

TABLE OF CONTENT

February 2003

SECTION 1. INTRODUCTION	2
1.1 GENERAL DESCRIPTION	2
1.2 TECHNICAL SPECIFICATIONS	4
1.3 INSTALLATION	5
1.4 STARTING THE ANALYZER AND THE MAIN MENU	6
SECTION 2. OPERATION - ROUTINE	9
2.1 ENTERING TEST REQUESTS MANUALLY	9
2.2 LOADING REQUESTS FROM LAB-COMPUTER	12
2.3 PRINTING OR VIEWING THE LOAD-LIST	13
2.4 PRINTING WORKLISTS	14
2.5 CALIBRATION	14
2.6 START ANALYZER	18
2.7 DILUTE & REPEAT TESTS	19
2.8 VERIFY RESULTS / ENTER MANUAL RESULTS	21
2.9 REPORTING RESULTS	21
2.10 PREDILUTION	23
2.11 QUALITY CONTROL	24
SECTION 3. PROGRAMMING AND FORMATTING	25
3.1 PROGRAMMING CHEMISTRIES	25
3.2 MODIFY METHODS	25
3.3 PRINT METHODS	27
3.4 CONFIGURATING PROFILES	27
3.5 FORMATTING REPORT HEADER	28
3.6 SETTING DATE AND TIME	28
SECTION 4. MAINTENANCE	28
4.1 ADJUST PERISTALTIC PUMP	29
4.2 CHECK ASPIRATION SYSTEM	29
4.3 PRIMING THE DILUTER	30
4.4 RINSING THE FLOW-CELL	30
4.5 CHECKING THE FILTERS	30
4.6 POSITION FILTER AND READ O. D.	31
4.7 SELECT PRINTER	31
4.8 MAINTENANCE	31
4.9 TROUBLE SHOOTING	32
4.10 MECHANICAL TESTS	33

SECTION 5. REMOVAL AND REPLACEMENTS	34
5.1 REMOVAL OF THE CABINET	34
5.2 REPLACEMENT OF THE SYRINGE	35
5.3 REPLACEMENT OF THE LAMP	36
5.4 SETTING AMPLIFIER'S VOLTAGES	36
5.5 CLEANING THE AIR FILTER	37
APPENDIX 6-A	38
APPENDIX 6-A	39
APPENDIX 6-B	40

SECTION 1. INTRODUCTION

1.1 GENERAL DESCRIPTION

The KUADRO is a patient selective batch analyzer: the instrument detects patient by patient the tests required and groups them, then it performs the routine test by test, in order to achieve the fastest speed. The KUADRO has been designed for the small labs in order to achieve the best compromise between the price and the flexibility of operations. The system is a compact instrument with a built in single chip computer with a control custom board mounted in. Computer controls all functions of KUADRO and permits data handling functions from requesting to reporting and quality control.

Another important feature of the KUADRO is the capability of selecting the number of reagents and samples according to the patients and requests entered. It's possible to operate with a minimum of 2 Reagents and 72 samples up to the opposite situation of 8 samples and 18 Reagents on line. This solution has been designed in order to have the possibility of saving time of operations according to the different situations existing in a small lab.

NOTE: Although it is possible to have 18 reagents on the tray, it's however possible to run only 16 tests max for each sample, the 18 positions available have been conceived to allow the use of bi – reagent tests as well as serum blank tests.

The KUADRO is composed of the following Main Parts :

A Reagents/Samples compartment : This rotating tray can be used for reagents, samples, controls and standards according to the function in operation, and it's surrounded by a reaction tray. It's cooled by a blowing fan, in order to avoid a large amount of evaporation on the samples and reagents because of the surrounding reaction tray, which is heated for incubation. The incubation tray contains 10 segments of 18 wells each one for a total of 196 reactions on line, as one segment is used for washing the flow cell system.

A Sampling/Aspirating robotic arm : This single arm provides the sampling operations, working in a Sip and Dip mode, using a single 1000 µl syringe pump with an electrovalve system and a small reagent coil, which contains the reagent and the sample without any contamination of the syringe. The sampling probe is provided with a washing tip system to reduce dramatically the amount of carry over. The same robotic arm provides to the aspiration of the reaction mixture into a flow cell system for the reading of the reaction. The whole hydraulic system and the peristaltic pump are located on the right side of the unit in a position, which is studied to avoid any damage to the electronic and to the mechanical parts in case leakage may occur.

A Photometric system : This is basically the same photometric system used on the others instruments produced by BPC Biosed, it consists of a lamp, mounted into an optical block, in the center of a rotating ring, which contains six interference filters from 340nm to 620nm, and the electronic amplifier of the light detector. The only difference is the AD converter PCB that has been joined to the amplifier PCB, this in order to reduce any interference due to long connections, wires etc. The flow cell is a 50 µl cell heated with Peltier effect system.

The equipment works in a Sip and Dip way, the syringe pump is always filled up with distilled water, then during sampling it aspirate reagent, sample and dispenses the mixture into reaction well. Between water and reagent, reagent and sample and after the sample, there are gaps of air to avoid any contamination. Samples and reagents are mixed by sprinkling them into the micro-reaction vessels. From here the reaction mixture is aspirated into the photometer and subsequently measured, after each aspiration of the reaction mixture, water is aspirated into the flow cell for washing.

Up to 200 patients can be either programmed manually or downloaded from a laboratory computer.

1.2 TECHNICAL SPECIFICATIONS

Type of access	: Sequential
Way of working	: Batch selective
Types of Test	: End-Point Initial Rate Kinetic Bichromatic Differential (sample blank) Turbidimetric
Throughput	: 120-140 Test/hour On Screen indication of Time Required for Routine
N. of reagents	: Up to 2 different reagents for each test
Patient file	: 40 tests / patient Up to 72 reports
Sample holders	: Up to 72 samples
Reagents Tray	: Up to 18 reagent containers 45ml each.
Reaction Tray	: 198 wells - 12 sectors of 18 wells
Photometer	: 6 interference filters + 1 option in the range from 340 to 620 nm resolution 0.0001 Abs. flow-through cell of 50 µl peltier elements temperature control: 37°C ± 0.1°
Reagent volume	: variable from 50-900 µl
Sample volume	: variable from 2-100 µl
Processing	: Internal single PCB computer
Video display	: Backlit LCD display
Keyboard	: alphanumeric
Printer	: standard thermo printer, 40 characters built in
Serial port	: RS 232 C
Parallel port	: Centronics Printer compatible
Dimensions	: 445 x 570 x 510 mm (W x D x H)
Weight	: 30 Kg.
Power requirements	: 220 V - 50 Hz - optional: 110 V 60Hz / 240 V 50 Hz
Power consumption	: 250 Watt

1.3 INSTALLATION

After unpacking, check:

- The presence of water container
- The presence of a power cable
- If the power on site corresponds with the power specified on your instrument (220V or 110V). In case it's necessary the operator can change the voltage setting by using the small switch located near the main switch.

