



Chapter 5

On-line Communication

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5.1 COMTEST 2000

5.1.1 Description

The COM TEST 2000 is a hyperlink program, found normally under "accessories" in "Start Menu\Program", and is used to check the COM ports in the LIAISON PC with one another. This serves the purpose of (1) identifying the functionality of each COM port and (2) identifying the correct port in case of wrong labeling.

5.1.2 Set up

The COM TEST 2000 icons are located inside the "LIAISON® Tools" folder on the "Desktop". Each icon represents its appropriate numbered COM port. (See below)



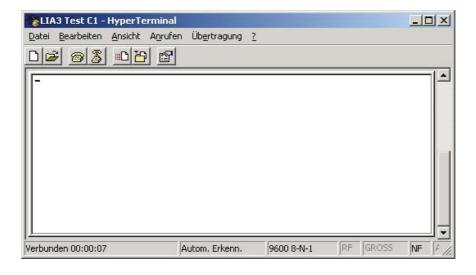
COM TEST 2000 is previously configured and must only be activated in order to check the COM ports.

5.1.3 Instructions

After successful installation of the LIAISON software 2.07, COM TEST 2000 icons will automatically be present in the Liaison tools folder. The actual program is located in the folder "HyperTerminal" under "C:\Documents and settings\Administrator\Start Menu\Programs\Accessories\Communication\".

The COM TEST is to be utilized as follows:

- 1. With the LIAISON® software closed, remove the RS232 Cable from the LIAISON® analyzer and connect it to the two COM port jacks to be checked located in the back of the LIAISON® PC.
- 2. Open the "LIAISON® Tools" folder located on the "Desktop" and double click one of the connected COM port icons. The following window will appear:







- Double click on the second connected COM port icon and a similar window will appear.
- 4. Click on the symbol and on both windows to activate them.
- 5. Now type on the keyboard and if the system is working correctly, the typed items should appear on the non-activated window.
- 6. Click in the other HyperTerminal window and type on the keyboard to send data in the opposite direction.
- 7. End the connection by pressing the icon [3]. The windows may now be closed.
- 8. If the HyperTerminal is not working as expected, there may be a problem with one or more of the COM ports. In order to locate the problem the cable should be changed on one end and reconnected between the remaining COM ports and the process should be repeated between the newly connected COM ports.

Example:

- The COM port 3 is assumed to be broken.
- Use COM 1 as a reference COM port, assuming it is functioning properly because of the constant communication between PC and analyzer
- Connect COM 3 to COM 1 via RS232 cable and perform the COM Test.
- If the COM Test is successful, COM 3 is working.
- If the COM Test is not successful, check the correctness of the COM Test settings by performing the COM Test excluding COM 3 (i.e. the test can be repeated between COM 1 & COM 2).
- If the result of this test confirms that COM 3 is not working properly, it may be necessary to replace the port or in worst-case situations, replace the PC.





5.2 LIA32D.ini

The "LIA32D.ini" is a WordPad file located in the folder "C:\Lia32.m\bin_d". This file is used by engineers to set certain default settings in the LIAISON® software. The following sections describe what each setting means and which possibilities are available to change any particular settings. An *.ini file is divided in sections and entry's. The section is the clipped term and the entry is the term in front of the equal character.

5.2.1 Data structure

[Application]

Company=BYK
Language=Engl
IFULanguage=Engl
CDDrive=D

[DatabaseDir]

Dictionary=C:\Lia32.m\
Data=C:\Lia32.m\Data\
Working=C:\Lia32.m\
System=C:\Lia32.m\
Errors=C:\Lia32.m\
Validate=C:\Lia32.m\

[AccessRights]

StorageName=C:\Lia32.m\Data\AccessRights.dat
Backup=Yes

[LISInterface]

LoadingQuery=N
TransmitValidResults=Y
UploadFrequency=0
NoOfTries=3
MaxHostFrequency=30
CompressedOrderQuery=N

[RS232]

Astm=Yes Lia2=no

[Loading]

LIS=no
Barcode=yes
Ext.Bottles=yes

[Prefixes]

Controls=#
Standards=\$

[Programs]

Brendan=C:\Lia32.m\QC\qc.exe

[Defaults]

Percent_DiveInRight=50
Percent_DiveInLeft=0
Percent_DiveInIncu=0
temp_unit=Celsius
RunMode=0
QC-Flag=1

Asy-Import1=D:\V20\

Definitions

[Bold Black Print] = ini file sections

Normal black Print = Sub-entries for each section

Bold Blue Print = Additional data included in the SW version 2.07 ini file





Asy-Import2=A:\V2.0\
Asy-Import3=C:\assays\
Asy-Import4=<Select & Edit>
sortCrit[0]=4
sortCrit[1]=6
sortCrit[2]=0
sortCrit[3]=3
sortCrit[4]=4
sortCrit[5]=3
Spacing=10
QC-Flag=1
AutoReflexCollect=6
ReportResults=0

5.2.1.1 Definition of LIA32D.ini entries (except Host entries)

The following table lists all "LIA32D.ini entries except settings for Host connection (see section 3)

Section	Entry	Value	Description		
[Application]	Company	BYK	Program of operation. No changes possible.		
[Application]	Language	engl, dani, gree, fren, germ, ital, port, span, swed	 This entry sets the language for the LIAISON[®] software. The language may only be changed if the selected language files are installed in the proper software folders. engl = English; dani = Danish; gree = Greek; fren = French; germ = German; ital = Italian; port = Portuguese; span = Spanish; swed = Swedish 		
[Application]	IFU Language	engl, dani, gree, fren, germ, ital, port, span, swed	 The language for the IFU icons located in the software. The language should be selected to match the language of the Liaison program. engl = English; dani = Danish; gree = Greek; fren = French; germ =German; ital = Italian; port = Portuguese; span = Spanish; swed = Swedish 		
[Application]	CDDrive	D, E,	The setting of the CD drive for the PC		
	,				
[DatabaseDir]	Dictionary=C:\Lia32.m\ Data=C:\Lia32.m\Data\ Working=C:\Lia32.m\ System=C:\Lia32.m\ Errors=C:\Lia32.m\ Validate=C:\Lia32.m\	No changeable value	These entries determine where software essential data is stored and retrieved from the software. These data are non-changeable. If these data are changed, the software may not function properly!!		
[AccessRights]	StorageName=C:\Lia32.m\Data \AccessRights.dat Backup=Yes	No changeable value	These entries determine where access rights data is stored and retrieved from the software. These data are non-changeable. If these data are changed, the software may not function properly!!		
[DunC]	Combined 1	N.L.	This pater determines which a substitute of the		
[Prefixes]	Controls=#	No changeable value	This entry determines which symbol must be present for the software to automatically recognize a control in the Dialog <sample loading=""> (reported in Dialog <daily -="" journal="" lab="">). This entry is non-changeable. If this entry is changed, the software may not function properly!!</daily></sample>		
[Prefixes]	Standards=\$	No	This entry determines which symbol must be		





