Connectivity Manual

ELISYS QUATTRO

Cat.-No.: 16300/4

CE

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1 INTRODUCTION

This manual is considered as a part of the instrument; it has to be at the operator's hand as well as at the maintenance operator's availability. For accurate installation, use and maintenance, please read the following instructions carefully. In order to avoid instrument or personal damages, carefully read the "GENERAL SAFETY WARNINGS" in the user manual, describing the suitable operating procedures. In case of breakdowns or any troubles with the instrument, apply to the local Technical Service.

1.1 Purpose

To describe the various methods of importing and exporting information or data for the ELISYS QUATTRO software.

1.2 Scope

Document includes description for the ASTM link, and ASCII file exchanges.

2 CONNECTIVITY

The ELISYS QUATTRO has been designed to easily integrate into a laboratory environment. It provides a variety of connection methods for importing and exporting data. Imported data is for ASCII patient information that allows the system to create work lists and download of worklists. It is not possible to import absorbance data, pipette data or other file types from other systems or readers. Export data is for the patient results in a variety of formats; the software supports a flexible format report structure, that can create ASCII files as well as utilising the ASTM link to up load patient results.

3 ASTM LINK OVERVIEW

This section is intended to document the interface for exchanging information between the ELISYS QUATTRO instrument and a host computer.

Communication between the ELISYS QUATTRO 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 ELISYS QUATTRO host interface consists of:

- ASTM 1381 low-level transfer protocol used to transmit or receive messages
- Interpretation of received data from the intermediate files and entering it into the ELISYS QUATTRO database

The general procedure at the ELISYS QUATTRO related to communication with an external host, as well as the specific implementation 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.

4 PROCEDURE

ELISYS QUATTRO communication sessions with a host computer can be initiated on request of the ELISYS QUATTRO operator. An operator can upload test results on request through a ELISYS QUATTRO menu selection. The host may also send test orders spontaneously.

When a sample is placed on the instrument, all tests previously ordered for the sample at the host and downloaded to the ELISYS QUATTRO will appear on the ELISYS QUATTRO *SampleLoadingScreen*. After a test is performed, the results become available for transferring to the host computer. An operator can upload results to the host.

5 ASTM INTERFACE

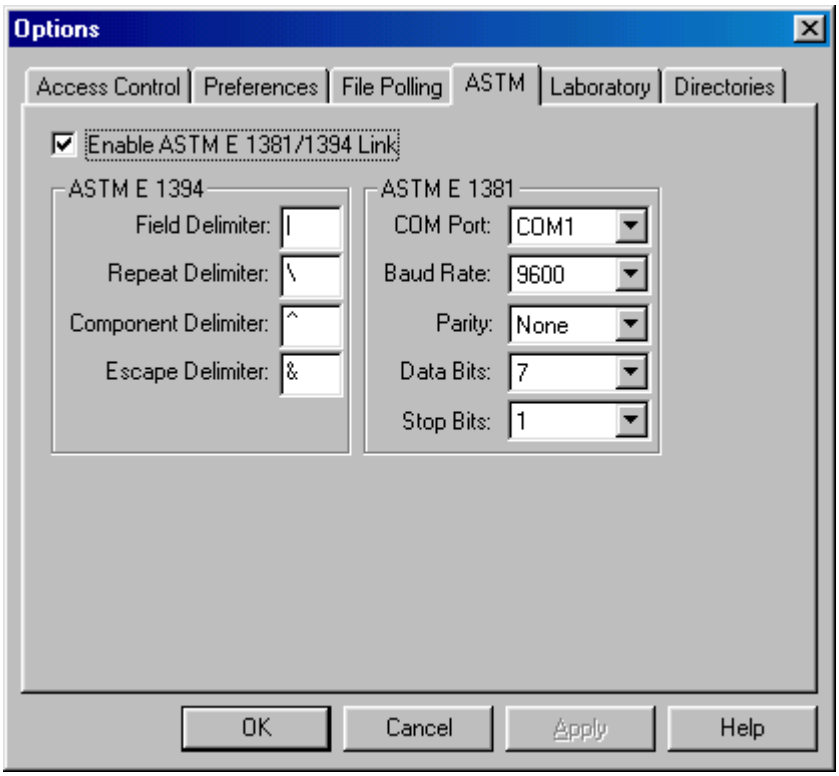
5.1 Setup

By means of the following *Dialog* the LIS interface can be customised:

1. ComPORT : This field specifies the serial port used for host transmissions. This must be different to the system com port.
2. BaudRate : Specifies the Baudrate used for transmissions between the ELISYS QUATTRO and the host any values from 110 to 56,000 can be chosen. Default is 9600
3. DataBits : 7 or 8, default is 7.
4. StopBits : 1, 1.5 or 2, default is 1.
5. Parity : None, odd, even, mark, space, default is None.
6. DateTemplate : Must not be changed, in all cases, dates shall be recorded in the YYYYMMDD format as required in the ASTM1394 standard.
7. TimeTemplate : Must not be changed, in all cases, dates shall be recorded in the HHMMSS format as required in the ASTM1394 standard.
8. Delimiters: These fields specify the set of delimiters used for transmissions.

The ASTM setup screen can be accessed from ***Utilities, Options*** menu. Select the ASTM tab and check the 'Enable ASTM E 1381/1394 link to enable. The ASTM E 1394 delimiters could be configured as well as the ASTM E 1381 communication ports. Select the correct com ports.

Please make sure, that you must not select the port used to connect he PC to the analyzer.

