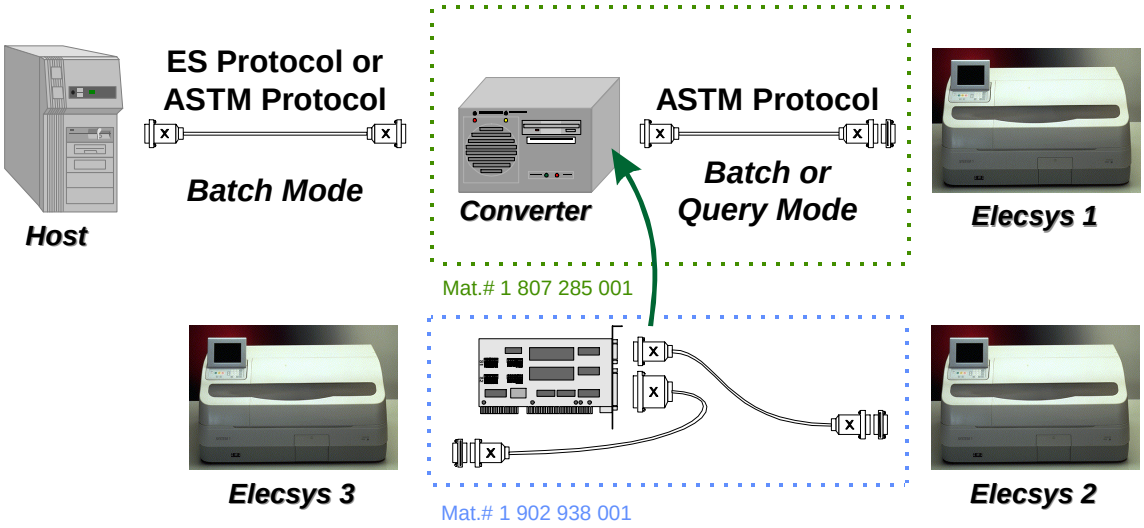
ES-Elecsys-Converter Version 2.0 - Operator Manual
(Update 2.06)

1 Functionality:

The **ES-Elecsys-Converter** *(ID# 1 807 285 001)* of Boehringer Mannheim allows to connect Elecsys© 2010 Analyzers as well as Elecsys© 1010 Analyzers to an existing online connection of an Enzymun System© Analyzer. In that case the converter behaves as an ES analyzer connected to a host. Test selections are transmitted via batch download from the host to the converter. Between the Elecsys© analyzer and the converter an automatic exchange of test selections and results takes place. Via batch upload existing results can be sent to the host any time.

Actions at the converter are initiated by pressing a button or are scheduled by a timer. Two LED´s indicate requests (red) or results (yellow) being available at the converter.



1.1 Extensions:

Version 2.0 of the converter software combined with the "*Extension package for protocol converter*" *(ID# 1 902 938 001)* extends the capability of the converter to connect three instruments simultaneously.

For detailed description how to install the extension package please refer to the Modification Manual delivered with that package.

For host protocol the ES as well as the ASTM protocol can be selected. Each of the three instrument ports can be setup separately. Test parameters can be assigned to one ore more instruments, so simple distribution rules might be defined.

An additional software tool now allows to investigate the converter's data base in case of problems.

The Converter Software Version 2.0 replaces an older software, so a new setup of all parameters is necessary.

1.2 Start:

The converter starts when switched on. No diskette must be in the drive. A four times beep indicates the converter is ready.

The converter should be always on.

1.3 Download:

1.3.1 ES-Protocol:

Master Mode:

The transmission of test selections from the host is released by the download button, confirmed by an acoustic signal (beep). When the host is ready, this process can be initiated any time.

The download alternative to the upload can also be controlled by a timer. In that case the download button is disabled.

Slave Mode:

The transmission of test selections is initiated by the host.

Red LED:

When the red LED under the download button is light test selections are available in the converter which are not yet sent to the instrument.

1.3.2 ASTM-Protocol:

There is no query mode between converter and Host. Therefore the Host downloads test selections to the converter as soon as they are available.

1.4 Upload:

1.4.1 ES-Protocol:

Master Mode:

The transmission of results to the host is released by the upload button, confirmed by an acoustic signal (beep). When the host is ready, this process can be initiated any time.

When the button was pressed and there is no beep to confirm, no results are ready to be transmitted. In that case no communication takes place.

The upload alternating to the download can also be controlled by a timer. In that case the upload button is disabled.

Also all results without test selections from the host will be passed through to the host.

Slave Mode:

The transmission of results is initiated by the host.

Yellow LED:

When the yellow LED under the upload button is light results are available in the converter which are not yet sent to the host.

1.4.2 ASTM-Protocol:

The converter uploads test results to the Host as soon as they are available.

1.5 Repeated Upload:

1.5.1 ES-Protocol:

Master Mode:

All results in the data base can be sent to the host again while pressing the upload button until the beep goes off. The following process is accompanied by activity of the hard disk control LED (H.D.D). When the hard disk control LED goes off all stored results are ready to be sent. The yellow LED is on.