		changeable value	present for the software to automatically recognize standards (also known as calibrator or system controls) in the Dialog <sample loading=""> (reported in Dialog <daily -="" journal="" lab="">). This entry is non-changeable. If this entry is changed, the software may not function properly!!</daily></sample>
[Programs]	Brendan=C:\Lia32.m\QC\qc.ex e	No changeable value	This entry determines where the QC program shall be accessed and data is stored and retrieved from the software. This entry is non-changeable. If this entry is changed, the QC software will not function properly!!
[Defaults]	Percent_DiveInRight	0 to 100	 This parameter specifies (in percent), how deep the tip should dive into the distance between the globally taught in ZDispense and the individually taught in ZMax before performing the dispense in the rightmost cuvette position. A value of 0% means that the probe doesn't move any deeper and dispenses from the z value taught in Global_ZDispense. A value of 50% means that the probe moves half the way down to Individual_ZMax and dispenses from there. A value of 100% means that the probe moves all the way down to Individual_ZMax and dispenses from there. Default: 0
[Defaults]	Percent_DiveInLeft	0 to 100	 This parameter specifies (in percent), how deep the tip should dive into the distance between the globally taught in ZDispense and the individually taught in ZMax before performing the dispense in the leftmost cuvette position. A value of 0% means that the probe doesn't move any deeper and dispenses from the z value taught in Global_ZDispense. A value of 50% means that the probe moves half the way down to Individual_ZMax and dispenses from there. A value of 100% means that the probe moves all the way down to Individual_ZMax and dispenses from there. Default: 0
[Defaults]	Percent_DiveInIncu	0 to 100	 This parameter specifies (in percent), how deep the tip should dive into the distance between the globally taught in ZDispense and the individually taught in ZMax before performing the dispense in the incubator. A value of 0% means that the probe doesn't move any deeper and dispenses from the z value taught in Global_ZDispense. A value of 50% means that the probe moves half the way down to Individual_ZMax and dispenses from there. A value of 100% means that the probe moves all the way down to Individual_ZMax and dispenses from there.





			Default: 0
[Defaults]	temp_unit=Celsius	Celsius, Fahrenheit	Displays the default temperature measurements in the LIAISON® software. Default: Celsius
[Defaults]	RunMode=0	0 - 1 Defines the used run mode (Random access Batch, Run optimized) Default: 0 = Random access 0: Random access 1: Batch	
[Defaults]	Spacing	1 n	In the result printout the spacing between sample results (not between replicates) in #of pixels
[Defaults]	QC-Flag=1		
[Defaults]	Asy-Import1=D:\V20\ Asy-Import2=A:\V2.0\ Asy-Import3=C:\assays\	No changeable value	Displays the priority order for importing a method file. These entries may be changed only under direct information from DiaSorin.
[Defaults]	Asy-Import4= <select &="" edit=""></select>		The last priority of order for method file importing. The " <select &="" edit="">" may be set to a path wished by the customer.</select>
[Defaults]	sortCrit[0]=4 sortCrit[1]=6 sortCrit[2]=0 sortCrit[3]=3 sortCrit[4]=4 sortCrit[5]=3	See sort criteria table below	These entries define the default order for results that are found in the LIAISON® software.
[Defaults]	AutoReflexCollect	1 n	The given number (n) determines how many AutoReflex & Autodilution results will be collected before starting these with a STAT status. When no number is given in this position the default will be present (1). This can (in a worst case situation) lead to the software recalculating the scheduled jobs every 18 seconds. This leads in turn to an overload in the PC and nothing will be processed. 6 is an acceptable standard value. The higher the value, the higher the possibility that the cuvettes will be used effectively.
[Defaults]	ReportResults	0 / 1	 "0" Shows no results when "low liquid" or "no liquid" appears. Results are shown as "Failed" "1" Allows results to appear regardless of "low liquid" or "no liquid".





5.2.1.2 Sort Criteria entries

The following table describes the order listed in the "sort criteria" entries.

Table: "Sort criteria"

Entry	Description
sortCrit[0]	Defines the default sort criteria in the Dialog < Daily Result Journal>
	0 = chronological
	1 = SampleID + Assay
	2 = Assay + SampleID
	3 = Sender
	4 = PatName
	5 = Status
	6 = Position
sortCrit[1]	Defines the default sort criteria in the Dialog < Valid Results Journal >
	0 = chronological
	1 = SampleID + Assay
	2 = Assay + SampleID
	3 = Sender
	4 = PatName
sortCrit[2]	Defines the default sort criteria in the Dialog <control journal="" results=""></control>
	0 = chronological
	1 = SampleID + Assay
	2 = Assay + SampleID
	5 = Status
sortCrit[3]	Not used
sortCrit[4]	Defines the default sort criteria in the Dialog < Calibrator Results Journal >
	0 = chronological
	1 = SampleID + Assay
	2 = Assay + SampleID
	5 = Status
sortCrit[5]	Defines the default sort criteria in the Dialog <event log=""></event>
	0 = chronological
	1 = Error Code





5.3 Host Connection setup

The following pages describe the LIS (Host) setup on the LIAISON® analyzer. It is important to read and understand all instructions completely before starting to configure a LIS (Host) setup on an actual LIAISON® system.

5.3.1 Introduction

 $LIAISON^{\otimes}$ system can be set up to communicate with LIS in different configurations; these are available changing the configuration setting file "Lia32D.ini" present in the directory c:\Lia32.m\bin_d\.

Note: *LIS = Laboratory Information System*: system used for computerized management of labs dedicated to chemical-clinical or microbiological analysis.

Note: The LIAISON[®] software must be closed before starting the modifications.