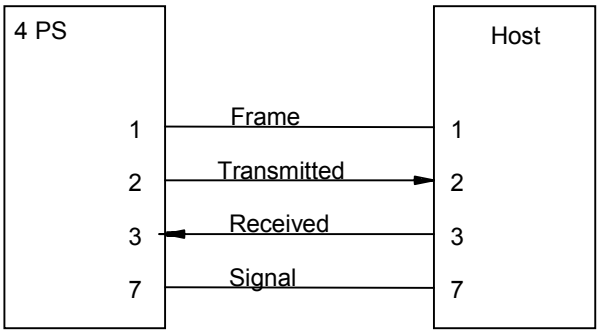


Picture 1 - ASTM configuration

5.2 Low-Level Protocol

5.2.1 Physical Layer

(refer to ASTM 1381, section 5)



Picture 2 - RS232 Connection to Host

5.2.2 Data Link Layer

5.2.2.1 Establishment Phase

(refer to ASTM 1381, section 6.2)

5.2.2.2 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 <EOT> the ELISYS QUATTRO does **not** stop transmitting and chooses to ignore the interrupt request.

5.2.2.3 Termination Phase

(refer to ASTM 1381, section 6.4)

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

5.2.2.4 Error Recovery

(refer to ASTM 1381, section 6.5)

The ELISYS QUATTRO 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 (ie. 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 ELISYS QUATTRO 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 ELISYS QUATTRO proceeds to the termination phase.

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

During the transfer phase, the ELISYS QUATTRO 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 ELISYS QUATTRO will also timeout if a reply to a frame is not received within 15 seconds.

5.3 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 (Record TypeID)	Comments
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 ELISYS QUATTRO
2	Test Order Record	'O'	
3	Result Record	'R'	
common	Comment Record	'C'	
1	Manufacturer Information Record	'M'	not allowed for ELISYS QUATTRO

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

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

A lower level record may never appear without the preceding 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.

(In some other descriptions a record might also be called segment.)

5.4 Incoming and Outgoing Transmission Examples

5.4.1 Host to ELISYS QUATTRO

(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 received 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.

Example:

H|\^&|||LaborEDV||||||||1|19941115202738
P|1|PatID01|||Meier^Anna||19741001|F|||||MARTINEZ
O|1|SampleID01||^^^AFP^1:10||19980506|||||||||S|||||||||X
P|1|PatID02|||Mueller^Fritz||19741001|F|||||MARTINEZ
O|1|SampleID02||^^^AFP||19980506|||||||||S|||||||||X
O|1|SampleID02||^^^TSH||19980506|||||||||S|||||||||X
O|1|SampleID02||^^^T3||19980506|||||||||S|||||||||X
O|1|SampleID02||^^^T4||19980506|||||||||S|||||||||X
P|1| Barcode0815|||Otto^Hans||19741001|F|||||MARTINEZ
O|1| Barcode0815||^^^AFP^1:10||19980506|||||||||S|||||||||X
P|1|12345|||||F|||||MARTINEZ
O|1|12345||^^^AFP^1:10||19980506|||||||||S|||||||||X
L|1|N

After the ELISYS QUATTRO 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.

5.4.2 Test Results

Only the final calculated result (Abs, concentration or interpretation) is transferred per test. For multiple replicate results the mean is transmitted only.

ELISYS QUATTRO 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 n Comment 1 : Patient Information Record n 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 n Comment 1 Message Terminator Record	→	Frame 1 : Frame n

Example:

H|\^&|||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|
L|1|N

5.5 Data Record Usage

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

Each record sent by the ELISYS QUATTRO will contain up to the last field used by the ELISYS QUATTRO, which may or may not be all fields possible for the record. An 'O' in Required or Sent field indicates optional. The first <**MaxLength**> characters are significant only. Any more characters transmitted for a specific field are ignored.

5.5.1 Message Header Record

Field No.	ASTM Field	Description	Valid Contents	Max Length	Required
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**
3	Message Control ID				N
4	Access Password				N
5	**Sender Name / ID**			**20**	**N**
6	Sender Street Address				N
7	Reserved Field				N
8	Sender Telephone No.				N
9	Characteristics of Sender				N
10	**Receiver ID**				
11	Comment				N
12	Processing ID				N
13	**Version No.**		**'1'**	**1**	**N**
14	**Date and Time of Message**	**Format is YYYYMMDD HHMMSS**		**14**	**N**

5.5.2 Patient Information Record

Field No.	ASTM Field	Description	Valid Contents	Max Length	Required
1	**Record Type ID**	**Character identifying the record as a patient information record**	**'P'**	**1**	**Y**
2	**Sequence Number**				**Y**
3	Practice Assigned Patient ID				N
4	**Laboratory Assigned Patient ID**	**Becomes our PatientID**			**Y**
5	Patient ID No. 3				N
6^1	**Patient Name**				**O**
6^2	**Patient First Name**				**O**
7	Mother's Maiden Name				N
8	**Birthdate**			**8**	**O**
9	**Patient Sex**			**1**	**O**
10	Patient Race - Ethnic Origin				N
11	Patient Address				N
12	Reserved Field				N
13	Patient Telephone Number				N
14	**Attending Physician ID**	**Becomes our SenderID**			**N**
15	Special Field 1				N
16	Special Field 2				N
17	Patient Height				N
18	Patient Weight				N
19	Diagnosis				N
20	Active Medications				N
21	Diet				N
22	Practice Field No. 1				N
23	Practice Field No. 2				N
24	Admission and Discharge Dates				N
25	Admission Status				N
26	Location				N
27	Nature of Alternative Diagnostic Code and Classifiers				N
28	Alternative Diagnostic Code and Classification				N
29	Religion				N
30	Marital Status				N
31	Isolation Status				N
32	Language				N
33	Hospital Service				N
34	Hospital Institution				N
35	Dosage Category				N

