BASIC

70VB0358
70VB0370

User's manual

Ref. 0NVBAU

Manual version: 1.19

$\mathsf{C}\mathsf{E}$

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NOVA ANALYTICS

SYSTEME QUALITE CERTIFIE

NF EN ISO 9001 : 2000
A S C I I
CERTIFICAT 2003 - CLXV.
QUALITATEM
ACCREDITATION N° 4-016/98

cofrac
CERTIFICATION
D'ENTREPRISES
& DE PERSONNELS

SUMMARY

1 REMARKS

The Automatic aspiration system kit is manufactured by SECOMAM.

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SECOMAM
BASIC

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Reference	Date of last modification	Version	Date of document.	Writer	Controller	Approving
0NVBAU	07/12/04	**1.19**		JM		

2 WARRANTY

The new equipment and material sold by SECOMAM is guaranteed against any manufacturing defects for one year (unless otherwise stated by SECOMAM) with effect:
- From the technical acceptance of the equipment in the factory by the buyer or his designee,
- or failing this :
  * For Metropolitan France: from the date on the delivery note.
  * For other destinations: from the date of factory shipment certified by air waybill, consignment note or bill of lading.

The SECOMAM company guarantee applies exclusively to defectiveness arising from a design fault or from a concealed defect. It is strictly limited to the free dispatching of replacement parts (except for consumable items) or to the repairing of the equipment in our workshops within a deadline of 10 working days (shipping delay not included).

By express agreement, the following are strictly excluded from our guarantee:
- All damages, notably for staff costs, loss of earnings, business trouble, etc
- Any breakdown due to an incorrect use of the equipment (non adapted mains, fall, attempt at transformation, etc) or to a lack of maintenance by the user or to poor storage conditions.
- Any breakdown due to the use of parts not supplied by SECOMAM, on SECOMAM equipment
- Any breakdown due to the transporting of the equipment in packaging which is not its original packaging
- The lamps, the cells and generally any item which appears in the "accessories" section on the price list.

Our customers are kindly asked to apply for our consent before returning any instrument for repair. No return of materials may be accepted without the prior written consent of our Sales Management which will precise the terms of such return.
If the above consent is given, articles shall be returned in their original packaging on a prepaid basis to the following address:

SECOMAM - 91 avenue des Pins d'Alep – 30100 ALES FRANCE

We reserve the right to reship all instruments received collect failing such consent.

Whatever method and conditions of transport are chosen for the shipment of the equipment to be repaired under guarantee, in the original packaging, the corresponding costs and the insurance costs will be payable by the customer.

Any damage connected to the return transport of the equipment falls within the framework of the guarantee on the express condition that the customer has sent his complaint within forty-eight hours by registered letter with acknowledgement of receipt to the carrier. A copy of the letter should be sent to SECOMAM.

For equipment with a guaranty card, this is only applicable if the card delivered with the equipment is returned to SECOMAM duly completed.

SOFTWARE GUARANTEE

The software is guaranteed by the designer or the distributor of the software under the conditions specified in the literature accompanying the aforementioned software packages.

Under no circumstances whatsoever will SECOMAM supply any type of guarantee for software packages.

By express agreement, all damages, notably for staff costs, lost of earnings; business trouble, etc are strictly excluded from our guarantee.

The customer is informed that the software cannot be guaranteed exempt from defects or bugs.

TRADE SECRET AND PROPERTY RIGHTS

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SECOMAM grants a license to use its software to the user. This may not be disclosed, used or duplicated with the intention to save it, without SECOMAM's written permission. The beneficiary must attach a copy of this document to all authorized partial or total reproductions.

3 INFORMATION

The SECOMAM equipment has been designed, manufactured, tested and inspected according to the ISO 9001 standards.

If the unit is not immediately installed, it should be stored in a dry and clean area. The storage temperature should be between 10 and 35°C.

SECOMAM equipment is carefully inspected before it is packed. As soon as you receive your equipment, check the condition of the packaging and if you notice any problems, notify your carrier within 48 hours. Then consult the packing list and check that everything is in order. Finally, if you discover that something is missing, or if the goods are damaged immediately notify SECOMAM.

IMPORTANT:
In order to benefit from SECOMAM's service (application notes, SECOMAM information, technical assistance, etc.) immediately complete the attached guarantee card and return it to the following address:

SECOMAM
Service PRODUIT
91 Avenue des Pins d'Alep
30319 ALES Cedex
FRANCE

Tel: +33 4 66 54 35 60
Fax: +33 4 66 54 35 69
E-mail: info@secomam.com
Service Department: +33 4 66 54 35 63
Technical support: +33 1 39 35 42 12

4 PRECAUTIONS OF USE

> **Always make sure that the instrument is connected on the good voltage. (Between 100 – 240V 50-60Hz)**

> **Always disconnect the mains plug before starting any work inside the instrument.**

> **When dangerous substances for health and environment are used, the laboratory or site rules, where the instrument is installed must be followed.**

> **Take all the necessary precautions, during the use the instrument, to protect the operator from eventual liquids leaks or spills or possible radiations (protective gloves, anti radiation glasses , protected clothes, etc)**

All operations made inside the instrument, must be done by SECOMAM or by SECOMAM's authorized technicians.

5 PRELUDE

The BASIC was designed within the framework of In Vitro Diagnostic to cover the need of semi-automatization in clinical biochemistry analysis.

It includes the principal functions required by this kind of analysis such as:
- Wavelength range 340-700 nm,
- Peltier thermostated cell holder
- Calculation method adapted to enzymatic reading of results and parameters
- Quality control management
- Partial management of laboratory practice

BASIC complies with the requirements in CE marking of medical devices for In Vitro Diagnostics (98/79/EEC)

6 DESCRIPTION

6.1 GENERAL OVERVIEW

Front view :{ XE "Front view" *}*
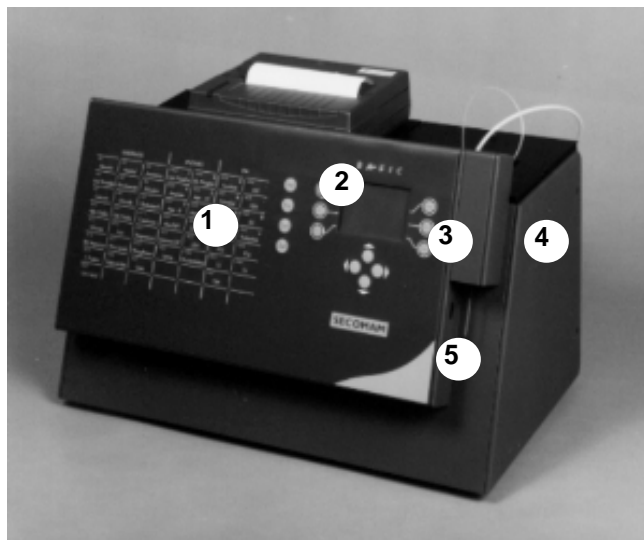
← Program keys + number keys.

↑ Control keys.

→ Screen.

↓ Function keys.

° Cursors.

{ XE "Screen" **}{** XE "Keyboard" **}**

6.2 SCREEN AND KEYBOARD
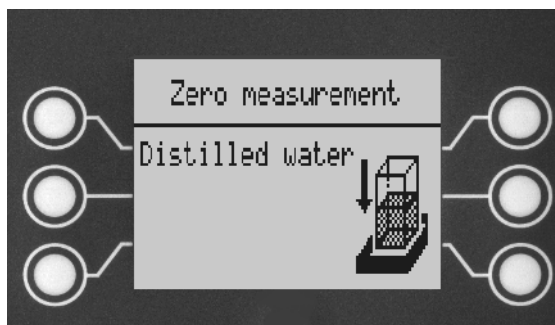
Function and screen keys : Thanks to these keys, working with BASIC is simplified. Screen instructions as well as the function keys guide you throughout the analysis.

On the display, Function keys correspond to an icon or a value. Simply validate by a light stroke.

- *Cursor* keys : Use these keys to have access to other functions of the keyboard such as :
  - elevator mouvement : BASIC test methods on the primary and secondary positions, next screen display,
  - right arrow for double rinse

{ XE "Cursor" **}{** XE "Program keys" **}**

Program keys : each program key can contain two test methods : on the primary position and the secondary position (secondary position are M1 to M47). These program keys are preassigned to give you an idea of the program capacity and calculation method the instrument is capable of. You can modify any given test me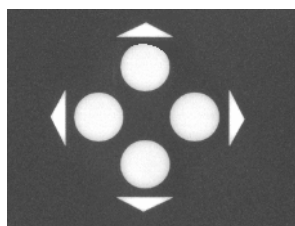thod at any time, experiment your own parameters, place it at a different key than the original and call it just by one stroke. Before modifying, it is recommended to print the existing test method.