Slave Mode:

In slave mode upload is repeated as described above.

1.5.2 ASTM-Protocol:

For ASTM protocol upload is repeated as described above.

1.6 Reorganization of the Data Base:

The data base of the converter is reorganized once a day at the time defined in the setup.

When reorganization time is "-1:-1“ then a manual reorganization must be done by the operator by pressing "R" on a keyboard connected to the converter.
Since a keyboard and a monitor are not available it is also sufficient to boot with a diskette inserted in the floppy drive. This diskette must contain the file "GETDATA.BAT" with the following content.

```
del c:\eselkv\xchange.dat
```

1.7 Review of the Data Base:

There is a software tool CVIEW.EXE which allows to investigate the data in the database XCHANGE.DAT. Execute CVIEW in the same directory where XCHANGE.DAT is located.

```
MB Data Control AG              XChange -View                13.09.97  02:00:00
```

#Index	Org. Host IDNo	Barcode IDNo	Status	RackID	RackPos
1	10099	10099	0065	5801	2
2	10102	10102	0065	5801	3
3	10105	10105	0065	5801	4
4	10108	10108	0065	5801	5
5	10111	10111	0065	5821	1
6	10114	10114	0065	5821	2
7	10117	10117	0065	5821	3
8	20099	20099	0065	5954	1
9	20102	20102	0065	5954	2
10	20105	20105	0065	5954	3
11	20108	20108	0065	5954	4
12	20111	20111	0065	5954	5
13			0000		
14			0000		
15			0000		
16			0000		
17			0000		
18			0000		
19			0000		

```
              F2 Display All
```

From there pick up a sample ID and press F2 for further information display.

```
MB Data Control AG              XChange -View                13.09.97  02:00:00
IndexRecord
===========

IdentNo         : 10099
Status          : 0065  Binary: 0000000001100101
RackId,RackPos  : 5801  2
SeqNo           : 21

BodyRecord
==========

Org HostId      : 10099
SampleTyp       :
ControlCode     :
LotNumber       :
Dilution        :
InstrumentID    :
Patient         :    01.01.1600
OperatorName    :

Assay  ParStatus  NumResult QualiRes Flag    Unit          Date started      Da

    10 00011001      8.92             0  F  uIU/ml      25.09.1996/15:51:22  25
    50 00011001      5.95             0  F  nmol/l      25.09.1996/15:52:04  25
   170 00011001     28.76             0  F  mIU/ml      25.09.1996/15:53:28  25
   200 00011001     0.010             0  F  ng/ml       25.09.1996/15:54:10  25
```

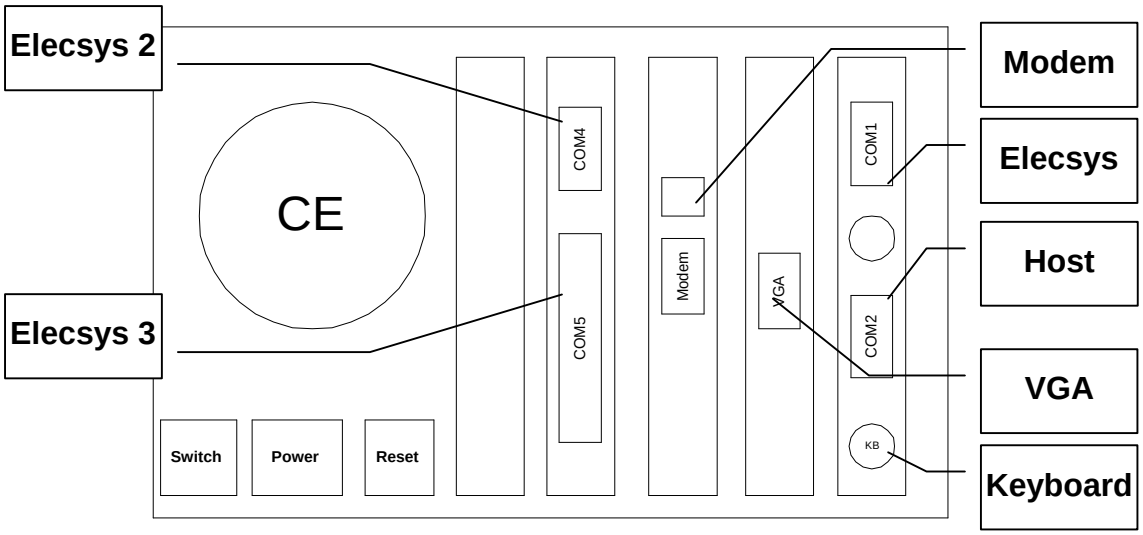
2 Trouble Shooting:

To support trouble shooting the converter has a built in modem and a remote access software installed (PCAnyWhere 5.0). When accessible via phone the service engineer of Boehringer Mannheim is able to contact the converter for additional information which helps solving problems or allows to install a new software release.