5.5.3 Test Order Record

Field No.	ASTM Field	Description	Valid Contents	Max Length	Required
1	**Record Type ID**	**Character identifying the record as a test order record**	**'O'**	**1**	**Y**
2	**Sequence Number**				**Y**
3	**Specimen ID**				**N**
4	**Instrument Specimen ID**				**N**
5^4	**Universal Test ID**	**Test Abbreviation**			**Y**
5^5	**Dilution**				**N**
6	**Priority**				**N**
7	**Requested/Ordered Date and Time**				**N**
8	Specimen Collection Date and Time	**'YYYYMMDDHHMMSS'**		14	O
9	Collection End Time				N
10	Collection Volume				N
11	Collector ID				N
12	Action Code				N
13	Danger Code				N
14	Relevant Clinical Information				N
15	Date/Time Specimen Received				N
16	**Specimen Descriptor (Type)**				**N**
17	Ordering Physician				N
18	Physician's Telephon Number				N
19	User Field No. 1				N
20	User Field No. 2				N
21	Laboratory Field No. 1				N
22	Laboratory Field No. 2				N
23	Date/Time Results Reported or Last Modified				N
24	Instrument Charge to Computer System				N
25	Instrument Section ID				N
26	**Report Types**				**N**
27	Reserved Field				N
28	Location of Ward of Specimen Collection				N
29	Nosocomial Infection Flag				N
30	Specimen Service				N
31	Specimen Institution				N

5.5.4 Result Record

Field No.	ASTM Field	Description	Valid Contents	Max Length	Required
1	**Record Type ID**	**Character identifying the record as a result record**	**R**	**1**	**Y**
2	**Sequence Number**				**Y**
3	**Test ID**				**N**
4	**Data or Measurement Value**			**depends on value**	**Y**
5	**Units**				**Y**
6	Reference Ranges				Y
7	**Result Abnormal Flags**				**N**
8	Nature of Abnormality Testing				N
9	**Result Status**				**N**
10	Date of Change in Instrument Normative Values or Units				N
11	Operator Identification				N
12	Date/Time Test Started				N
13	**Date/Time Test Completed**				**N**
14	**Instrument ID**				**N**

5.5.5 Comment Record

Comment Records are used either to describe reasons for rejected test orders or to supply additional result information, e.g. result relevant flags.

5.5.6 Request Information Record

Not applicable.

5.5.7 Message Terminator Record

Field No.	ASTM Field	Description	Valid Contents	Required	Sent
1	Record Type ID	Character identifying the record as the last record in the message	'L'	Y	Y
2	Sequence Number			Y	Y
3	Termination Code			N	N

5.5.8 Scientific Record

must not be sent

5.5.9 Manufacturer Information Record

must not be sent

6 ASCII FILE TRANSFER

6.1 Introduction

The ELISYS QUATTRO has the possibility to receive worklist files and transmit result files from and to a network server. Both file formats (Import and Export) can be defined within the ELISYS QUATTRO software.

The import of worklist files can be performed manually by the user or automatically with a polling sequence.

6.2 Hardware Configurations

The communication between the ELISYS QUATTRO and the host system is established using an Ethernet card. In case that the ELISYS QUATTRO computer should be connected to an other host system, please install the necessary protocol or client and configure it according to the specifications for this host. .

Note:

For all type of servers take care of following restrictions:

1) The file names should no be longer than 20 characters

2) Do not use special characters in the file names accept "-" and "_"

3) Characters for file names allowed: Numbers from 0 to 9

Letters from A to Z (small and big capitals)

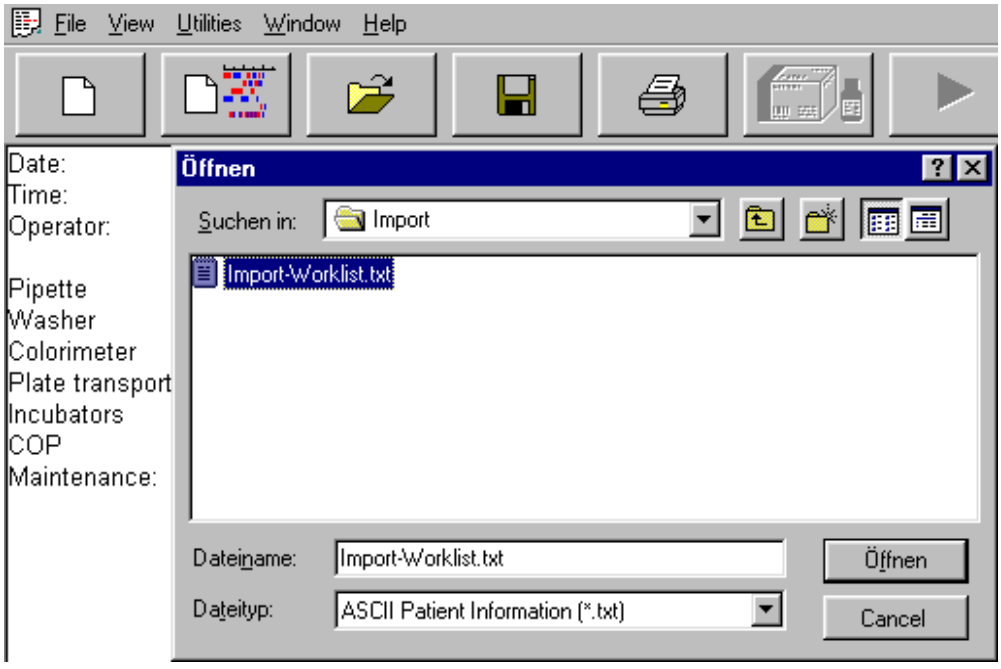
6.3 Manual Import of a Worklist

6.3.1 Import a Worklist File

At the main menu of the ELISYS QUATTRO software chose "File" "Open" and the Win-Explorer will be opened. Select the worklist file from the created folder on the host.

