prietest TOUCH

Biochemistry Analyser

USER MANUAL

User Manual Version
With Incubator 2.622A

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1. GENERAL INFORMATION

1.1. Warranty Information:

Each Instrument is completely tested and guaranteed for twelve months from delivery. The warranty applies to all the mechanical and electrical parts. It is valid only for proper installation, use, and maintenance in compliance with the instructions given in this manual.

ROBONIK will at its discretion repair or replace parts, which may be found defective in the warranty period. The warranty does not include any responsibility for direct or indirect personal and material damages, caused by improper use or maintenance of the instrument.
Parts that are inherently subject to deterioration are excluded from the warranty. In case of defects due to misuse of the instrument, any travel and man-hour expenses will be charged extra.

1.2. Technical Service:

ROBONIK is always accessible to the customers for any kind of information about installation, use, maintenance, etc. When asking for service, please refer to this manual, and report the data reported on the identification label (serial number).
Only qualified technicians are entitled to fix the instrument; the user, as described in this manual, should carry out ordinary maintenance.
ROBONIK technical service or an authorized service center with specialized technicians, with suitable instrumentation and original spare parts only are always available for extraordinary maintenance (repair), under a yearly maintenance contract or on specific demand.

1.3. Disposal Instruction:

In case of removal or disposal of instrument, following instructions need to be followed

- Do not dispose in municipal waste; follow local regulations for instrument disposal.
- Plastic parts, Electronic PCBs and components can be recycled, so return back the instrument to manufacturer.

1.4. Contacts:

Manufacturer:

ROBONIK (INDIA) PVT LTD
A-374, TTC, MIDC Industrial Area,
MAHAPE, NAVI MUMBAI -400710
INDIA

Tel: +91-22-67829700,
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2. GENERAL SAFETY WARNINGS

2.1. Danger – warnings symbols:

The following symbols are used to inform the user of the safety rules.

This symbol indicates generic danger. It means that, serious damage can occur to the operator if described precautions are not observed.

This symbol indicates HIGH ELECTRIC VOLTAGE. It is dangerous to touch any part having this label. Only qualified operators can access these components, after unplugging the instrument from the Supply.

This symbol indicates that the instrument involves the handling of samples, which can be infected (urine or human serum). In this condition, infection or contamination might occur. Pay attention to the general safety warnings when in presence of such biological substances. Use Protective clothes, gloves and glasses.

This symbol in the user manual indicates that damages to the instrument or erroneous results could occur if the given warnings are not followed.

This symbol indicates a portion, which is particularly important, and should be studied carefully.

This symbol indicates a Protective Earth or Ground terminal.

General Symbols

Symbol for “Manufacturer”

Symbol for “ IN VITRO DIAGNOSTIC MEDICAL DEVICE”

Symbol for “AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY”

2.2. Use of the instrument:

- The instrument has to be used for the designed purposes under specified conditions, following proper procedures and safety rules, by qualified personnel.
- **THIS MANUAL CONTAINS INSTRUCTIONS FOR OPERATION BY QUALIFIED PERSONNEL.**
- A qualified user has to make sure that environmental condition is suitable, the installation is correct, the use and maintenance are proper, according to the general safety rules as well as to the particular precautions described in the manual. (However, he is not entitled to repair the instrument).
- A qualified technician is entitled to maintain and fix the instrument, according to the instructions given, using the original spare parts. Maintain room temperature and Humidity as specified in the manual.
- The instrument has to be used as described in this manual. If it is not use the protection provided by the instrument may be impaired.
- Alterations to the instrument are prohibited. The user is liable for any improper modification to the instrument, and for the deriving consequences.
- Should the instrument need extraordinary maintenance, contact MANUFACTURER service or authorized service center. Specialized technicians who will be able to repair the instrument using original spare parts will carry out the maintenance**.**
- This IVD equipment complies with the emission and immunity requirements as per IEC61326 series.

- **Warning :** This equipment has been designed and tested to CISPER11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference."
- An advisory that the electromagnetic environment should be evaluated prior to operation of the device.

- **Warning :** Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded international RF sources), as these may interfere with the proper operation.

3. INTRODUCTION

3.1 DESCRIPTION:

prietest TOUCH is a programmable Biochemistry Analyzer with a user-friendly touch screen. It measures the optical densities of samples and it uses algorithm to calculate results, which are used for biochemical investigation. It is a photometer operating in the visible range. The instrument is an open photometer suitable for absorbance (optical density) measures as well as sample concentration determination. It has a user-friendly program and capacity of storing the programmed analytical methods and the QC results. It is intended for in vitro diagnostic use.

3.2. FEATURES:

- Effective temperature regulation system with Peltier controlled cuvette /flow cell block.
- Dual reading mode
- Robust system with built in stabilizer.
- Latest technology with battery back up for 250 tests with QC, more than 2000 results.
- Robust in built 20 Column Thermal Printer with 384 stationary heads.
- Unique circuitry for long lamp life.
- Reliable peristaltic pump with maintenance free operations.
- Sophisticated software for kinetic graph with built in delta calculation for saturated (high) samples from graphic display without diluting and rerunning the samples.
- Monochromatic, Bichromatic Measurement
- Multi Standard Calibration
- Patients ID entry.
- Editing of saved tests.
- Human machine user interface:
  Touchpad, Keypad
- Built in Incubator
- Levey Jennings and standard deviation graphs.
- Optional interface for External Printer
- Patient report with PID & Name
- Access to Test by Touch of Key

3.3. Technical specification of prietest TOUCH

Human Machine Interface	TOUCH PANEL / KEYPAD
Linear measurement range	0.000 to 3.000 Absorbance Units (A).
Photometric Accuracy	± 2% or 0.007 whichever is higher, from 0 to 1.5 A ± 3% from 1.5 A to 3.0 A
Drift	<0.007 A/hr
Photometric Linearity	2.2 A
Optical measurement	Photodiode
Filters Type of filter Wave Length Half Bandwidth Filter Selection	 Interference 340, 405, 510, 546, 578 and 630 nm & Two Optional 10nm ± 2nm Automatic by Stepper Motor.
Flow Cell Sipping Volume Flow cell Volume Sipping Mode	 300 to 1000 µl 18µl Automatic by specially designed Peristaltic Pump
Cuvette Volume	500 µl
Dry Block Incubator Number of cuvettes Temperature	 15 Test Tubes 37^0 C
Temperature of cuvette/flow cell Block Method Temperature	 By Peltier effect 25, 30 and 37^0 C
Light source	Tungsten Halogen
Warm up Time	90 Sec
Display	5” Graphic LCD, Negative Blue, STN
Printer	Built in thermal printer
Memory	64 KB – Non volatile RAM with Battery back up
Storage Capacity	250 Open tests, with 30 QC results / test (Normal and abnormal controls) and more than 2500 Patient results with patient ID (6 digits)
Analysis Mode	Absorbance Kinetic End Point Differential Ratio Fixed Time Coagulation
Concentration Calculation	By factor or by Standard
RS232 serial port	9600 baud, 1 start, 8 data, 1 stop, no parity bits
Power Wattage Voltage	 50 watts 115 – 230 Volts ± 10 %, 60 – 50 Hz
Operating Position	On horizontal, flat, rigid and vibration free surface
Operating Conditions Temperature Relative Humidity	 From + 18^0C to + 35^0C Up to 85 %
Storage Condition Temperature Relative Humidity	 From –10^0C to + 60^0C Up to 85 %
Enclosure	ABS Fire retardant
Size (cm)	30 X 38 X 13.5 (l X b X h)
Weight	5.5 Kgs. (Approx)

4. PACKING, TRANSPORT, AND STORAGE

4.1. GENERAL WARNINGS:

Instrument has to be decontaminated before packing for transportation.

4.2. PACKING:

Packaging is needed whenever the instrument is to be transported or shipped by courier or other means.
To pack the instrument follows the instructions below:

- Decontaminate the instrument as explained on decontamination chapter of this manual.
- Put the instrument into the original packaging box; Instrument has to be properly protected by plastic protective material. Put copy of safety clearance certificate (copy of Safety clearance certificate is attached at the end of this manual).
- Mark the package with address, instrument identification and warning labels .

4.3. INSTRUMENT TRANSPORTATION

The transportation of the instrument in unpacked condition must be limited within the room where it is used, to avoid damage.

4.4. STORAGE OF INSTRUMENT

Before storing the instrument for a long period, pack it carefully as described above and store indoors.

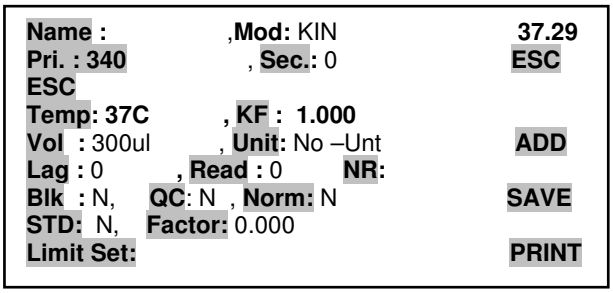
Relative humidity has to be less than 85%, and temperature between -10ºc and -60ºC.

5. INSTRUMENT DESCRIPTION

5.1. Touch Sensitive screen.

prietest TOUCH provides a *Touch sensitive LCD panel* and a *KEYPAD* for easy user interface. The Menus are displayed; the text of the parameter forms the TOUCH ZONE.

Touch screen Layout
For Example: In Kinetic Mode.



Above is the generic representation of a Test Screen. The Highlighted zones are TOUCH ZONES, which are active. On touching the “Touch Zone” of a parameter, a sub menu/menu is displayed or the requested action is carried out, and rest of the “Touch Zone” is deactivated.

For Example:- *To activate the selection.*

- *To enter the primary filter value*, touch any point in the shaded area “**Pri**” on the LCD screen. On proper selection the analyser responds with blinking of the parameter text and also the TOUCH ZONE and a submenu is displayed.

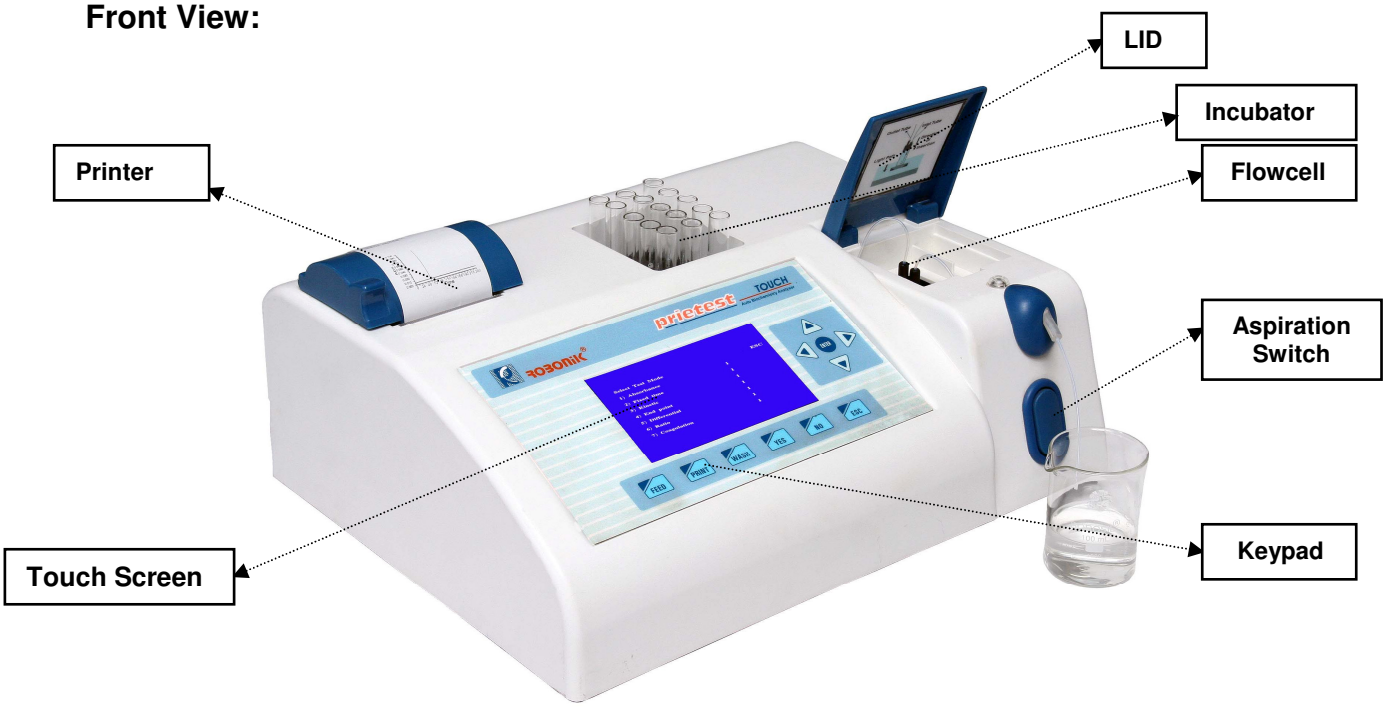
- *To enter Test Name:* Touching the “**Name**” touch zone provides a alphanumeric screen. Enter the Test name by touching the Touch zone of that variable. The selected value blinks and is displayed next to the parameter.