If there is no phone line the available data necessary can be stored onto a diskette. To produce this information make a copy of the *diskette 3:* ***get TRACE***. Then this diskette must be inserted into the drive and then the converter must be rebooted. The four times beep indicates when ready. Then via diskette the stored information is available for the service engineer of Boehringer Mannheim.

3 Connections (Cables):

The Elecsys connection and the host connection as well as the modem connection are at the back side of the converter:



Due to different manufacturing and assembling it might by possible that the PC-cards are not in exactly the same slot position as the picture shows.

4 Installation and Configuration:

The installation and configuration of the converter is managed by diskettes.

4.1 Installation:

The converter is pre installed with version 1.x when delivered.

Upgrade the converter with the *Extension Package* as described in the *Modification Manual*.

To install the software release 2.06 of the converter software insert the diskette ***Elecsys Protocol Converter Version 2.06*** into the floppy drive and reboot the converter (r*eset button at the back side of the converter*). A four times beep indicates when ready.

Only the test parameters from the previous version will automatically be converted to the new format. If the old parameters should not be used any more but a new copy of the test parameter then delete all files *.dta on the converter before installing the new software version.

Manual conversion of the old test parameter version 1.x (PARASTAM.DTA) can be done with the program KVOLDSTA.EXE. Execution of this program in the directory c:\eselkv will create the new test parameter file PARASTA2.DTA.

Before starting work the converter should be rebooted again.

Note: Data of a version 2.x older than 2.06 can not be overtaken.

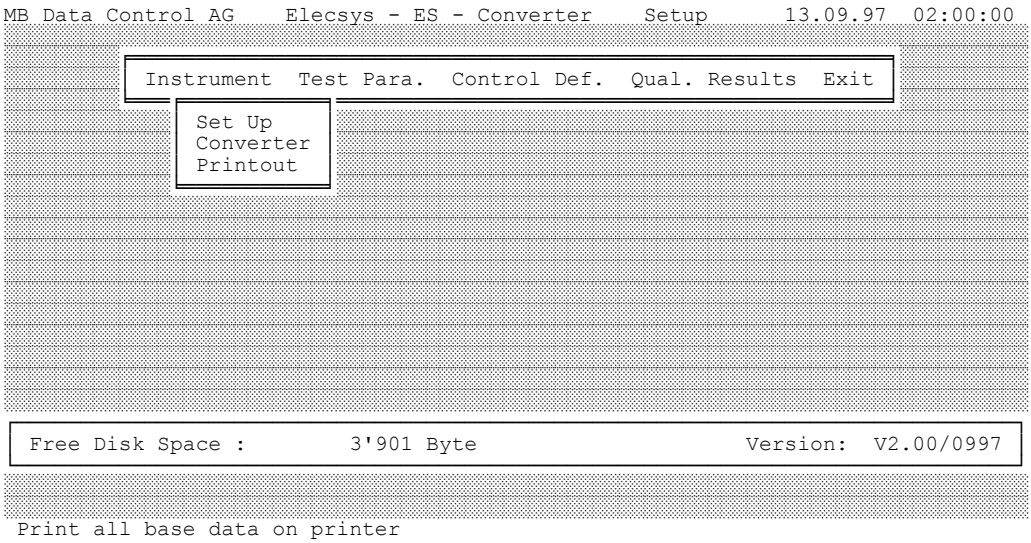
4.2 Configuration:

As preparation insert a DOS formatted, empty diskette into the floppy drive and reboot the converter. Then the configuration data and program are stored on this diskette.

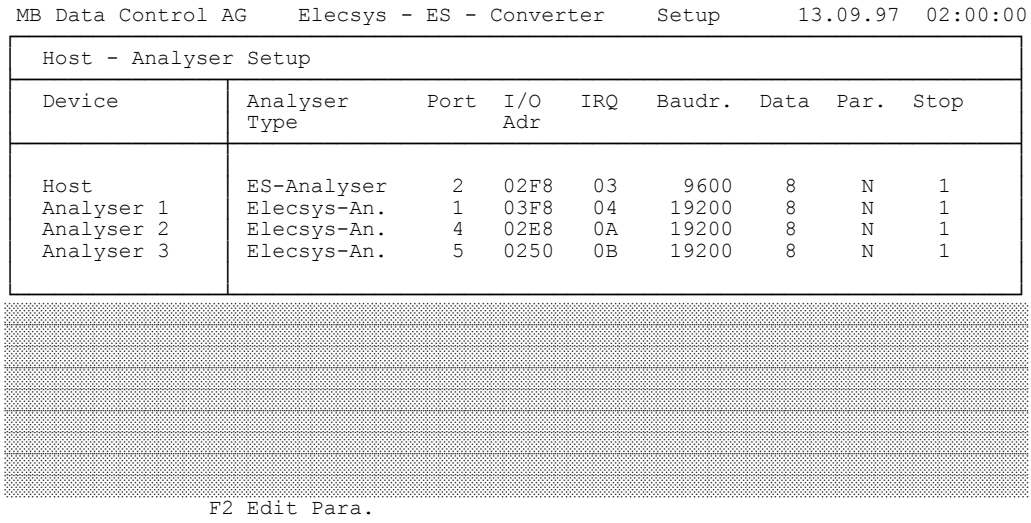
The actual change of the configuration takes place with this diskette at another DOS compatible computer. The configuration program is invoked by typing **KS** from drive A:.