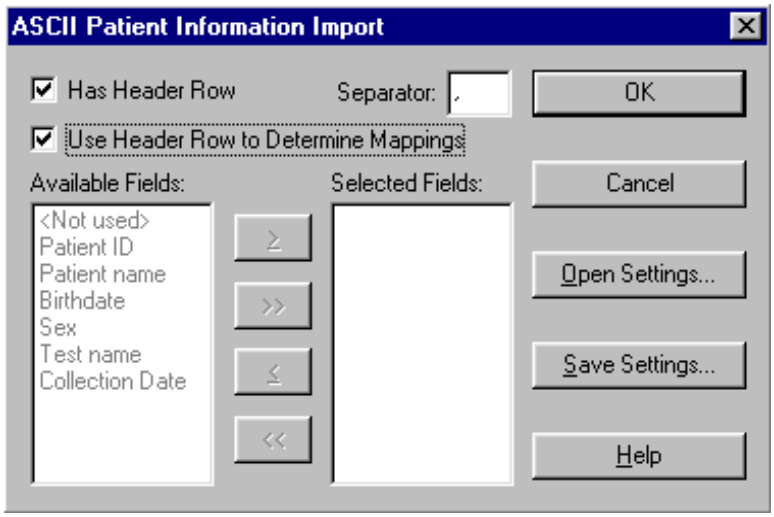
The directory should be \\network_drive\ELISYS QUATTRO\Import.

As file type "ASCII Patient Information (*.txt) must be selected.



Double click the file (e.g. ImportTorch.txt) and the following window will be displayed.

The file format of “ImportTorch.txt” is described in 6.3.2.1.



This setup menu allows you to define the format of the files that you want to import.

Mark ‘Has Header Row’ if the file has, as it’s first record the heading labels.

Please note, that the Header labels must consists of the same records as shown in the “Available Fields” list.

Mark “Use Header Row to determine Mappings” or create the “Select Fields” box, if the header from the file should not be used to determine mappings. The “Selected fields” must be created in the order they appear in the file.

Select the separator character. As default ‘comma’ is defined.

Once a ‘Patient Import’ setting has been created, it can be saved for re-use later.

Available fields to import:

Patient ID	*Alphanumeric strings accepted.*
Patient Name	*No limits on patient name*
Birthdate	*YYYYMMDD*
Sex	*ASTM states M, F, or U but no actual restrictions*
Test name	Test name must correspond exactly to the assay protocol stored in the ‘Assay Protocol Files’ sub-directory – default C:\ELISYS QUATTRO\Assaydefinitions. E.g. CMV-G (no extension or directory)
Collection Date	*YYYYMMDDHHMMSS*

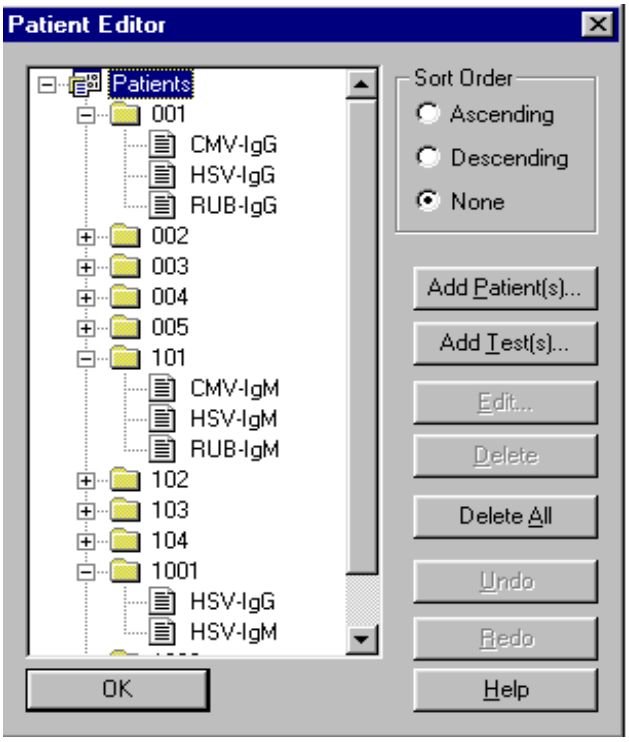
If all settings have been done the file import is confirmed with a message

“……has been successfully imported”.

Note:

This message just confirms that the file has been imported – this message does not confirm the correct import of all the date fields.

The imported information is transferred into the ELISYS QUATTRO “Patient Details…” and is displayed as shown in the picture below:



6.3.2 Examples of Import files

6.3.2.1 File includes Patient ID and Test names

Patient ID,Test name,Test name,Test name,Test name ← ***Header Row***

001,CMV-IgG,HSV-IgG,RUB-IgG,TOX-IgG
002,CMV-IgG,HSV-IgG,RUB-IgG,TOX-IgG
003,CMV-IgG,HSV-IgG,RUB-IgG,TOX-IgG
004,CMV-IgG,HSV-IgG,RUB-IgG,TOX-IgG
005,CMV-IgG,HSV-IgG,RUB-IgG,TOX-IgG
101,CMV-IgM,HSV-IgM,RUB-IgM,TOX-IgM
102,CMV-IgM,HSV-IgM,RUB-IgM,TOX-IgM
103,CMV-IgM,HSV-IgM,RUB-IgM,TOX-IgM
104,CMV-IgM,HSV-IgM,RUB-IgM,TOX-IgM
1001,HSV-IgG,HSV-IgM
1002,HSV-IgG,HSV-IgM
1003,HSV-IgG,HSV-IgM

