Thermo SCIENTIFIC

KRYPTOR INTERFACE MODULE (KIM)

Instructions for the Host Laboratory

Thermo SCIENTIFIC

Table

0. Reference Documents

For an ASTM connection :

ASTM E1381-91 *" Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems "*

ASTM E1394-91 *" Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems "*

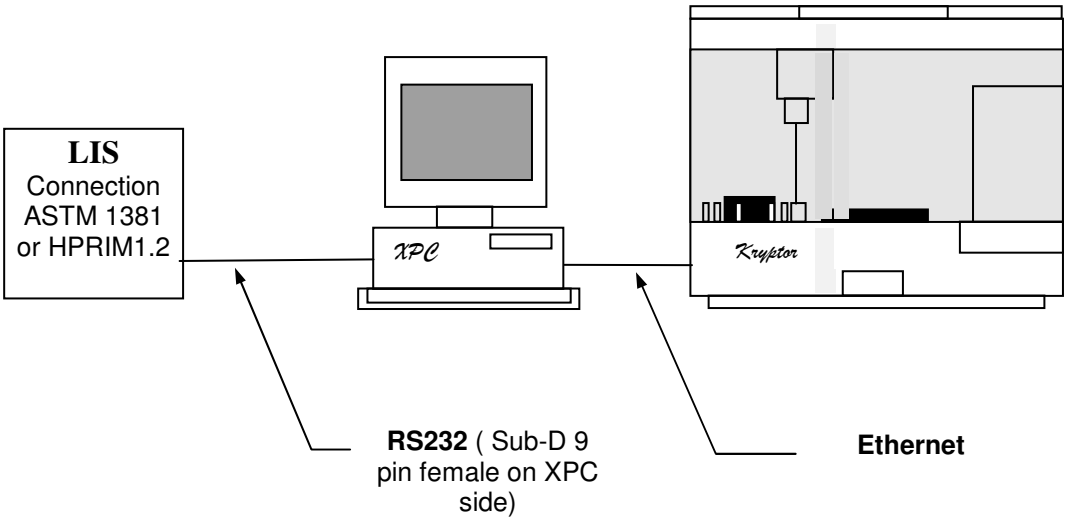
For an HPRIM connection :

ASTM E1238 *" Standard Specification For Transferring Clinical Observations Between Independent Computer Systems "*

H.P.R.I.M laboratory version 1.2

1. Equipment Configuration

Laboratory / KRYPTOR Connection



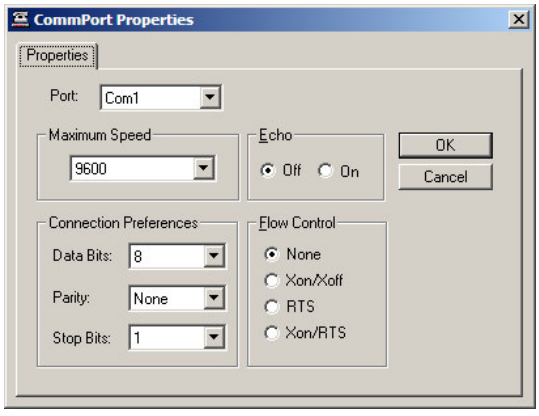
RS232 Cable : Null Modem

Example of a DTE-DTE connection

Sub-D 25	Sub-D 9		Sub-D 9	Sub-D 25	
8	1		1	8	CD
3	2		2	3	RxD
2	3		3	2	TxD
20	4		4	20	DTR
7	5		5	7	SG
6	6		6	6	DSR
4	7		7	4	RTS
5	8		8	5	CTS
22	9		9	22	RI

Communication parameters on the RS232

The following default parameters are set up on the XPC



2. Possible configurations

Configuration 1 : KIM + LISDLL
Protocol : ASTM 1381
Advantages : Simple and fast configuration for the XPC

Configuration 2 : LISDLL alone
Protocol : HPRIM 1.2
Advantages : Several laboratories may be connected
Transfer of HPRIM files by a network may be contemplated

3. The ASTM 1381 Connection for Configuration 1

Follow the codification specified in the reference documentation, which is complemented by the following :

3.1. LOADING THE ANALYSER

The analyser worklist can be built :

- through the sending of a worklist initiated by the laboratory
- using the query mode , initiated by Kryptor

3.1.1. QUERY :

If kryptor is running in Query mode , the requests are formatted as follow :

HEADER
H|\^&|||KRYPTOR^AUTOMATE KRYPTOR|||||LIS||P|1|199709010810<CR >

QUERY
Q|1|^123456||ALL||||||||O<CR>
Field 12.3, 2nd component : sample ID read on the carousel.