5.3.2 On Line Setting

When the LIAISON[®] is Host connected, a setting can be done from the main program, using the ASTM Setup Dialog present in "System → Online" (Fig.1)

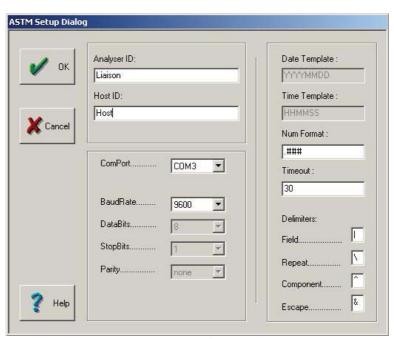


Fig.1

AnalyserID	This field allows to assign an unique InstrumentID to the LIAISON®		
HostID	This field allows to assign a name to the host		
ComPORT	This field specifies the serial port used for host transmissions. Host can be connected to any free COM port, except for COM1 (used for the connection to the Analyzer)		
BaudRate	Specifies the Baudrate used for transmissions between the LIAISON® and the host any values from 4800 to		





	19200 can be chosen. LIAISON® and Host have to have			
	the same Baudrate speed			
NumFormat	Specifies the character used as decimal point and the maximum number of digits sent after the decimal point. Any numerical formats specified in the assay definition and containing more digits will be truncated.			
Timeout	Within <timeout> seconds the LIAISON® expects a response to a query messages sent to the host. If within <timeout> seconds transmission of a response has not started yet the LIAISON® will abort the session. Default value is 30, modification is not recommended.</timeout></timeout>			
Delimiters	These fields specify the set of delimiters used for			
	transmissions.			

All these setting are saved in the file ASTM_INI.dat present inside the directory c:\Lia32.m\bin_d (for software 1.9X and lower) or c:\Lia32.m\data (for software 2.07 and higher)

5.3.3 How to upload/download from the main software

Any settings allow the download of the job-list using the button "Online" in the Results/Journal (Fig.2).



Fia.2

Two different icons can be found in the "Journal" end/or in the "Valid" menu but with different functions:



Requesting job list from LIS (Download)



Sending results to LIS (Upload)





5.3.4 LIA32D.ini file Settings for Host connection

There are different modes to run the LIAISON[®]-Host connection. This table describes the host entries located in the lia32d.ini files and which values may be used for each entry. The Query mode settings are in the sections [LISInterface] and [Loading].

Section	Entry	Value	Description
	Entry		
[LISInterface]	LoadingQuery	y/n	Specifies if host queries will be sent when loading samples Default: Y
[LISInterface]	TransmitValidResults	y/n	Specifies if results shall automatically be sent to LIS (when they are measured) (N) or kept by the system and be sent only after inspection and validation by the operator (Y) Default: Y There are two ways for a result upload to the Host. By validating at the LIAISON® and uploading the valid results a "Y" must be inserted. By uploading results without validating them, a "N" must be inserted.
[LISInterface]	UploadFrequency	0 n	Specifies how many results shall be grouped into one transmission session, value is relevant only if "TransmitValidResults =N", otherwise ignored Default: 6 After a given amount of results (n), a result message is generated and automatically uploads to the LIS. Automatic result upload can be disabled by setting UploadFrequency=0.
[LISInterface]	NoOfTries	1 n	Specifies how often the communication should be retried Default: 3
[LISInterface]	MaxHostFrequency	1 n	Specifies how often a LIS may send queries to Liasion. If LIS sends queries more often than once in "MaxHostFrequency" seconds the query is ignored from Liaison. Default: 30sec
[LISInterface]	CompressedOrderQuery	y / n	Specifies if queries for test orders shall be sent using repeat delimiters or not. Default: N
[RS232]	Astm=Yes	Yes/No	Specifies if LIS connection operates over [RS232] connection. Default: Yes If "No" is selected the LIS connection will not function.
[RS232]	Lia2=no	Yes/no	
[Loading]	LIS	Yes/no	 Insert "yes", if the default AssayList (in the SampleLoadingDialog) is to be displayed in "Entire" mode Insert "no", if the default AssayList (in the SampleLoadingDialog) is to be displayed in "Edit" mode
[Loading]	Barcode	Yes/no	 Insert "yes" when wanting to read the patient information via barcode. Insert "no" if no barcodes are available. The "Proposal-Button" can be used in this case to get the sample ID.
[Loading]	Ext.Bottles	yes	•





[Loading]

LIS=no → The Sample Loading Dialog is displayed in "Edit" mode (Fig.3)

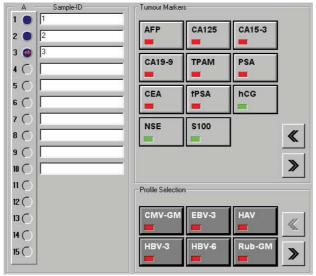


Fig.3

LIS=yes → The Sample Loading Dialog is displayed in "Entire" mode (Fig.4)

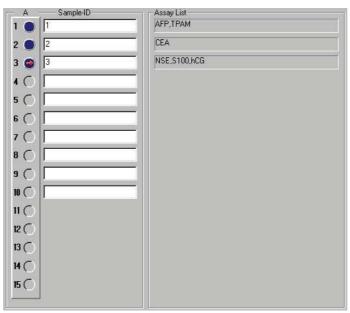


Fig.4





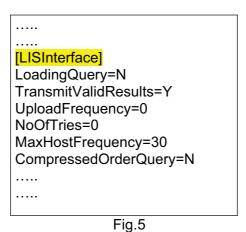
5.3.5 INI File setting

- **Query all**: LIAISON® sends a query (using online button) for all the patients the LIS send the complete (All) job list.
- Host Query: When you load the samples on the Liaison, after closing the flap or within a
 certain period of time (<1 minutes), the Liaison sends a query and the LIS
 send back the job list associated to those samples.

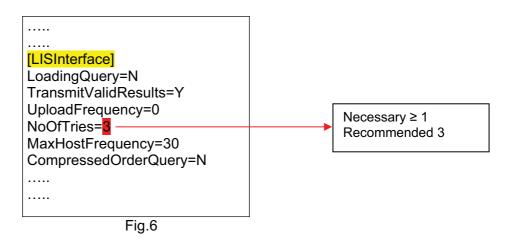
Different setting:

- a. Query all
- b. Host query with validation on LIAISON®
- c. Host query without validation on LIAISON® as manual sending of results
- d. Host query without validation on LIAISON® as automatic sending of results

Settings to be done on Lia32D.ini file have to be performed in the paragraph [LISInterface] (Fig.5).



5.3.5.1 Query all (Fig. 6)

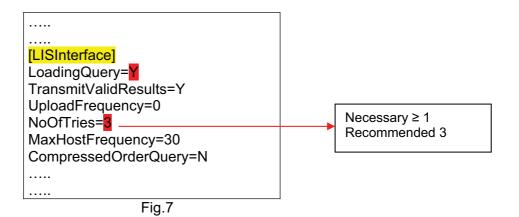


The default ini file installed by the software 2.07 is already prepared for query all mode.