Separator “,”

Data fields

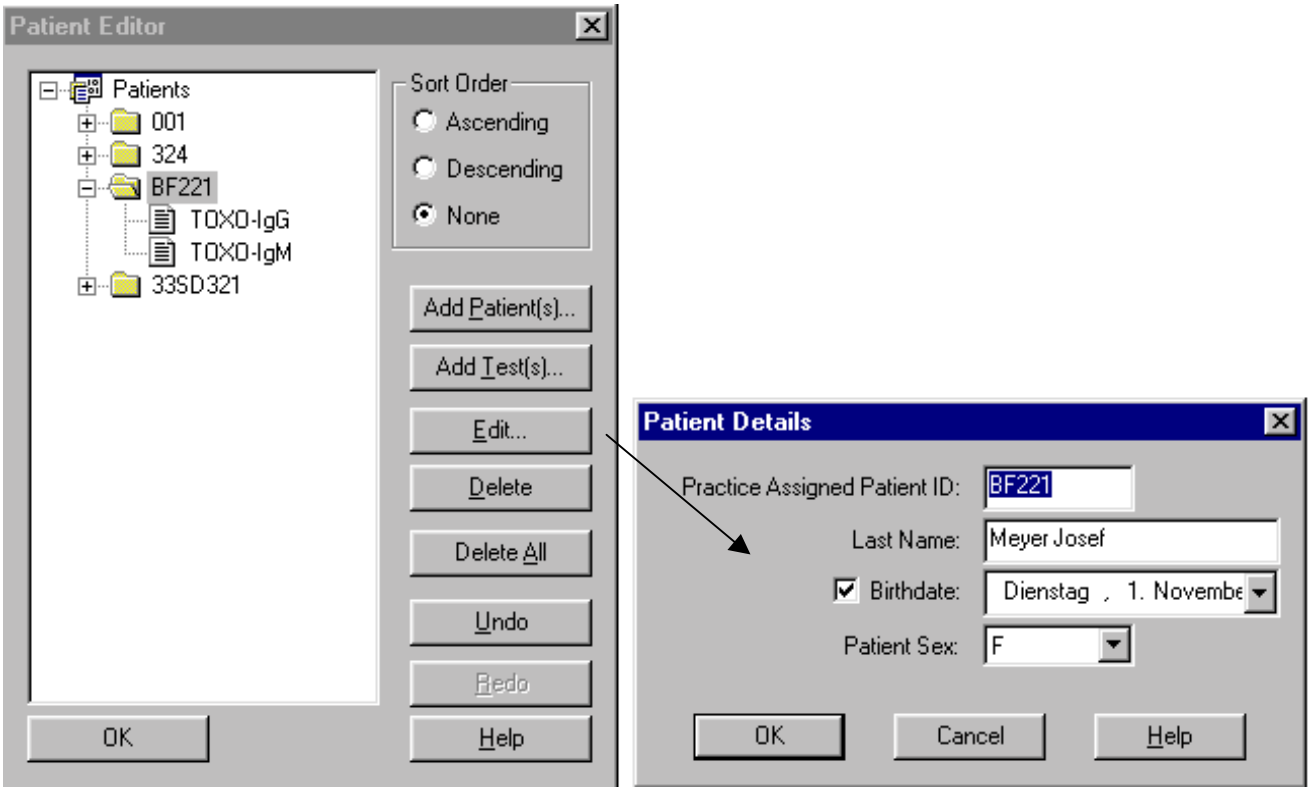
Separator “,”

6.3.2.2 File includes Patient ID, Test names and Details

Patient ID,Patient name,Test name,Test name,Birthdate,Sex,Collection Date
001,David,CMV-IgG,HSV-IgG,19690330,M,20000930102944
324,Marco,HSV-IgG,,19770119,M,20000930103344
BF221,Meyer Josef,TOXO-IgG,TOXO-IgM,19661101,F,20000930112121
33SD321,Muster Hans,TOXO-IgG,,19770202,M,20000924120229

If a patient does not have all fields which are defined in the header (e.g. Patient "33SD321" has just one Test name), the data field must be empty but separated via ",".
This means: Number separators Header Field = Number separators Data Field

The "Patient Detail…" box represents the above file as following (by selecting a Patient ID and "Edit" there is access to the Patient Details.