Number keys : otherwise indicated on the display, numbers are to be entered by way of program keys (date, hour, sample values, sample numbers, ...).

{ XE "Number keys" **}**

SUBSTRATES			ENZYMES		EIA	
M1 Albumin	M2 Alcohol	M3 Ammonia	M23　　1 Acid Phosphat.	M24　　2 Alk.Phosphat.	M35　　3 Ferritine	M36　　• IGE
M4 Anti Thrombin	M5 Bicarbonate	M6 Bilirubin	M25　　4 Amylase	M26　　5 Apo - A1	M37　　6 Estradiol	M38　　− FSH
M7 Calcium	M8 Chloride	M9 Cholesterol	M27　　7 Apo - B	M28　　8 Asat/GOT	M39　　9 HCG	M40　　0 LH
M10 HDL Choles.	M11 LDL Choles.	M12 Creatinine	M29 Alat /GPT	M30 Ck.NAC	M41 Progesterone	M42　　+ Prolactine
M13 Glucose	M14 Iron	M15 Magnesium	M31 Gamma GT	M32 LDH	M43 FT3	M44 FT4
M16 RBC Magnesium	M17 Phos.Lipids	M18 Phosphorus	M33 Lipase	M34 Nucleotidase	M45 T3	M46 T4
M19 T.Protein	M20 Triglycerides	M21 Urea			M47 TSH	
M22 Uric Acid						

BASIC

- *BASIC's software control keys :*

Val	Validate an operation
Esc	Quit active screen
Conf	Reach software configuration screen
Del	Erase & correct data
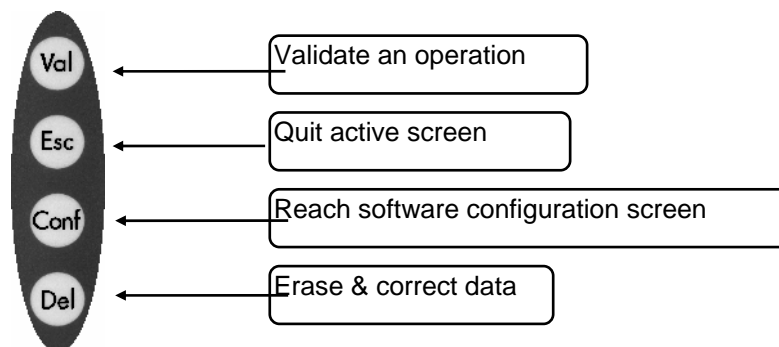
6.3 DISPLAY DESIGN
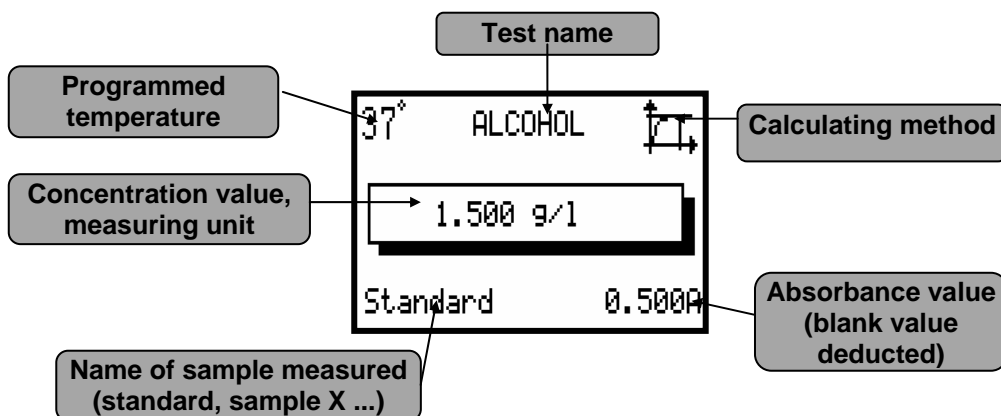
When using cuvette by cuvette method, you will see :
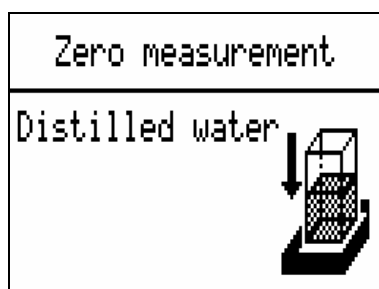
While for pumping aspiration :
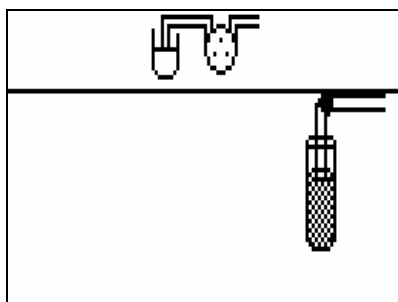
7 SET-UP

7.1 GENERAL SET-UP

{ XE "General set-up" **}**
Step-by-step set-up of BASIC is done through the « **CONF** »key

CLOCK

Use (F1) to (F5) keys to modify the values. Abort modification with ESC key, register with VAL key.

- CONFIGURATION -

STAND-BY

Access to a sub-menu allowing to choose the duration before starting the stand-by (screen saver)

CONF

PRINTER

Access to set-up menu for the printer

DATA FILES

Access to : -Patient identification –Patient report –Data archiving to PC or Printer – Memory reset.

PROGRAM

Access to program modification.

- CONFIGURATION -

PROGRAM   QUALITY

PUMP

Access to pump set-up menu

Use the pump?

YES   ▸ NO

QUALITY CONTROL

Quality control

YES   ▸ NO

Display

Confirm (F1) or skipping (F4) the quality control function. Display (F3) values and dates of previous control.

NOTE :

FRANCAIS   ITALIANO

ENGLISH ◂   ESPANOL

CONFIGURATION screen is active when you see an elevator in the middle of the screen. Use upward and downward cursor keys to activate and have access to the next display screen.**{** XE "Elevator" **}**

7.2 LANGUAGE SET-UP

This would be the first configuration to check upon starting the instrument. Successively press « CONF », « downward cursor key », (F1) « Language set-up » then (F3) « English ». **{** XE "Language set-up" **}**

FRANCAIS ◂   ITALIANO

ENGLISH   ESPANOL

DEUTSCH

中文

BASIC

7.3 DATE AND CLOCK SET-UP

```
   - CONFIGURATION -        05/29/1997  10:26 am
  ○ ⌘ 31  ▲        ○   D+1 Day          Time  T+1
  ○       ▓     ①  ○   M+1 Month      Minute  M+1
  ○ 🖨     ▼   ⊟?  ○   Y+1 Year
```
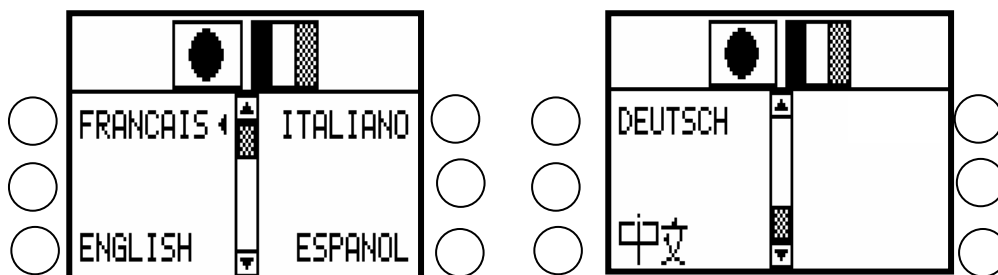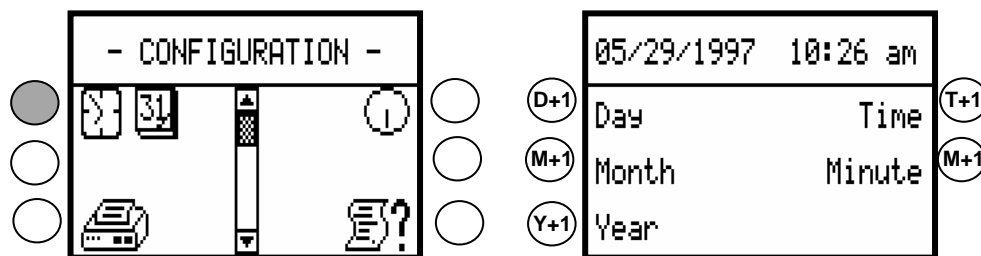
Use the corresponding function key to increment date and time. Then « VAL » to **{** XE "Date set-up" **}{** XE "clock set-up" **}**store, « ESC » to return to previous display.