TERMINATOR :
L|1|F<CR>

Only one request record may be outgoing at a time. The receiver of the request must give a response to the query . Kryptor will wait for this response before sending the next message.

3.1.2. BATCH DOWNLOAD and QUERY ANSWER

HEADER :
H|\^&|||LIS|||||KRYPTOR||P|1|19970901103100<CR >

field 7.5	: " LIS "	*Name of the host*
field 7.10	: " KRYPTOR "	*Name of the receiver*
field 7.12	: " P "	*Processing ID = (P)roduction*
field 7.13	: " 1 "	*Version*
field 7.14	: YYYYMMDDHHMMSS	*Date and time of the request*

PATIENT :
P|1|REF_PATIENT|||NAME of the PATIENT^First name of the patient|||M<CR >

In this segment, only field 8.2 is required.

Warning: the patient ID has to be unique.
It is not possible to use the same patient ID for 2 different patient names.

A comment segment may follow the PATIENT segment :

C|1|P|Comment for this patient, 70 characters maxi<CR>

Patient ID, patient name (truncated to 13 characters) and comments are downloaded to the KRYPTOR, but these fields are **not returned** with the results upload.

The other fields (field 8.8 : date of birth, field 8.9 : sex...) are not used in this configuration.

TEST REQUEST :

Batch mode :

O|1|01201^01^10||^^^CEA^^1\^^^AFP^^2^19970512V26.1\^^^LH|R||||||A|||||||||||||O<CR >

Field 9.3 : 1th component : sample identification with a maximum of 15 alpha-numeric characters.

2nd component : cassette number - numeric , from 01 to 99
3rd component : position number - numeric from 01 to 10
Those 2 components are optional. Their value are transmitted to KRYPTOR if specified.

Field 9.5 : 4th component : mnemonic KRYPTOR test code .
(see Analyte codes)

6th component : dilution . When no dilution is specified, 1 is the default value

7th component : previous result with the following format : AAAAMMJJV999.99
date AAAAMMJJ
letter " V " followed by value
The previous result value is transmitted to Kryptor

Field 9.6 : " R " *Routine*
" A " *Very urgent*
" S " *Urgent*
both A and S are handled by Kryptor as Stat samples

Field 9.12 : " A " *Add the test*
" Q " Consider that sample as a quality control sample. (not implemented in KIM V 1.20)
In this case, both name and PID will be replaced by text " Control ".

Field 9.26 : " O " *For a "batch" mode request.*

Query mode :

If a response exists for the requested sample , the answer is the same as a request message in batch download mode except for field 9.26 :

O|1|01201||^^^CEA^^1\^^^AFP^^2^19970512V26.1\^^^LH|R||||||A|||||||||||||Q<CR >

Field 9.26 : " Q " *For a "query" answer with informations.*

If no response for the query

O|1|01201||||||||||||||||||||||Z<CR >

Field 9.26 : " Z " *For a "query" answer without any information.*

TERMINATOR :
L|1|F<CR >

3.2. UPLOADING THE RESULTS

HEADER
H|\^&|||KRYPTOR^ KRYPTOR ANALYSER|||||LIS||P|1|199709011410<CR >

PATIENT :
P|1|||||||U<CR >
In this configuration, the PID et PATIENT NAME are not sent back (uploaded).

ORDER :
O|1|03104^01^04||^^^NSP^^5|R||||||A|||||||01^04||||||F<CR >
The unique test code is sent back.
Cassette and position are returned in 9.3 and 9.20 fields.

COMMENT (optional) :
C|1|I|Comment about this order<CR>
Comment as it was manually entered on the analyser.

RESULT :
R|1|^^^NSP^^5^^F|8.123|||L||F|||19970901133025|1997090114091O|517017000187<CR >

Field 10.3 : *test and dilution used*
Field 10.4 : *result with 3 decimals*
Field 10.7 : *flags*

L	*: pathological low*
H	*: pathological high*
<	*: below range*
>	*: above range*

A comment segment detailing Kryptor error codes follows this result segment

Field 10.9 : *Result Status*

” F ”if the test has been performed according to the specifications

” X ” if the test has not been performed (rejected , cancelled , failed)

In that case , the result field is assigned the default value ” 0.000 ”

Field 10.12 : *date and time on which the test has been started*
Field 10.13 : *date and time on which the test has been performed*
Field 10.14 : *Kit Id*

COMMENT (optional) :
C|1|I|33\39<CR>

Field 11.4 : Error flags given by KRYPTOR, separated by a repeat delimiter.
See table ” Error codes ” below.