Selection Indicator

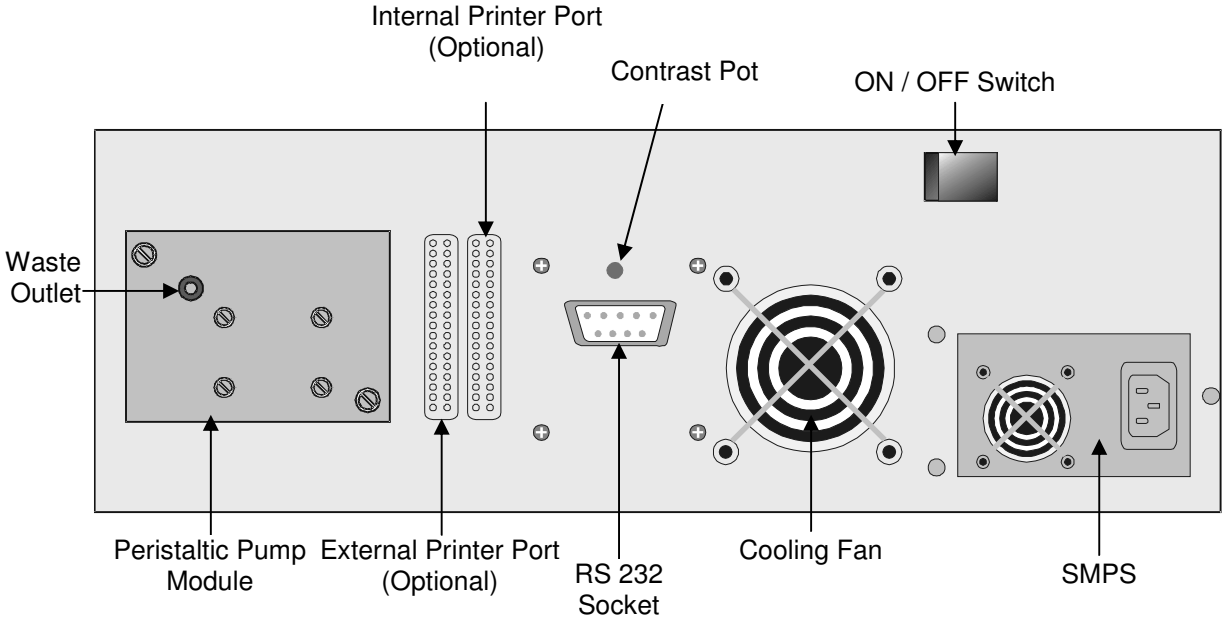
Selected onscreen item is shown in a shaded background. When the screen first displays, the default selection is shown. Pressing a selection either highlights that item or activates it.

5.2. Perspective view

Front View:



Rear View:



5.3. KEYPAD

The FEED key is used to advance the printer paper by 1 line.

PRINT key is used to take the print.

WASH key is provided for aspiration of liquid into the Flowcell and for washing flow cell.

YES key is display / program specific

NO key is display / program specific

ESC key is used for escaping

These are navigation keys for direct selections of tests.

ENTER Key

5.4. Probe

The instrument is provided with a probe to aspirate the sample into the flow cell. The push button (Aspiration Switch) has to be pressed to activate the peristaltic pump.

5.5. Peristaltic pump

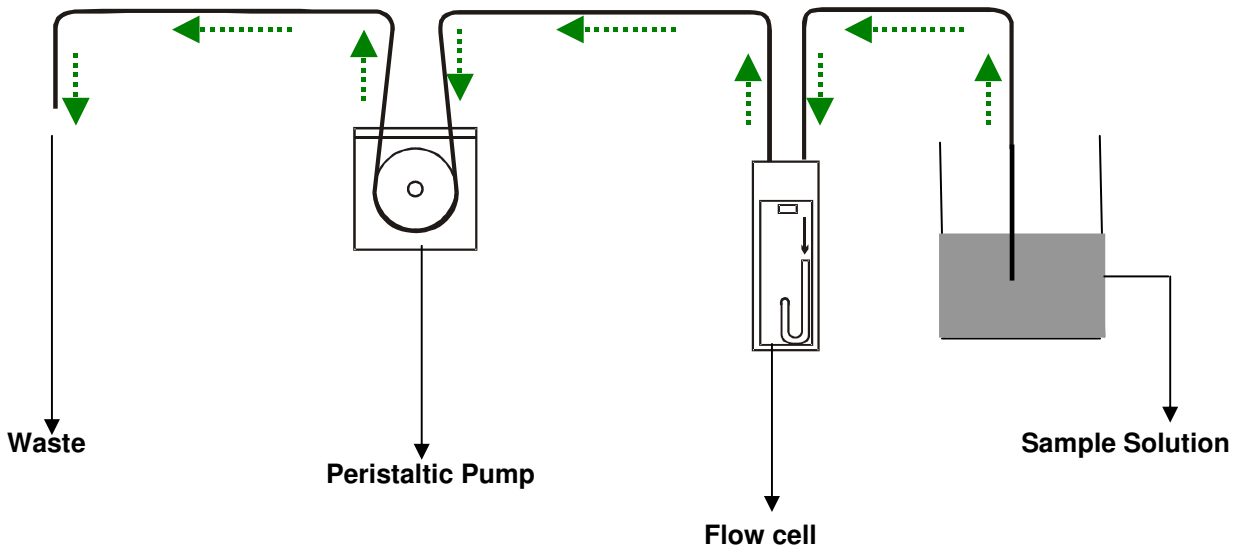
The instrument is provided with a peristaltic suction pump. The aspiration push button switch activates the peristaltic pump. The pump is enabled during wash and during "**Aspirate sample**" message

5.6. Instrument working principle

Instrument functional sequence:

- Switch on the instrument
- Program the test.
- Aspirate the sample into the flow cell
- The measures and the calculations are carried out according to the assay method

Following is the diagram representing the fluid system of the instrument. The peristaltic pump is activated by the push button located on the probe. The sample is sucked into the flow cell for the photometric reading

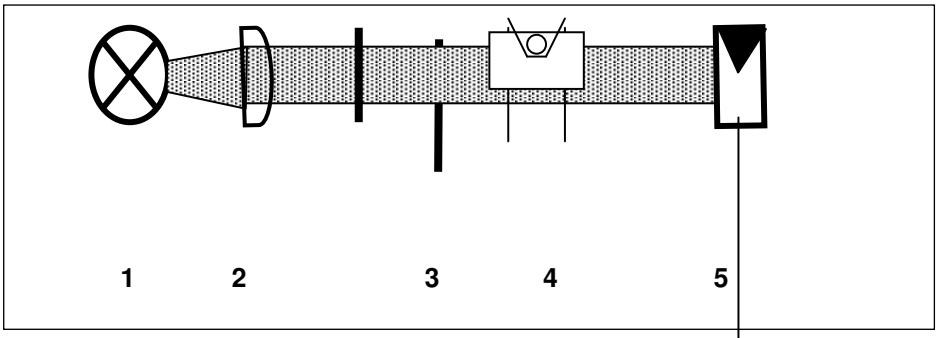


Direction of Arrows represents liquid flow

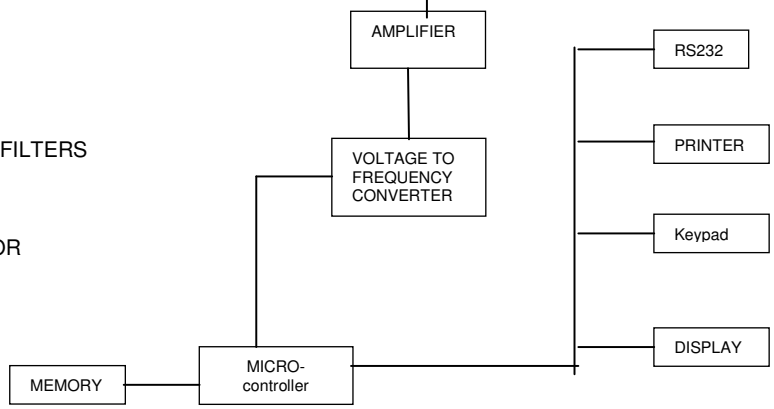
Sample is aspirated from the sample tube when aspiration switch is pressed. Aspirated sample is then carried to the flow cell, carefully pushing previous sample from the flow cell. Flow cell has 18µl reading volume.

PRINCIPLE OF WORKING :

Below is the diagram representing the main functional elements of the instrument.
White light produced by the lamp is focused into a beam by lens and passes through the interference filter and monochromatic light beam falls on the sample. Part of the light is absorbed by the sample, the remaining is transmitted. The transmitted light is focused onto the photodiode. The photodiode converts the received light in to an electrical signal that is transformed into digital form from which the microprocessor calculates the optical density, taking in account of the blank and bichromatic selection.



1 LAMP
2 LENS
3 INTERFERENCE FILTERS
4 FLOW CELL
5 PHOTODETECTOR



5.7. Printer

A)Internal Printer (Thermal Printer)

prietest TOUCH comes with a built in 20 column Thermal Printer. User has to take proper care to handle this delicate instrument.

TIPS FOR CAREFUL USAGE OF PRINTER

Do not pull the paper when loaded

1. Lift the paper lever carefully and load the paper
2. Keep the instrument clean and dust free

prietest TOUCH gives line feed automatically wherever it is necessary for clear reading like

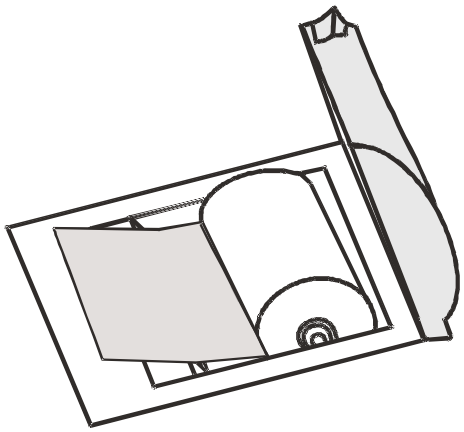
a. While powering on
b. In between character lines

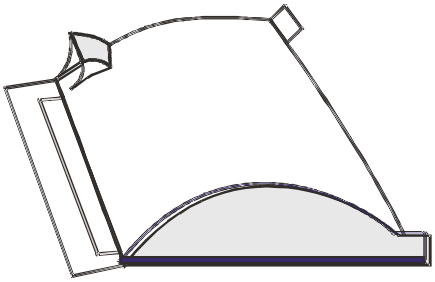
User may operate the instrument by disabling the printer from the utilities menu.

How to insert the paper

Insert the thermal paper roll by placing the sensitive side facing down. The sensitive paper side is recognizable by its smoother face.

Before inserting the paper **After inserting the paper**





B) External Printer (Optional)

Switch off the analyser before connecting the printer.

Disconnect the small cable from the external printer port (Ref Diagram in 5.3) provided on the rear of analyser. User can then connect the external printer using the standard communication cable to external printer port.

(Note : If an external printer is connected then the internal printer is disabled.)

6. Installation and start-up instructions:

While installing and setting up the instrument, the safety warnings and general precautions described in section 7 must be observed.

6.1. Placing the instrument

Place the instrument on a flat working surface or bench top capable of supporting the weight of the instrument. A clearance of at least 3 inches around the instrument is required to assure optimal ventilation. Room temperature should be between 18ºC and 35 ºC with a relative humidity below 85%. Protect it from direct sunshine and maintain the instrument in a clean, relatively dust free environment to ensure maximum performance.

6.2. Power supply

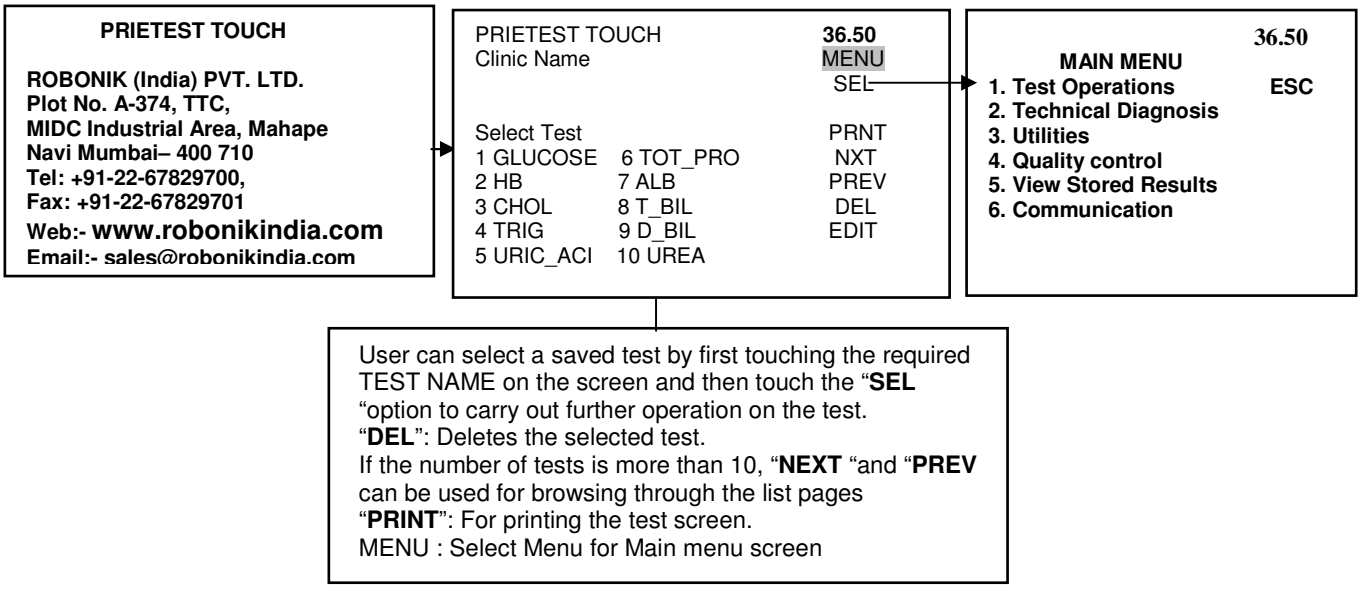
Once the instrument has been placed, plug it into a power source by using the locally available approved plug-in cable. Power cord should be CE, CSA and UL marked
Voltage : 115 - 230 Volts ± 10%, 60- 50 Hz

6.3. Protective Grounding

Warning: Make sure that electrical power source is properly grounded.

6.4. Start up Instructions

1. Switch on the instrument.
2. The instrument initializes all the parameters internally, and carries out a power on self-test and then displays the following screen



- If a printer is enabled, Model Name ,Version Number ,Clinic name / Serial Number ,current time and date will be printed .(Note: If a printer is not enabled, "Disable printer" message is displayed .Touch YES to disable or NO to proceed. Refer 5.7 for Printer settings)
- Once initialization is over, a lamp located within the instrument will glow. This lamp requires 90 seconds for stabilization.
- After the instrument completes the above steps, a TEST MENU SCREEN / MAIN MENU Screen appears.
- The instrument is now in IDLE mode, and ready for use.
- Note: If the instrument is in Flow cell Mode and flow cell is missing, "Insert flow cell" message will appear on the screen.

7. PRECAUTIONS

- λ **Keep the place dry and clean.**
- λ **Check all the grounding wires properly.**

Repeat the readings, if Absorbance is more than 2.0 A.

Use original Packing for transportation.

- λ **Use clean Cuvettes. Check the blank absorbance of the cuvette at regular intervals.**
- λ **Check the temperature of cuvette block at regular intervals, especially before running kinetic and fixed time tests.**

Check the linearity of the instrument at regular intervals using standards.

