403100	Mandatory
TUBE_ID	Identifier of the primary tube as read on the barcode	312011223344	Mandatory
PRIMARY_STATUS	Status of the current actions for the Sample ID of the primary tube **Valid values:** Success Failure	Success	Mandatory
RACK_ID	Identifier of the rack where the tube has been placed	200329	Mandatory
HOLE_ID	Coordinates in the rack where the tube has been placed	A2	Mandatory
PRIMARY_WIDTH	Width of the Sample ID in mm	15.3	Optional
PRIMARY_HEIGHT	Height of the Sample ID in mm	100	Optional
CAP_TYPE	Cap type of the Sample ID	Yellow	Optional
VOLUME_ESTIMATION	Estimated available volume of the Sample ID in mL	2.4	Optional
H_VALUE	Estimation of a hemolyzed sample's ID	True	Optional
I_VALUE	Estimation of an icteric sample's ID	False	Optional
L_VALUE	Estimation of a lipemic sample's ID	False	Optional
PICTURE_URL	HTTP to download the captured image of the primary tube in JPEG format	http://10.0.0.10/32131434.jpeg	Optional
PRIMARY_COMMENT	Comment related to the integrity of the primary tube	Label placed too low	Optional
TEST1..N	Identifiers of the tests linked to a sample's ID	GLU	Mandatory
TEST_ACTION_RESULT	Result of the operations done according to that test **Valid values:** Success Failure	Success	Mandatory

SEC_TUBE_ID	Identifier of the secondary tube generated	223011223344	Mandatory
SECONDARY_COMMENT	Comment related to the generated secondary tube	Not capped	Optional
SECONDARY_VOLUME	Volume dispensed in the secondary tube in mL	0.7	Optional
SECONDARY_STATUS	**Valid values:** Success AspirationError TubeGenerationError FamilyCancelError LisError DispenseError PipettorStateError NoResult AliquotePending DiameterTooHighForOutputHole TubeCheckFailure	Success	Mandatory

Examples of situations:

- A Sample ID has multiple sorting destinations related to different tests and the tube is sorted into the one with higher priority.
  - The answer will include “Success” in the “TEST_ACTION_RESULT” only for the tests leading to that destination, and “Failure” for the tests that had a different sorting destination.
- A Sample ID has multiple secondary tubes to generate and it fails because there is not enough sample.
  - The answer will include “Success” in the “TEST_ACTION_RESULT” only for the tests that were included in the secondary tubes completely filled, and “Failure” for the tests included in the secondary tubes not filled completely.

Response Message

```
<?xml version="1.0" encoding="UTF-8"?>
<S:Envelope xmlns:S="http://schemas.xmlsoap.org/soap/envelope/">
   <S:Body>
      <SendResultsResponse xmlns="http://www.ngnydevices.tech/aqualis/3-0">
         <Result>RESULT_RECORDED</Result>
      </SendResultsResponse>
   </S:Body>
</S:Envelope>
```

The following table gives more detailed information about this structure:

Variable	Description	Usage
RESULT_RECORDED	**Valid values:** Success InternalError	

6. Contact

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