To power the instrument, use a 'clean' line, with no variations in voltage, and provided with an effective ground.

Avoid placing the instrument into direct sunlight.

To install the KUADRO, once unpacked, put it on a work bench, not under direct sunlight and far enough from air conditioning hoses. Connect the tubing for the waste and for the external water reservoir and connect the power cord to an AC outlet paying attention to the voltage corresponding to the indications on the instrument. Lift the Built in printer's lid and install the thermal paper roll following these instructions :

1. Cut the paper edge to obtain a triangle shape
2. Insert the edge of this triangle into the small space on the lower back side of the printer
3. Be careful to insert the edge on the side opposite at the side where the printer's head is located in rest position, this to avoid any damage to the printer's head
4. Once the edge of the paper comes out from the opposite side of the printer, pull it gently until the paper passes through the printer
5. Make the edge of paper passing through the cutting slot on the printer's lid and close it

Once completed these operations the instrument is ready to operate.

NOTE: Do not forget to fill up the water reservoir with a solution of distilled water and BPC Cleaning agent mixed with a ratio 1:10.

1.4 STARTING THE ANALYZER and the MAIN MENU

To switch on KUADRO, simply switch on the main switch, located on the back side of the instrument, on the right lower part of the back panel, near to the power cord connection.

The program is loaded automatically, and then the following message will be prompted on the screen:

REMOVE SEGMENT 1

First provide to empty the reaction sector 1 if it's full of water or replace it if it appears dirty or contaminated, now you can press the ENTER key on the keyboard located on the upper front of the instrument, on the LCD screen will appear the following message :

[INSTRUMENT IN OPERATIONS]

and after a while the system will request to confirm actual Date and Time :

DATE (ddmmyyyy) : [05122001]
TIME (hhmm) : [1120]
F1= CONTINUE

Once entered the correct date and time, press the F1 key and the following PATIENTS MENU will appear :

PATIENTS MENU	
1 - ENTER PATIENTS	
2 - REPORTS PRINTOUT	
3 - RESULTS PRINTOUT (BY TEST)	
4 - VIEW PATIENTS LIST	
5 - PRINT PATIENTS LIST	
6 - WORKLISTS PRINTOUT	
7 - ENTER MANUAL RESULTS	
8 - RECEIVE PATIENTS (RS232)	
9 - TRANSMIT RESULTS (RS232)	
F1- ANALYZER MENU	DATE: 01/01/2000

BPC BioSED srl



The PATIENTS MENU offers access to all patient data handling functions. By pressing the F1 key, it's possible to scroll through the three different Menues of the instrument: the ANALYZER MENU and the UTILITIES MENU.

In the ANALYZER MENU there are all the functions related to the instrument's operations, including the maintenance and the Test Functions. The UTILITIES MENU offers the access to all the User Programmable functions, as the Profiles definition and the Laboratory Header composition.

By pressing the F1 key the operator can scroll through the several menus and the LCD display will display each time the related functions for each MENU.

By this if the operator presses the F1 key while in the PATIENTS MENU, the LCD will display the following MENU, whose name is prompted beside the F1 indication in the lower left side of the screen, in this case the ANALYZER MENU:

ANALYZER MENU	
1 - START ANALYZER	
2 - CALIBRATION	
3 - METHODS PROGRAMMING	
4 - MAINTENANCE	
5 - TEST ANALYZER	
6 - QUALITY CONTROL	
7 - PREDILUTIONS	
8 - REPEAT TESTS	
F1- UTILITY MENU	DATE: 01/01/2000

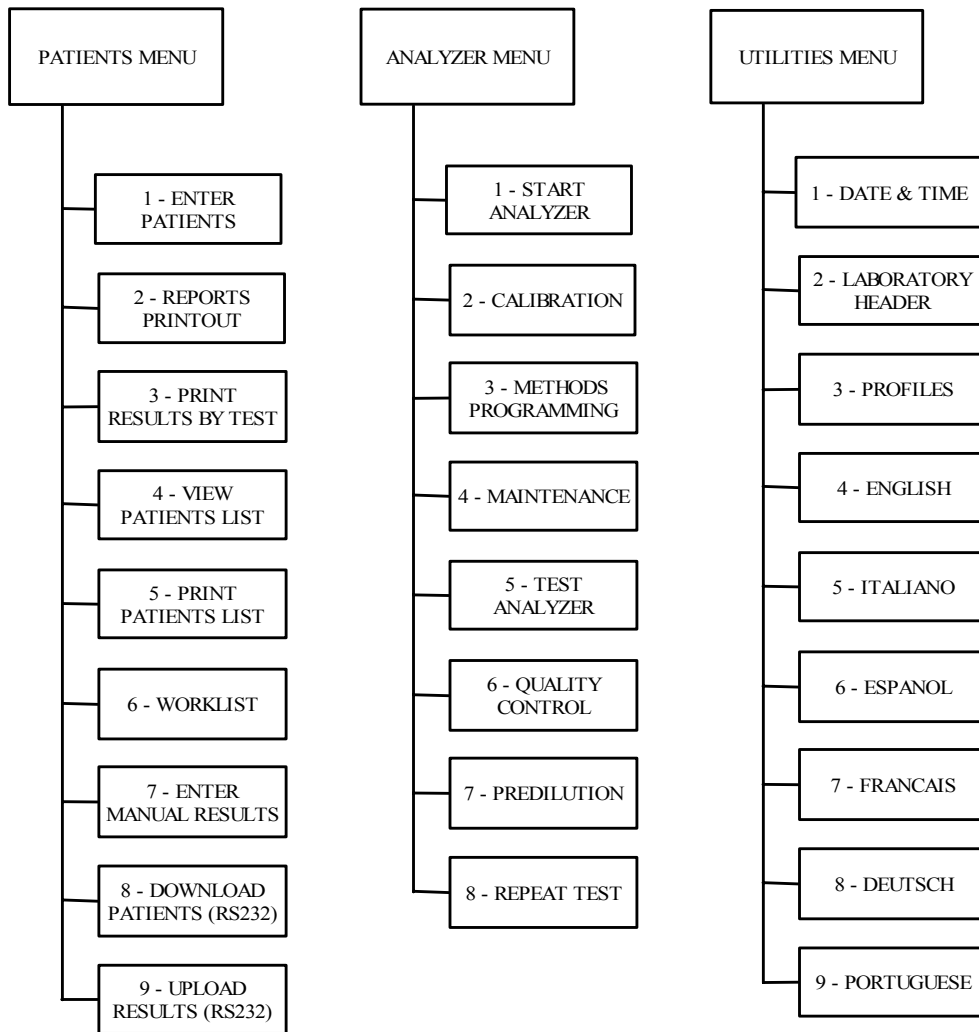
Again by pressing the F1 key the operator can scroll through the several menus and the LCD display will display each time the related functions for each MENU.