- λ **Do not take any reading when the lid is open**
- λ **Incubate the cuvettes at set temperature for at least 30 minutes before using**

- λ **Incubate the reagents at set temperature for at least 30 minutes before using**
- λ **Wash the flow-cell immediately after high OD samples (1.5 A and above)**

- λ **Normally, avoid reading HIGH OD samples immediately after referencing**
- λ **Wash the flow cell everyday morning before using and evening before closing down**
- λ **Do not use any sharp objects on the Touch Screen. Always use the STYLUS provided to operate the touch panel.**

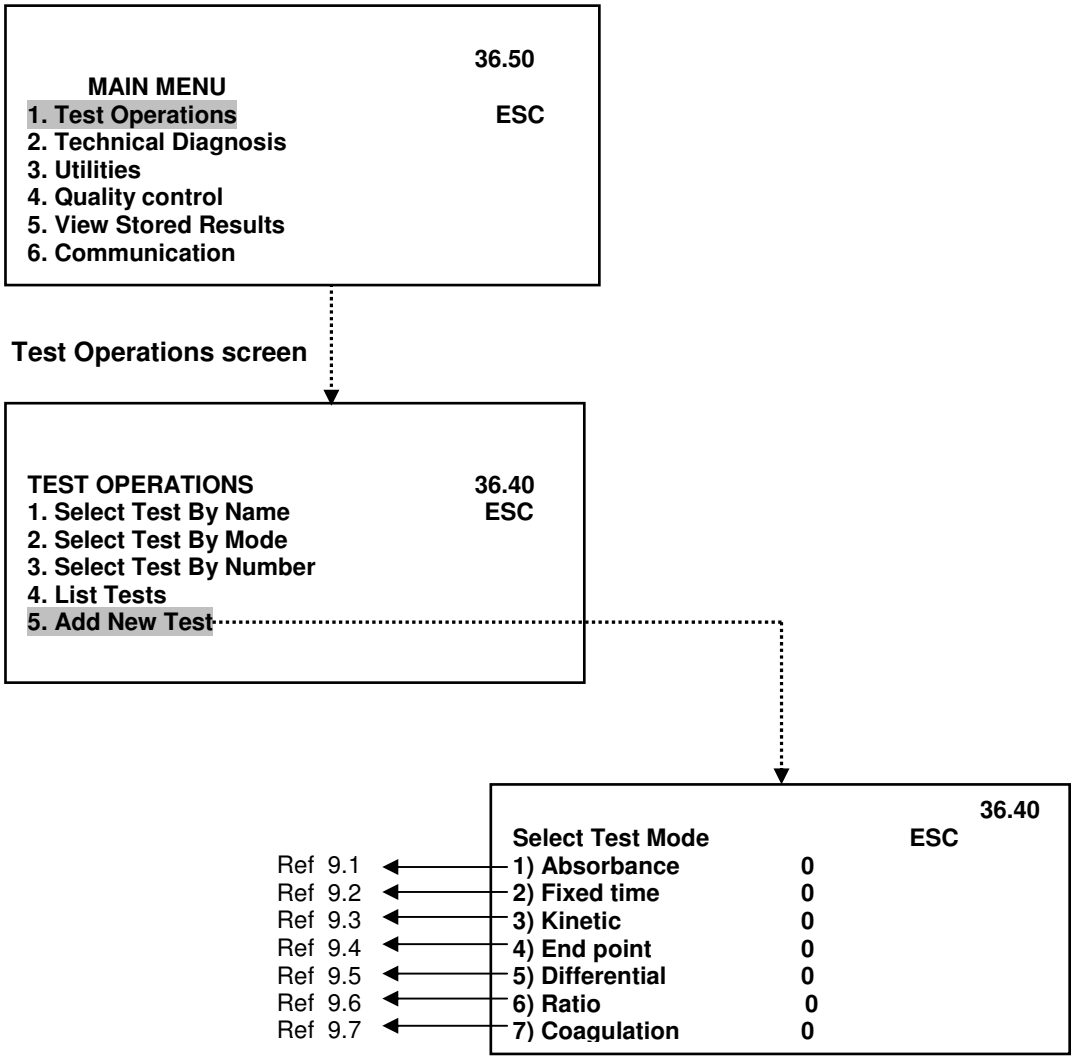
8. MAIN MENU

8.1. TEST OPERATIONS

A) Programming/ADDING a NEW TEST

When the unit is first turned on, **Test List screen** / **Main Menu Screen** appears on the display.

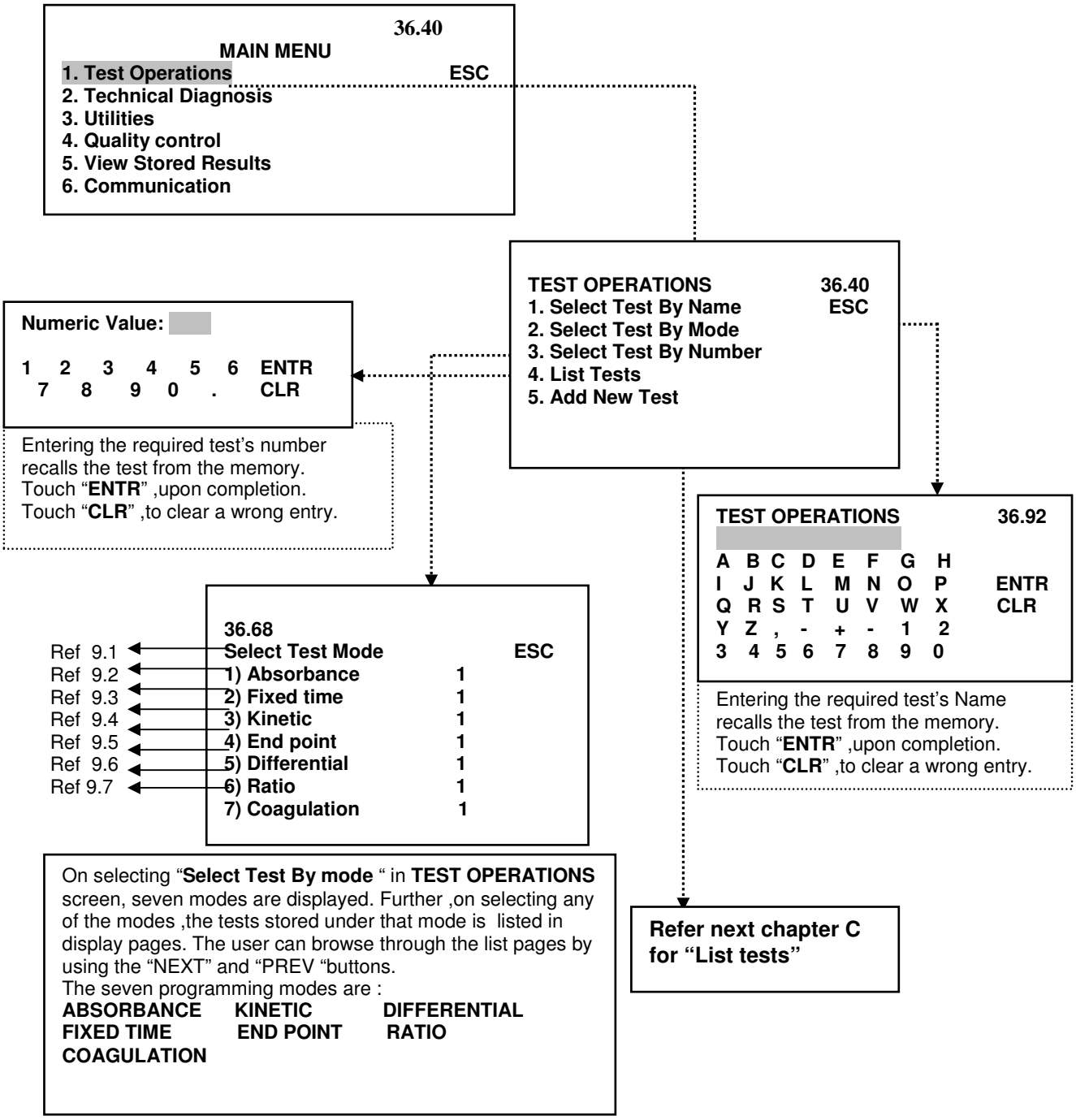
Main Menu screen



B) Recalling /Running a Saved TEST (Operating the programmed Tests)

The **Programmed/Saved** Test can be recalled/selected, either by **Name, Mode, Number or List Tests** When the unit is first turned on, **Test List screen** / **Main Menu Screen** appears on the display.

Main Menu screen

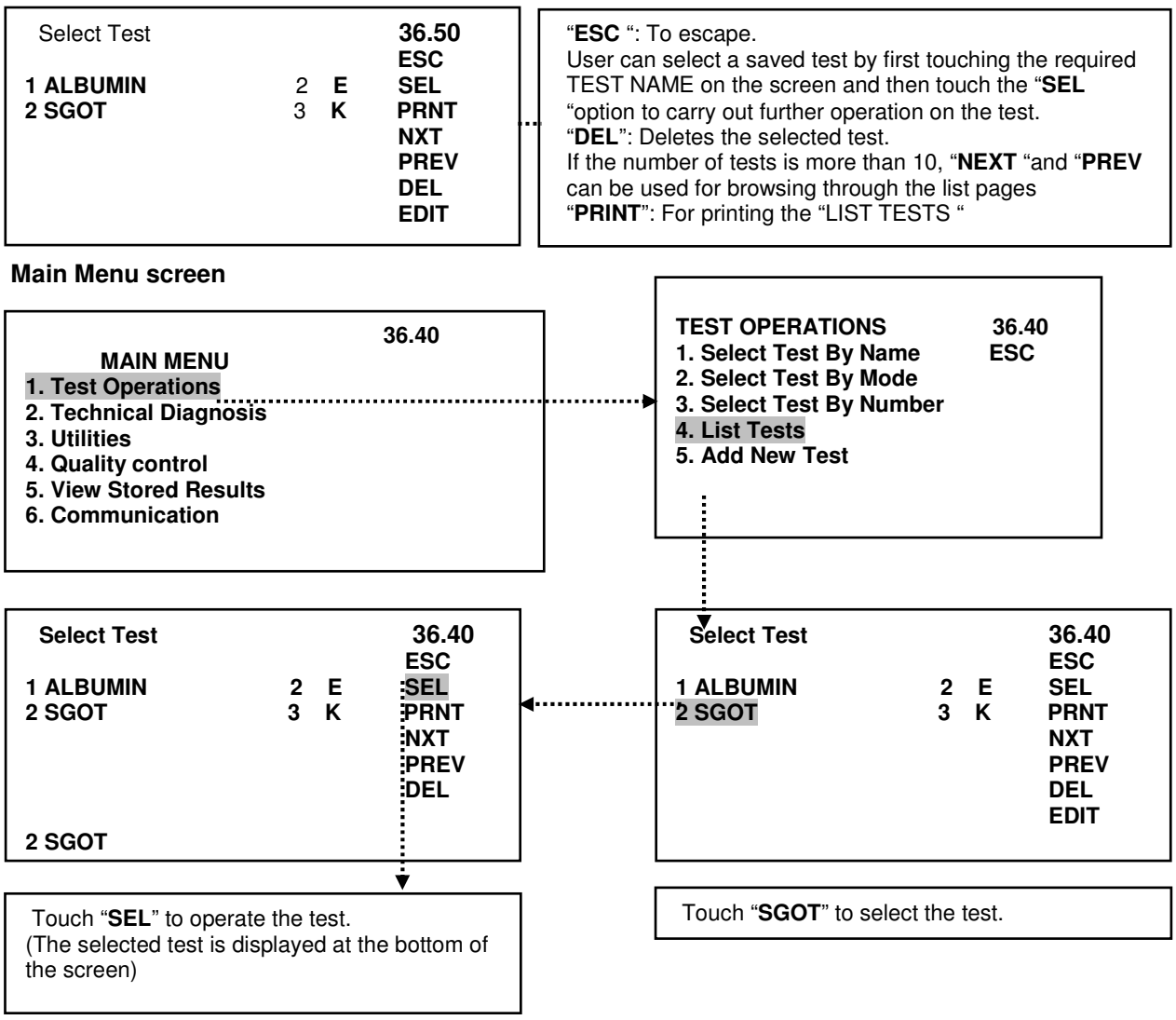


C) List Tests:

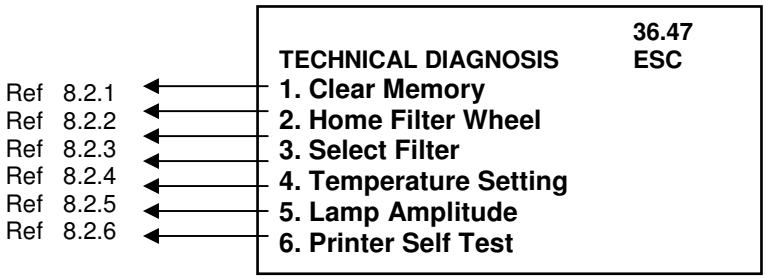
- Displays max. of 10 Tests/ Page .

A "**List tests**" screen would look like the screen shown below ,
First column : "**Test Number**", second column : "**Test Name**" ,Third column :Number of times the test has been run, and fourth column : "**Mode**" in which the assay is programmed (**K**-Kinetic, **A**-Absorbance-, **E**-Endpoint, **R**-Ratio, **D**-Differential, **F**-Fixed time.)