7.4 PUMP SET-UP

```
   - CONFIGURATION -
  ○ ◨◼ ◉  ▲   ⌐🐭  ○
  ○         ▓        ○
  ○ PROGRAM  ▼ QUALITY ○
```
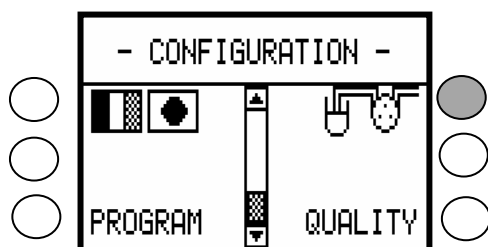
{ XE "Pump set-up" **}**
Access to pump functions & set-up : debit , dead volume, aspiration volume.
For your convenience, these volumes are factory preadjusted.
(Note : upon changing pump and tubings , you have to readjust setting).

Press (F3) « PUMP SET-UP » , you will obtain :

```
      Use the pump?
  ○                      ○
  ● YES ◂          NO    ●
  ○                      ○
```
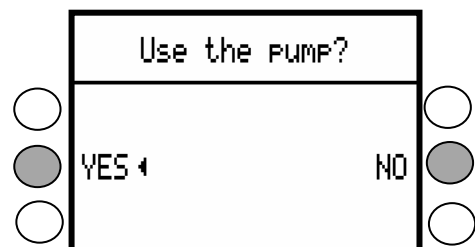
Press (F5) « NO » for manual cuvette by cuvette operation (recommended to use on highly-contaminant tests).
By answering (F2) « YES », you obtain three choices :

```
         ⌐🐭
  ● Pump rate          ○
  ● Delay              ○
  ● Dead vol.          ○
```
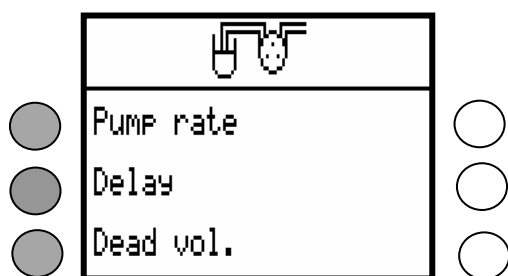
Pump rate (calibration) :

Prepare ahead :
- four test tubes with 2000 µl of distilled water each,
- one test tube with 1000 µl of distilled water to use as standard.
- One graduated pipette (vol. up to 1000 µl)

To adjust pump volume, you need to: **{** XE "Pump calibration" **}**
- Return to « CONFIGURATION ».
- Go to menu « PUMP ».
- Use pump « YES ».
- Exit from « CONFIGURATION » (ESC twice).
- Rince twice consecutively (using right cursor button) to fill the tube with water.

Then :
- Again return to « CONFIGURATION »,« PUMP »,« YES ».,« PUMP RATE »
- Introduce the first tube containing 2000 µl of distilled water to the aspiration noozle.
- Press (F3) « SUCK » and « VALidate » the message of 1000 µl. The pump should have aspirated 1000 µl. Compare the remaining volume with the volume of standard tube. Or better yet, aspirate the remaining distilled water with the pipette and verify the volume. If the remaining volume is more (or less) than 1000 µl, « DELete» the message of 1000 µl on display and enter the real volume sucked by the pump using the number keys (calculation example : initial volume of 2000 µl – remaining volume = new volume to program). Introduce the second tube containing 2000 µl of distilled water.
- Press (F3) « SUCK » and « VALidate ». The remaining volume should be 1000 µl, same as the volume of standard tube (or verify again with the pipette). If another adjustment is to be done, repeat this process untill the instrument aspirated the right 1000 µl volume.

Always validate at the end of process by (F6) «OK». (To keep previous volume, press « ESC »).

Delay :

Is the frequency (in seconds) to program for sample introduction following one reading.
You can work faster by shortening pump aspiration delay when you are more familiar with the system.

```
┌─────────────────────────┐
│ Delay before measure    │
├─────────────────────────┤
│ 1                     4 │
│                         │
│ 2                   ▸ 5 │
│                         │
│ 3                     6 │
└─────────────────────────┘
```

BASIC

beginning of the dead volume
2 cm
Dead volume
Sample
Joint
Flow through cell
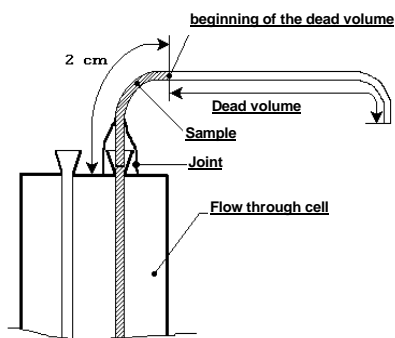
Dead volume :

Dead volume is needed to avoid contamination of samples. It is represented by a certain volume of air. Dead volume is influenced by the length of aspiration tube. It is recommended to program dead volume in such a way that the end of the aspirated sample remains approximately 2 cm on top of the cell tip (see drawing).
{ XE "Dead volume" **}**

Upon selecting F3 Dead Volume, you will get a choice of 6 volumes.

.**{** XE "Volume" **}**
200 µl is the factory preprogrammed volume:

0	▸ 150
100	175
125	200
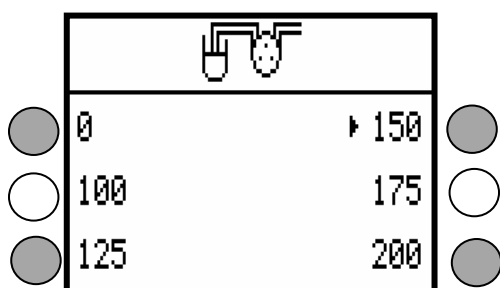
7.5 PRINTER SET-UP

{ XE "Printer set-up" **}**

– CONFIGURATION –
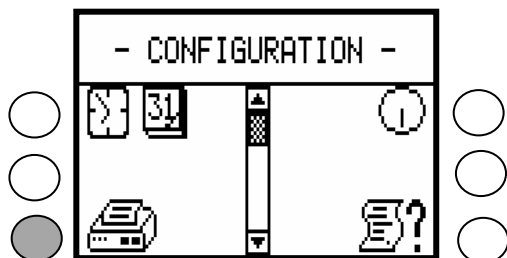
Select « PRINTER OPTION » by pressing F3.
Printer should be an 80 column or has an 80 column set-up.

When using a printer, select (F2)« YES », (F1) « TYPE » , enter the type of printer.
A selection of 4 printers are proposed : a KYOLINE, CITIZEN IDP562S, HEWLETT PACKARD and

YES ◂   NO
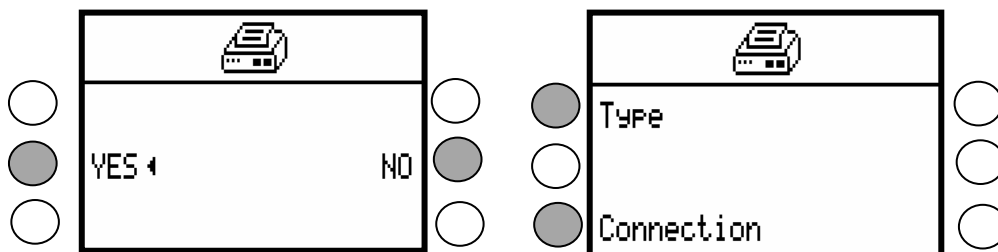
Type

Connection

EPSON. Choose one. Next, check the type of port « connection » either serial RS232C or Parallel. Connect IDP or KYOLINE printer using its ***serial*** *printer cable* to BASIC's *serial RS232C port.*

Warning : never connect a serial printer with a 25-pin cable to the parallel port. This will do serious damage to BASIC and the instrument will emit a continuous beeping noise. This type of error is not covered by the warranty.

```
┌─────────────────────┐          ┌─────────────────────┐
│  Printer language   │          │  Printer connection │
├─────────────────────┤          ├─────────────────────┤
│ KYOLINE      ▸HP    │          │                     │
│                     │          │ Serial◂    Parallel │
│ IDP          EPSON  │          │                     │
└─────────────────────┘          └─────────────────────┘
```

Exit from set-up by « ESC ».