UTILITY MENU	
1 - DATE AND TIME	
2 - SET LABORATORY HEADER	
3 - PROFILES	
4 - ENGLISH	
5 - ITALIAN	
6 - SPANISH	
7 - FRENCH	
8 - GERMAN	
9 - PORTUGUESE	
F1- PATIENTS MENU	DATE: 01/01/2000

To select the single functions of each MENU, simply press the related number key and the LCD will immediately display the related screen.

NOTE : In case another language is selected for the operation, it's necessary to switch the instrument off, then on again, thi in order to enable the correct setting of the language, otherwise malfunctioning may occur.

KUADRO'S MENUES AND SUB-MENUES



Selected tests will appear on the screen with an asterisk, as follows :

ENTERING PATIENTS				
Pat.: [1]				
Name :[FRANK JACKSON]				
Pat. ID. :[001] TEST: []				
CHO *	BUN *	GLU *	TRI	UA
GOT *	GPT *	GGT	CRE	BIT
BID	TP	ALK	ACP	LDH
CHE	AMY	FE	CA	PH
MG	HDL	CK		
F1=Next	F2=UP		F3=STAT	
F5=Copy till N.			F6=Previous	

Once a patient is ready, hit **F1** to go to the next number. Hitting **F6** you go to previous patient entered. When the last patient has been entered, hit **ESC** to return to the main menu.

F5 KEY

With this key it is possible to copy the last patient entered into the next numbers, until a user selectable number. It is used for long series of tests (research).

F3 KEY

Pressing this key it's possible to select urgent patients to be executed with priority. A normal patient it's executed following the routine, an urgent entering is executed with priority all over other patients. In this case will be necessary to stop the current routine and start a new one after having entered the STAT patients

F2 KEY

By pressing this key the operator can go to the previous fields on the screen, i.e. if the operator is in the block test and wants to change the name of the patient because mistakes etc. then by pressing the key F2 he can move back to the previous fields and perform the correction.

2.2 LOADING REQUESTS FROM LAB-COMPUTER

As an alternative to manual entering, the patients and test requests can be downloaded from a computer.

With the option RECEIVE PATIENTS from the PATIENTS MENU, it's possible to download the patients with related requests from an external lab computer, whenever a central lab managing software is installed.

By selecting this option the system will display on LCD screen:

RECEIVING PATIENTS (RS 232)	
DELETE EXISTING PATIENTS ? EXISTING PATIENTS : 8	
F1=NO	F5=YES

By pressing the F1 key, all patients already entered into the system will be kept and not deleted, then all the patients which will be received from an external computer via RS 232, will be appended to the existing patients.

By pressing the F5 key, all existing patients are deleted and the new patients received via RS 232 will be downloaded starting at N. 1.

Whenever one of the two keys is pressed, on the screen will appear :

RECEIVING PATIENTS (RS 232)
EXISTING PATIENTS : 8 WAITING FOR CONNECTION

At this stage the system is waiting for the acknowledge signal from the host computer, the KUADRO sends periodically a signal to the host computer in order to enquiry the connection.

When nothing appears, it means that the computer is not ready or there are problems in the hardware connection, in this case it's suggested to check the serial port if the selected port corresponds to the existing one.

When the connection is established, the LCD screen displays :

RECEIVING PATIENTS (RS 232)
EXISTING PATIENTS : 8 COMPUTER ON LINE

At this stage the download of the patients starts.

You can escape from this program at any time by pressing the key **ESC**.

2.3 PRINTING OR VIEWING THE LOAD-LIST

Once the patients have been entered, a load list for the sample trays is to be printed.

The options **VIEW PATIENTS LIST** and **PRINT PATIENT LIST** from the **PATIENTS MENU** allows the operator to display or print a list of all patients loaded into the instrument with their position no. and all the information related, including the **TESTS** requested for each patient, even the results if these patients have already been worked out.

Once selected one of these options, by typing the number of the function related, the LCD screen will display the related mask or print the list, i.e. if the operator presses the key 4, to select the function **VIEW PATIENTS LIST**, on the screen will appear :

VIEW PATIENTS LIST PATIENTS LIST	
Pat. : [1] Name : [GEORGE WASHINGTON] Pat. ID.: [01001]	
GOT :	BUN :
F1: Next	F6: Previous

By pressing the F1 or F6 keys it's possible to page up or down through the existing patients.

If in the PATIENTS MENU the operator selects the option 5, by pressing the 5 key, the system will print a list of all existing patients. According to this list the sample tray can be loaded with the appropriate patients' sera.

2.4 PRINTING WORKLISTS

The option WORKLISTS from the PATIENTS MENU offers the possibility to list the work to be done on a per test basis.

It is NOT necessary to print these lists to run the routine but it may serve other purposes, e.g. a REST-LIST, to see which tests are not finished yet.

Pressing the key 6, this option is selected and on the screen will appear :

WORKLISTS			
TEST []			
CHO [2] GPT [2]	BUN [1]	GLU [3]	GOT [2]
F1= PRINT F3= PRINT ALL TESTS			

In the array in the lower part of the screen will appear all the tests which have been entered with the patients, beside them in parenthesis there are the number of patients having those tests, i.e. GLU [2] means that there are two patients with the test glucose selected.

In the TEST field the operator types the test code for the test whose work list he requires, then the selected tests will appear with an asterisk beside the code, i.e. GLU [2] * means that the test glucose has been selected to print the related work list.

Once the selection of desired tests has been performed, by pressing the F1 key, the printout will be executed.

If the worlist for all tests is required, it's enough to press the F3 key.

Press the ESC key to escape from this menu.

2.5 CALIBRATION

KUADRO is a batch selective analyzer, but in order to save time in execution of the tests it's possible to run a calibration routine prior to run the patients routine.

Another important feature of KUADRO is the possibility of performing the calibration with more than one point of calibration (more than one calibrator). This in order to achieve the best accuracy in measurement of samples and in results calculation.

When in method's programming function, the operator is prompted to enter the number of calibrators to be used to calibrate the test, note that this number cannot be lower than 2.

If only the calibrator 1 is selected, the system will refuse to accept it.

The calibrator 1 should always be 0 as it should be just water, calibrator 2 can be the calibrator selected, or in case a multiparametric calibrator is used, the value of the multicalibrator.

Of course in case a multiparametric calibrator is used, it's necessary to indicate it in the apposite field, in order to enable the sharing of it among all the methods where it is used.

The calibration in this case is not calculating just a numeric factor which is to be used as a multiplier for the absorbencies measured during the routine operations, but is a linear or non linear function which is applied for every measured absorbency value read and by this gives out a result which is more accurate and responding to the eventual deviations which can affect the chemical reaction.

The calibration operation can be done before or after having entered the patients and their tests.

To carry out all calibrations required select the option CALIBRATION from the ANALYZER MENU, by pressing the key 2, the following screen is displayed:

[CALIBRATION]			
TEST : []			
+ CHO (2) GPT (2)	+ BUN (1)	GLU (3)	GOT (2)
F1=Continue (+ Test Calibrated)	F3=View F2= Delete Calib.	F4=Print Calib.	

In the lower block the tests that can be calibrated are being displayed, together with the number of samples for each.