For example: **To recall/run a saved test** "SGOT"

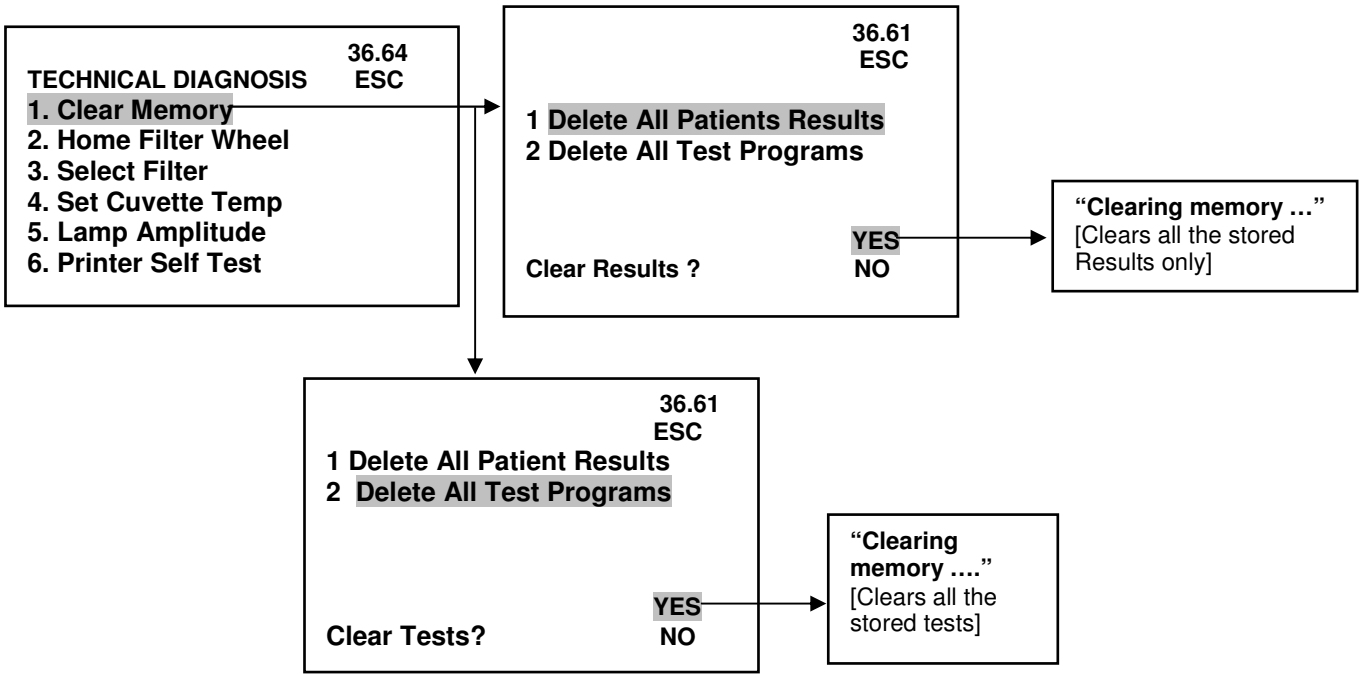


8.2. TECHNICAL DIAGNOSIS:

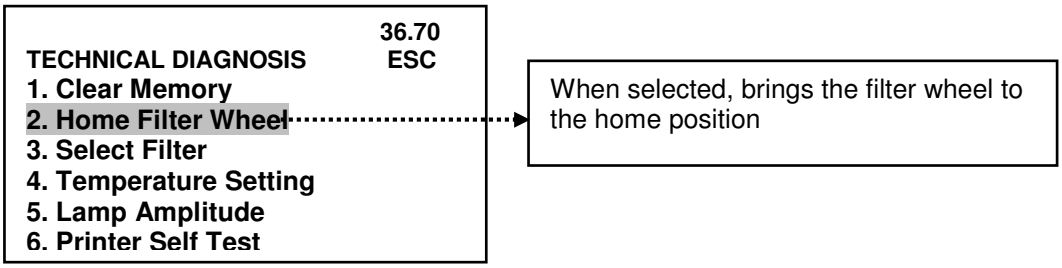


8.2.1. Clear Memory

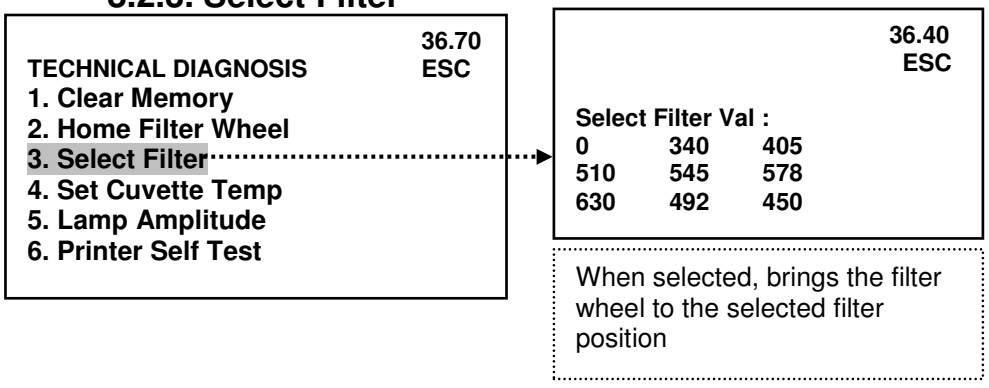
To clear memory. Tests and results are stored separately.



8.2.2. Home Filter wheel

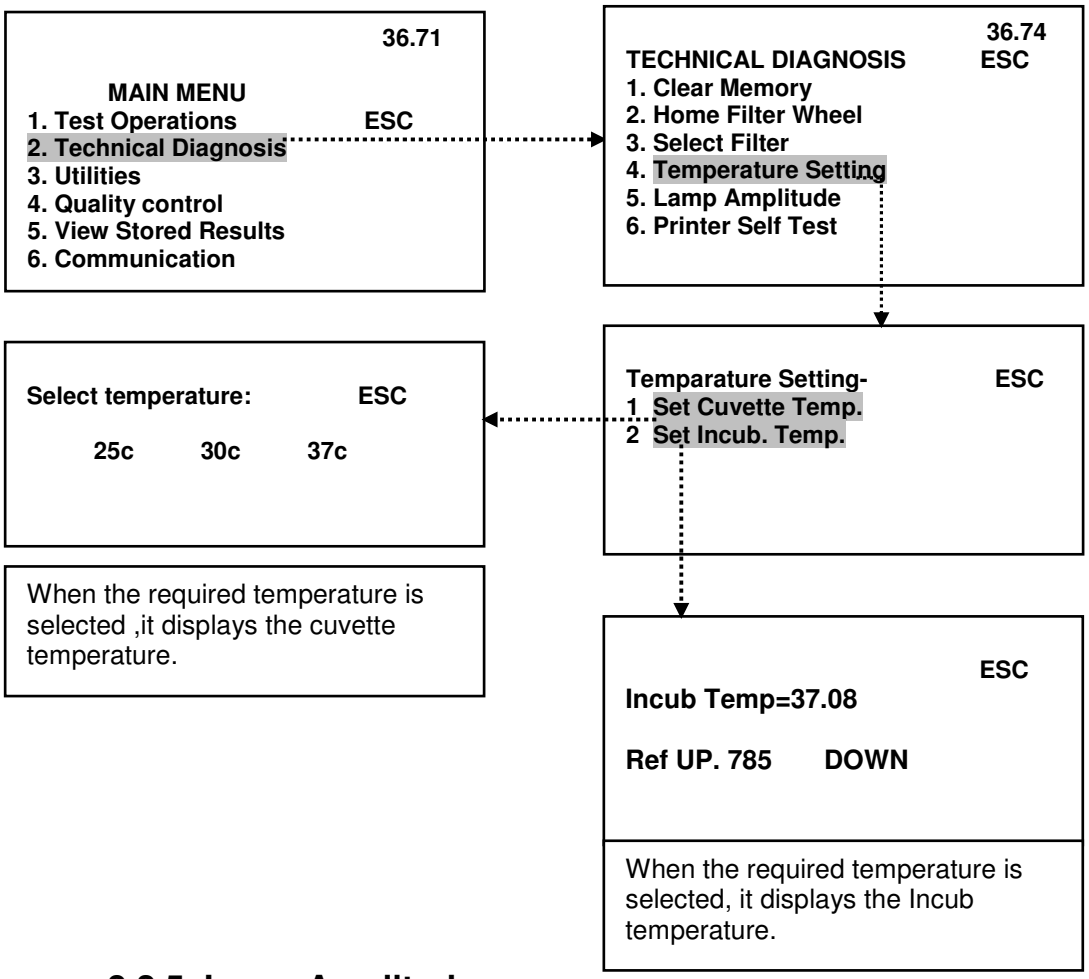


8.2.3. Select Filter



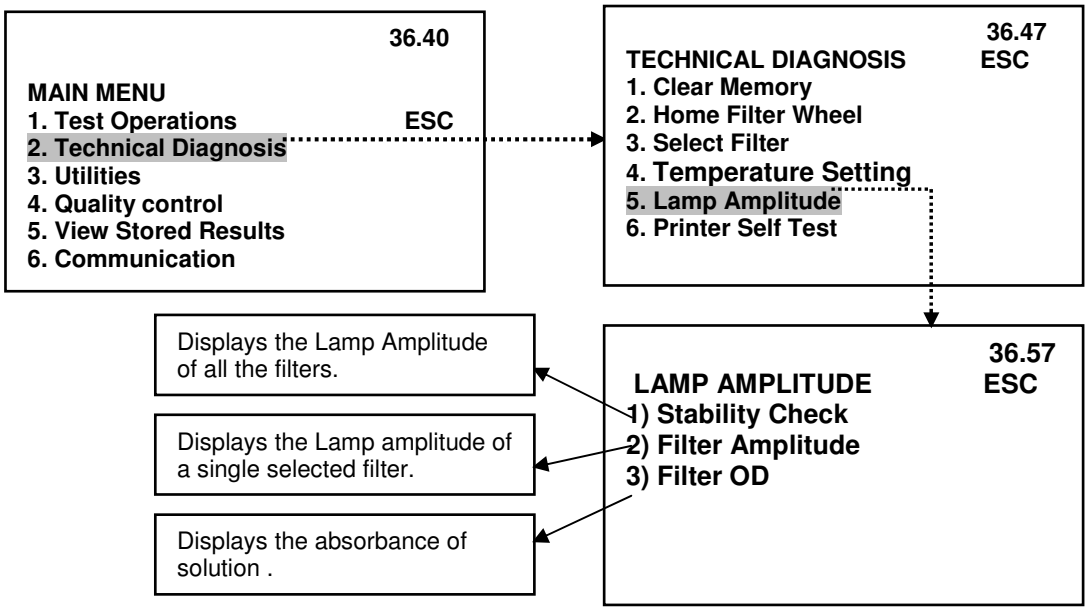
8.2.4. Temperature Setting

To verify the set temperature.



8.2.5. Lamp Amplitude

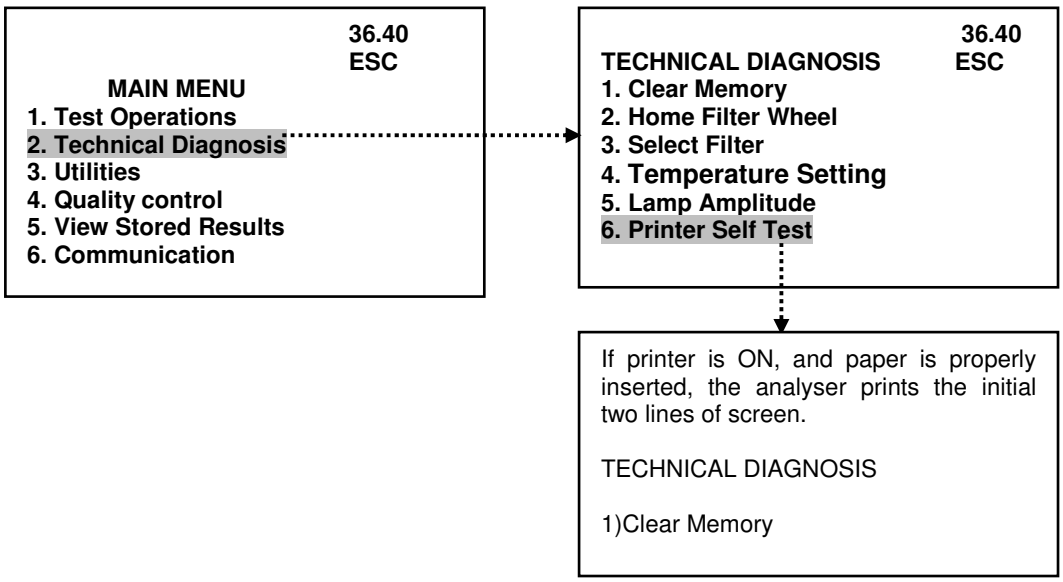
To check lamp amplitude of the filters



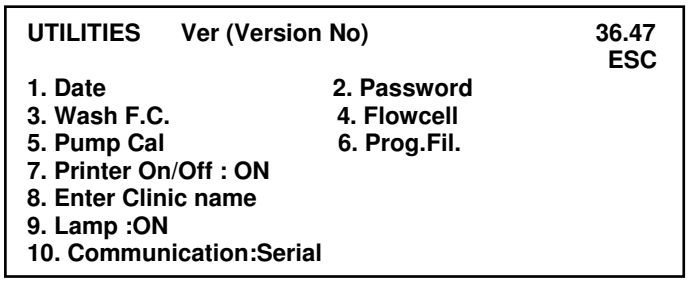
Note : The amplitude ideally should be in the range of 3.000 to 10.00 for all filters.