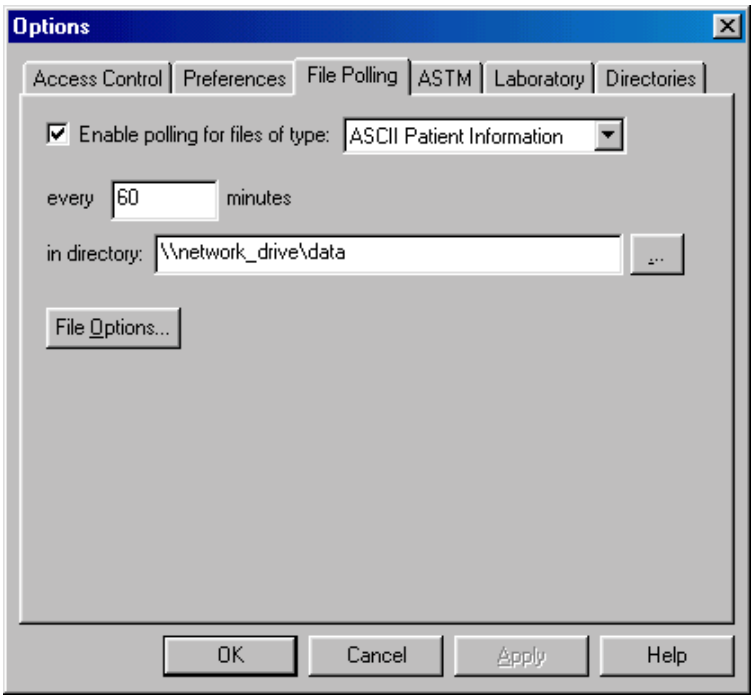
6.4 Automatic Import of a Worklist File

6.4.1 File Polling

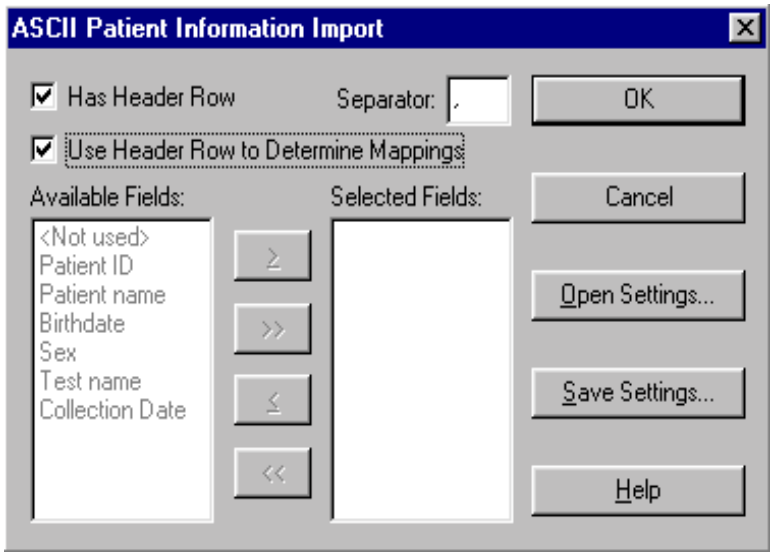
The ELISYS QUATTRO software allows the User to configure specific locations that the software will poll looking for ASCII patient information files. When a valid file is found, it is imported into the software, interpreted and the patient database updated with the new patient details. The User determines the frequency the software polls the specified directory.

6.4.2 Setup Polling

To set up 'File Polling' choose from the main menu "Utilities" and "Options". Click on the File Polling tab and the following dialog appears. To specify the ASCII file format click on the 'File Options' button and select the appropriate labels.



File Options is the same dialog when used manually from the File Open menu item (6.3.1.)



Note:

The system time of the server and the system time of the ELISYS QUATTRO computer ***must be synchronised!***

If the system time of the server is ahead of the system time of the ELISYS QUATTRO computer ***and they deviate more than the defined polling time the worklist files will never be imported !***

7 EXPORT OF FILES

The ELISYS QUATTRO allows the ASCII export of data.

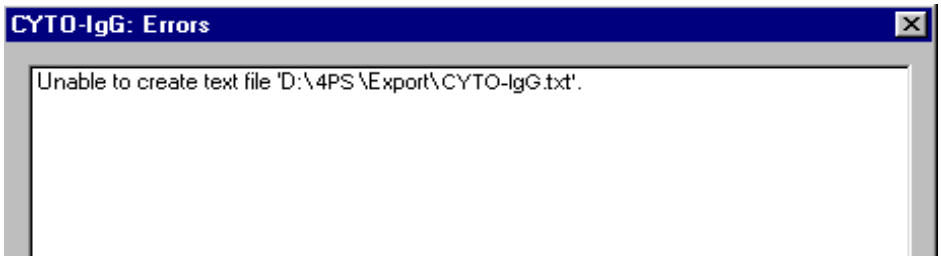
The destination where the Export Files shall be transferred can be defined in the “Utilities – Options” menu of the ELISYS QUATTRO.

Highlight the file-type for which you want to change the export destination, e.g. “Export Files” and click on “Browse”. The explorer screen open from where you can navigate trough the available network and select the target folder (default setting is C:\..\Exportfiles).

> ***Note:***
>
> ***If you want to change the path for “Export Files”, a files has to be copied first into your new targer directory.***
>
> ***Do not change the target folder for the result files.***

As soon as a result is available the Software generates an ASCII file (*.txt) which is than automatically transferred to the defined target folder.

If a file should be exported and the target file is not available, the following message appears::