7.6 TRACEABILITY SET-UP

{ XE "Trace-ability set-up" **}**

```
┌─────────────────────┐
│  - CONFIGURATION -  │
├─────────────────────┤
│ ⟩⟨ 31̲     ▲    ⓘ   │
│        ▓▓▓          │
│ 🖨      ▓▓▓    📜?  │
│        ▼            │
└─────────────────────┘
```
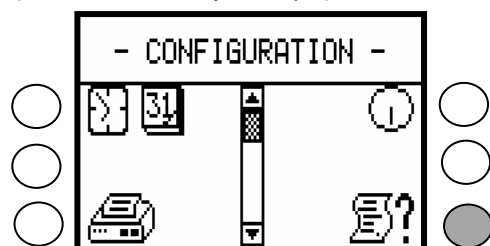
Data identification, filing, report etc. are given in this (F6) TRACE-ABILITY function :

   F1 BASIC - PC : this function allows you to download data (patient reports) to the PC (see chapter 5.6.1)

   F2 BASIC – PRT : use this function to download data to a printer. Two types of printed documents can be obtained :

- global daily report of all patients (**enter** Nr 0) or
- patient by patient report (selectable : example Nr 114, 121).

You can print previous day's result (if it is not crushed/erased yet) by reprogramming the date (see CONFIG, DATE).

Note :For two samples bearing the same number, only the latest will be edited.

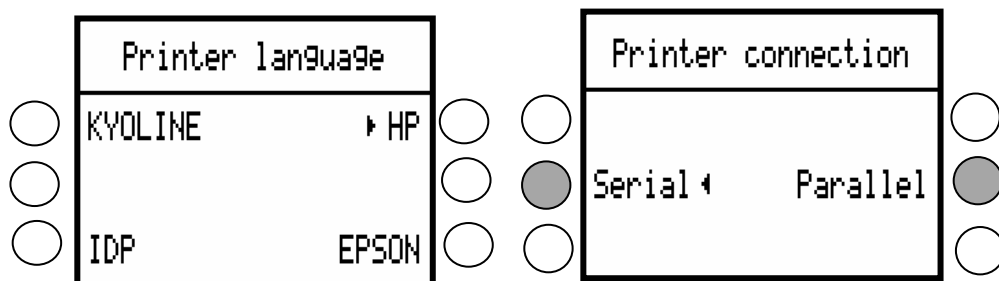   F3 INIT is used to clear result memory. Be sure to save/print results before deleting.

   F4 YES : by choosing this function, BASIC will report kinetical reading points per segment.

   F5 NO : by this function, BASIC will give brief kinetical report.

   F6 ORDER is to select the printing order of a given patient, for example Nr 114 first then Nr 121.

BASIC


```
            ≣)?
 ○  Basic-PC        YES   ○
 ○  Basic-Prt      ▸ NO    ○
 ○  Init.         ORDER   ○
```
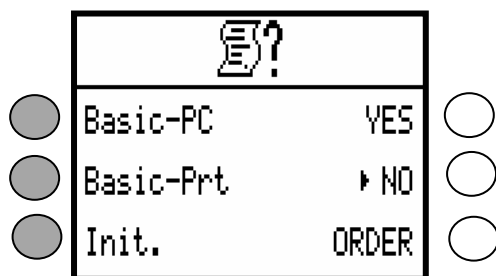
7.6.1 Downloading to a PC : F1 « BASIC –PC »

Connect BASIC to the PC using ref : 0X6807 cable and if needed, an adaptator.
{ XE "Download to a PC (Win 95)" **}**

> **FOR WINDOWS 95**

♦ Click on « START », PROGRAM », « ACCESSORIES », « HYPERTERM », windows 95 opens a window where you will find « HYPERTRM.EXE ».

♦ Open « HYPERTRM.EXE » which will give access to other window « NEW CONNECTION » and « DESCRIPTION OF A CONNECTION ».

♦ Choose the name and icone of this connection (bearing in mind the type of instrument which is your source of data) then « OK ».

♦ You'll see « DESCRIPTION » disappear to leave space to a new windows called « TEL NUMBER », also « NEW CONNECTION HYPERTERMINAL » will appear as « NAME OF INSTRUMENT-HYPERTERMINAL ». Select the COM number where the connecting cable is plugged. Validate « OK ».

♦ When « PROPERTY COMx » shows up, and you should feed the following informations :

> **Bits / second : 9600**
> **Data bit : 8**
> **Parity : none**
> **Stop bit : 1**
> **Flux control : none**

♦ Then validate « OK ».

♦ Check that option « ADD LINE MODIFICATION AT THE END OF ENTERING LINES », in menu « FILES », « PROPERTY » index « PARAMETERS » button « CONFIG ASCII » at framed level « ASCII RECEPTION » is activated.

♦ To save the parameters, select « FILES » then « SAVE ». Windows register selected parameters under predefined name.

♦ To receive result file from the instrument, click on « TRANSFER » then « CAPTURE TEXT » menu.

♦ Windows opens a dialog box « CAPTURE TEXT ». Choose in which repertory you will save the data result file also under which name, either by entering the pathway or the name with « .TXT » extension, or by selecting « FOLLOW » icone.

♦ Type « start », and your terminal will be on reception mode.

♦ On BASIC itself, press « BASIC-PC » button, you will see its data on the PC screen.

<div align="center">

FOR WINDOWS 3.x

</div>

Open « TERMINAL » program which is usually under program group « ACCESSORIES ».

To create acquisition program, do the following :
Select « PARAMETERS », « TERMINAL EMULATION » and select « DEC VT 100 (AINSI) » option.
Then select « PARAMETERS », « TERMINAL PARAMETERS », then the following options :

> **Character terminal : terminal**
> **column : 80**
> CR > CR/LF   ☒ Entry   ☐ Exit

Continue by selecting « PARAMETERS » « COMMUNICATION » and define the page as follows :

> **transmission rate : 9600 bauds**
> **Data bits : 8 bits**
> **Stop bits : 1 bit**
> **Parity : none**
> **Flux control : none**
> **Parity control : ☐ (non selected)**
> **Beared detection : ☐ (non selected)**

{ XE "Download to a PC (Windows 3.x)" **}**
Then choose COM number where the connecting cable is plugged.

To register the parameters, select « FILE » then « SAVE ». Windows will open a dialog box « SAVE ». Choose in which repertory you want to save the program, also give a name with « .TRM » then enter « OK ». That file name is shown on PC's title bar.

To receive result file from the instrument click menu « TRANSFER » then « RECEIPT A TEXT FILE ».
A dialog box « RECEIPT A TEXT FILE » is opened. Choose in which repertory you will save the data result file, also under which name with « .TXT » extension. Press « OK », your terminal will be on reception mode.

• On BASIC itself, press « BASIC-PC », data will appear on PC's screen.

7.6.2 Downloading to a printer : F2 « BASIC-PRINTER »

{ XE "Download to a printer" **}**
Connect BASIC to a printer.
Press « BASIC-PRT ».
You will obtain :

BASIC

	1	2	3	4	5
M	47;E;	0	0.0;%;	29/08/1997;08H17;	-;?
M	47;E;	1	210.4;%;	29/08/1997;08H19;	L;?
M	47;E;	2	-0.0;%;	29/08/1997;08H19;	;?
M	47;E;	3	-0.0;%;	29/08/1997;08H20;	;?
M	47;E;	4	9.9;%;	29/08/1997;08H20;	;?
M	47;E;	5	9.9;%;	29/08/1997;08H20;	;?
M	47;E;	6	9.8;%;	29/08/1997;08H21;	;?
M	47;E;	7	9.8;%;	29/08/1997;08H22;	;?

Column 1 : Sample number + characteristics :

           B = Reagent blank,
           S = Standard,
           E = Sample,
           C = Control,
           b = Blank of reagent blank,
           s = Standard blank,
           e = Sample blank,
           c = control blank.

Column 2 : Sample number.

Colonne 3 : Concentration value and unit.

Column 4 : Date and time.

Column 5 : Status :

        - :   No problem,
        > :   Result superior to normal value,
        < :   Result inferior to normal value,
        L :   result superior to linearity limit,
        – **:**   negative concentration value
        B :   Blank value superior to linearity limit,
        Q :   Control non performed,
        ! :   Control badly performed,
        - :   Control normal.