8.2.6. Printer Self Test

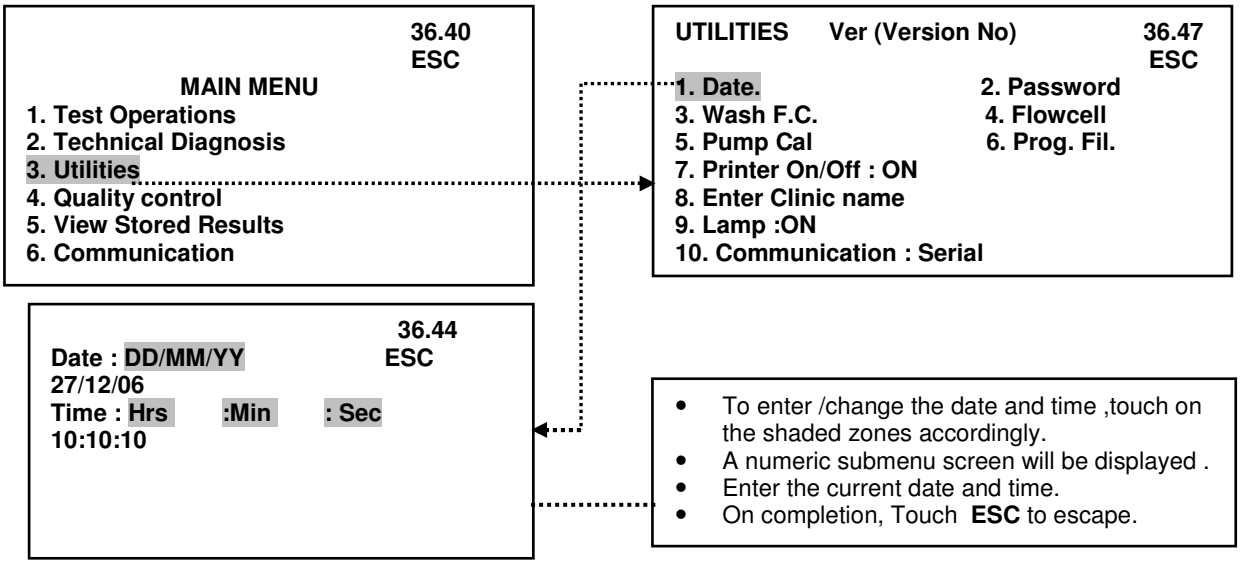
Routine test to check printer. When selected,



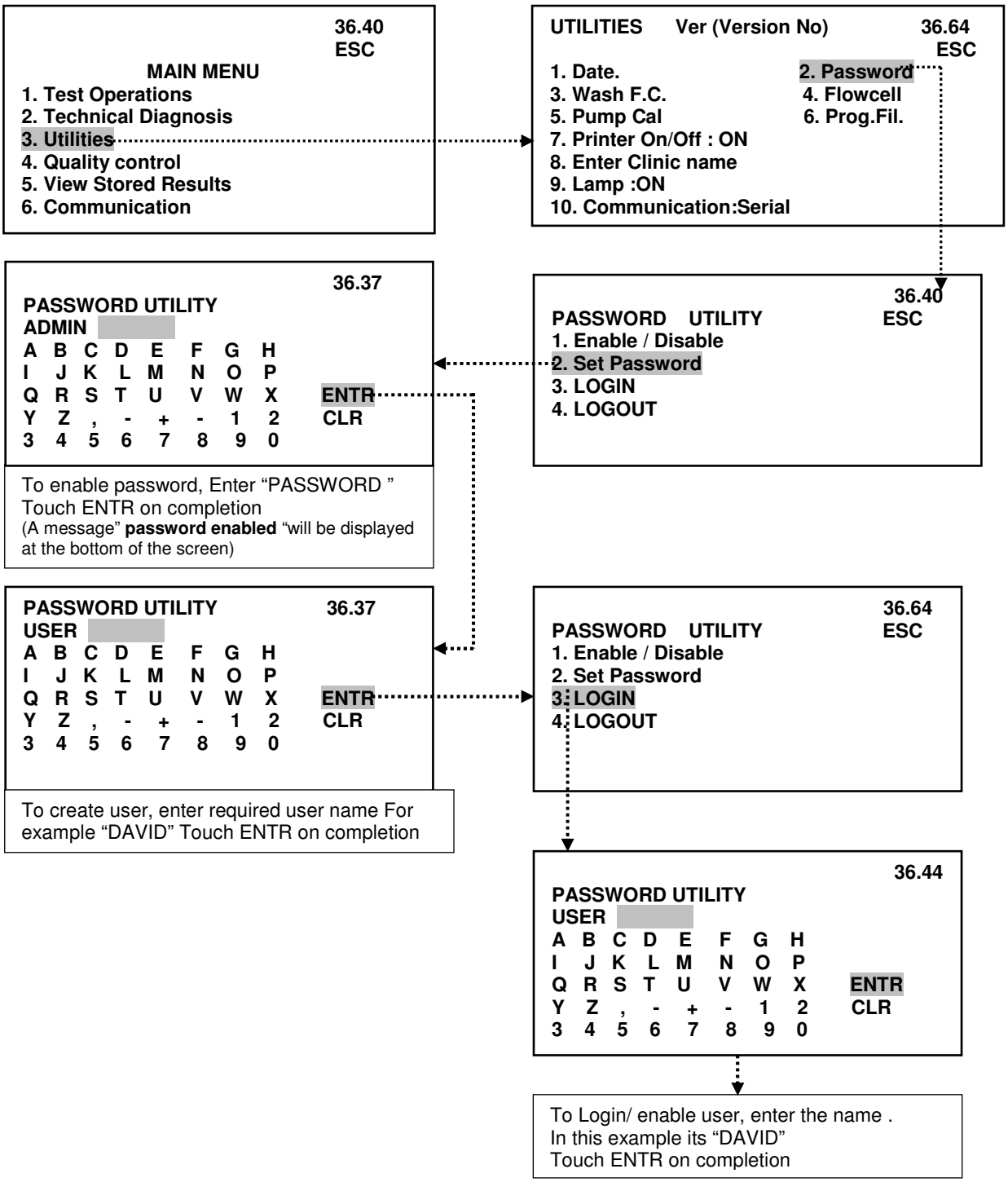
8.3. UTILITIES SCREEN



8.3.1. To ENTER/CHANGE Date and Time

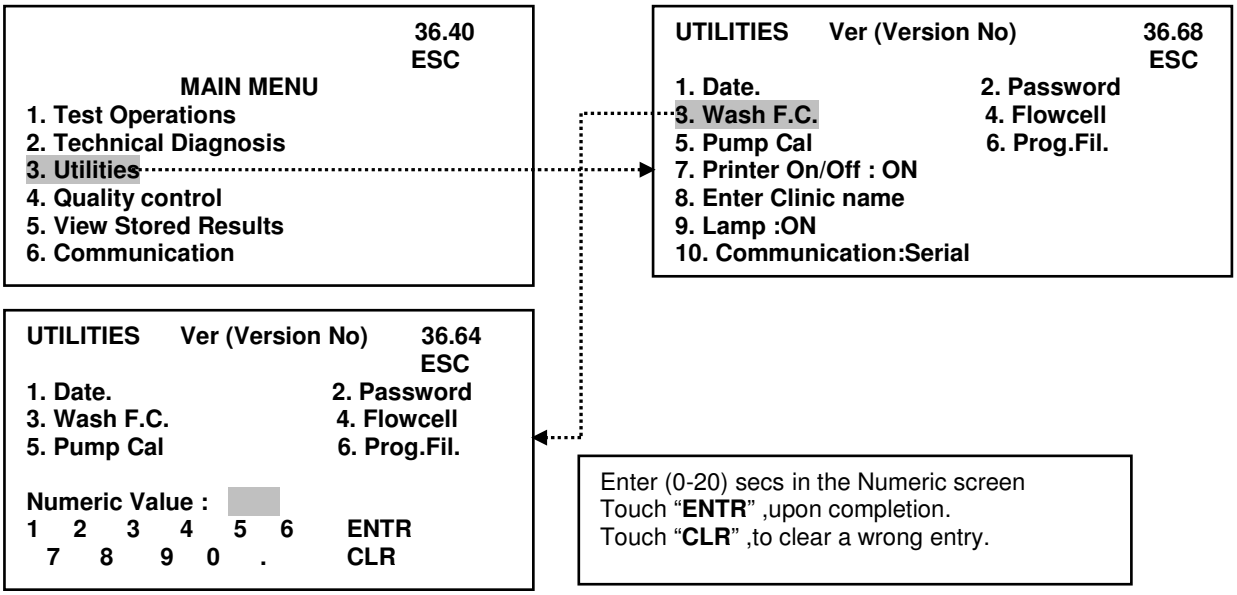


8.3.2. Password Utility



8.3.3 WASH F.C

Wash Flow cell is used to wash the flow cell .Selecting "**Wash F.C**" will allow the aspiration of water or cleaning solution in the Flowcell.

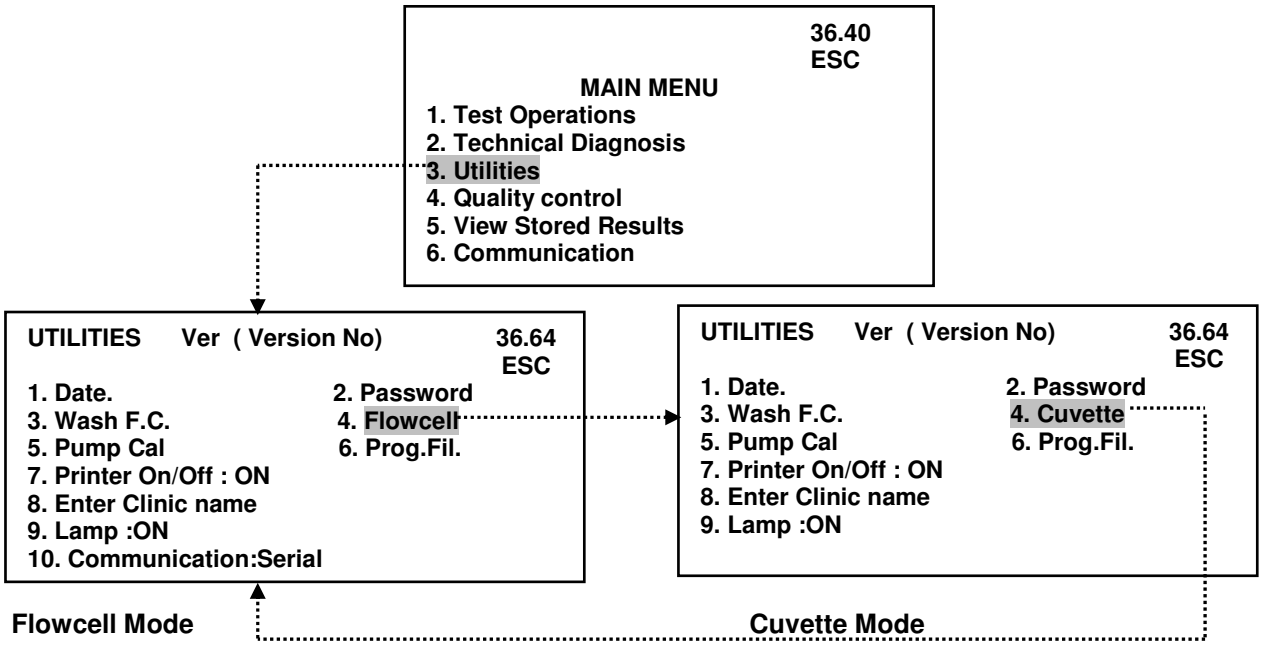


Enter (0-20) secs in the Numeric screen
Touch "**ENTR**" ,upon completion.
Touch "**CLR**" ,to clear a wrong entry.

8.3.4 Mode:

To Change Mode: Flow cell or Cuvette

It is possible with prietest TOUCH to use either the Flowcell or cuvettes to execute readings. The analyser is factory fitted with a Flowcell in the optical block. To operate the analyser with cuvettes select "UTILITIES" in Main Menu and change the mode accordingly.



In the above screen ,the analyser is in Flowcell Mode.
To change the mode to cuvette ,touch on "**Flowcell**" and then touch "**ESC**" to proceed

To change the mode to Flowcell, touch on "**cuvette**" and then touch "**ESC**" to proceed

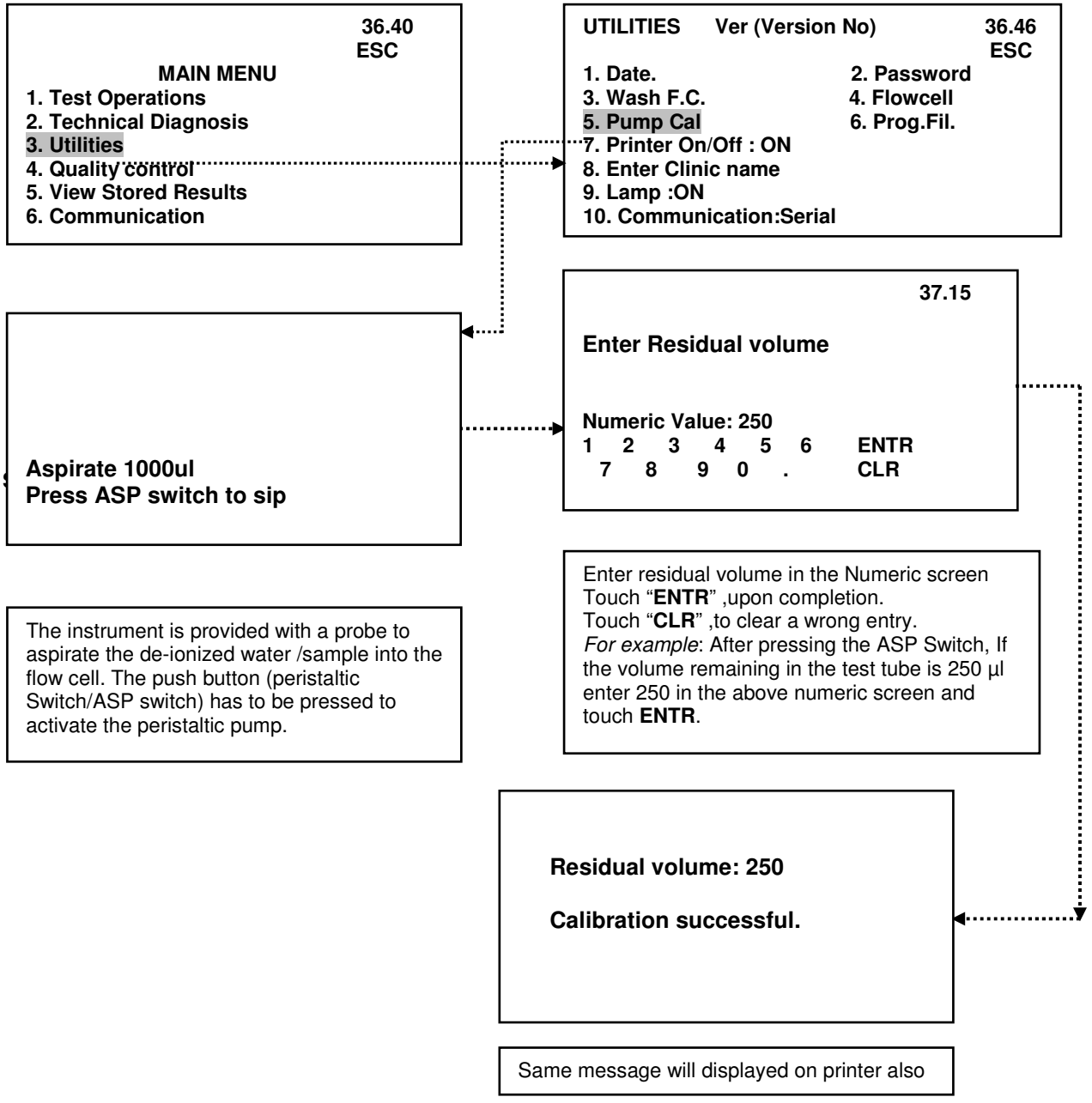
In Flowcell mode, automatic pump calibration is implemented. So while doing the pump calibration, only enter the exact measured residual volume out of 1000 ul. Don't enter any less or higher value than the residual volume. Refer to 8.3.5 for Pump Calibration.