To select tests to be calibrated it's possible to proceed in different ways:

BPC BioSED srl

1. Typing letter or capital letter beside test to be calibrated, remember that a letter and a capital letter are not indicating the same test.
2. selecting profile number to calibrate all test grouped in that number
3. Moving with arrow keys and typing Enter key to select tests

When tests to be calibrated are selected, press F1 to continue and execute calibration, note that beside test codes, in square parenthesis are indicated the number of samples per test.

After having pressed F1 Key, will be prompted the following screen:

```

[CALIBRATE]
TEST  POS  VOL      TEST  POS  VOL
COD  R1 R2  R1 R2   COD  R1 R2  R1 R2
.....
GLU   1   10      GOT  2   12
CHO   4   11      BUN  3   15
  
```

F1=START F2=ONLY BLANK F3=WITH CAL.
 F4=CALIBRATORS F5=NO CONTROLS

By pressing the F1 key we start the calibration routine, but there are other functions we can access from this screen .

By pressing the F2 key, it's possible to run a calibration routine using the existing factor we have obtained by a previous calibration, in this case the reading of reagent blank only will be performed.

By pressing the F3 key it's possible to return to the calibration using calibrators (standards) whenever we have selected the calibration using factors.

By pressing the F4 key we can display on the screen the values of the calibrator or calibrators we are using for the calibration, i.e.:

```

[CALIBRATION]
GLU  CALIBRATORS  C1  C2
POS.  S1  S2
CONC.  0  105

F1=CONTINUE
  
```

By pressing the F1 key, we will scroll through the different tests calibrators until we finish, then we return automatically to the initial calibration menu.

BPC BioSED srl



By pressing the F5 key we can select whether or not we want to run the controls. This function works in a toggle mode: if the screen shows CONTROL NO, it means that the system will perform the reading of control sera, as programmed in the method, during calibration. If the screen shows CONTROL YES, it means that the control sera will not be read during the calibration. This means that what appears on the screen is the function we want to be performed.

At this stage, if we press the F1 key, we will have the following screen displayed :

```
[CALIBRATION]
CHECK !
If water container is full
If waste container is empty
Reagents are in position
Samples or Cal. And Controls on tray
Sampling and Aspiration probes
Segments are introduced

OPERATION TIME hh:mm      00:03
F1=START
```

When calibration is completed, the instrument goes back to main menu.

NOTE Normally the Calibrations must be executed before starting the routine. The positions for standards (calibrators) are always indicated on the tray with Sand a number (S1-S6), the controls positions are indicated on the tray with C1 and C2.*

There is the possibility of running a test with a linear multi standard calibration, in this case more than one standard may be used, it depends however on the method programming.

IMPORTANT*

It's normal that KUADRO starts filling up with water all wells of the first reaction segments, as it uses them for washing the flow cell.

On the screen will appear the usual final warning before the start of operations :

[START ANALYZER]
 CHECK !
 If water container is full
 If waste container is empty
 Reagents are in position
 Samples or Cal. And Controls on tray
 Sampling and Aspiration probes
 Segments are introduced

OPERATION TIME hh:mm 00:35
 F1=START

Fill the reagent containers with the amount of reagent needed and place them in the proper positions in the reagent tray.

Check if there is water in the water container.

When you are sure that everything is OK, you can start the analyzer. Press the F1 key to start the routine.

On the screen the function being executed on each moment is being displayed immediately.

2.7 DILUTE & REPEAT TESTS

At the end of the routine the KUADRO produces an acoustical signal to draw the attention of the operator in order to replace the used reaction segments.

Once replaced the used segments, it's possible to repeat tests whose results are not affordable, select REPEAT TESTS in the ANALYZER menu. When this option is selected the following screen appears :

[REPEAT TEST]			
TEST : []			
CHO (2) GPT (2)	BUN (1)	GLU (3)	GOT (2)

Type the code for the test you want to repeat the samples then hit Enter :

TEST : [GLU]			[REPEAT TEST]	PAT. N.: []
1	2	3		
F1=CONTINUE		(And delete results)		
F2=ALL		(Pat.N. + D to repeat with dilution)		

At this stage type the number of the sample you want to repeat and pres Enter to confirm it.

The selected sample number will appear highlighted on the screen.

Whenever we want to repeat a sample with dilution we have to type the number of the sample followed by D and then press Enter, on the screen will appear i.e. 2D to mean that sample number 2 is to be repeated with dilution.

Then if we press the F1 key, the results of the selected samples will be deleted and the screen will show the previous mask to select another test.

Once all selections have been made, to start the repetitions we have to activate agane the function START ANALYZER.

The F2 key is used whenever we want to select all the samples for a specific test, in this case all the numbers on the creen, which represent the existing samples for that test, will be highlighted to mean that they have been selected.

NOTE : Dilution factors as programmed for the chemistry in question will be used in case the repetition of a sample with dilution is selected. Dilution in this case means e.g. if normally 10 μ l of sample are used, and the dilution factor equals 4, the sample will be repeated with 2.5 μ l.

NOTE : The system allows 198 reactions on line before it's necessary to replace the reaction segments, however whenever the reaction segments are over and it's necessary to replace them all, the system will give an acoustic and visual signal on the screen to prompt the operator to perform this operation.

2.8 VERIFY RESULTS / ENTER MANUAL RESULTS

The first level at which the results must be verified is on the test protocol that is being printed during the analysis. This check may lead to the conclusion that complete tests has to be repeated (3.8) when e.g. the standard or the reagent wasn't good. Also samples may be detected that have to be diluted and then repeated.

The option ENTER MANUAL RESULTS of the PATIENTS-menu serves to modify the results obtained for clinical plausibility or to enter the results of off-line chemistries, i.e. chemistries that are not determined on the KUADRO like e.g. Na and K.

This way a more complete test report can be achieved.

Once selected this option the following screen will appear:

[ENTER MANUAL RESULTS]		
PAT.: 1		
NAME : [GEORGE OPPENDORF]		
PAT.ID : [0100]		
CHO : [200]	BUN : [32]	GLU : [150]
F1=NEXT	F6=PREVIOUS	

Results can be entered on a per patient basis.

Enter the desired patient number and the patient appears completely with the results that are already determined. Results can be added or deleted.

When ready go back with ESC.

2.9 REPORTING RESULTS

Results can be printed in two ways:

- as patient reports
- on a per test basis

◆ PRINTING PATIENT REPORTS

With this option of the PATIENTS-menu the collated reports can be printed. Note that as in this instrument is not possible to have any long time storage, it's possible only to print the reports for the daily patients.

Whenever this option is selected, on the screen will appear the following :

[REPORT PRINTOUT]
FIRST PATIENT: [] LAST PATIENT : [] NAME : []
F5=SEARCH BY NAME F6=SEARCH BY ID F1=PRINT F3=PRINT ALL

The reports to be printed can be selected in several ways:

- From Number:
- Till Number:
- Selectively by number
- All
- after searching by name
- after searching by Patient ID.