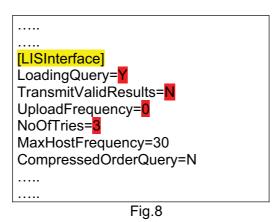




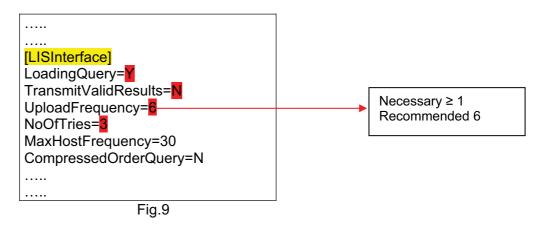
5.3.5.2 Host query with validation on LIAISON® (Fig. 7).



5.3.5.3 Host query without validation on LIAISON® as manual sending of results (Fig. 8).



5.3.5.4 Host query without validation on LIAISON® as automatic sending of results (Fig. 9).



When the message "ALL TESTS DONE" appears in the message box all the pending results will be automatically transmitted by the LIAISON® to LIS.





Note: for the configurations "C" & "D" (when TransmitValidResults=N) the button "Valid" in the <u>Daily Lists</u> and in the <u>Daily Lab Journal</u> will not appear (Fig. 10 and 11).

A new Online button to upload results will appear in the <u>Daily Lab Journal</u>. (Fig. 11)

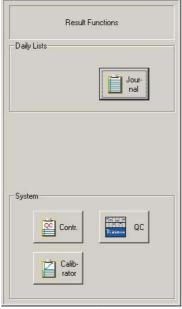


Fig.10

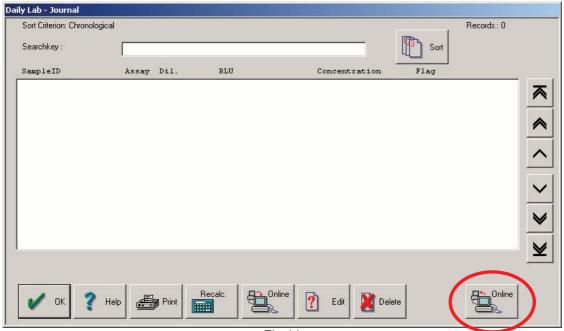


Fig.11

Note: In all the above mentioned settings, the LIS can send a query (ALL) and the LIAISON[®] will sends back ALL the results to LIS.





5.4 LIAISON® Host Interface Manual

Specifications for Host connection with LIAISON® as listed below should be provided to the central software departments for correct configuration of Host computers.

NOTE: Originated by Stratec document "LISInterface_SSD.doc" (Revision 10 12/07/2004 14.50)

5.4.1 Introduction

5.4.1.1 Purpose

This document is intended to describe the software specification for Liaison V2.0 in a concrete and unambiguous manner, so that all requirements as specified in related documents are met.

5.4.1.2 Scope

This document is part of a series of documents describing the functionalities of the entire Liaison Software. It includes the specification of the message exchanged between the Liaison system and a host system.

5.4.2 General Information and Specification

This description is intended to document the interface for exchanging information between the Liaison instrument and a host computer.

Communication between the Liaison and an external host computer consists of receiving test requests from the host and reporting results back to the host. This is accomplished via an RS232 connection and follows the ASTM 1394 (high level) and 1381 (low level) standards for communication.

The Liaison host interface consists of:

- ASTM 1381 low-level transfer protocol used to transmit or receive messages
- intermediate files used for temporarily storing data received (local to the Liaison application)
- interpretation of received data from the intermediate files and entering it into the Liaison database
- intermediate files used to temporarily store data to be sent to the host

The general procedure at the Liaison related to communication with an external host, as well as the specific implemenation of the ASTM standards are described here.

The ASTM 1394 defines how the data to be transmitted is represented as a structured message consisting of several records as described in section 5 below. These messages are then translated into one or more frames that will actually be transmitted according to section 3 below and ASTM 1381.



5.4.2.1 Procedure

- 1. Liaison communication sessions with a host computer can be initiated on request of the Liaison operator.
- 2. An operator can download all pending test orders from the host (Results -> Journal -> Online



3. An operator can upload all or a selection of test results on request through a Liaison menu



- selection (Results -> Journal -> Online
- 4. In addition the LIAISON can generate query messages "spontaneously" during patient loading to query test orders for barcoded patient samples.
- 5. The LIAISON can upload patient results whenever results have become available. Conditions for sending both query and result messages are configurable. (See 0 5.4.2.3 Interface Configuration).

The host may as well send test orders spontaneously and may send queries for results. Queries for test results are handled only, if "ALL" is entered into the "Starting Range ID" and "Universal Test ID" field of the query message, otherwise the query is responded with an empty "No information available" message (See message examples in 0 5.4.5 Incoming and Outgoing Transmission Examples).

If Liaison receives a query for ALL test-results and "TransmitValidResults=Y", then Liaison generates a response message containing all results from the ValidResultsJournal.

If Liaison receives a query for ALL test-results and "TransmitValidResults=N", then Liaison generates a response message containing all but the calibrator results from the DailyResultsJournal.

When a sample is placed on the instrument, all tests previously ordered for the sample at the host and downloaded to the LIAISON will appear on the LIAISON SampleLoadingScreen. After a test is performed, the results become available for transferring to the host computer. An operator can upload any or all either validated or unvalidated results to the host. (See 0 5.4.2.3 Interface Configuration). Conditions for automatic result upload are:

[LISInterface]

TransmitValidResults=N

UploadFrequency=XXX (where XXX is ≥1)

2. Automatic result upload did not fail more often than specified in

[LISInterface]

NoOfTries=YYY

- 3. All Replicates measured (ResultStatus = done or failed)
- 4. Concentration is calculated, i.e.a calibration must be available.