8.3.5 Pump Cal:

The option of "**Pump Cal**" allows the operator to adjust the volume being aspirated through the Flowcell.
The adjustment of the peristaltic pump has two functions:
To adjust the volume of liquid aspirated into the flow cell. The volume of liquid must be enough to rinse Flowcell sufficiently, but not more than the reaction mixture;
To adjust the volume aspirated during a wash cycle
If the aspiration volume is too high, air will be sucked into the flow cell. If aspiration volume is too low, not enough liquid will flush the Flowcell. Whenever this occurs it is necessary to adjust the aspiration volume.

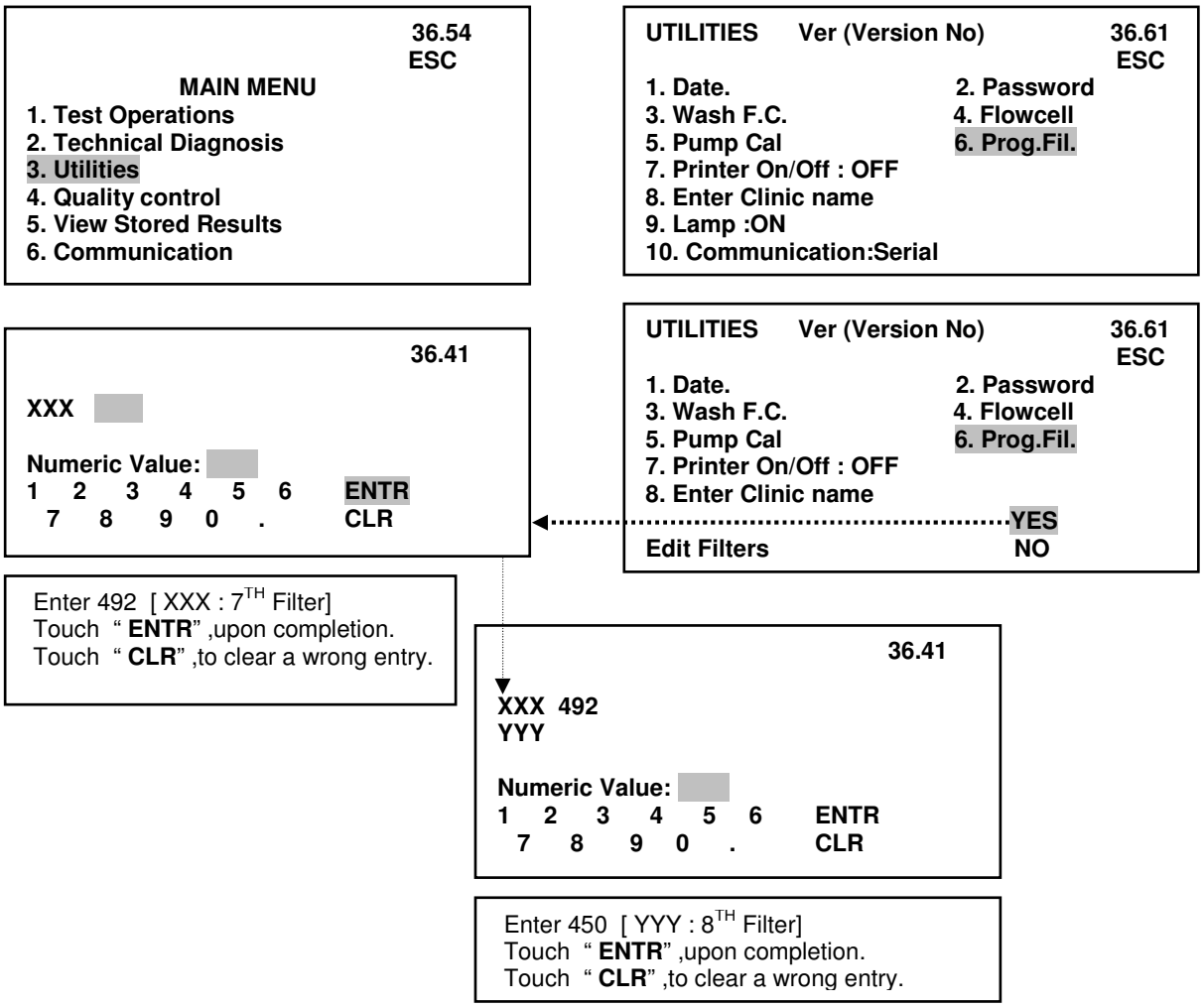
Step1: Go to utilities

Step2: Select "Pump cal"



8.3.6 Program Filter

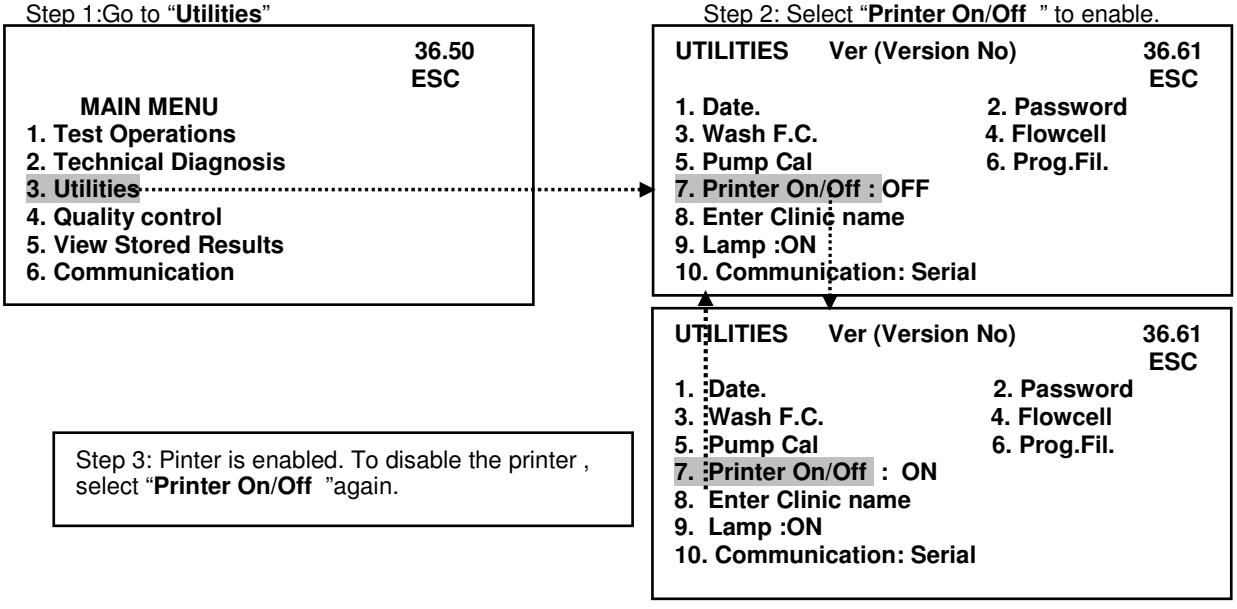
The option of "**Prog. Fil.**" allows the operator to enter the wavelength of the filters in 7th and 8th position. This option is to be used only in case of instruments where it is required to filters in 7th and 8th position. (7th and 8th Filter is optional)



8.3.7. To disable or enable the Printer

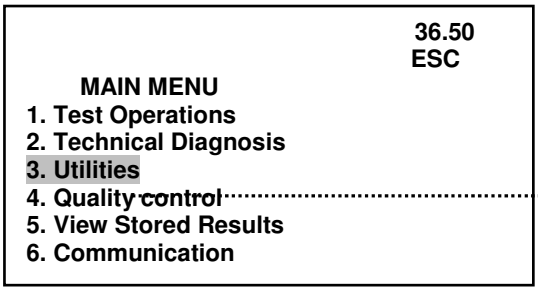
It is a toggle to disable or enable the printer.

(Toggle : Any instruction that works first one way and then the other; it turns something on the first time it is used and then turns it off the next time)

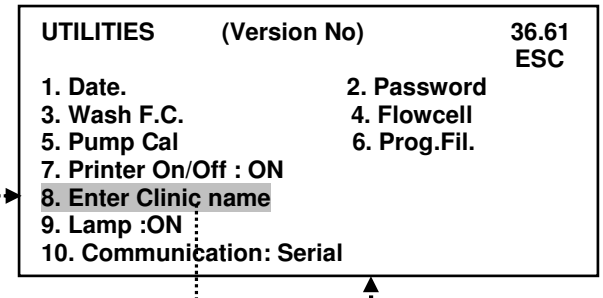


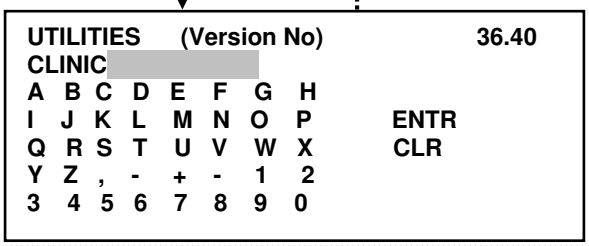
8.3.8 To Enter Clinic / Doctor Name:

Step 1:Go to "**Utilities**"



Step 2: Touch "**Enter Clinic Name**"





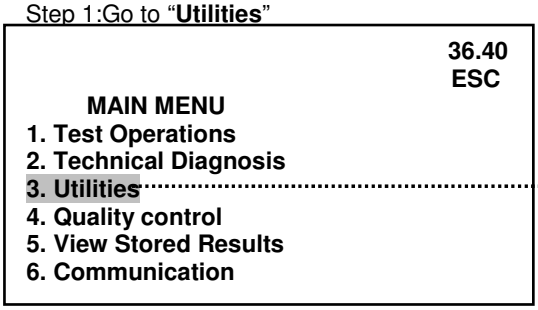
Enter Clinic Name(Mix-Up to 19 characters)
Touch " **ENTR**" ,upon completion.
Touch " **CLR**" ,to clear a wrong entry.

8.3.9 Lamp: ON

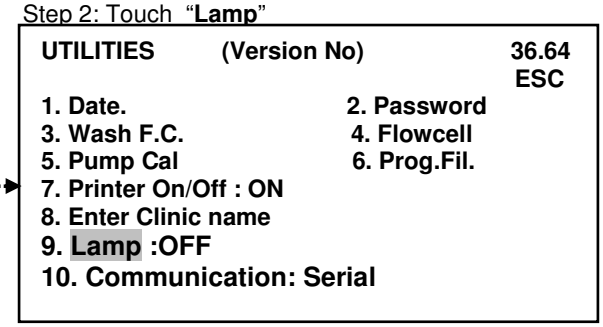
It is a toggle to switch the lamp ON and OFF.

(Toggle : any instruction that works first one way and then the other; it turns something on the first time it is used and then turns it off the next time)

Step 1:Go to "**Utilities**"

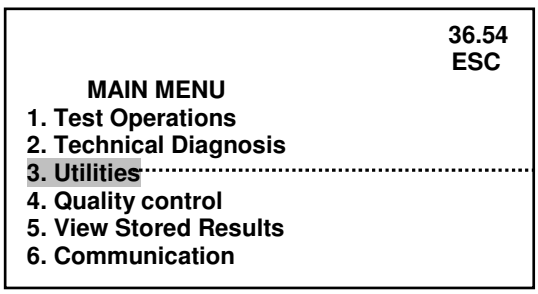


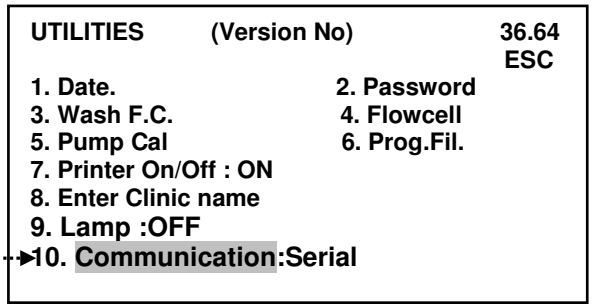
Step 2: Touch "**Lamp**"



8.3.10 Communication: Serial

With this option user can select the, medium of data transfer from instrument to computer either 'Serial' or 'USB'.