TERMINATOR :
L|1|F<CR >

Several samples for several patients may be included in the same ASTM message.

3.3. DIALOG EXAMPLE :

Lis ***XPC***

Query

<ENQ>

<ACK>

<STX>1H|\^&|||KRYPTOR^AUTOMATE KRYPTOR|||||LIS||P|1|199709011038<CR ><ETX>xx<CR ><LF >

<ACK>

<STX>2Q|1|^01500|||ALL|||||||O<CR ><ETX>xx<CR ><LF >

<ACK>

<STX>3L|1|F<CR ><ETX>xx<CR ><LF >

<ACK>

<EOT>

Response to Query :

<ENQ>

<ACK>

<STX>1H|\^&|||LIS|||||KRYPTOR||P|1|199709011040<CR ><ETX>xx<CR ><LF >

<ACK>

<STX>2P|1|9401134001|||DUPONT^Marthel||19580613|F<CR ><ETX>xx<CR ><LF >

<ACK>

<STX>3O|1|01500||^^^AFP\^^^FSH|R||||||A|||||||||||||Q<CR ><ETX>xx<CR ><LF >

<ACK>

<STX>4L|1|F<CR ><ETX>xx<CR ><LF >

<ACK>

<EOT>

New Query

<ENQ>

<ACK>

<STX>1H|\^&|||KRYPTOR^AUTOMATE KRYPTOR|||||LIS||P|1|199709011050<CR ><ETX>xx<CR ><LF >

<ACK>

<STX>2Q|1|^01501|||ALL|||||||O<CR ><ETX>xx<CR ><LF >

<ACK>

<STX>3L|1|F<CR ><ETX>xx<CR ><LF >

<ACK>

<EOT>

Response to Query :

<ENQ>

<ACK>

<STX>1H|\^&|||LIS|||||KRYPTOR||P|1|199709011051<CR ><ETX>xx<CR ><LF >

<ACK>

<STX>2P|1<CR ><ETX>xx<CR ><LF >

<ACK>

<STX>3O|1|01501||||||||||||||||||||||Z<CR ><ETX>xx<CR ><LF >

<ACK>

<STX>4L|1|F<CR ><ETX>xx<CR ><LF >

<ACK>

<EOT>

<EOT>

***Kryptor WL download** : (batch mode) :*

<ENQ>

<ACK>

<STX>1H|\^&|||LIS|||||KRYPTOR||P|1|199709011100<CR ><ETX>xx<CR ><LF >

<ACK>

<STX>2P|1|9401134002|||RIEUSSET^HENRI||19260430|M<CR ><ETX>xx<CR ><LF >

<ACK>

<STX>3C|1|P|mon commentaire patient limité à 70<CR ><ETX>xx<CR ><LF >

<NAK>

<STX>3C|1|P|mon commentaire patient limité à 70<CR ><ETX>xx<CR ><LF >

<ACK>

<STX>4O|1|02315000^01^10||^^^CEA^^1^19970512V46.2\^^^FSH^^^19970104V450|R||||||A|||||||||||||O<CR >
<ETX>xx<CR ><LF >

<ACK>

<STX>5L|1|F<CR ><ETX>xx<CR ><LF >

<ACK>

<EOT>

Results upload :

<ENQ>

<ACK>

<STX>1H|\^&|||KRYPTOR^AUTOMATE KRYPTOR|||||LIS||P|1|199709011638<CR ><ETX>xx<CR ><LF >

<ACK>

<STX>2P|1|||||||U<CR ><ETX>xx<CR ><LF >

<ACK>

<STX>3O|1|02315000^01^10||^^^CEA^^1|R||||||A|||||||01^10|||||F<CR ><ETX>xx<CR
><LF >

<ACK>

<STX>4R|1|^^^CEA^^1^^F|126.854|||H||F|||19970901151020|19970901163000|517017000187<CR ><ETX>xx<CR ><LF>

<NAK>

<STX>4R|1|^^^CEA^^1^^F|126.854|||H||F|||19970901151020|19970901163000|517017000187<CR ><ETX>xx<CR ><LF >

<ACK>

<STX>5C|1|I|40<CR <<ETX>xx<CR ><LF >

<ACK>

<STX>6L|1|F<CR ><ETX>xx<CR ><LF >

<ACK>

<EOT>

Contention :

The instrument system has priority to transmit information. When the LIS sends an <ENQ> to begin a transmission and receives <ENQ> for response, KRYPTOR takes priority.
The LIS system will have to stop trying to transmit, and prepare to receive by sending <ACK>

Retries :

3 retries maximum after receiving a NAK. After 3 retries, the message upload is aborted , and the sender ends the communication through sending a ” EOT ”.