5.4.2.2 Setup

The following data is available through the ASTM Setup Dialog (See SystemMenu_SSD. §4.6) By means of the following *LISSetupDialog* the LIS interface can be customized:

#	Item	Description
2	AnalyserID	This field allows to assign an unique InstrumentID to the LIAISON. It is used to Used to verify that a transmission is intended for the Liaison/Advantage and corresponds with the ReceiverID sent in field#10 of the MessageHeaderRecord. In messages sent from the LIAISON to the HOST AnalyserID will be sent in field#5 (SenderID) of the MessageHeaderRecord and in field#14 (InstrumentID) of the ResultRecord. This field allows to assign a name to the host. It will be sent
	HOSCID	as ReceiverID (field#10) in MessageHeaderRecords sent from the LIAISON to the Host.
3	ComPORT	This field specifies the serial port used for host transmissions. Host can be connected to any free COM port, except for COM1 (used for the connection to the Analyzer)
4	BaudRate	Specifies the Baudrate used for transmissions between the LIAISON and the host any values from 4800 to 19200 can be chosen.
5	DataBits	Must not be changed, default is "8".
6	StopBits	Must not be changed, default is "1".
7	Parity	Must not be changed, default is "None".
8	DateTemplate	Must not be changed, in all cases, dates shall be recorded in the YYYYMMDD format as required in the ASTM1394 standard.
9	TimeTemplate	Must not be changed, in all cases, dates shall be recorded in the HHMMSS format as required in the ASTM1394 standard.
10	NumFormat	Specifies the character used as decimal point and the maximum number of digits sent after the decimal point. Any numerical formats specified in the assay definition and containing more digits will be truncated.
11	Timeout	Within <timeout> seconds the LIAISON expects a response to a query messages sent to the host. If within <timeout> seconds transmission of a response has not started yet the LIAISON will abort the session.</timeout></timeout>
12	Delimiters	These fields specify the set of delimiters used for transmissions.

5.4.2.3 Interface Configuration

The following parameters in the [LISInterface] section of the LIA32D.INI file can be used to customize the generation of specific messages.

ľ	-1	ıe	:	LI	Α.	32	υ.	IN	ı
	[]	Ί	SI	Ιn	te	er	fá	ac	e į

 ${\tt LoadingQuery=Y/N}$

// Enables/Disables the generation of query messages during sample loading.

TransmitValidResults=Y/N

// yes: Results will be uploaded to the LIS from the ValidatedList only. No automatic upload options available no: Results can be uploaded directly from the DailyJournal. The ValidatedList is not available in that case.

UploadFrequency=XXX

// XXX denotes a cardinal value as "no. of results". On availability of every "XXX" results a result message is generated automatically and uploaded to the LIS. Automatic result upload can be disbled by setting





UploadFrequency=0. This parameter is ignored if

TransmitValidResult=yes.

NoOfTries=YYY // Specifies how many times communication should be retried.

MaxHostQueryFrequency=ZZZ // ZZZ denotes a cardinal value in seconds.

Specifies how often a LIS may send queries to Liaison. If LIS sends queries more often than once in "MaxHostFrequency" seconds the query

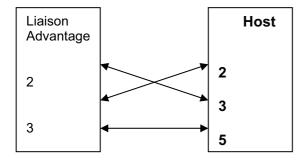
is ignored from Liaison.

CompressedOrderQuery=Y/N // Specifies if queries for test orders shall be sent using repeat delimiters or not.

5.4.3 Low-Level Protocol

5.4.3.1 Physical Layer

(refer to ASTM 1381, section 5)



connector description: 9-pin female

5.4.3.2 Data Link Layer

Establishment Phase

(refer to ASTM 1381, section 6.2)

5.4.3.2.1 Transfer Phase

(refer to ASTM 1381, section 6.3)

The checksum is encoded as two characters sent after the <ETB> or <ETX> character. The checksum includes the first character after <STX> (the frame number) up to and including <ETB> or <ETX>. It is computed by adding the binary values of the characters, keeping the least significant eight bits of the result.

During the transfer phase, if the LIS responds to a frame with an <EOF> the LIA3 does **not** stop transmitting and chooses to ignore the interrupt request.

5.4.3.2.2 Termination Phase

(refer to ASTM 1381, section 6.4)

After the LIA3 transmits or receives the <EOT>, indicating that all messages have been sent, the line is considered to be in the neutral state.

Additional information about termination phase





NOTE: Request of termination phase from the receiver (in according with standard ASTM 1394).

Please refer to the instruction below.

If the Liaison sends <EOT> when the Host is transferring the record "P", the Host have to ignore the command <EOT> and complete transmission, sending records "O" and "L".

This way, LIAISON can overtake priority and continue to send the next queries only after the record "L" sent by Host.

This ensures that all samples are correctly associated to the appropriate job.





WRONG Termination Phase

TX by Host	<stx>1H \^& Host Liaison P 20040528173336<cr><etx>5C<cr><lf></lf></cr></etx></cr></stx>					
TX by LIA	<ack></ack>					
TX by Host	<stx>2P 1 295-28/05/2004^ U </stx>	<cr><etx></etx></cr>	CE <cr><lf></lf></cr>			
TX by LIA	<ack></ack>					
TX by Host	<\$TX>3O 1 00000295 ^^^ToxoG N 20040528					
TX by LIA	<ack></ack>					
TX by Host	<stx>4P 1 262-28/05/2004^ U </stx>					
TX by LIA	<eot></eot>					
TX by Host	<enq></enq>	<enq> Evidenced in red: EOT command</enq>				
TX by LIA	<enq></enq>					
TX by Host	<enq> sent by Liaison</enq>					
TX by LIA	<enq></enq>					
TX by Host	<ack></ack>					
TX by LIA	<stx>1H \^& Liaison Host 1 20040511101214<cr><etx>07<cr><lf></lf></cr></etx></cr></stx>					

CORRECT Termination phase

TX by Host	<stx>1H \^& Host Liaison P 20040528173336<cr><etx>5C<cr><lf></lf></cr></etx></cr></stx>
TX by LIA	<ack></ack>
TX by Host	<stx>2P 1 295-28/05/2004^ U </stx>
TX by LIA	<ack></ack>
TX by Host	<stx>30 1 00000295 ^^^ToxoG N 20040528 S O <cr><etx>A8<cr><lf></lf></cr></etx></cr></stx>
TX by LIA	<ack></ack>
TX by Host	<stx>4P 1 262-28/05/2004^ U </stx>
TX by LIA	<eot></eot>
TX by Host	<stx>50 1 00000262 ^^^Toxo-G N 20040528 </stx>
TX by LIA	<eot></eot>
TX by Host	<stx>6L 1 N<cr><etx>09<cr><lf></lf></cr></etx></cr></stx>
TX by LIA	<eot></eot>
TX by LIA	<eot></eot>
TX by LIA	<enq></enq>
TX by Host	<ack></ack>
TX by LIA	<stx>1H \^& Liaison Host 1 20040511101214<cr><etx>07<cr><lf></lf></cr></etx></cr></stx>





5.4.3.2.3 Error Recovery

(refer to ASTM 1381, section 6.5)

The LIA3 checks every frame it receives to guarantee its validity and sends an <ACK> for a valid frame, or a <NAK> for an invalid frame. Frames are invalidated when:

- a) Any character errors are detected (i.e. parity error, framing error)
- b) The frame checksum does not match the checksum computed on the received frame.
- c) The frame number is not the same as the last accepted frame or one number higher.