Memory initialisation**{** XE "Memory initialisation" **}**

To erase the results stored in memory, press « init ».

7.6.3 KINETICAL REPORT

On methods using KINETICS, you have a choice of having a short one line final reading report by choosing F5 « NO » or segment per segment reading through F4 « YES ».

7.7 QUALITY CONTROL SET-UP

```
┌─────────────────────────────┐
│     - CONFIGURATION -        │
│  ▌▐ ◆   ▲                   │
│            ᶜ⌐ᵔᵕ              │
│  PROGRAM   ▓   QUALITY       │
│            ▼                 │
└─────────────────────────────┘
```
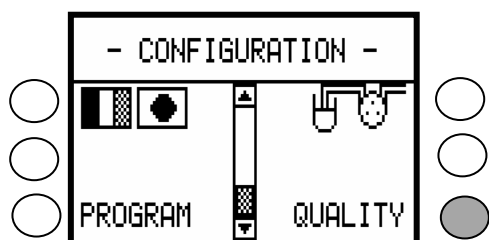
Each Quality Control runned is memorized automatically.
F4« NO » gives you the choice not to run QC.
F3« DISPLAY » allows to display on screen as graph the values and dates of previous control (only after at least two controls of the same analysis method have been made). Printout of QC can be obtained after programming TRACE-ABILITY function, YES.
{ XE "Quality control set-up" **}**

```
┌─────────────────────────────┐
│      Quality control         │
│ YES              ▸ NO        │
│                              │
│ Display                      │
└─────────────────────────────┘
```

```
┌─────────────────────────────┐
│ 37°   ALBUMIN        ⌐┐      │
│                      └┘᛭     │
│     Check analysis?          │
│                              │
│ YES               NO         │
└─────────────────────────────┘
```
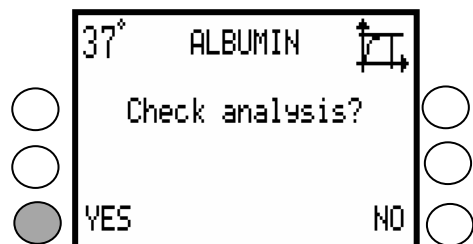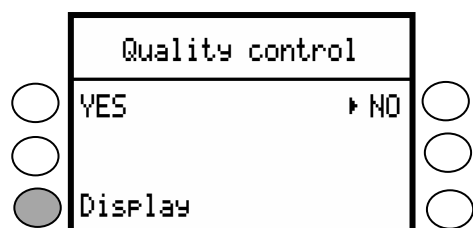
Upon validating (F1) « YES » , you will be reminded to run Quality Control later on upon running a test method (CHECK ANALYSIS) and flags will be given according to the « MAXIMUM & MINIMUM TOLERANCE VALUES » entered. **Q** preceding result indicates that QC was not performed.

Note : Upon using a test method for the first time in the day, you will be suggested to run a control. However, once QC is done for the day, no need to run another one, hence F6 « NO ».

```
 ┌──────────────────────┐
 │    Max-tolerance     │
 ├──────────────────────┤
 │                      │
 │   Value : 2.00       │
 │          ‾           │
 │                      │
 └──────────────────────┘
```

```
 ┌──────────────────────┐
 │    Min-tolerance     │
 ├──────────────────────┤
 │                      │
 │   Value : 1.00       │
 │          ‾           │
 │                      │
 └──────────────────────┘
```

```
 ┌──────────────────────┐
 │37°    AMYLASE        │
 │                      │
 │Reagent Blk           │
 │                      │
 └──────────────────────┘
```

This control can be done at a regular interval, defined in days :

```
      ┌──────────────────────┐
      │     Programming      │
      ├──────────────────────┤
  ⬤   │Modify                │   ◯
      │                      │
  ◯   │                      │   ◯
      │                      │
  ◯   │Print                 │   ◯
      └──────────────────────┘
```

To do so, return to « PROGRAMMING », F1« MODIFY », select the corresponding analysis method, and validate till you obtain the following display :

```
      ┌──────────────────────┐
      │   Check frequency    │
      ├──────────────────────┤
      │                      │
      │    Value : 1         │
      │            ‾         │
      │       (in days)      │
      │                      │
      └──────────────────────┘
```

{ XE "Control frequency" **}**
Enter the frequency (in days) and validate . This procedure determines QC periodicity. Control can be done daily, for 31 days.

This way, daily/periodically, the instrument memorizes analysis results & quality controls.

Status of control

Chronological filing of control

Use upward/downward arrows to visualize controls .

```
37°    ALBUMIN

0-05/06/1997 OK

1-06/06/1997 >

2-07/06/1997 <
```

Printing control results
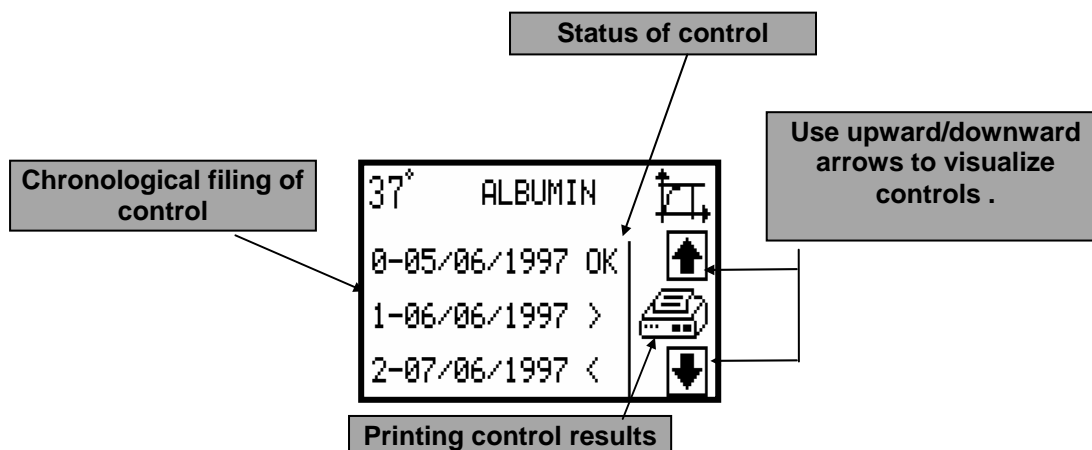
Exemple of print-out (analysis comprising one quality control per day :

SECOMAM - Polyphotometer UV-Vis BASIC V1.11
Date : 04/06/1997   Hour : 09H25

User :

Analysis : ALBUMIN   **37°C**

Sample	Abs.	Concentration	Status
Reagent Bl.	0.000	**0.00 g/l**	
Standard	0.100	**1.00 g/l**	
Control	0.150	**1.50 g/l**	**OK**
OK Control - Le 05/06/97			
Normal value: 38.00 à 54.00 g/l			
S. # 1	0.150	**1.50 g/l**	<
S. # 2	0.300	**3.00 g/l**	<
Std. # 3	0.700	**7.00 g/l**	<
Std. # 4	1.300	**13.00 g/l**	<
Std. # 5	1.250	**12.50 g/l**	<

BASIC

SECOMAM - Polyphotometer UV-Vis BASIC V1.11
Date : 05/06/1997   Hour : 09H26

User :

Analysis : ALBUMIN   **37°C**   **2nd day**

Sample	Abs.	Concentration	Status
Reagent Bl.	0.000	**0.00 g/l**	
Contrôle	2.100	**21.00 g/l**	**P B**
Control Pb Le 06/06/97			
Normal value : 38.00 à 54.00 g/l			
S. # 1	0.100	**1.00 g/l**	**<**
S. # 2	1.600	**16.00 g/l**	**<**

SECOMAM - Polyphotometer UV-Vis BASIC V1.11
Date : 06/06/1997   Hour : 09H27

User :

Analysis : ALBUMIN   **37°C**   **3rd day**

Sample	Abs.	Concentration	Status
Reagent Bl.	0.000	**0.00 g/l**	
Control	0.990	**9.90 g/l**	**P B**
Control	0.990	**9.90 g/l**	**P B**
Control Pb Le 07/06/97			
Normal value: 38.00 à 54.00 g/l			

Status :

> **:** Sample concentration superior to upper limit.
< **:** Sample concentration inferior to lower limit..
PB **:** Problem on control.
OK **:** satisfactory control.
Q **:** Appears next to analysis result when control is programmed but not runned.
! **:** Appears next to analysis result when the control is out of tolerance range.
L **:** The result in concentration is no longer within the linearity limit of the analysis.
− **:** The result in concentration is negative.