After the configuration is copied to the diskette insert this diskette into the converter and reboot. The new configuration is active after the four times beep. Now remove the configuration diskette from the converter and put it in a safe place.

4.2.1 Main Menu:



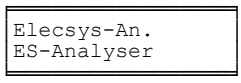
4.2.2 Set Up:



In the menu "*Host - Analyzer Setup*" an analyzer type with its protocol is assigned to each port. The port addresses, their IRQ´s and the interface parameters are displayed in an overview.

For the **Host port** select between the two options

Elecsys An. → ASTM-protocol (no query)
ES-Analyzer → ES-protocol



For each **Analyzer port** select between the four options

Elecsys An.	→ ASTM-protocol (batch or query)
ES-Analyzer	→ ES-protocol
CLAS	→ special option for CLAS
None	→ no analyzer at this port

```
Elecsys-An.
ES-Analyser
CLAS
None
```

4.2.3 Configuration for an ES Analyzer:

```
MB Data Control AG    Elecsys - ES - Converter    Setup      13.09.97  02:00:00
ES Host Interface Definition
Baudrate  :  9600_ (300..19200)     Databits :  8    (7,8)
Stopbit   :  1     (1,2)            Parity   :  N    (N,E,O)

Instrument Identification : Converter   Transfer Mode: M (M=Master,S=Slave)

Download from Host        : Y      (Y,N)
Request  : P=RQ:03,IN:18,TC:06,RR:20;

Upload to Host            : Y      (Y,N)
Header   : P=HD:03,II:10,ON:10,DA:08;
Result   : P=MD:06,TY:02,IN:18,TC:06,RA:08,ST:02,UN:06;


Block Length   : 255 (32..255)
Delay to   STX :  0   ACK :  0   ENQ :  0  DLE :  0  EOT :  0  (1/10 sec)
# of Repetition:  3
Timeout Master : 15  ( sec )
Term. Chars    : 13  10  (decimal value)     Result mapping :  RS =
<Esc> Exit                  <^Enter> Save and Exit
```

Communication parameters for ES are adapted to the TWIN setup in the mask *„ES Host Interface Definition“*. In the special case when there was a setup with the additional program *„host“* at the ES analyzer for result mapping to a different format this is adjusted in this screen as well

4.2.4 Configuration for an Elecsys Analyzer:

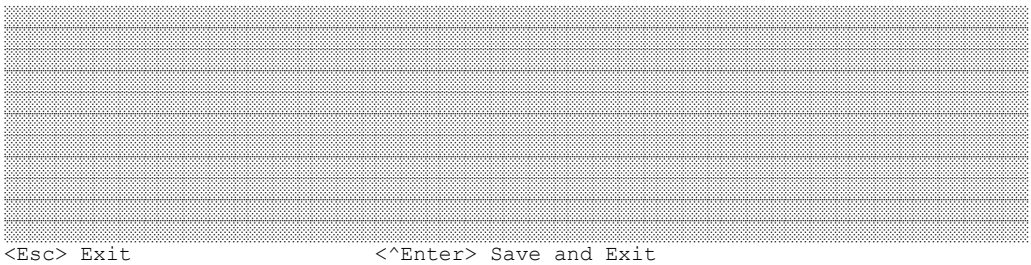
```
MB Data Control AG    Elecsys - ES - Converter    Setup      13.09.97  15:07:49

 Elecsys Interface Setup

 Baudrate  :  19200 (4800..19200)    Databits :  8   (7,8)
 Stopbit   :  1     (1,2)            Parity   :  N   (N,E,O)

 Operator Name             : ElecConvAnalyzer1

 Elecsys Communication Mode: Q  (Q = Query ,B = Batch)
```



```
<Esc> Exit                  <^Enter> Save and Exit
```

In this screen the communication parameters for the Elecsys must be adjusted. Here it is also defined if the instrument works in query or batch mode.