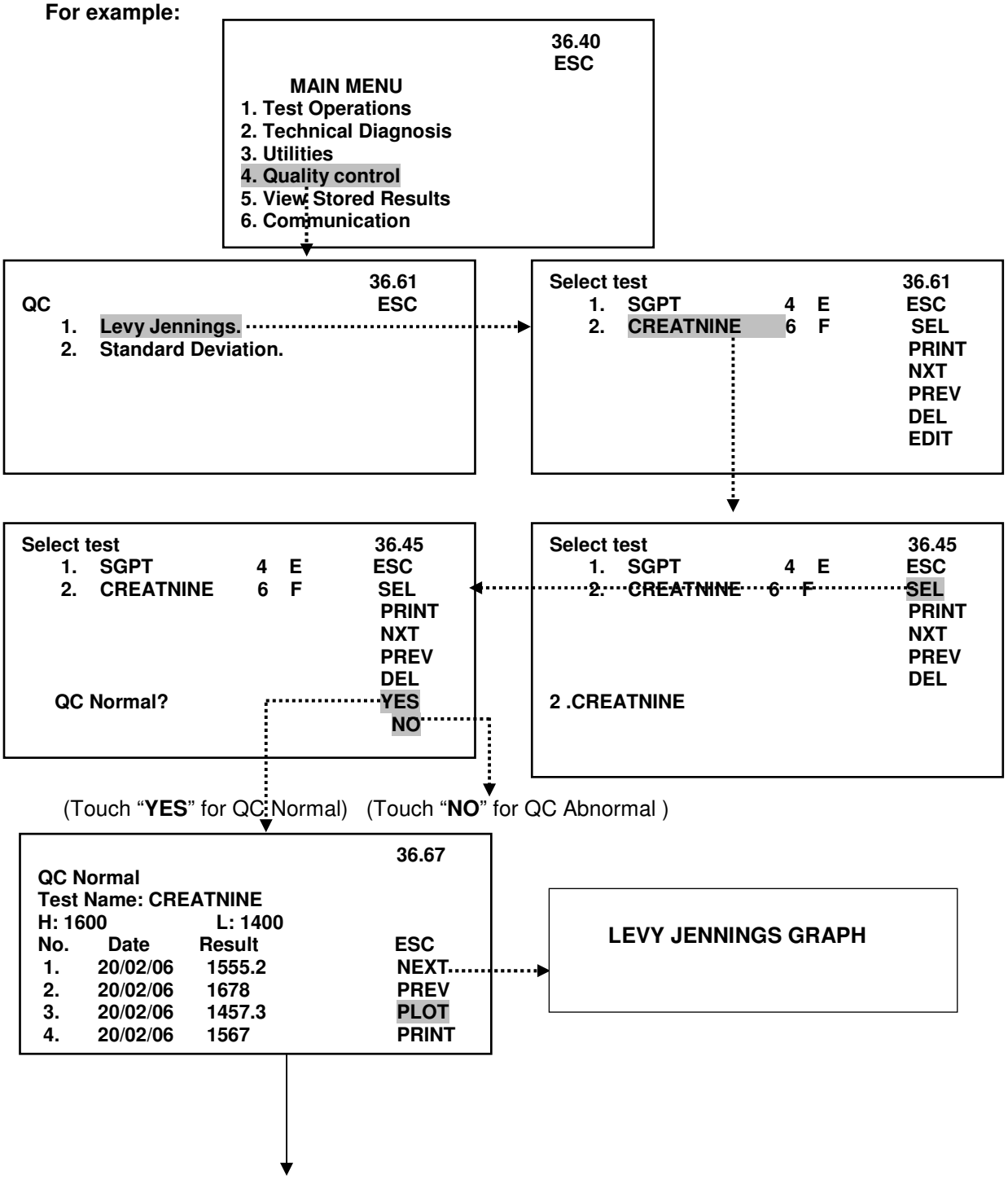


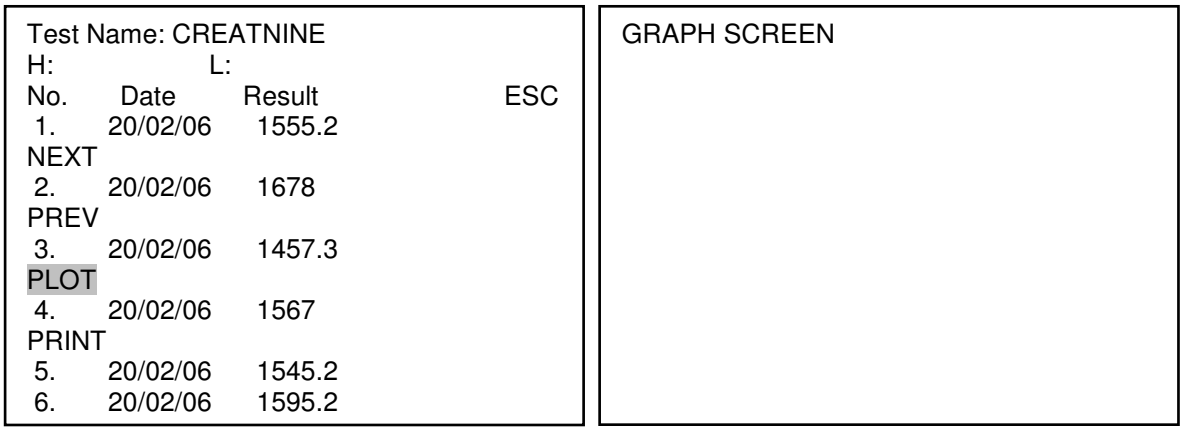


8.4. QUALITY CONTROL

Quality Control is a process that checks an instrument or testing site to make sure it is reporting accurate results on patients. The reproducibility of a result from a testing site or instrument should fall within a certain range. Control solutions of known values are often times used for checking quality control. An institution may choose how often control solutions are run depending on the accrediting body and test complexity the analyte falls under. Levy Jennings charts are often used identify problems with QC results.

A **levy Jennings** chart is a graph that quality control data is plotted on to give a visual indication whether a laboratory test is working well.
SD Standard Deviation : A measure of variability representing an average distance of the data from the mean. The greater the standard deviation, the greater the difference between the individual determinations and the less the precision of the method.
For example:

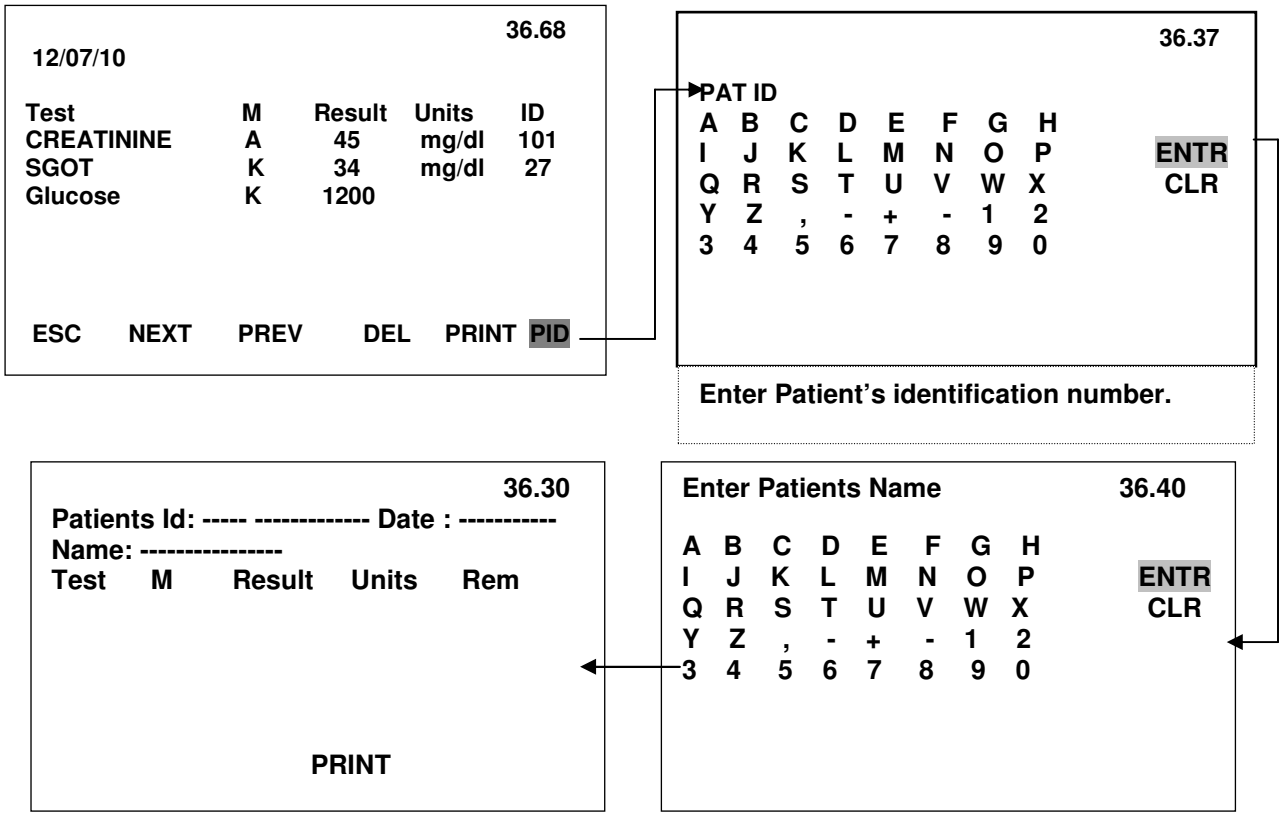




8.5. View Stored Results/ Print Patient Report.

Displays the latest10 stored tests results.

The system can store 1000 results in its database. The moment a sample is RUN, the result is stored in the system database. The variables stored in the database are as follows



- **"PRINT"**: Prints the Patient report with the patient name and identification number

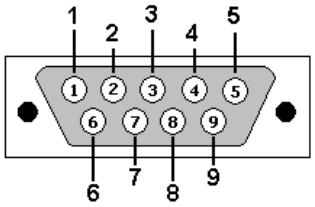
  Note: The patient's name and identification number (PID) can be entered up to six places

- **"DEL" :**To delete the selected result**.**
- **M: Mode** (2ND Column):**A-**Absorbance **, F-**Fixed time **,K-**Kinetic **,E-** Endpoint **,D-** Differential **,R**-Ratio

8.6. Communication:

The instrument is equipped with an RS232 serial port for PC configuration (user-computer interface.). A cable is available to link the instrument to PC

RS232 DB9 (EIA/TIA 574)

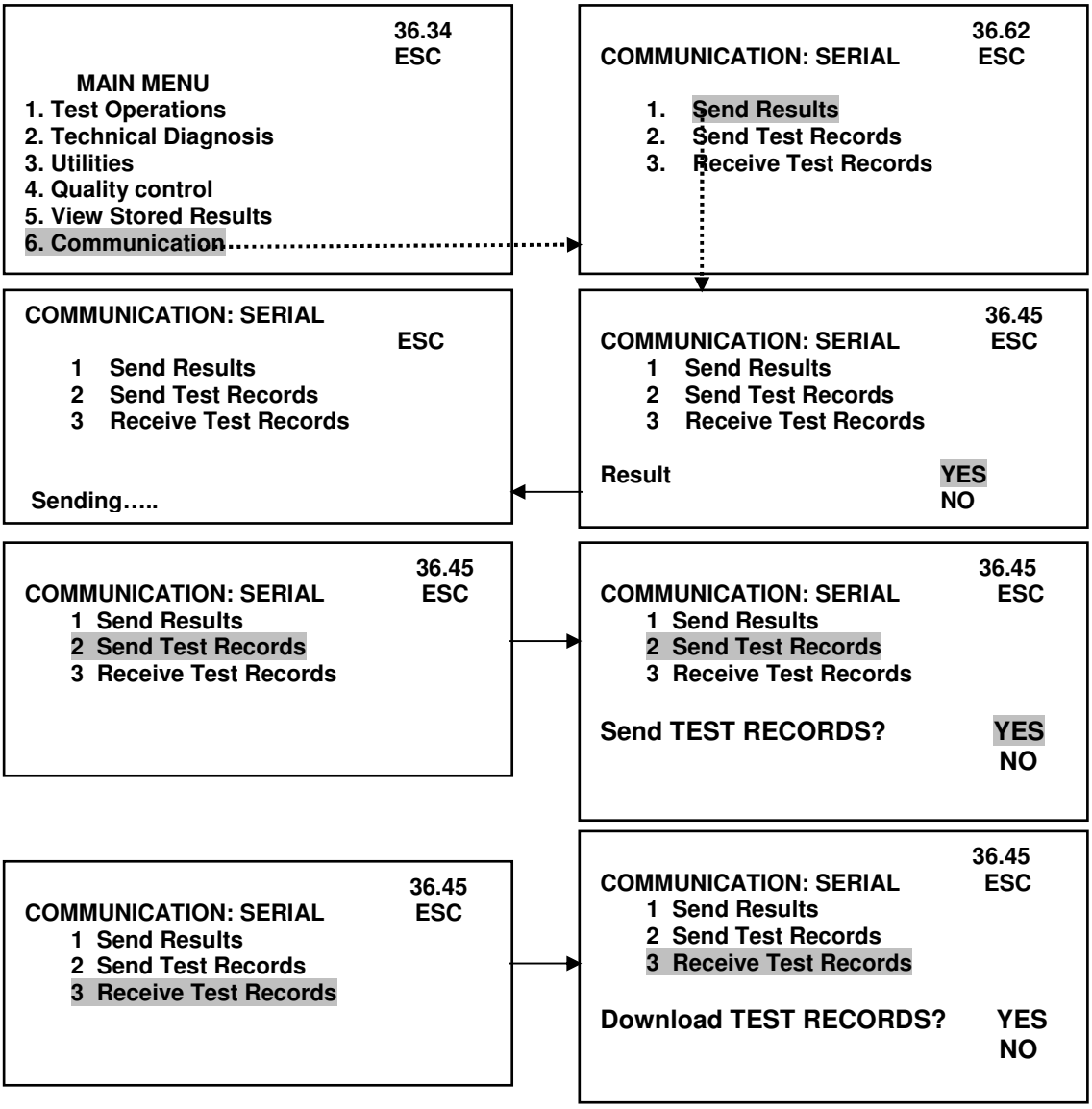


Communication will only start when both ends detect the presence of an active terminal or device.

RS232 port settings in a windows Operating system

PORT SETTINGS

Bits per second : 9600
Data Bits : 8
Parity None : None
Stop Bits : 1
Flow control : None

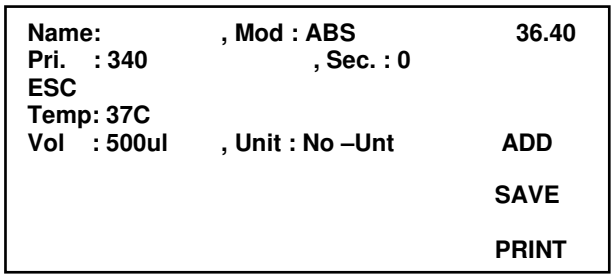


9. Programming Modes.

9.1. ABSORBANCE

The instrument measures the blank transmittance and the sample transmittance, subtracts them and calculates the sample absorbance(**monochromatic mode**).It is possible to repeat the measure with a different wavelength(Filter 2/ secondary filter) and consider the difference between the two measures. (**Bichromatic mode**)

PROGRAMMING / ADDING a NEW TEST (Refer chapter 8)

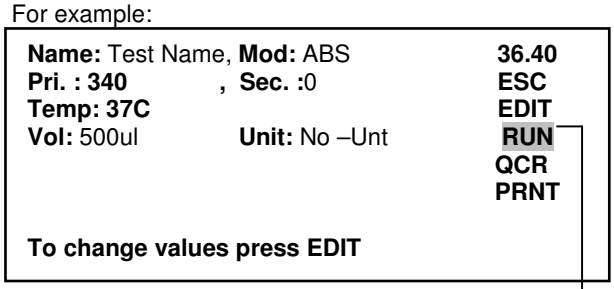


ABSORBANCE Mode screen before programming would look like the above screen

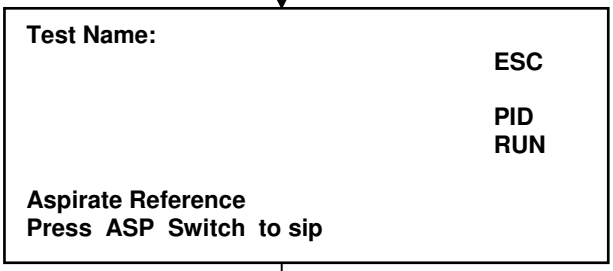
Refer chapter11 for entering the test parameters .On completion, touch "SAVE" to save the programmed test

Recalling /Running (Operating) a pre-programmed test .(Refer chapter 8)

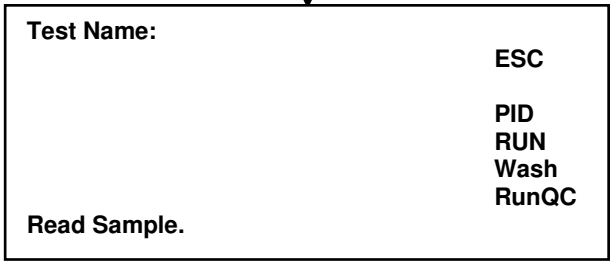
For example:



ABSORBANCE Mode screen after recalling a saved test.
To change values, touch" **EDIT**"
To run the programmed test, touch "**RUN**"
To print, touch **"PRINT"** (Printing is optional)
To escape, touch "**ESC**"



At this stage, the analyser will wait till the temperature of cuvette reaches the set temperature. The instrument prompts for REFERENCE, and prompts the user to place the reference solution (distilled water) below the tube and to press the aspiration switch. The instrument aspirates the solution and automatically adjusts the reference.
*(To abort temperature setting, touch "***ESC***" once)*
(In cuvette mode when the instrument prompts reference "close the lid and Press RUN" before inserting sample cuvette)



Now the analyser is ready for reading samples.
The user has to place the sample solution below the tube and press the aspiration switch. The instrument aspirates the sample and displays the readings. To continue reading more samples do the same.
(PID is not enabled only in absorbance mode)

9.2. FIXED TIME

Change in absorbance of sample is taken at programmed time interval and concentration is calculated either from the factor fed by the user or using standard.