> ⚠
>
> **Upon modifying analysis method, memorized results are erased.**

8 PROGRAMMATION

Through **configuration**, select « PROGRAMMING » to modify a preset analysis method or to create a new one.

Programmable parameters are :
- suction volume,
- temperature,
- unit
- accuracy,
- calculation mode,
- analysis mode
- time (lag time, interval time and number of intervals),
- wavelength,
- linearity limit,
- normal range (high/low)
- check frequency,
- ⚠ previous results & standard control will be crushed upon saving a new method.

Note : At any case, arbitrary values are labeled by small arrows on the right or the left side of the value.
{ XE "Program keys" **}**

8.1 PROGRAM KEYS

To program an analysis test, simply return to set-up procedure : « CONFIGURATION », then « PROGRAM », PROGRAMMING : F1« MODIFY » :

```
        Programming
  ◉  Modify              ◯
  ◯                      ◯
  ◯  Print               ◯
```
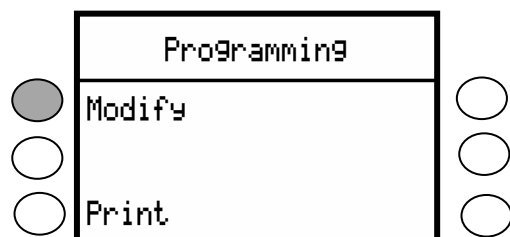
Next you will obtain the « **ANALYSIS »** selector panel : simply press ↑ or ↓ or cursor key for access to program keyboard.

```
      ANALYSIS                    ANALYSIS
      SUBSTRATES                  SUBSTRATES
   M1 | M2 | M3              M1 | M2 | M3
   ALB |  ◖ | AN            ALB |  ◖ | AN
   M4 | IM | IM6             M4 | IM | IM6
```
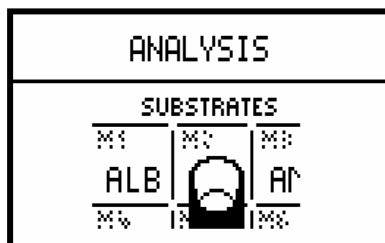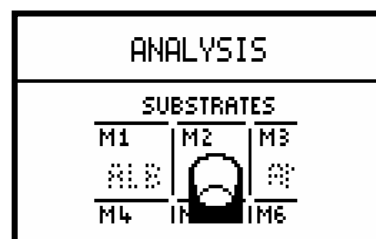
Primary position   Secondary position

Select one of the program key to place the new test method.

```
           ALBUMIN
    ┌──────────────────────────┐
 ○  │ A        ▲           D   │  ○
    │ B        ▒           E   │
 ○  │          │               │  ○
    │ C        ▼           F   │
 ○  └──────────────────────────┘  ○
```

ADJUSTMENTS RELATED TO ANALYSIS

Name the analysis method should be done first. It is recommended **_not_** to use the same name as the one found in the primary position. DELete test method name and replace. Choose letters and numbers with F1 to F6 keys and ↑ or ↓ cursor. Validate at the end.

Aspiration volume :

■ 800 µl is the recommended pump aspiration volume. However a selection of six volumes from 500 to 1500 µl are available.

To modify the volume, press the F key corresponding to the volume to program.

Temperature :

{XE "Temp"**}**
BASIC is equiped with a Peltier-effect temperature control cell-holder.
Recommended temperature to use is given by the test method technical sheet.
Use F key to program the temperature. Note :during warm-up, the programmed temperature digits will blink, rather fast at first, slowing down afterwards. It takes 15 minutes to stabilize the cell-holder and cuvette to 37°C Once temperature is reached, the digits will be displayed permanently.
Peltier-effect is deactivated when programmed at XX (Room temperature/F1)
Note on work organization : it is adviced to run all test methods using the same temperature in one session to avoid warm-up delay. For your convenience, the cell-holder will remain on the last

<u>*Room temp*</u>

```
    ┌──────────────────────────┐
    │        ▐██▌▭▭▭           │
    │                          │
 ●  │ XX°              30°     │  ○
    │                          │
 ○  │                          │  ○
    │ 25°             ▸37°     │
 ○  └──────────────────────────┘  ○
```

temperature used.

Unit :
Choose measuring unit according to the recommendation of the reagent technical sheet.

BASIC

```
          Unit : g/l
   ,   ,                    IU/l
   g/l                    mmol/l
   mg/l                   µmol/l
```

Result resolution (decimals) : Concentration result is given by the number of decimals programmed.

```
          Accurate
   X                 ▸ X.XX



   X.X                 X.XXX
```

Calculation mode :
A choice of three calculation modes are proposed :

```
        Calculation mode
   Factor

   Linear ◂

    Non-linear
```

F1 Factor : in **Kinetic** mode, enzymatic factor (coefficient) value is used instead of calibration factor. Enter factor value indicated on the reagent technical sheet (DELete, then enter numbers). Results will be calculated using this factor.

```
          Factor

      Value : 1.00
```

F2 Linear :   In **End-point, End-point with blank and Two-points-kinetics** analysis modes, calibration is needed (which means, the calculation is done using standard(s)). Enter standard(s) value(s) (DELete, then enter numbers).

```
┌─────────────────────────┐
│       Standard 1        │
├─────────────────────────┤
│                         │
│     Value : 1.00        │
│             ‾           │
│                         │
│                         │
└─────────────────────────┘
```

F3 Non-linear :   E.I.A tube methods use this calculation mode (polynomial, log/logit, spline, multi-points). Enter the number of standards used, then the values of each. Up to 6 standards can be used.

```
      ┌─────────────────────────┐
      │   Number of standards   │
      ├─────────────────────────┤
 ◯    │ 4 ◂                     │   ◯
 ◯    │ 5                       │   ◯
 ◯    │ 6                       │   ◯
      └─────────────────────────┘
```

```
┌─────────────────────┐        ┌─────────────────────┐
│     Standard 1      │        │     Standard 4      │
├─────────────────────┤        ├─────────────────────┤
│                     │        │                     │
│   Value : 1.00      │   ━▶   │   Value : 4.00      │
│           ‾         │        │           ‾         │
│                     │        │                     │
└─────────────────────┘        └─────────────────────┘
```

Wavelength :

{ XE "Wavelength" **}**

Wavelength to use is indicated by the reagent technical sheet. You may not find the exact same wavelength among those proposed by BASIC. In that case, select one closest to the ideal wavelength .
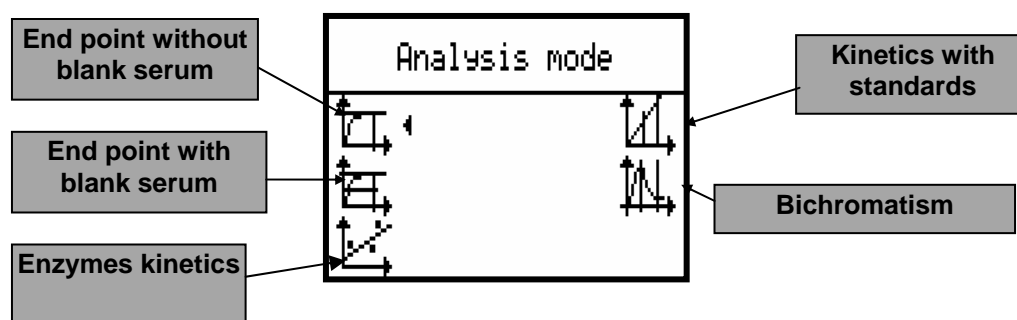
```
      ┌───────────────────────┐               ┌───────────────────────┐
      │      Wavelength       │               │      Wavelength       │
      ├───────────────────────┤               ├───────────────────────┤
 ◯    │ 340          ▲  405   │  ◯       ◯    │ 510          ▲  578   │  ◯
 ◯    │              ▓        │  ◯       ◯    │              ▓        │  ◯
 ◯    │ 380          ▼  492   │  ◯       ◯    │ 546          ▓  ▸ 623 │  ◯
      └───────────────────────┘               └──────────────▼────────┘
```

{ XE "Analysis mode" **}**

BASIC

Analysis mode :

End point without blank serum		Kinetics with standards
End point with blank serum	Analysis mode	
Enzymes kinetics		Bichromatism

.F1. ***End-point analysis mode :***
When using this mode, reading is done at the final absorbance (optical density) point (at the end of the reaction process). Zero is adjusted using reagent alone (reagent blank) or distilled water.