Once selected the patients whose report is wanted, press the F1 key to print the reports.

◆ PRINTING RESULTS PER TEST

With this option of the PATIENTS-menu the results can be listed for the individual tests. Tests can be selected one by one, or all tests can be listed automatically.

By selecting this option, the following screen is displayed :

[PRINT RESULTS BY TEST]			
TEST : []			
CHO (2) GPT (2)	BUN (1)	GLU (3)	GOT (2)
F1=PRINT F3=PRINT ALL			

Select with the cursor keys and Enter or by typing the code of the wanted test and then Enter, once the tests are selected, these appear with an * beside the code. At this stage press F1 to print the results for the selected tests.

With the F3 option is possible to print the results for all the tests.

2.10 PREDILUTION

The option PREDILUTION of the ANALYZER-menu offers the possibility to use the KUADRO to pre dilute automatically samples.

Selecting pre dilution function on the Analyzer Menu, you enter in the following screen :

[PREDILUTION]

N. OF SAMPLES TO DILUTE (1-6) : []
SAMPLE VOLUME μ l (1-200) : []
DILUENT VOLUME μ l : []
DILUENT POSITION : [1]

DILUENT + SAMPLE MAX VOLUME 700 μ l
F1=CONTINUE

At this stage we enter the desired volumes of sample and diluent and we press F1:

[PREDILUTION]

ATTENTION ! PLACE :

SAMPLES IN POSITIONS : [S1]
EMPTY CUPS IN POSITION : [9]

F1=CONTINUE

If there are more than one sample to be prediluted, the following screen will appear in order to change the single samples volume ratios :

[PREDILUTION]

SAMPLE VOLUME μ l (1-200) : [50]
DILUENT VOLUME μ l : [200]
SAMPLE VOLUME μ l (1-200) : [100]
DILUENT VOLUME μ l : [500]

F1=CONTINUE

Press F1 to start the pre dilution function.

2.11 QUALITY CONTROL

With this option of the ANALYZER-menu it's possible to perform a calculation of the Mean, SD and CV for a row of values which the operator can type in.

Once selected this option, on the LCD screen will be displayed :

```
[QUALITY CONTROL]

VALUE (NEGATIVE TO ELIMINATE) : [  ]
F1=CONTINUE
```

Now type in the values whose Mean, SD and CV you want to calculate :

```
[QUALITY CONTROL]

12    13    15    12    13

VALUE (NEGATIVE TO ELIMINATE) : [  ]
F1=CONTINUE
```

By pressing the F1 key on the LCD screen will appear the calculated data (Mean, SD and CV) of the row of values entered :

```
[QUALITY CONTROL]

12    13    15    12    13

TOT. DATA : 5
S.D. : 1.115
MEAN : 13.02
CV : 3.21 %

F1=CONTINUE
F3=PRINT
```

SECTION 3. PROGRAMMING and FORMATTING

3.1 PROGRAMMING CHEMISTRIES

Up to 40 chemistries can be programmed on the instrument disk on chip.

To program or modify a method, select the option METHOD PARAMETERS from the ANALYZER menu. The following screen will appear :

[METHODS PROGRAMMING]				
TEST CODE : []				
GLU GOT	BUN GPT	CHO CRE	UA ALK	TRI TP
F1=VIEW / MODIFY F2=PRINT SELECTIVELY F3=PRINT ALL				

3.2 MODIFY METHODS

To modify an existing test press the F1 key, on the screen will be displayed the following mask with all the parameters which make a chemistry :

[CLINICAL CHEMISTRY]

COD. : BUN	UNITS : MG/DL
FULL NAME : UREA	
METHOD (EP=1 KIN=2 IR=3 BIC=4 DIFF=5)	: [3]
VALUE MIN : 10	MAX : 50
BLANK MIN : .9	MAX : 1.8
N. REAGENTS : 1	LINEARITY : 400
REAGENT 1 VOL. : 500	REAG. 2 VOL. :
REAGENT 1 POS. : 7	REAG. 2 POS. :
SAMPLE VOL. µl : 5	WATER VOL. µl :
INCUBATION TIME : 60	REAG. 2 ADD. :
PREINCUB. TIME : 0	READING TIME : 25
DECIMALS : 0	MIXING (0 / 1) : 1
SAMP. WASHINGS : 2	FLOWCELL WASH : 3

F1=OTHER PARAMETERS

F2=CARRIAGE RETURN

By pressing the F1 key, it's possible to have access and to modify the other parameters of the chemistry.

```

[CLINICAL CHEMISTRY]

COD. : BUN                                UNITS : MG/DL

REACTION INCR. (0)  DECR. (1)           : 1
FILTER 1           : 340
DILUTION   1 : 2                            SUBSTRATE OD EXP.   : 8
MODEL ( 1-6 ) : 6                          NUM. CALIB.        : 3

[CALIBRATORS]

CAL 1 : 0                                CAL 2 : 50
CAL 3 : 145                              CAL 4 :
CAL 5 :                                  CAL 6 :

C1 (Y=1 N=0) : 1                          C2 (Y=1 N=0) : 1

VALUE C1   MIN : 0   MAX : 100
VALUE C2   MIN : 0   MAX : 200

F1=CONTINUE      F3=CARRIAGE RETURN      F4=STORE
    
```

Whenever we want to create a new test, enter a test code which is not displayed on the block and the system will ask for confirmation of creation of a new test, then press F1.

Here is an explanation of the parameters available to create a test :

- TYPE of Reaction (1-5) :
- 1: Endpoint
 - 2: Kinetic - enzymatic tests
 - 3: Initial Rate
 - 4: Dichromatic endpoint
 - 5: Serum Blank
- Full Name : (15 char.)
- Units : (6 char.)
- Value MIN : Lower normal value
- Value MAX : Upper normal value
- Blank MIN : Limits for reagent blank O.D.
- Blank MAX : considered normal and reliable
- N. Reagents (1-2) : Up to 2 reagents per test.
- Linearity : Limit of Linearity for the test

Volume Reagent-I (µl)	:	
Position Reag.-I (1-15)	:	
Volume Reagent-II (µl)	:	
Position Reag.-II (1-15)	:	
Sample Volume (µl)	:	
Factor	:	To be used for kinetic reactions
Preincubation time (sec.)	:	Time in seconds for stabilization in flow-cell before reading
Incubation time (sec.)	:	Time between sampling and aspiration into the flow cell
Time elapse for 2nd Reag.	:	Time elapsing before the addition of reagent 2
Number of Decimals (0-4)	:	
Reaction Incr.(0)/Decr.(1)	:	0 for kinetics increasing 1 for decreasing
Substrate expletion (O.D.)	:	Warning level for substrate expletion.
Dilution factor	:	factor for automatic dilution when a test is being repeated
1st filter (nm)	:	
2nd filter (nm)	:	- (in case of dichromatic)
No.of washes sampler	:	- (washings of sampling system at the end of the test)
No.of washes aspirator	:	- (washings of flow cell at the end of the test)

3.3 PRINT METHODS

To have a printout of a preprogrammed test, there are two options :

F2=PRINT SELECTIVELY

Using this function it's possible to select which test whose parameters we want to print, simply press F2 then type the code of each test whose printout we want followed by Enter, then press ESC to start the printing.