3.4. RESTRICTION FOR BATCH MODE

In batch mode, the number of orders in the same communication frame is limited to 10 (between ENQ and EOT).

4. HPRIM 1.2 transfer, Configuration 2

Follow the codification specified in the reference documentation, which is complemented by the following :

4.1. LOADING THE ANALYSER

The HPRIM protocol does not implement the query mode which is not described

HEADER :
H|^~\&|||LIS2 ||ORM|||KRYPTOR ||P|H1.2|199709011213<CR>

field 7.5	: " LIS2 "	*Name of the host*
field 7.10	: " KRYPTOR "	*Name of the receiver*
field 7.12	: " P "	*Processing ID = (P)roduction*
field 7.13	: " H1.2 "	*Version*
field 7.14	: YYYYMMDDHHMM	*Date and time of the request*

PATIENT :
P|1|PID123|||SMITH^Arnold|||U<CR>

In this segment, only the field 8.2 is required.
Warning: the patient ID has to be unique.
It is not possible to use the same patient ID for 2 different patient names.

Field 8.3 : PID, taken into account and sent back, if specified
Field 8.5 : Additional patient identification, sent back, if specified.
Field 8.6 : Patient Name, sent back if specified
Field 8.8 : date of birth, taken into account but not returned
Field 8.9 : sex, taken into account but not returned

The patient ID and name (truncated to 13 char) are downloaded to KRYPTOR.
Optional comment segments associated to patient segments are not taken into account

TEST REQUEST :
OBR|1|01280^REQUEST_NUMBER||02020~01170~03680|R|||||N||||1||||01^05<CR>

The field 9.3 may have 2 components :
component 1 : Sample identification, 15 characters (alphanumeric) maximum.
component 2 : File number (or Request number) , 10 characters

Field 9.5 : Test identification
EUCLIDE codes are used. *(see Analyte codes)*

The dilution cannot be specified and the default dilution (1) is used.

Field 9.12 : " N " New
Value " Q " for this field, to specify a quality control sample, is accepted even though the ASTM 13 table does not mention it .

Field 9.16 : specifies the sample type (serum, plasma, urine, etc.) - optional

Field 9.20 : Cassette and position
Those 2 components are optional but must be specified if the choosen download mode needs them. (See installation procedure).
If omitted, the request will be discarded.

Previous results are not taken into account in this configuration

TERMINATOR :
L|1|F<CR >

4.2. UPLOADING THE RESULTS

HEADER
H|^~\&|||KRYPTOR^KRYPTOR ANALYSER||ORU|||LIS2||P|H1.2|199709011455<CR>

PATIENT :
P|1|PID123|||SMITH^Arnold|||U<CR>
The patient data : PID, patient name are sent back.

ORDER :
OBR|1|01201^REQUEST_NUMBER||02020|R|||||| N|||||||01^05<CR>
The unique analyte code is uploaded.
Cassette and position are sent back (non operationnel with version 2.03)

RESULT :
OBX|1|NM|02020||0.63|||>|||F||19970901151000|19970901152010|C16034123432<CR>

Field 10.4 : *test and dilution used*
Field 10.6 : value of the measurement, expressed according to the precision defined on the XPC, but with a maximum of 3 digits after comma .
Field 10.9 : *flags*

L	*: pathological low*
H	*: pathological high*
<	*: below range*
>	*: above range*

A comment segment detailing Kryptor error codes follows this result segment

Field 10.12 : *Result Status*
" F "if the test has been performed according to the specifications
" X " if the test has not been performed (rejected , cancelled , failed)
In that case , the result field is assigned the default value " 0.000 "

Field 10.14 : *date on which the test was started*

Field 10.15 : *date on which the test has been achieved on the analyser.*

Field 10.16 : kit id (lot id + kit number within lot)

COMMENT :
C|1|L|36~40<CR>

Field 11.4 : Error flags given by KRYPTOR, separated by a repeat delimiter (the max length is 20 characters)

See table ” Error codes ” below.

TERMINATOR :
L|1|F<CR >

4.3. SENDING HPRIM FILES BY USING NETWARE

For this configuration, HPRIM files may be sent :

- by using a serial port, and the Kermit protocol,
- by using the netware.