F2. ***End point with*** ***blank***:
A number of environments, in particular biological ones, may be the object of spectral interferences at the wavelength selected for the dosage. This is the case for colored molecules (haemoglobin, bilirubin, ...) These interferences which are independent of the parameter to be measured, will be eliminated by measuring the sample alone or with a reagent which does not trigger a coloring effect. : this is called a **sample/serum blank**.
When there is only one reagent and such a reagent may add a parasitical color to the wavelength of the reading, it is deducted from such reading; this is referred to as **reagent blank.**
***End point with serum blank:* : {**XE "End point with serum blank "**}**

$$\text{Conc. Std} = (\text{abs. Std} - \text{Abs. reagent Blank}) \times \text{coef. Calibr.}$$

***End point without serum blank*:.{** XE "End point without blank serum" **}**
$$\text{Conc. Std.} = \left[(\text{Abs. Std.} - \text{Abs. Serum Blank}) - (\text{Abs. Blank} - \text{Abs Blank blank}) \right] Coef.$$

F3 ***Enzyme kinetics{***XE "Enzyme kinetics"***} :*** Called also zero order kinetics. This method calculates the evolution of a sample, in Absorbance, against a time period defined in a certain number of intervals. BASIC computes the straight regression line which will average the means of the points.
BASIC allows you to select the duration of analysis reading as well as the number of intervals to be measured. Also lag time between each intervals should be indicated.

$$slope = \frac{(N \, x \sum XY) - (\sum X \, x \sum Y)}{(N \, x \sum X^2) - (\sum X)^2} \, x \, 60$$

N :   Total number of point of the kinetic curve (nb of segments x segment time).
ψ**X** :   1+2+3+...+N x (N+1) /2
ψ**Y** :   total of absorbances at points 1, 2, 3, ... N=A+A2+A3+...+AN
ψ**XY** :   (A1 x 1)+(A2 x 2)+(A3 x 3)+...+(AN x N)
ψ**X^2** :   1+4+9+...+N^2 = N(N+1)(2N+1) /6

The slope thus calculated is expressed in delta of Abs./min.

F4 ***Kinetics with standards{***XE "Kinetics with standards"***} :*** Called also two-point kinetics or first order kinetics. This analysis method allows to perform measurements of Concentration in Kinetics mode. That is, to calculate the absorbance variation of a solution within the time and to multiply the differences of Absorbance by a coefficient or to compare to a standard measured with the same measuring conditions.
Thus, global waiting time of measurement should be indicated. Then BASIC requires confirmation on the time consumed between the two point reading.

$$R = \frac{(ABS\ \mathbf{t}1 - ABS\ \mathbf{t2})\ x\ f\mathbf{actor}\ x\ 60}{tm}$$

ABS t1 :   Abs of the solution at the end of the lag time.
ABS t2 :   Abs of the solution at the end of the measuring time.
factor :   Coefficient of molecular absorption.
tm :   Measuring time.
60/tm :   Ratio reducing the result to one minute.

The slope thus calculated is expressed in delta of Abs./min.

F5 **_Bichromatism_** : **{**XE "Bichromatism"**}**is recommended when sample is cloudy (turbid). Reading is done using 2 wavelengths multiplied by a factor.

$$\left(\text{Abs. Smpl}_{\lambda 1} - \text{Abs. Smpl.}_{\lambda 2}\right)F$$

BASIC

For both KINETIC modes, enter Lag time (the waiting time before reaction starts), number of intervals and time segments of each interval. Indicate also whether it is an increasing/decreasing type of reaction.

Analysis mode

Lag time
Value : 5
(in seconds)

Number of intervals
2	5
3	6
4	7

Interval time
Value : 10
(in seconds)

reaction-Direction

Linearity limit :

{ XE "Linearity limit" **}**

```
┌─────────────────────┐
│    Linear limit     │
├─────────────────────┤
│                     │
│   Value : 69.00     │
│             ‾       │
│                     │
│                     │
│                     │
└─────────────────────┘
```

The maximum measuring limit is given in the reagent technical sheet. If result is beyond this limit, it is recommended to dilute the sample or rerun the test.
CAUTION : in hyper-active samples having decreasing kinetic-type of reaction, total substrate can be consumed before first measure starts. (Shown by reading result close to zero, below the depletion limit). It is user's responsibility to interprete reading result taking into account this element.

Normal high : Normal High & Low values border the acceptable pathological range. It is also called the usual expected values. Flags will be shown on abnormal result.

```
┌─────────────────────┐
│    Normal high      │
├─────────────────────┤
│                     │
│   Value : 54.00     │
│             ‾       │
│                     │
│                     │
│                     │
└─────────────────────┘
```

{ XE "Normal high" **}**

Normal low:

```
┌─────────────────────┐
│    Normal low       │
├─────────────────────┤
│                     │
│   Value : 38.00     │
│             ‾       │
│                     │
│                     │
│                     │
└─────────────────────┘
```

{ XE "Normal low" **}**
CHECK FREQUENCY:
 At the end of programming, you are asked the frequency of analysis quality control checking : whether daily or periodically. A signal will remind you to do the quality control every day or once every x days. Result of the QC can be found at « CONFIGURATION », « QUALITY CONTROL », and you can ask for « DISPLAY ».

BASIC

8.2 RECOMMANDATION FOR DAILY ANALYSIS

Zero measurement will be asked at the beginning of each day.
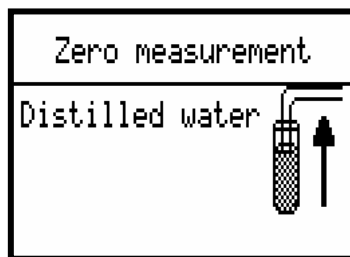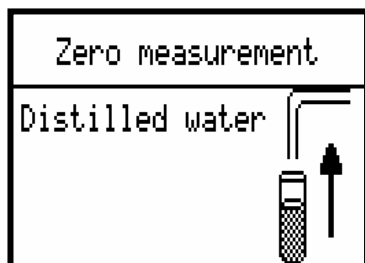
SAMPLE ASPIRATION :
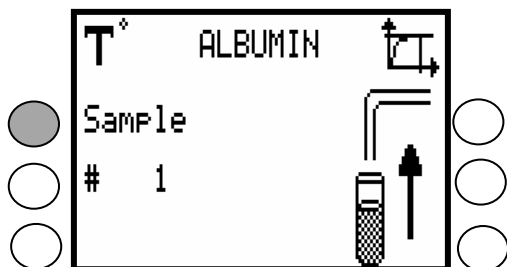
Introduce tube to the noozle upon instructed by display. Audio beeper indicates aspiration. **Remove tube as soon as aspiration ceased**. Resume with next sample simply by introducing the tube.
In case of aspiration detector failure, use F1 button to start aspiration.

MODIFICATION OF STANDARD VALUE :
Standard concentration value can be modified during analysis.
SINGLE STANDARD : use F3 « MODIFY ».**{**XE "Single standard"**}** Enter new standard value.
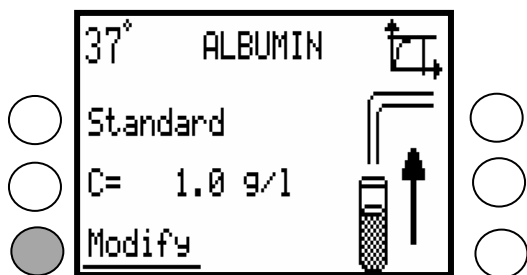
MULTI-STANDARDS : **{** XE "Multi-standard" **}**

Confirm whether standard values to use are as programmed (« OK ») or remeasurement are to be done (« Repeat »).

If you confirm the latter, you will see :

```
37°    ESTRADIO    ⌐⌐,

S1: 0.100 │ S4: 0.700

S2: 0.200 │ S5: 0.900

S3: 0.400 │ S6: 1.000
```

Modification of each standard value can be done through the corresponding F button.

```
     Standard 3

  Value : 3.00
```

...alues on display are correct, validate.
...ise modify using numerical keys, then
...e.

```
37°    ESTRADIO    ⌐⌐,

Reagent Blk
```

Start with reagent blank reading. This will be deducted automatically from other readings :

Measuring results will be displayed as :

```
    ESTRADIO    ⌐⌐,

   0.00 pg/ml

Reagent Blk    0.100A
```

```
T°   ESTRADIO   ⌐⌐,

Standard

Nr 1
```

```
37°   ESTRADIO   ⌐⌐,

Standard

Nr 2
```

The standards will be called one after another to establish standard curve to calculate sample values.

```
┌─────────────────────────────┐
│ 37°   ESTRADIO        ⌐┐     │
│                             │
│ S1: 0.100 │ S4: 0.400       │
│ S2: 0.200 │ S5: 0.500       │
│ S3: 0.300 │ S6: 0.900       │
│                             │
│ Repeat?              OK     │
└─────────────────────────────┘
```

As soon as the standards are read , the curve will be displayed. Absorbance values of standards are also displayed.