4.2.5 Configuration of Special Converter Functions:

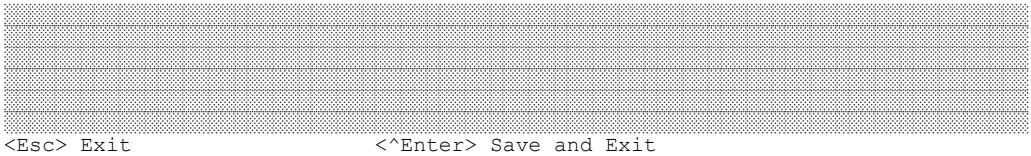
```
MB Data Control AG    Elecsys - ES - Converter    Setup      13.09.97  15:34:12

 Converter Special Setup                Project:  Test Version 2.0 MBC

 Looptime  Upload,Download :      seconds     ( 0 for release via button  )
 Time for reorganisation   :   7:00  hh:mm
 Tracefile size            :   100000        ( Byte )

           Sample-ID Manipulation : ES-Host ->> Elecsys

 cut # of chars from front :  __
 cut # of chars from tail  :
 Prefix                    :
 Suffix                    :
```



```
<Esc> Exit                  <^Enter> Save and Exit
```

In the input mask *„Converter Special Setup“* the following special parameters are entered:

Project Name:

A free editable description for the organization running the converter which will be printed on the configuration print out.

Setup for Flow Control:

Looptime Upload, Download: When 0, upload and download are released via button.
When not 0, upload and download are scheduled by a timer in a cycle of n seconds (max. 999 sec).
Example =900:
Every 15 minutes upload and download are initiated alternating.

Time for reorganisation: At a special time the data base is reorganized (data is erased).
Example =7:00:
At 7:00 AM the reorganization is executed. (Manual deletion of the file XCHANGE.DAT reorganizes data as well.)
Example = -1:-1:
No automatic reorganization will be done. If keyboard connected operator must do it by pressing "R" or using diskette as described in chapter 1.5.2.

Trace file Size: The size of the trace file can be limited to the number of bytes input here.

Input to Manipulate Sample Identification:

It may occur that the sample identification (bar code) does not match to the identification, coming from the host. Since Elecsys has positive identification in opposite to the ES analyzer, this leads to a problem when assigning samples. The built in functions for *„Sample-ID Manipulation : ES-Host ->> Elecsys“* allow the following manipulation:

cut # of chars from front: n (2 byte) leading characters are removed from the sample identification coming from the host.
Example n=2:
sample ID from host = **00**123456, but
sample ID at Elecsys = 12345.
Example n=11:
sample ID from host = **23.11.1996/**123, but
sample ID at Elecsys = 123.

cut # of chars from tail: m (2 byte) trailing characters are removed from the sample identification coming from the host.
Example m=1:
sample ID from host = 123456**0**, but
sample ID at Elecsys = 12345.

Prefix (string before sample ID):aaaaaa (max. 6 characters)
The string aaaaaa is added at the beginning of the sample identification coming from host.
Example aaaaaa=AB:
sample ID from host = 123456, but
sample ID at Elecsys = **AB**12345.

Suffix (string after sample ID): bbbbbb (max. 6 characters)
The string bbbbbb is appended to the sample identification coming from host.
Example bbbbbb=CD:
sample ID from host = 123456, but
sample ID at Elecsys = 12345**CD**.

4.2.6 Printout:

The printout option is new. With this option it is possible to make a print out of the actual configuration of the converter.

The output device is selected as command line parameter when starting the setup program KS, e.g.

```
ks screen
```

The following printer types are optional:

SCREEN	display on monitor
STANDARD	standard printer (default)
EPSONFX	Epson 9 pin matrix printer
EPSONLQ	Epson 24 pin matrix printer
HPLJII	HP Laserjet
THINKJET	IBM ink jet

After selection of the menu option *Instrument - Printout* the execution of the command must be confirmed:

```
Printer ready Y/N ?  [N] _
```

4.2.7 Configuration of Test Parameter:

MB Data Control AG Elecsys - ES - Converter Setup 18.12.97 02:06:00

Elecsys ES-Analyser Test Parameter Setup

Assay-Ref	Testcode	ES-Code	ES-No	An-1	An-2	An-3	Qualit.	Inv.	Meas. range
10	TSH	TSH	1	10	10		N	N	0.005 - 100.00
20	T4	T4	2				N	N	3.0 - 320.00
30	FT4	FT4	3				N	N	0.3 - 100
40	T-UP	TBK	4				N	N	0.2 - 1.9
50	T3	T3	5	50	50	50	N	N	0.3 - 10.0
60	FT3	FT3	6				N	N	0.4 - 50.0
100	E2	E2	10				N	N	10.0 - 4600.0
110	TESTO	TESTO	11				N	N	0.02 - 15.0
120	PROG	PROG	12				N	N	0.15 - 100.0
130	PRL	PRL	13				N	N	10.0 - 10000.
140	LH	LH	14	140		140	N	N	0.110 - 198.0
150	FSH	FSH	15				N	N	0.1 - 200.0
160	CORT	CORT	16				N	N	-
170	HCGSTAT	HCG	17	170	170		N	N	0.5 - 10000.
180	HCG	HCG_	18				N	N	0.5 - 10000.
200	TNTSTAT	TROPT	20		200	200	N	N	0.01 - 25.0
210	CKMBSTAT	CKMB	21		210	210	N	N	0.15 - 500.0