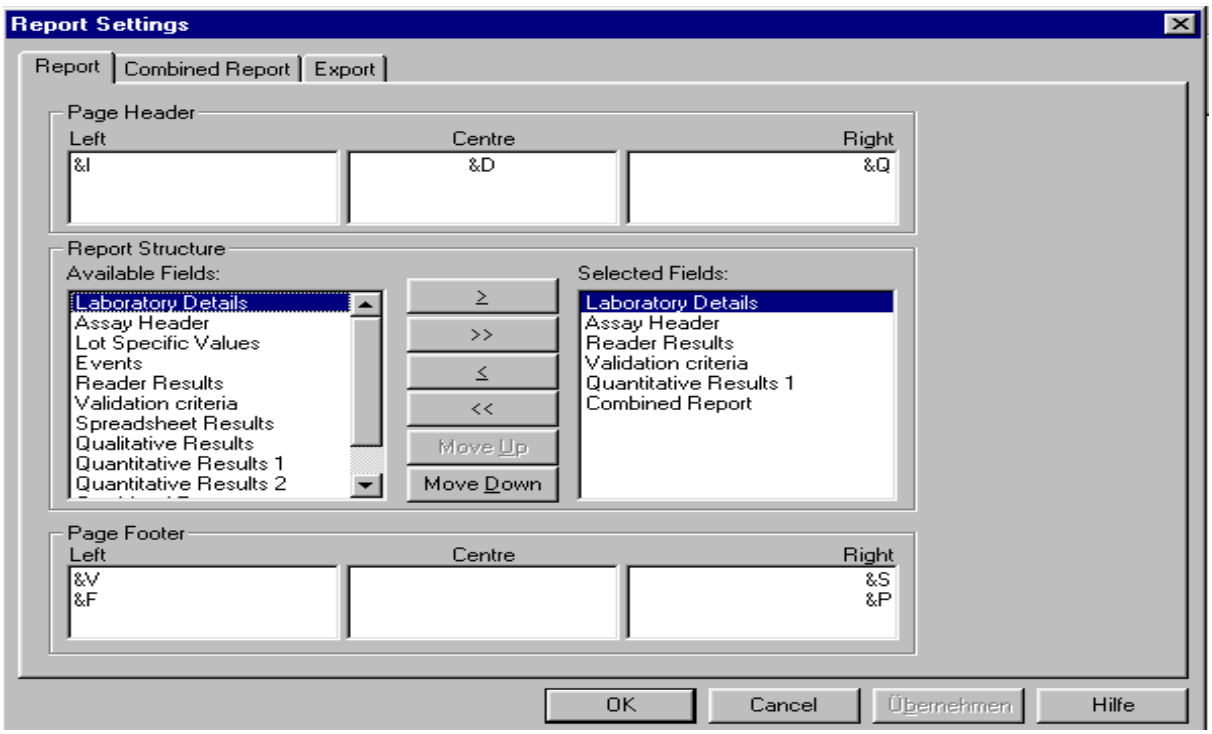


As soon as the communication is build up again, open the Result File in ELISYS QUATTRO (Subdirectory Result Files) once again and the Export File will be generated and transferred automatically.

Within every assay definition you will find in the sub-category “Read” a report section which can be customised to the customer needs.

To set up or open the settings, click on Read.

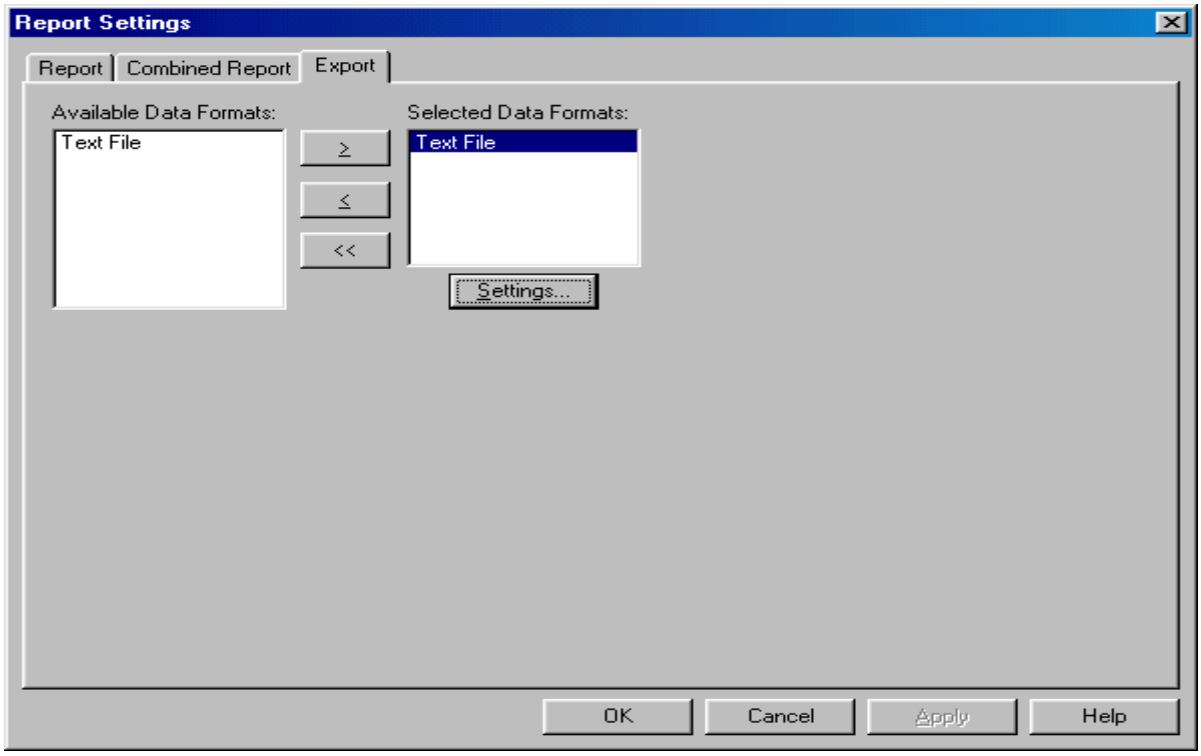
Double click on Report Settings and the following screen opens:



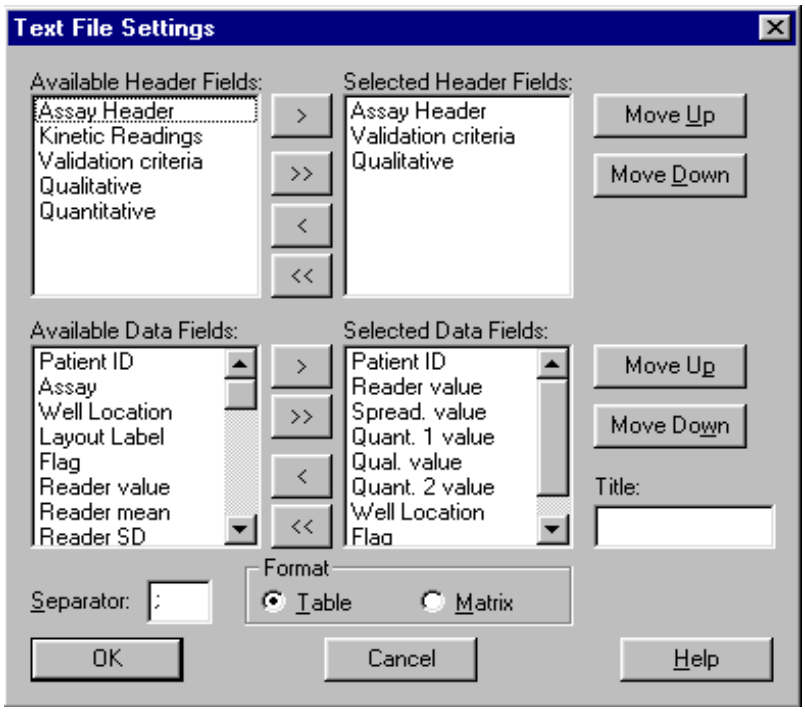
Please note, that the default setting only includes the assay header and reader results.

The export file format can be individually customised for each test according to the customer needs.

Select the Export tab and click on Settings.



The following screen opens:



The format can be table or matrix, normally a table format is used for ASCII export.

Define the settings according to the customer needs from the available header and data fields windows.

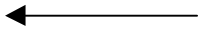
Available Header and Data Fields are:

Assay Header	Date and time, OVER limit, operator and wavelengths
Kinetic readings	Raw data from each read
Validation criteria	QC evaluation
Qualitative	Qualitative QC, qualitative equations and notes
Quantitative	Quantitative notes
Patient ID	Patient ID
Assay	Assay name
Well Location	e.g. A1
Layout Label	e.g. T1
Flag	Clot detection, No liquid detected , etc.
Reader value	Reader value for that replicate
Reader mean	Averaged reader value across replicates
Reader SD	Standard Deviation of replicates
Reader CV	%co-efficient of variation of replicates
Reader SE	Standard Error of replicates
Reader units	Reader units
Qual. Value	As above, but for qualitative results
Qual. Mean	As above, but for qualitative results
Quant. 1 value	As above, but for 1st curve fit (quantitative)
Quant. 1 mean	As above, but for 1st curve fit (quantitative)
Quant. 1 SD	As above, but for 1st curve fit (quantitative)
Quant. 1 CV	As above, but for 1st curve fit (quantitative)
Quant. 1 SE	As above, but for 1st curve fit (quantitative)
Quant. 1 units	As above, but for 1st curve fit (quantitative)
Spread. value	As above, but for spreadsheet results
Spread. Mean	As above, but for spreadsheet results
Spread. SD	As above, but for spreadsheet results
Spread. CV	As above, but for spreadsheet results
Spread. SE	As above, but for spreadsheet results
Spred. units	As above, but for spreadsheet results
Quant. 2 value	As above, but for 2nd curve fit (quantitative)
Quant. 2 mean	As above, but for 2nd curve fit (quantitative)
Quant. 2 SD	As above, but for 2nd curve fit (quantitative)
Quant. 2 CV	As above, but for 2nd curve fit (quantitative)
Quant. 2 SE	As above, but for 2nd curve fit (quantitative)
Quant. 2 units	As above, but for 2nd curve fit (quantitative)

Example of Export Files

Export Files without Header Fields defined:

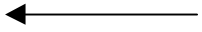
[HBsAg]



No header information

[Results]

Patient ID,Assay,Reader value,Qual. value



Data field header separated via “,”

"","HBsAg","0.009","NC1"
""," HBsAg","0.011","NC2"
""," HBsAg","0.093","NC3"
""," HBsAg","1.455","PC1"
""," HBsAg","1.465","PC2
"001"," HBsAg","0.004","neg"
"002"," HBsAg","0.011","neg"
"003"," HBsAg","0.011","neg"
"004"," HBsAg","0.002","neg"
"005"," HBsAg","0.987","pos"
"006," HBsAg","0.009","neg"
"007 HBsAg","0.075","equ"
"008 HBsAg","0.011","neg"

Export Files with Header Fields defined:

[HBsAg]
Time:;11:15:00 --------
Date:;27/09/00
OVER limit:;3.000 ***Assay Header Field***
Operator:;User
Wavelengths:;450nm/620nm ---------
-0.01<=NCi<=0.50;-0.01<=0.010<=0.50
;-0.01<=0.009<=0.50
;-0.01<=0.011<=0.50
;-0.01<=0.093<=0.50;Removed ***Validation Criteria Header Field***
Valid(NC)>=2;2>=2
PCi>=0.550;1.460>=0.55
;1.455>=0.55
;1.465>=0.55
valid(PC)=2;2=2 ---------
If 'Sample<(NC+0.05)*0.9' Then Result:='neg'
If 'Sample>=(NC+0.05)*1.1' Then Result:='pos' ***Qualitative Header Field***
Default result := equ ----------
cut off;(NC + 0.055);0.060 ***Quantitative Header Field***

[Results]
Patient ID,Assay,Reader value,Qual. value ← ***Data field header separated via “,”***
"","HBsAg","0.009","NC1"
"","HBsAg","0.011","NC2"
"","HBsAg","0.093","NC3"
"","HBsAg","1.455","PC1"
"","HBsAg","1.465","PC2
"001","HBsAg","0.004","neg"
"002","HBsAg","0.011","neg"
"003","HBsAg","0.011","neg"
"004","HBsAg","0.002","neg"
"005","HBsAg","0.987","pos"
"006,"HBsAg","0.009","neg"
"007 HBsAg","0.075","equ"
"008 HBsAg","0.011","neg"

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