By validating F6 « OK », the values are stored in memory.

8.3 ERROR MESSAGES

```
┌─────────────────────────────┐
│ 37°   ALCOHOL        ⌐┐      │
│                             │
│                             │
│                             │
│                             │
│ Reagent Blk      -.---      │
└─────────────────────────────┘
```

{ XE "Error messages" **}**
Sample absorbance value is superior to 2,5 (above the reading limit of BASIC) : in this case the software will show « -,--- ». Check any possible manipulation errors : the sample not prepared correctly or the cleanlinest of the cuvette.

```
┌─────────────────────────────┐
│ 37°   ALBUMIN        ⌐┐      │
│                             │
│  NQ    5.0 g/l     <        │
│                             │
│                             │
│ Sam. #   1       0.500A     │
└─────────────────────────────┘
```
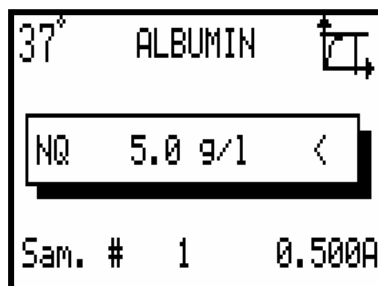
The result in Concentration is superior or inferior to the normal (high or low) value. In this case, a sign « < » or « > » will be displayed following the result. Negative Concentration value will be indicated by the sign −.

The result in Concentration is no longer in the linearity limit of the analysis : another sign « < » shows up in front of the result (in this case the result is also beyond the normal high or low range).

Non executed quality control procedure will be signaled by « Q».

```
┌─────────────────────────────┐
│ 37°   ALBUMIN        ⌐┐      │
│                             │
│  NQ    5.0 g/l     <        │
│                             │
│                             │
│ Sam. #   1       0.500A     │
└─────────────────────────────┘
```
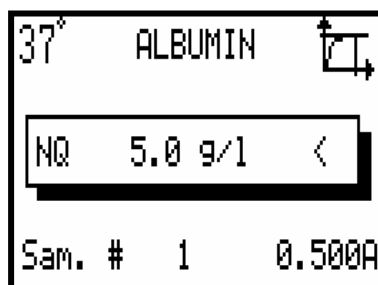
During decreasing kinetics method, if the difference of Optical Density between the initial O.D. at T0 and at T1 (end of the latent time) is superior to the depletion limit, the software does not display any result.

If the initial O.D. value of the blank is superior or inferior to the limit , a warning sign appears following the concentration result.
If the Quality Control value is beyond the specified limit, the sign « ! » appears in front of the Concentration result.
In case of Peltier failure Tsign appears instead of the temperature programmed.
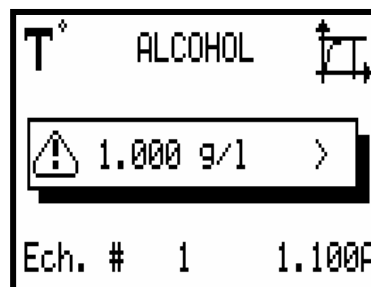
PATIENT REPORT & PRINT-OUT

PATIENT REPORT :
Daily analysis are memorized automatically by BASIC and indicated at the bottom of the result display as a blinking line. User is recommended to empty the memory at the end his working session.
This can be done by :

transferring all data to print (see chapter 5.6.2.) or
downloading all data to file on a PC (see chapter 5.6.1.) or
selecting particular data to print (see chapters 5.6.2 & 5.6.3.). In this case, remember to use patient number as selection criteria. Note : the latest of sample bearing identical number will be reported.

{XE "Print out"**}**
When quality control is programmed, error messages will be given on « status » column.

SECOMAM - Polyphotometer UV-Vis BASIC V1.11
Date : 04/06/1997   Hour : 09H24

User :

Analysis : ALBUMIN   **37°C**

Sample	Abs.	Concentration	Status
Regeant Bl.	0.000	0.00 g/l	
Standard	1.000	1.00 g/l	
Control	0.900	0.90 g/l	**P B**

SECOMAM - Polyphotometer UV-Vis BASIC V1.11
Date : 04/06/1997   Hour : 09H24

User :

Analysis : ALBUMIN   37°C

Sample	Abs.	Concentration	Status
Reagent Bl.	0.000	0.00 g/l	
Std	1.000	1.00 g/l	
Control	0.600	0.60 g/l	**P B**
Control	0.990	0.99 g/l	**P B**
Control	0.990	0.99 g/l	**P B**
S . #	0.500	0.50 g/l	**<**
S . #	0.500	0.50 g/l	**<**
S . #	1.200	1.20 g/l	**<**
Std . #	2.000	2.00 g/l	**<**

When everything goes well OK will be indicated:

SECOMAM - Polyphotometer UV-Vis BASIC V1.11
Date : 04/06/1997   Hour : 09H24

User :

Analysis : ALBUMIN   37°C

Standard	Abs.	Concentration	Status
Bl. Reagent	0.000	0.00 g/l	
Sample	1.000	1.00 g/l	
Control	1.500	1.50 g/l	**O K**

8.4 SAMPLE NUMBERING

Sample numbers will be incremented automatically. However you can assign another number through F2 key. Example : Sample # 3 is to be modified. Press F2, and you will see Sample Nr.1 on the screen. Press **Del**ete and replace by the number you want using number keys.

9 MAINTENANCE

9.1 TECHNICAL CHARACTERISTICS

{ XE "Technical characteristics" }

PARAMETERS IN MEMORY	94
READING MODE	SIMPLE ABSORBANCE
	END POINT WITH SERUM BLANK
	END POINT WITHOUT SERUM BLANK
	REAL KINETICS
	KINETIC TWO POINTS
	BICHROMATISM
CALIBRATION	LINEAR / NON LINEAR
	6 STANDARDS
LIGHT SOURCE	HALOGEN LAMP
MONOCHROMATOR	HOLOGRAPHIC GRATING
DETECTOR	SILICIUM DIODE ARRAY
SAMPLE COMPARTMENT	DRY TEMPERATURE PELTIER SYSTEM
OPERATING TEMPERATURE	AMBIENT - 25 - 30 - 37°C
TYPE OF CUVETTE	FLOW-THROUGH µCUVETTE 30 µl 10 mm OPTICAL PATH
ASPIRATION VOLUME	PROGRAMMABLE, 500 to 1500µl
QUALITY CONTROL	MANAGEMENT OF QC RESULTS/MONTHS
POWER REQUIREMENTS	110 / 220V
INTERFACE	SERIAL RS232C AND PARALLEL
CERTIFICATION AND APPROVALS	ISO 9001 AFAQ N°1995/4102 - CE - EMC
LANGUAGES	MULTILINGUAL

10 MEMO

BASIC

Note down the analysis names you have modified.

SUBSTRATES			ENZYMES	
M1	M2	M3	M23	M24 ....
M4	M5	M6	M25	M26 ....
M7	M8	M9	M27	M28 ....
M10	M11	M12	M29	M30 ....
M13	M14	M15	M31	M32 ....
M16	M17	M18	M33	M34 ....
M19	M20	M21		
M22				

Note down the analysis names you have modified.

SUBSTRATES			ENZYMES	
Albumin	Alcohol	Ammonia	Acid Phosphat.	Alk. Phosphat. ....
Anti Thrombin	Bicarbonate	Bilirubin	Amylase	Apo-A1 ....
Calcium	Chloride	Cholesterol	Apo-B	Asat / GOT ....
HDL Choles.	LDL Choles.	Creatinine	Alat / GPT	Ck. NAC ....
Glucose	Iron	Magnesium	Gamma GT	LDH ....
RBC Magnesium	Phos. Lipids	Phosphorus	Lipase	Nucleotidase ....
T. Protein	Triglycerides	Urea		
Uric Acid				

11 GLOSSARY