When the LIA3 receives a <NAK> for a frame rejected by a host it resends the frame. If a single frame is sent and rejected six times, the LIA3 proceeds to the termination phase.

During the establishment phase, the LIA3 expects to receive a reply within 15 seconds after sending <ENQ>. During the transfer phase, the LIA3 expects to receive a reply within 15 seconds after transmitting the last character of a frame. If a timeout occurs, the LIA3 proceeds to the termination phase.

During the transfer phase, the LIA3 expects to receive a frame or <EOT> within 30 seconds after first entering the transfer phase or replying to a frame. After a timeout, the last incomplete message is discarded and the line is considered to be in the neutral state. The LIA3 will also timeout if a reply to a frame is not received within 15 seconds.

5.4.4 Logical Structure of the Message Level Protocol

The blocked stream of data sent between a host computer and the analyzer at a given time is called a message.

Messages consist of a hierarchy of records of various types:

Level	Segment Name	Identifier	Comments
		(Record	
		TypeID)	
0	Message Header Record	'H'	
0	Message Terminator Record	'L'	
1	Patient Information Record	'P'	
1	Request Information Segment	'Q'	
1	Scientific Record	'S'	not allowed for Liaison /Advantage
2	Test Order Record	'O'	
3	Result Record	'R'	
common	Comment Record	,C,	
1	Manufacturer Information	'M'	not allowed for Liaison /Advantage
	Record		

A record is identified by the first field of a record, the RecordTypeID.

An unknown RecordTypeID will cause an error and aborts the interpretation session.

Most of the various record types are related to each other in a definite hierarchy:

A lower level record may never appear without the precending higher level record.

(Order records must be preceded by a patient record, result records must be preceded by an order record...)

A sequence of records at one level is terminated by the appearance of a record of the same or higher level.

A violation of the record hierarchy will cause an error and aborts the interpretation session. (In some other descriptions a record might also be called segment.)





Messages to be transmitted to the host, such as a request for test orders or result data, are first written to a file "UPLOAD??.DAT". After all messages for a single operator action have been written to the file, they are transferred. The upload file is deleted after all contents are successfully transmitted.

Data received from the host is immediately written to the file "ASTM????.DAT", and after all information is received, the LIAISON begins processing the download file and adding records to the database. If an error occurs during interpretation of data from the host, a message is displayed to the operator.

5.4.5 Incoming and Outgoing Transmission Examples

Test orders downloading is used to request test orders from the host that are available for the Liaison / Advantage instrument. The download session is initiated by the Liaison / Advantage program only by using the Request Information Record (see chapter 12 in ASTM E 1394-91). A transmission must never be initiated by the host computer.

5.4.5.1Test Orders

In case the query for test orders is generated manually by the operator through a LIAISON menu option the query record contains "ALL" in the "Starting Range ID" and "Universal Test ID" fields:

LIAISON to Host: (request for test orders from host)

Structure defined by ASTM 1394 (multiple records comprise a single message)		Structure defined by ASTM 1381 (each record is sent as one or more frames)		
Message Header Record Request Information Record Message Terminator Record	\rightarrow	Frame 1 : Frame n		

Example:

```
H|\^&|||Liaison|||||LaborEDV|||1|19941115202738
Q|1|ALL||ALL|||||||0
L|1|N|
```

In case the query for test orders is generated automatically through the PatientLoading sections of the LIAISON program the query message comprises up to 15 query records.

LIAISON to Host: (request for test orders from host)

Structure defined by ASTM 1394 (multiple records comprise a single message)		Structure defined by ASTM 1381 (each record is sent as one or more frames)
Message Header Record Request Information Record 1 : Request Information Record m Message Terminator Record	\rightarrow	Frame 1 : Frame n





Example:

```
H | \^& | | | Liaison | | | | LaborEDV | | | 1 | 19941115202738

Q | 1 | Sample01 | ALL | | | | | | | 0

Q | 1 | Sample02 | ALL | | | | | 0

Q | 1 | Barcode0815 | ALL | | | | | | 0

Q | 1 | 12345 | ALL | | | | | 0

L | 1 | N |
```

If CompressedOrderQuery is enabled in the Lia.Ini file ("CompressedOrderQuery =Y") the query for test orders is generated using repeat delimiters:

Host to LIAISON: (response from host includes patient demographics, patient ID, sample ID, and test orders according to the following record hierarchy)

The response to requests for test orders is expected to be reveived within <Timeout> seconds after the request has been sent. <Timeout> is to be specified in the LISSetupDialog.

Structure defined by ASTM 1394 (multiple records comprise a single message)		Structure defined by ASTM 1381 (each record is sent as one or more frames)
Message Header Record Patient Information Record 1 Test Order Record 1 : Test Order Record n : Patient Information Record n Test Order Record 1 : Test Order Record n Message Terminator Record	→	Frame 1: Frame n

In case there are no test orders available the LIS should respond with an empty message containing header and terminator records only. The terminator record should contain an 'I' (no information available) flag in the Termination Code Field.

The comment record is used to return "bad test" etc messages back to the host after download session.

After the LIAISON receives all test orders from the host, the records are interpreted. Valid test orders are entered into the loadlist database, while invalid test orders are not. After the interpretation segment of the download session, the LIAISON sends a message to the host containing information about all rejected or invalidated test orders as follows:

LIAISON to Host: (information about rejected test orders)

ı	Structure defined by ASTM 1394	Structure defined by ASTM 1381
ı	(multiple records comprise a single	(each record is sent as one or more frames)
I	message)	





```
Message Header Record
  Patient Information Record 1
    Test Order Record 1
     Result Record 1
     Comment 1
    Test Order Record n
     Result Record 1
      Comment 1
                                               Frame 1
   Patient Information Record n
                                               Frame n
     Test Order Record 1
      Result Record 1
      Comment 1
     Test Order Record n
       Result Record 1
       Comment 1
Message Terminator Record
```

Example:





Reasons for rejection of test orders are:

Comment string	Description
BAD_TEST	No match found for the testcode specified in TestOrderRecord, Field 5, Component 4.
MULTI_SAMPLE_TYPE	This SampleID has been introduced to the system as a different SampleType already. Please verify the Specimen Type field in the Test Order Record.
QC_SAMPLE_ID	SampleID with leading '#'-character are controls. QC material can't be ordered by the host.
BAD_SAMPLE_ID	SampleID filed was either empty or the SampleID had a leading '\$' character. Leading '\$'-characters designate calibrator materials. Calibrators can't be ordered by the host.
BAD_DILUTION	The dilution specified in TestOrderRecord, Field 5, Component 5 can not be applied to the test specified in TestOrderRecord, Field 5, Component 4.
WRONG_INSTRUMENT	The InstrumentID which is sent in the ReceiverID field of the Message Header Record doesn't match the InstrumentID in the LISSetupDialog.
OTHER ERROR	Other error





5.4.5.2 Test Results

Only the calculated result (concentration calculated from mean of RLU values) is transferred per test. For multiple replicate results the mean is transmitted only.