F2 Edit Para. F3 Insert Rec F4 Delete Rec F5 Append Rec

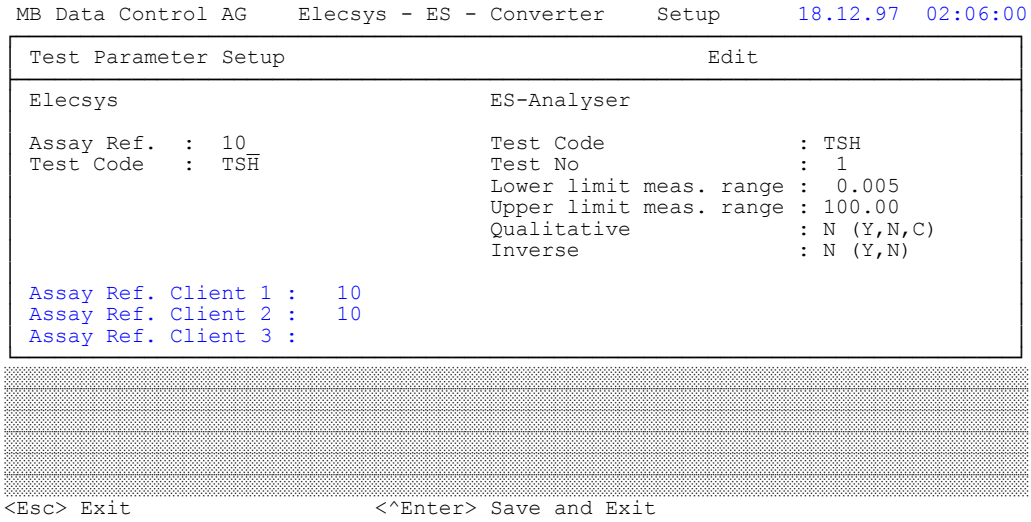
In this input mask the parameters for test selection as well as the measuring range are entered:

Assay-Ref:	Assay Reference number for Host
Testcode:	Elecsys Test Code
ES-TestCode:	ES Test Code (adapt to host)
ES-TestNo:	ES Test Number (adapt to host)
An-1 / An-2 / An -3	Test can be performed on analyzer 1, 2 or 3 by defining an assay reference number (empty means test does not run on that analyzer)
Qualit.	Cutoff Test (Yes/No), Cutoff Index (C) will be sent instead of neg/pos
Invers:	negative result means POSITIVE (for cutoff tests)
Meas. range:	For Elecsys software versions < 1.35 the measuring range is entered here. Therefore the converter is able to flag the results corresponding to the TWIN conventions (<,>). The measuring ranges can be found in the test package inserts for the Elecsys tests.

With the function keys F2 = Edit Parameter, F3 = Insert Record, F4 = Delete Record and F5 = Append Record the test parameter table can be filled out. New tests which might be available in the future can be added.

For details of test parameters please refer to the actual Assay Reference Table (see below).

When a test is selected via F2 button, the parameters are entered in the following screen:



Assay Reference Table (Default = unit1)

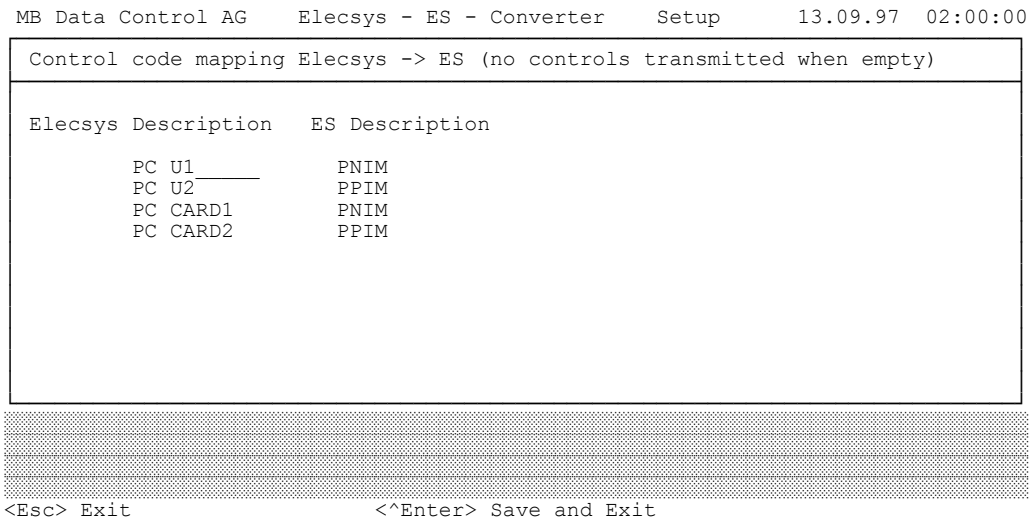
Elecsys			ES					
Test No.	**Application Code**	**unit 1 unit 2**	**Test Code**	**Test No.**	**Quali-tative**	**Inverse**	**lower limit**	**upper limit**
010 **01**1 **01**2	TSH	µIU/ml	TSH	1	N	N	0.005	100
020 **02**1 **02**2	T4	nmol/l µg/dl	T4	2	N	N	3 0.23	320 24.86
030 **03**1 **03**2	FT4	pmol/l ng/dl	FT4	3	N	N	0.3 0.023	100 7.77
040 **04**1 **04**2	T-UP	TBI	TBK	4	N	N	0.2	1.9
050 **05**1 **05**2	T3	nmol/l ng/ml	T3	5	N	N	0.3 0.195	10 6.51
060 **06**1 **06**2	FT3	pmol/l pg/ml	FT3	6	N	N	0.40 0.26	50.0 32.55
100 **10**1	E2	pg/ml pmol/ml	E2	10	N	N	10 36.7	4600 16882
110 **11**1	TESTO	ng/ml nmol/l	TESTO	11	N	N	0.02 0.069	15 52
120 **12**1	PROG	nmol/l ng/ml	PROG	12	N	N	0.15 0.48	100 318
130 **13**1	PRL	µU/ml ng/ml	PRL	13	N	N	10 0.472	10000 472
140 **14**1	LH	mIU/ml	LH	14	N	N	0.1	200
150 **15**1	FSH	mIU/ml	FSH	15	N	N	0.1	200
160 **16**1	CORT	nmol/l	CORT	16	N	N		
170 **17**1 **17**2	HCGSTAT	mIU/ml	HCGSTAT	17	N	N	0.5	10000
180 **18**1 **18**2	HCG	mIU/ml	HCG	18	N	N	0.5	10000
200 **20**1 **20**2	TNTSTAT	ng/ml	TNTSTAT	20	N	N	0.01	25