F3=PRINT ALL

Using this function we can print the parameters of all the test existing in memory.

3.4 CONFIGURATING PROFILES

Profiles are groups of tests that can be composed by the user and serve to speed up the manual entering of test-requests.

With the option PROFILES of the UTILITIES-menu up to 9 profiles can be selected (1-9). Each profile can have as many tests as there are in the test file.

3.5 **FORMATTING REPORT HEADER**

The heading of a patient report consists out of 4 lines, that can be adapted to the laboratory in question. Select the option REPORT HEADER of the UTILITIES menu. The program offers the option to just VIEW the header (without danger to change it accidentally) or to MODIFY.

In case of MODIFY:

Select the line to be modified with the UP and DOWN cursor keys.

Use the other cursor keys and the Back-Space to modify the line.

3.6 **SETTING DATE AND TIME**

With the options 1 of the UTILITIES menu the date or the time can be adjusted. As the computer has got a battery operated clock on board, the date and time should always be right after switching on and off.

SECTION 4. MAINTENANCE

Before, during and after the routine the KUADRO rinses according to a programmed schedule probes, syringe, tubing and flow-cells and also checks the interference filters.

The operator has however the possibility to:

- start a complete rinsing and checking cycle as a daily maintenance
- execute one specific step of this cycle in case a part of the system is suspected of malfunctioning

The option MAINTENANCE of the ANALYZER MENU offers the following sub options:

ADJUST PERISTALTIC PUMP
CHECK ASPIRATION SYSTEM
PRIME DILUTER
RINSE FLOW CELL
CHECK FILTER (Autozero)
POSITION FILTER and READ O.D.
SELECT PRINTER
DAILY MAINTENANCE

4.1 ADJUST PERISTALTIC PUMP

The adjustment of the peristaltic pump determines the volume of reaction mixture being aspirated through and into the flow-cells before measurement takes place.

The volume must be enough to rinse the flow-cell sufficiently but not higher than the total reaction mixture (sample vol. + reagent vol.)

If the volume is too high, air will be sucked into the cell. If the volume is too low, more liquid than normal stays behind in the reaction wells.

As the tubing of the peristaltic pump gets older, it loses some of its elasticity and the volume may get lower too.

When this option is selected, the following screen is displayed :

```
[ADJUST PERISTALTIC PUMP]

FLOW CELL PERISTALTIC PUMP
STEP (100-999)

[140]
```

Once entered the number of steps and pressed the Enter key, escape from this menu with the ESC key.

4.2 CHECK ASPIRATION SYSTEM

With this option, after the number of steps of the peristaltic pump has been entered, it's possible to verify the aspiration level if it matches the specifications described in the 4.1.

When this option is selected, on the screen will appear :

```
[CHECK ASPIRATION SYSTEM]

CHECK!
THE PRESENCE OF THE WASHING SEGMENT N. 1
AND THE CORRECT PROBES POSITIONING

F1=START
```

Press F1 to start the operation.

4.3 PRIMING THE DILUTER

With this option, the sampling system - syringe and tubing - can be rinsed (primed) up to 9 times.

Enter the number (1-9) in the window and hit the ENTER-key to execute the rinsing.

The actions taken are being displayed on the monitor.

the system will be rinsed. If no water is present the system will be emptied.

4.4 RINSING THE FLOW-CELL

With this option the flow-cell with tubing are being rinsed.

There are two options which can be selected when this function is activated :

[WASHING FLOW CELL]
F1=AUTOMATIC F3=WITH IPOCLEANING AND EXTRACLEANING

With the option F1 the system washes the flow cell automatically, with the option F3 the system prompts on the screen to place the appropriate solutions in the correct position for the periodic maintenance.

4.5 CHECKING THE FILTERS

At the start of each routine the filters going to be used for reading are being checked and 'auto-zeroed'. This means that with water in the flow cell the 0-Abs. (= 100% Transmission) is being adjusted. The 0% Transmission (dark) is set between the filters. The electronic values (voltage) of these settings are stored and applied during this single routine.

If the voltages found exceed factory-set limits, a warning is displayed at the monitor for the filter in question.

If all filters show a warning, there is a general problem (e.g. no water in the flow-cell).

If one channel shows warnings for all filters there can be an electronic or mechanical problem in that channel or the one flow- cell is very dirty.

If one channel shows a warning for one filter, the flow-cell can be dirty (depending on wavelength) or a filter can be bad or dusty.

After having rectified the problem this option offers the possibility to check flow cell and filters off-line (without starting a routine).

The operator can select the channel he wants to check.

4.6 POSITION FILTER and READ O. D.

This option permits to read the O. D. of a liquid at the wavelength of one of the filters present in the KUADRO.

The program prompts you to:

- select a wavelength
- auto-zero the flow cell (with water being present)
- disconnect the aspirating probe from the aspirator arm and put this probe manually into the mixture to be measured.
- aspirate the liquid
- read the O. D. (When Auto zero has been executed)

4.7 SELECT PRINTER

Standard the KUADRO has got a printer 'on-board'. It is however possible to replace the on-board printer by a faster external printer. Eventually it is possible to work without a printer, e.g. in case of an on-line connection to a lab-computer. This however is not recommended.

When this option is selected we have the following choices :

[SELECT PRINTER]

F1=BUILT IN
F2=NO PRINTER
F3=EXTERNAL
F4=EXTERNAL WITH FORM FEED IN REPORT PRINTOUT

If we select the F1 option we can work with the built in thermal printer, if we select the F2 option no printer is selected and will not be possible to get any printout.

Whenever we select the F3 or F4 options, these are referred to the use of an external printer connected to the parallel port, with the option F4 there is the possibility of having the form feed in the report printout.

4.8 MAINTENANCE

- Daily Maintenance

Although the system is rinsed automatically during the routine, the operator should apply an extra cleaning at the end of the working day.

The option DAILY MAINTENANCE of the MAINTENANCE menu executes the rinsing of the sampler, the aspirator and flow-cell and performs a filter check.

Water must be present in the water container.

Regarding the Weekly Maintenance and the Quarterly Maintenance refer to the enclosed maintenance chart.

Once every 3 months it is recommended to replace the tubing of the peristaltic pump as described in 5.4. The exact interval depends on the workload of the laboratory and has to be determined by experience.