For a netware exchange :

Worklist files, from LIS, will be created on XPC in the folder :
C :\LIS\DOWNLOAD
Those files will be named REQUEST.NNN where NNN is a sequential number.

Files will be archived, interpreted and deleted from this folder.

Results files, from KRYPTOR, will be created on XPC in the folder :
C :\LIS\UPLOAD
Those files are named RESULT.NNN where NNN is a sequential number, from 001 to 999.,

The LIS will use and delete the results files.

4.4. DIALOG EXAMPLE :

Download :

H|~&\^|||LIS2||ORM|||KRYPTOR|||H1.2|199709011711
P|1|12345678|||DURIEUX~Jocelyne~F~~Mlle||19581105|F||||||||||||||||||||R.A.S
OBR|1|01000106~Request number 1||04960|||||||N||||1~0~0
P|2|123456-0023456|||MARCELIN~Jean-Pierre~~~MR||19560613|M
OBR|1|01000107~Request number 2||04960|||||||N||||1~0~0
L|1|F

Result upload :

H|^~\&|||KRYPTOR^KRYPTOR ANALYSER||ORU|||LIS2^LIS CONFIGURATION 2||P|H1.2|199709011745
P|1|123456-0023456|||MARCELIN^Jean-Pierre^^^MR||19560613|M
OBR|1|01000107~Request number 2 ||04960|R||||||N||||1
OBX|1|NM|04960||126.85|||H|||F|||19970901174430
C|1|L|40
L|1|F

6. Kryptor's Analyte codes

Codes euclides List

ANALYTE	CODE
AFP	02020
ANTITG	00370
ANTITPO	00270
CA152II	01170
CA153	01180
CA199	01190
CEA	01320
CRP	27740
CTNI	00740
CYFRA211	34085
ESTRA	03760
FBHCG	17570
FERRI	02010
FSH	02130
HCG	17560
LH	03380
MYOG	03670

ANALYTE	CODE
OSTEO	24070
PAP	04030
PAPPA	04560
PCT	01230
PROG	04280
PROL	04290
PSA	04330
FPSA	04340
TESTO	04810
TG	33890
rac 2	33891
rac 10	33892
rac 40	33893
TG_REC 2	33894
TG_REC 10	33895
TG_REC 40	33896
NSE	03680
HTG	34000
RACH40	34001
RACH5	34002
HTG_RC40	34003
HTG_RC5	34004

All results are given as displayed on Kryptor result list interface. Unit can be modified in Kryptor analyte preferences.
Analyte names can be converted, by using the KLIS.INI file.

7. Error Codes

Code	Meaning
0	System Warning : Low Laser Power
1	System Error : Reaction Plate Position
2	System Warning :Reagent Cooler Out Of Range
3	System Warning : Incubator Out Of Range
4	System Error : Missed Reading
5	System Error : Unknown
6	System Error : Insufficient Sample Volume
7	System Error : Insufficient Reagent Volume
8	System Error : Insufficient Diluant Volume
9	System Warning : Late T0
10	System Warning : Late T1
11	System Warning : Late TE
12	System Error : Pipetting
13	System Error : Clot Detected
14	System Error : Pipetting in Sample Area
15	System Error : Pipetting in Dilution Area
16	System Error : Pipetting in Reagent Area
17	System Error : Pipetting in Wash Area
18	System Error : Pipetting in Reaction Area
19	System Warning : Heated Tip Out Of Range
20	System Error : Interrupted
21	System Warning : Not Performed
22	Calibration : Removed by User
24	Check Results
25	Math Error
26	Reflex Test Launched
27	Rerun by Reflex testing
28	Generated by Reflex testing
30	Data Error : Unknown Error
31	Data Error : Ratio
32	Data Error : Response
33	Data Warning : Abnormal
34	Data Warning : Out Of Range
35	Data Warning : Detection Limit
36	Data Warning : Above Max Range
37	Data Warning : Standard Warning
38	Data Warning : Calibrator Warning
39	Data Warning : Below Normal
40	Data Warning : Above Normal
41	Data Warning : Imposed
42	Concentration not consistent with dilution used
43	Data Warning : Control Warning
44	Data Warning : Abnormal Kinetics
45	Data Warning : Internal flag
46	Data Warning : Internal flag
47	Data Warning : → 25 mUI hCG
48	Data Warning: Control out of 2 SD range
51	Inconsistent incubation time
52	System Error: Missed Flashes
69	Pre-incubating in process
70	Error during phase 2 of pre-incubating