Elecsys			ES					
Test No.	**Application Code**	**unit 1 unit 2**	**Test Code**	**Test No.**	**Quali-tative**	**Inverse**	**lower limit**	**upper limit**
210 **21**1 **21**2	CKMBSTAT	ng/ml	CKMBSTAT	21	N	N	0.15	500
220 **22**1 **22**2	TN-T	ng/ml	TN-T	22	N	N	0.01	25
230 **23**1 **23**2	CK-MB	ng/ml	CK-MB	23	N	N	0.15	500
240 **24**1	MYO	ng/ml	MYO	24	N	N		
250 **25**1	MYO-STAT	ng/ml	MYO-STAT	25	N	N		
300 **30**1	CEA	ng/ml	CEA	30	N	N	0.2	1000
310 **31**1	AFP	U/ml ng/ml	AFP	31	N	N	0.5 0.604	1000 1210
320 **32**1	PSA	ng/ml	PSA	32	N	N	0.01	100
330 **33**1	CA 15-3	U/ml	CA 15-3	33	N	N		
340 **34**1	CA 125	U/ml	CA 125	34	N	N	0.600	5000
350 **35**1	CA 19-9	U/ml	CA 19-9	35	N	N		
360 **36**1	CA 72-4	U/ml	CA 72-4	36	N	N		
370 **37**1	CYFRA	ng/ml	CYFRA	37	N	N		
380 **38**1	FERR	ng/ml	FERR	38	N	N		
390 **39**1	FPSA	ng/ml	FPSA	39	N	N	0.010	50.00
400 **40**1	HBSAG		HBSAG	40	Y	N		
410 **41**1	AHBS	IU/l	AHBS	41	Y	N		
420 **42**1	HCV		HCV	42	Y	N		
430 **43**1	AHBE		AHBE	43	Y	Y		
440 **44**1	HBEAG		HBEAG	44	Y	N		

Elecsys			ES					
Test No.	**Application Code**	**unit 1 unit 2**	**Test Code**	**Test No.**	**Quali-tative**	**Inverse**	**lower limit**	**upper limit**
450 **45**1	AHBC		AHBC	45	Y	Y		
460 **46**1	HBCIGM		HBCIGM	46	Y	N		
470 **47**1	AHAV		AHAV	47	Y	N		
480 **48**1	HAVIGM		HAVIGM	48	Y	N		
490 **49**1	HIV		HIV	49	Y	N		
500 **50**1	P24AG		P24AG	50	N	N		
510 **51**1	APS4		APS4	51	N	N		
520 **52**1	TOXIGG	IU/ml	TOXIGG	52	N	N		
530 **53**1	TOXIGM		TOXIGM	53	N	N		
540 **54**1	RUBIGG	IU/ml	RUBIGG	54	N	N		
550 **55**1	RUBIGM		RUBIGM	55	N	N		
560 **56**1	A-HIVCOM		A-HIVCOM	56				
570 **57**1	A-HBENV		A-HBENV	57				
580 **58**1	HELICOB		HELICOB	58				
600 **60**1	B12	pg/ml	B12	60	N	N		
610 **61**1	FOL	ng/ml	FOL	61	N	N		
620 **62**1	DIG	ng/ml	DIG	62	N	N		
630 **63**1	IGE	IU/ml	IGE					
640 **64**1	HBA1C	%	HBA1C					
650 **65**1	INSULIN	µU/ml	INSULIN					
660 **66**1	OSTEOC	pg/ml	OSTEOC					