4.9 TROUBLE SHOOTING

SYMPTOMS POSSIBLE CAUSES & ACTIONS

Computer does not load - *Check the setup of BIOS*

Reagent and/or water not being aspirated

- *reagent probe clogged ?*
- *syringe assembly not functioning ?*
- *Check piston and powering of syringe*
- *tubing not properly connected or damaged?*
- *electrovalve not moving ?*

Reagent and/or water not being dispensed

- *sample probe clogged ?*
- *syringe assembly not functioning ?*

Sample not being aspirated

- *check piston and powering of syringe*
- *tubing not properly connected or damaged?*

Aspiration arm descends but liquid is not aspirated

- *the rotor of the peristaltic pump is too tight or too loosen*
- *silicone tubing of wrong diameter being installed on peristaltic pump*
- *silicone tubing on pump damaged or leaky*

The well for the waste is not emptying

- *malfunction of the waste pump*
- *tubing disconnected or broken*

Auto zero of filter wheel gives 0 V. on all filters

- *lamp of photometer burned out*
- *connector of lamp assembly disconnected*
- *filter wheel locked*

Erroneous auto zero

- *flow-cell not properly filled with water*
- *flow-cell dirty (to be cleaned)*
- *little air bubbles building up in the flow cell (to be cleaned)*
- *tubing disconnected, leaky or clogged.*

Erroneous auto zero

- *peristaltic pump malfunctioning*
- *dirty wash water in container*
- *bad-positioning of filter wheel*
- *no water in water container*

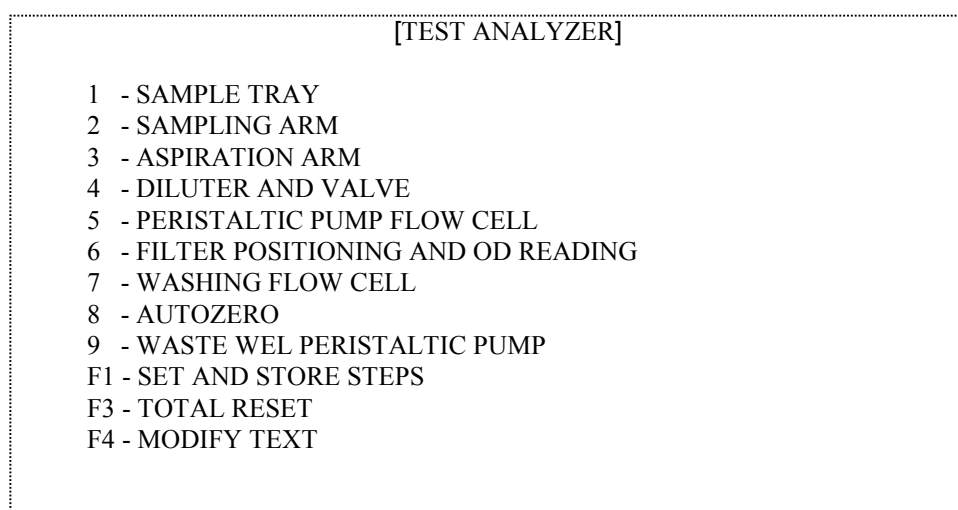
Erroneous, non-reproducible results

- check for little air bubbles in the flow cell (clean the flow cell)
- check aspirating system
- clean reaction sectors being used ?
- check temperature of reaction ring

4.10 MECHANICAL TESTS

With the option TEST ANALYZER in the ANALYZER MENU, it's possible to perform a control of all the main mechanical and electronic functions of the instrument. This in order to check in case a part is malfunctioning.

By selecting this option the following screen appears :



One important feature is the **F1** function : SET AND STORE STEPS, as all the mechanics centering and position adjustments are performed via software by using this function. Refer to the SERVICE MANUAL for more information on this subject.

The function **F4** - MODIFY TEXT, allows the operator to modify a text on the screen according to necessities of comprehension etc.

All the other features available on this Menu are used to test individually the mechanical movements and to check the several electrical and optical functions on the instrument, as a sort of diagnostic software.

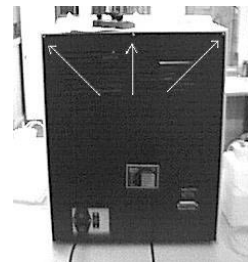
SECTION 5. REMOVAL AND REPLACEMENTS

This section has been conceived only as a quick support to the local engineers in a lab, in order to proceed with the standard replacements required by the scheduled maintenance. Any further disassembling or major replacement should be performed by a qualified service engineer.

5.1 REMOVAL OF THE CABINET

Before proceeding to replace the syringe, the piston and the syringe's seal, it's necessary to remove the whole cabinet. To remove the cabinet proceed as follows :

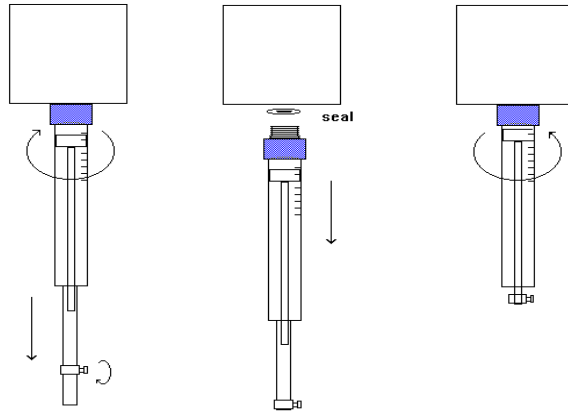
1. Disconnect the main plug and the water tubing connected to the water reservoir and to the waste bottle.
2. Remove the 3 screws located on the top of the back panel (picture 1)
3. Remove the printer assembly from the cradle (picture 2)
4. Disconnect the printer's cables (picture 3)
5. Remove the 5 screws located on the bottom of the metal base
6. Disconnect the keyboard and the LCD display cables. Access is from the back panel
7. Being careful to the sampling and aspirating tubing gently lift the whole cabinet and remove it
8. At this stage the syringe and the diluter assembly can be accessed



5.2 REPLACEMENT OF THE SYRINGE

To Replace the syringe proceed as follows:

- Turn the endless screw with the fingers until the bar moving the piston is at about half the way from the top
- Once the Piston moves down, loosen the screw fixing the piston to the moving bar of dilutor
- Move once again the endless screw down to the complete end of its run
- Unscrew the syringe from its header block and pull down the syringe with the piston, at this stage the piston can be removed and replaced, be careful to the O' Ring sealing the head of the syringe.
- Repeat inverse items to reassemble the syringe into the dilutor, check always that the piston's tip is not fully touching the top of the syringe, to avoid it can break the syringe head, it's better to connect the display and the keyboard and to make the system resetting to its home position before tightening the screw fixing the piston.



To avoid this trouble it's really better to tighten the moving bar screw on the piston, only when you are sure it doesn't touch the upper inside of the syringe (reset position).

Note! Check always the correct alignment of the piston with the syringe, this is achieved by turning manually the endless screw and by verifying that the piston's bottom part enters exactly into the apposite hole on the moving bar. In case it doesn't fit exactly into the hole, loosen the screws on the side of the diluter's top to adjust the slanting of the assembly until it fits into the hole without problems, then tighten the screws carefully.