LIAISON to Host: (transmit sample information with corresponding tests and results)

Structure defined by ASTM 1394 (multiple records comprise a single message)		Structure defined by ASTM 1381 (each record is sent as one or more frames)
Message Header Record Patient Information Record 1 Test Order Record 1 Result Record 1 Comment 1 : Result Record n Comment 1 : Test Order Record n Result Record 1 Comment 1 : Result Record 1 Comment 1 : Result Record n Comment 1 : Result Record n Comment 1 : Patient Information Record n Test Order Record 1 Comment 1 : Result Record 1 Comment 1 : Result Record n Comment 1 :	\rightarrow	Frame 1 : Frame n

Example:

```
H|\^&|||Liaison|||||LaborEDV|||1|19941115202738
P|1||PatID01||Meier^Anna||19741001|F|||||MARTINEZ
O|1|SampleID01||^^AFP||19980506||||||||||S||||||||||F
R|1|^^AFP|13.1|IU/ml||H||F||||19980506123145|Liaison
C|1|I|CALIBRATION_EXPIRED|I
L|1|N
```





The following comments can detail the result in the preceding result record: Table Result Flags:

Comment string	Flag in Ul	Description
NO REAGENT	*	No or not enough reagent found (pipetting error)
NO_SERUM	*	No or not enough sample found (pipetting error)
INC_TIME_EXCEEDED	t	Incubation time exceeded
JOB_FAILED	*	Job can't be done, mechanical failure
CALIBRATION_EXPIRED	С	Calibration or reagent integral expired
REAGENT_EXPIRED	Е	Reagent integral expired
BAD_QC	Q	QC material found outside reference range
MODIFIED_MANUALLY	М	Result value has been modified manually by the operator
DILUTION_ERROR	Over-	The result of a diluted sample is outside the validity range.
	diluted	
CLOT_DETECTED	*	Clot in sample position detected (pipetting error)
IN_REFLEX_ZONE1	&	Result is in the reflex zone1 as defined in the assay definition
IN_REFLEX_ZONE2	&	Result is in the reflex zone2 as defined in the assay definition
BAD_CALIBRATION	С	The math package (Kulovic) was unable to calculate a
		concentration result.
ASPIRATION_SKIPPED	X	Reagent aspiration skipped because integral not present
INC_TEMP_OFF_RANGE	Т	Incubation temperature out of range
AGITATION_RANGE_EX	Α	Agitation speed off range
RECALCULATED	R	Result was recalculated
SIGNAL_RANGE_EX	!	Result out of signal range
ABNORMAL_PARENT	?	The associated combi result is out of normal range
BAD_LLD_SIGNAL	*	The LLD signal did not pass plausibility check
NO_PMT_SIGNAL	*	No signal from PMT
NOT_MEASURED	*	Result was not measured
HIGH_BACKGROUND	*	High background

In case results cannot be evaluated due to mechanical errors the result is flagged ("X") in the ReportType field (Field 26) of the TestOrderRecord and in the Status field (Field 9) of the ResultRecord. The reason is then appended in an CommentRecord (See chapter 7.2.5)





Example for transmission of failed results:

In case more than one flag occured, they are transmitted using repeat delimiters:

Queries for test result, which are still in process are transmitted with an "I" flag ("in instrument pending") in the ReportType field (Field 26) of the TestOrderRecord and in the Status field (Field 9) of the ResultRecord.

Example for transmission of pending results:

Corrections of test results, are transmitted with an "C" flag ("correction of previously transformed result") in the ReportType field (Field 26) of the TestOrderRecord and in the Status field (Field 9) of the ResultRecord. This is the case if a result was recalculated using the "Recalc" function of the DailyJournal.

Example for transmission of corrected results:

Results below (above) assay range are transmitted with a numerical value of lower (upper) limit of the assay range and a '<' ('>') flag in the Result Abnormal Flags field (Field 7) of the ResultRecord. Example for transmission of off scale results ("<<" / ">>" assay range):





5.4.6 Data Record Usage

(refer to ASTM 1394, particularly sections 6 through 13)

Each record sent by the LIAISON will contain up to the last field used by the LIAISON, which may or may not be all fields possible for the record. The first **<MaxLength>** characters are significant only. Any more characters transmitted for a specific field are ignored.

5.4.6.1 Message send from LIS to LIAISON

Mandatory:

- Y: Field is mandatory and have to be considered
- N: Field is not mandatory, if send by the LIS is stored in Liaison

5.4.6.1.1 Header Record (H)

Field No.	ASTM Field	Description	Valid Contents	Max Length	Mandatory
1	Record Type ID	Character identifying the record as a message header	'H'	1	Y
2	Delimiter Definition	Any received delimiter set is accepted. The delimiters defined in ASTMSetupDialog are sent.		4	Y
10	Receiver ID	Used to verify that the transmission is intended for the Liaison / Advantage		20	If sent, it has to match the InstrumentID on ASTM- SetupDialog, otherwise is ignored





5.4.6.1.2 Patient Information Record (P)

Field No.	ASTM Field	Description	Valid Contents	Max Length	Mandatory
1	Record Type ID	Character identifying the record as a patient information record	'P'	1	Y
2	Sequence Number			5	Υ
4	Laboratory Assigned Patient ID	Becomes our PatientID		20	N
6^1	Patient Name			20	N
6^2	Patient First Name			10	N
8	Birthdate			8	N
9	Patient Sex			1	N
14	Attending Physician ID	Becomes our SenderID		6	N