Elecsys			ES					
Test No.	**Application Code**	**unit 1 unit 2**	**Test Code**	**Test No.**	**Quali-tative**	**Inverse**	**lower limit**	**upper limit**
670 **67**1	CROSSL	pg/ml	CROSSL					
680 **68**1	PTH	pg/ml	PTH					
690 **69**1	CYCLO-A	ng/ml	CYCLO-A					
700 **70**1	TG	ng/ml	TG					
710 **71**1	A-TG	IU/ml	A-TG					
720 **72**1	A-TPO	IU/ml	A-TPO					
730 **73**1	A-TSHR	U/ml	A-TSHR					
740 **74**1	DHEA-S	µg/dl	DHEA-S					
750 **75**1	SHBG	µg/ml	SHBG					
760 **76**1	B-HCG	IU/l	B-HCG					
770 **77**1	NSE	µg/l	NSE					

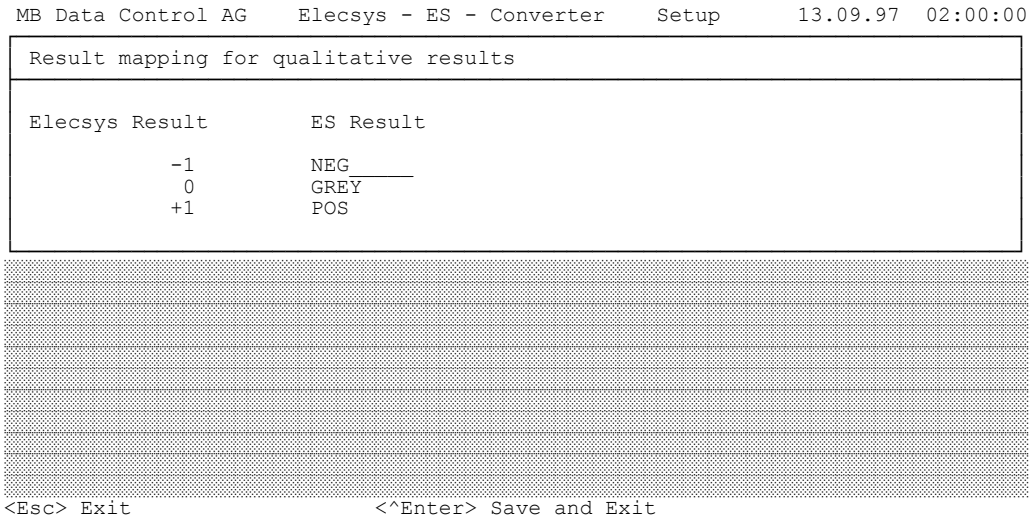
4.2.8 Configuration for Quality Controls:



In this input screen descriptions for quality control samples of the Elecsys are mapped to the descriptions for the host.

Only results for controls which are defined here are passed through to the host.

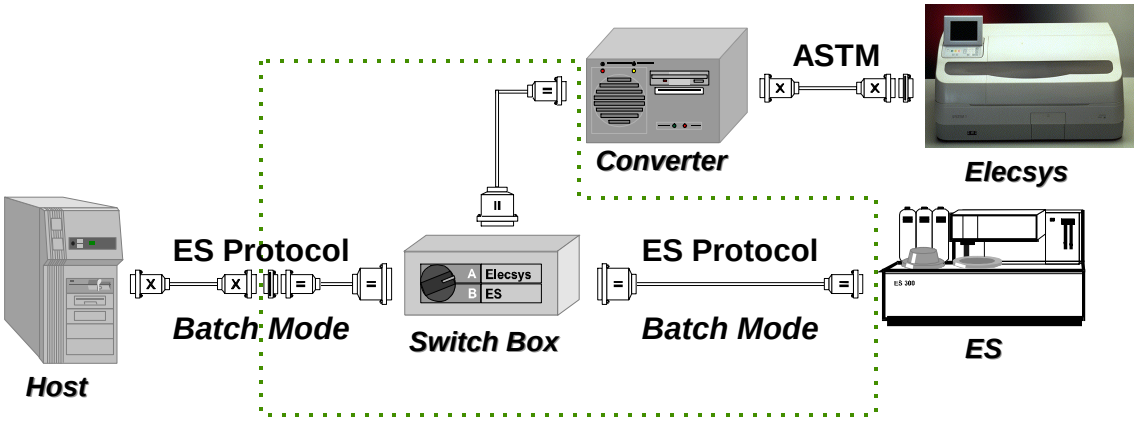
4.2.9 Configuration for Qualitative Results:



Here the text descriptions for qualitative tests (Cutoff) are defined.

5 Options:

If the converter is used in the conventional way with one Host one instrument port an additional manual **Switch Box** *(ID# 1 808 842 001) provides that an* Elecsys Analyzer and an ES Analyzer can use one only ES host connection in parallel.



Mat.# 1 808 842 001