5.3 REPLACEMENT OF THE LAMP

In this case it's unnecessary to disassemble completely the cabinet. Simply open the back panel and it's possible to have access to the photometer assembly. Proceed as follows :

1. Disconnect the lamp connectors from the housing beside the lamp itself
2. Remove the 3 screws fixing the lamp on the top of the photometer
3. extract the lamp
4. Insert a new one being careful not to touch it with the fingers
5. Fix back the 3 screws fixing the lamp assembly
6. Connect the lamp assembly's connectors to the apposite housings

5.4 SETTING AMPLIFIER'S VOLTAGES

Once replaced the lamp, it's necessary to adjust the gain and the offset of the photodiode amplifier, in order to achieve the optimal performance of the system.

To proceed with this adjustment follow these steps :

1. Perform an automatic cleaning cycle of the flow cell
2. Once it's assured that the flow cell is perfectly clean, perform an automatic washing with distilled water, to leave the flow cell filled up with distilled water
3. Enter in Menu Analyser, then in Mechanical Test
4. Select Autozero, this way the system will perform a check on all the voltages for each filter. Note the filter presenting the higher voltage beside.
5. Select the function FILTERS AND O.D. in Mechanical Test Menu, this function allows the adjustment of the gain and the offset on the amplifier
6. Select the filter, by selecting the FILTER voice and then by entering the required wavelength and pressing the Enter key. Normally the filter to be selected should be the one presenting the higher voltage in the Autozero screen.
7. Adjust the GAIN potentiometer located on the photometer block until on the LCD screen the voltage read is about 8.5 V
8. Select the OFFSET voice in order to display the offset voltage. This should be 0.003 or 0.004 V. In case it's 0.000 V or higher than the voltage specified adjust it by acting on the OFFSET potentiometer located beside the GAIN potentiometer.
9. Once completed this adjustment perform another Autozero to verify all the voltages for each filter.

Note! The lower limit for the AD converter input is 3,5V and the higher limit is 9,5V. In case one or more filters are too close to such limits it's necessary to check and eventually adjust the Gain. Always verify that the flow cell is perfectly clean before adjusting the Gain, otherwise problems may occur.

5.5 CLEANING THE AIR FILTER

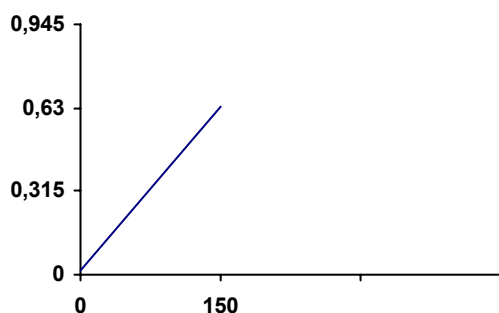
By opening the back panel it's possible to have access to the whole photometer block. Just in front of it it's located the air filter assembly. Periodically, according to the environmental conditions too, it requires to be cleaned or replaced. Simply extract it from its housing, then open the plastic frame containing the filter and clean it with alcohol to remove all dust residuals. In case it's necessary wash it or replace it if it's damaged. Dry it carefully before putting it back in its housing to avoid electric shock hazards.

Note! It's really important to have a correct ventilation of the photometer block, otherwise overheating of the system may occur with subsequent problems of reduced life of the filters.

TYPES OF CALCULATION

KUADRO instrument doesn't use a single number (the Factor) to calculate the results using the readings performed on samples. In this instrument we build a straight line passing by the minimum two points read during the calibration, then the absorbance read for each sample is applied to this curve and its related concentration is then obtained. With this method a better stability and linearity is obtained. This type of calculation is applied to all the End Point reactions.

Type of Calculation END POINT, BICHROMATIC and SERUM BLANK



To build up a calibration curve for this type of reactions it's necessary to have at least two points of calibration to build the straight line which represent the calibration curve and which will be used to calculate the result of concentration for any unknown sample whose absorbance is read by the system during the routine.

The first point A is a point with 0 concentration and a certain absorbance and represents the reagent blank absorbance. The second point B is a calibrator whose concentration is known and whose absorbance is the measured absorbance at the end point. Plotting the points on a Cartesian Diagram we have :

Point A (0,0.0152) ; Point B (150,0.632)

Then applying such values to a standard straight line equation $y = ax + b$ we obtain

$0.0152 = b$ This for Point A, demonstrating that it is the value of Reagent Blank only

$0.632 = 150a + b$ Replacing the value of b and solving the equation by a we obtain

$0.632 = 150a + 0.0152$ $a = 0.004112$

Then we have all the data to build the calibration curve's equation which will be applied for the routine results calculation :

$$y = x0.004112 + 0.0152$$

The result is calculated by replacing y with the absorbance read for the sample and solving the equation by X which represents the concentration's value.

Type of Calculation KINETIC

During the reading interval programmed for the test every second the absorption is measured. At the end of the time span a straight line is calculated through the points of measurement, using the linear regression method.

The coefficient of correlation (FIT) is used as a check on the linearity (must be > 0.97).

The calculated slope, expressed in Abs./min. is used to calculate the activity:

$$U/l = \text{Abs./min.} \times F$$

or:

$$\text{Conc.} = \Delta\text{Abs./min} \times \frac{\text{Conc. Standard}}{\Delta\text{Abs./min. (standard)}}$$

Results are FLAGGED:

in case of increasing (+) reactions:

- if the first reading > Start-Absorbance as programmed for the method in question.
- if the first reading < (RB + SE) where:
RB = Abs.Reagent Blank as measured at start of batch.
SE = O.D. for Substrate Expletion as programmed for method in question.

in case of decreasing (-) reactions:

- if the first reading < (RB - SE)

ON SCREEN FLAG CODES LIST

- L** Beyond linearity limit fixed in methods. Dilution is needed
- P** Out of normal values range fixed in method
- If first O.D. (in kinetics reaction as GOT and GPT) is minor than blank reagent O.D. - Substrate expl. limit O.D. as programmed in method.
It means reagent not working properly or activity of sample is extremely high try with dilution.
- FC** In immunochemistry means the sample is out of calibration curve.
- CK** Near reagent Blank O.D. it means O.D. out of range programmed in method.
Check reagent.
- CK** Near C1,C2,C3 it means control serum value is out of the range programmed in Method Valid only if control sera value are programmed (not=0)

ERROR MESSAGES ON SCREEN

WARNING NOT ENOUGH REAGENT (TEST NAME)

Tells operator to check level of reagent required for that routine , this warning does not stop batch in progress excluding test for which that reagent is required.

WARNING TEMPERATURE PROBLEM ON CH 1 (CH 2)

Check temperature alarm voltage (Refer to service manual, contact your dealer)

WARNING COMMUNICATION PROBLEM WITH CONTROLLER 1 (2, 3)

Problems of motor or electronic controllers.(Refer service manual, contact your dealer)

FILTERS OUT OF RANGE CH 1 (CH 2)

Check if lamp is burned out, flow cells dirty or clogged, in case this message does not disappear, contact your dealer.

WARNING SOME SETTING MISSING ON EEPROM

Repeat all the settings entering in Maintenance Menu and in Mechanical Test Menu. In case after having set all the required steps the message doesn't disappear, contact your dealer.