5.4.6.1.3 Test Order Record (O)

Field No.	ASTM Field	Description	Valid Contents	Max Length	Mandayory
1	Record Type ID	Character identifying the record as a test order record	, O	1	Y
2	Sequence Number			5	Υ
3	Specimen ID	Unique identifier assigned by HOST, becomes our sampleID		20	Υ
5^4	Universal Test ID	Test Abbreviation		6	Υ
5^5	Dilution	Specimen has to be diluted prior to performance of the test.	"1:10" or "1:500"	6	N
6	Priority	'S' or 'N'		1	N
7	Requested/Ordered Date and Time	'YYYYMMDD' 'HHMMSS'		14	N
26	Report Types		'O', 'F', 'I', 'C' or 'X'	1	N





5.4.6.1.4 Terminator Record (L)

Field No.	ASTM Field	Description	Valid Contents	Max Length	Mandatory
1	Record Type ID	Character identifying the record as the last record in the message	<u>'L</u> '		Y
2	Sequence Number				Υ
3	Termination Code		'N' (normal) or 'I' (no info available)		N





5.4.6.2 Message send from LIAISON to LIS

Mandatory:

- Y: Field is mandatory and have to be considered
- N: Field is not mandatory. The field have to be considered by the LIS, but it is transmitted only if information is available at Liaison. When the information is not available an empty field is transmitted

5.4.6.2.1 Header Record (H)

Field No.	ASTM Field	Description	Valid Contents	Max Length	Mandatory
1	Record Type ID	Character identifying the record as a message header	'H'	1	Y
2	Delimiter Definition	Any received delimiter set is accepted. The delimiters defined in ASTMSetupDialog are sent.		4	Y
5	Sender Name / ID	Analyzer ID defined in ASTMSetupDialog		20	Y
10	Receiver ID	Used to verify that the transmission is intended for the Liaison / Advantage. Host ID defined in ASTMSetupDialog.		20	Y
13	Version No.		'1'	1	Y
14	Date and Time of Message	Format is YYYYMMDD HHMMSS		14	Y





5.4.6.2.2 Patient Information Record (P)

Field No.	ASTM Field	Description	Valid Contents	Max Length	Mandatory
1	Record Type ID	Character identifying the record as a patient information record	'P'	1	Y
2	Sequence Number			5	Υ
4	Laboratory Assigned Patient ID	Becomes our PatientID		20	N
6^1	Patient Name			20	N
6^2	Patient First Name			10	N
8	Birthdate			8	N
9	Patient Sex		'M', 'F', 'U'	1	N
14	Attending Physician ID	Becomes our SenderID		6	N

5.4.6.2.3 Test Order Record (O)

Field No.	ASTM Field	Description	Valid Contents	Max Length	Mandatory
1	Record Type ID	Character identifying the record as a test order record	, O	1	Y
2	Sequence Number			5	Υ
3	Specimen ID	Unique identifier assigned by HOST, becomes our sampleID		20	Y
5^4	Universal Test ID	Test Abbreviation		6	Υ
5^5	Dilution	Specimen has to be diluted prior to performance of the test.	"1:10" or "1:500"	6	N
6	Priority	'S' or 'N'		1	Υ
7	Requested/Ordered Date and Time	'YYYYMMDD' 'HHMMSS'		14	Υ
26	Report Types		'O', 'F', 'I', 'C' or 'X'	1	Y





5.4.6.2.4 Result Record (R)

Field No.	ASTM Field	Description	Valid Contents	Max Length	Mandatory
1	Record Type ID	Character identifying the record as a result record	R	1	Y
2	Sequence Number			5	Υ
3^4	Universal Test ID			6	Υ
4	Data or Measurement Value			depends on value	N * See the note below
5	Units			10	N
7	Result Abnormal Flags		'L' (below normal range), 'H' (above normal range), '<' (below assay range), '>' (above assay range) or 'N' (within normal range)	1	N
9	Result Status		'F', 'l', 'C' or 'X'	1	Y
13	Date/Time Test Completed	'YYYYMMDD' 'HHMMSS'		14	N
14	Instrument ID		as defined in ASTM- SetupDialog		Y

* NOTE: The field is not mandatory because in case of Comment Record, it may be empty (See page 16 "Example for transmission of failed results")





5.4.6.2.5 Comment Record (C)

Field No.	ASTM Field	Description	Valid Contents	Max Length	Mandatory
1	Record Type ID	Character identifying the record as a comment record	,C,	1	Υ
2	Sequence Number			5	Υ
3	Comment Source	Clinical Instrument System	'l'	1	Y
4	Comment Text	Reason for Rejection or Result Relevant	See Table "Reason for Rejection of test orders" Chapter 6.1		Y
	Commont Tune	Flags	Table "Result Flags" Chapter 6.2		V
5	Comment Type	Instrument Flag Comments	'['	1	Υ

Note : In case result validation is NOT performed on the LIAISON, the Comment Record Field has to be always considered by the LIS





5.4.6.2.6 Request Information Record (Q)

Field No.	ASTM Field	Description	Valid Contents	Max Length	Mandatory
1	Record Type ID	Character identifying the record as a request information record	ŷ		Y
2	Sequence Number				Υ
3	Starting Range ID		"ALL"		Υ
5	Universal Test ID		"ALL"		Υ
13	Request Information Status Codes		'O'		Υ

5.4.6.2.7 Terminator Record (L)

Field No.	ASTM Field	Description	Valid Contents	Max Length	Mandatory
1	Record Type ID	Character identifying the record as the last record in the message	Έ'		Y
2	Sequence Number				Υ
3	Termination Code		'N' (normal) or 'I' (no info available)		Y





5.5 Restrictions and cautions

If the Termination Phase is not compiled as described in the chapter 4.2.3.1 (i.e. in according with standard ASTM 1394), it may happen that using host query mode when loading samples placed on several sample racks (one rack = one query), Liaison is not able to download completely the job-list since it want to overtake priority during communication with LIS and this may cause that the job-list for some samples is not acquired by Liaison.

Liaison sends an <EOT>, which interrupts the correct reception of the job-list, causing the following error message:

- Error 9045 LIS download failed. Reason ERROR Transmission aborted (MsgHeaderRec 0/0)
- Error 9045 LIS download failed. Reason ERROR Transmission aborted (TermRec 3/1)

The more sample racks are loaded, the more often the problem may occur. In this case the following procedure can be advised to the customer:

- a. Load no more than three sample racks in a row;
- b. Close the sample area door (allowing that the related queries are sent)
- c. Wait for the reception of the job-lists associated to the loaded samples
- d. Re-open the sample area door to load other racks (as needed)