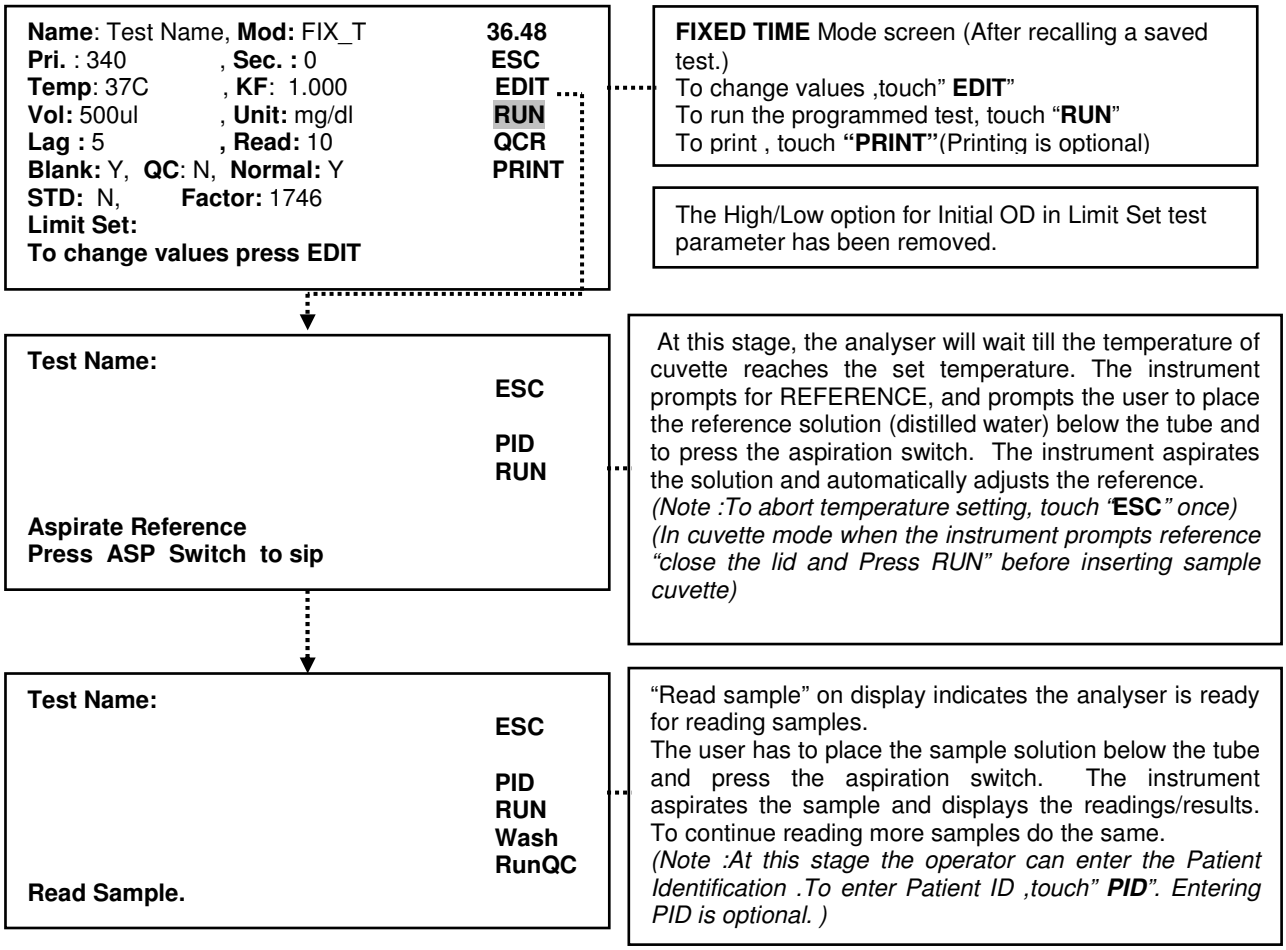
PROGRAMMING / ADDING a NEW TEST (Refer chapter 8)

Name:	, **Mod:** FIX_T	**36.54**
Pri. : 340	, **Sec. :** 0	**ESC**
Temp: 37C	, **KF**: 1.000	
Vol: 300ul	, **Unit:** No –Unt	**ADD**
Lag : 0	**, Read:** 0	
Blank: N, **QC**: N, **Normal:** N		**SAVE**
STD: N, **Factor :** 0.000		
Limit Set:		**PRINT**

FIXED TIME Mode screen before programming would look like the above screen
Refer chapter11 for entering the test parameters .On completion, touch "**SAVE**" to save the programmed test in memory.

Recalling /Running (Operating) a pre-programmed test. (Refer chapter 8)

For example:

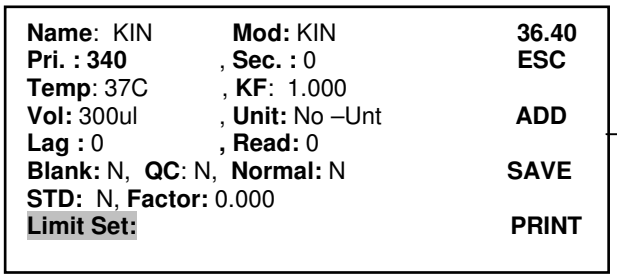


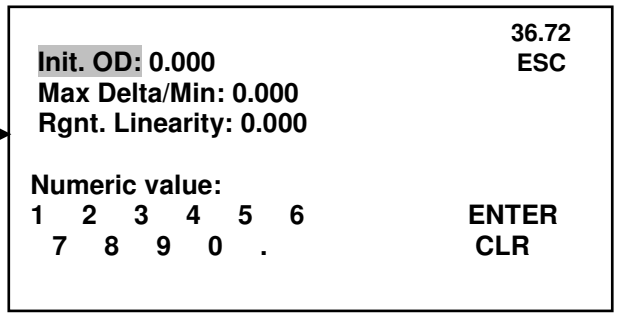
9.3. KINETIC

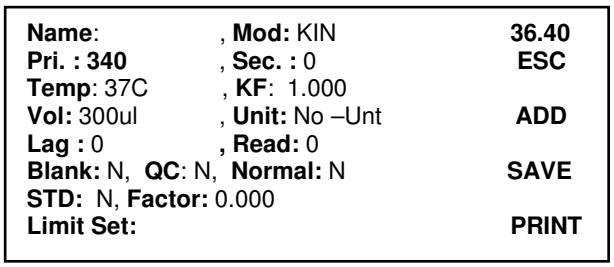
Multiple readings are taken at set temperature, at regular intervals and change in absorbance per minute is calculated. Concentration is calculated from the factor fed by the user or by using standard.

PROGRAMMING / ADDING a NEW TEST (Refer chapter 8)

Enter all the test parameters in Kinetic mode





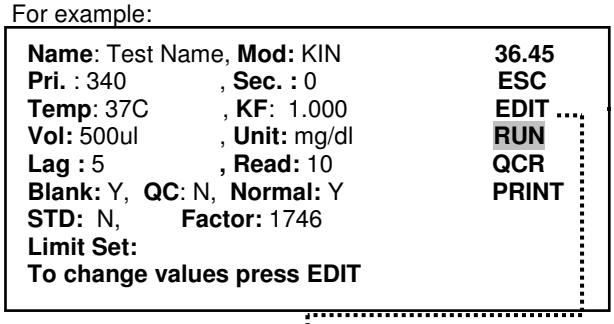


"Initial OD" in Limit Set is kept mandatory. Test will not get saved if initial OD limit is not entered. In such case it will give a message **"Enter Initial OD in limit Set"** The High/Low option for Initial OD in Limit Set test parameter has been removed.

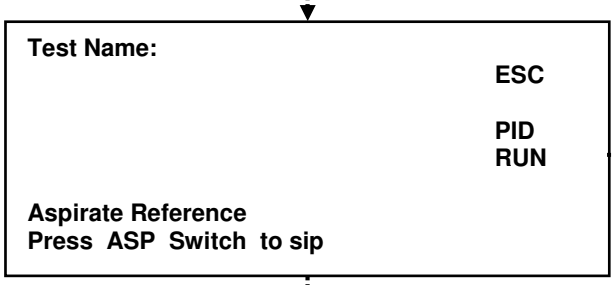
KINETIC Mode screen before programming would look like the above screen
Refer chapter11 for entering the test parameters .On completion ,touch "SAVE" to save the programmed test

Recalling /Running (Operating) a pre-programmed test .(Refer chapter 8)

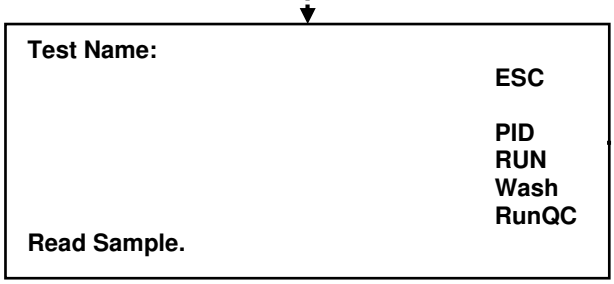
For example:



KINETIC Mode screen (After recalling a saved test.)
To change values ,touch" **EDIT**"
To run the programmed test, touch "**RUN**"
To print , touch **"PRINT"**(Printing is optional)
To escape ,touch "**ESC**"



At this stage, the analyser will wait till the temperature of cuvette reaches the set temperature. The instrument prompts for REFERENCE, and prompts the user to place the reference solution (distilled water) below the tube and to press the aspiration switch. The instrument aspirates the solution and automatically adjusts the reference.
*(Note :To abort temperature setting, touch "***ESC***" once)*
(In cuvette mode when the instrument prompts reference "close the lid and Press RUN" before inserting sample cuvette)



"Read sample" on display indicates the analyser is ready for reading samples.
The user has to place the sample solution below the tube and press the aspiration switch. The instrument aspirates the sample and displays the readings/results.
To continue reading more samples do the same.
*(Note :At this stage the operator can enter the Patient Identification .To enter Patient ID ,touch" **PID**". Entering PID is optional.)*

9.4. END POINT

The instrument reads absorbance of the sample and calculates concentration using fed Factor or calculates the factor from concentration of the standard.

PROGRAMMING / ADDING a NEW TEST (Refer chapter 8)

Name: , **Mod:** END-P	**36.45**
Pri. : 340 , **Sec. :** 0	**ESC**
Temp: 37C , **KF**: 1.000	
Vol: 300ul , **Unit:** No –Unt	**ADD**
Lag : 0 **, Read:** 0	
Blank: N, **QC**: N, **Normal:** N	**SAVE**
STD: N, **Factor:** 0.000	
Limit Set:	**PRINT**

END POINT Mode screen before programming would look like the above screen
Refer chapter11 for entering the test parameters .On completion ,touch "SAVE" to save the programmed test

Recalling /Running (Operating) a pre-programmed test .(Refer chapter 8)

For example:

Name: Test Name, **Mod:** END-P	**36.54**
Pri. : 340 , **Sec. :** 0	**ESC**
Temp: 37C , **KF**: 1.000	**EDIT**
Vol: 500ul , **Unit:** mg/dl	**RUN**
Lag : 5 **, Read:** 10	**QCR**
Blank: Y, **QC**: N, **Normal:** Y	**PRINT**
STD: N, **Factor:** 1746	
Limit Set:	
To change values press EDIT	

ENDPOINT Mode screen (After recalling a saved test.)
To change values ,touch" **EDIT**"
To run the programmed test, touch "**RUN**"
To print , touch **"PRINT"**(Printing is optional)
To escape ,touch "**ESC**"

Test Name:	
	ESC
	PID
	RUN
Aspirate Reference	
Press ASP Switch to sip	

At this stage, the analyser will wait till the temperature of cuvette reaches the set temperature. The instrument prompts for REFERENCE, and prompts the user to place the reference solution (distilled water) below the tube and to press the aspiration switch. The instrument aspirates the solution and automatically adjusts the reference.
*(Note :To abort temperature setting, touch "***ESC***" once)*
(In cuvette mode when the instrument prompts reference "close the lid and Press RUN" before inserting sample cuvette)

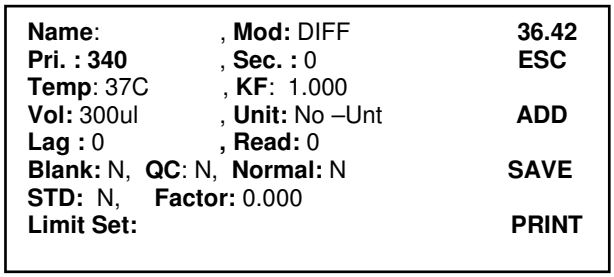
Test Name:	
	ESC
	PID
	RUN
	Wash
	RunQC
Read Sample.	

"Read sample" on display indicates the analyser is ready for reading samples.
The user has to place the sample solution below the tube and press the aspiration switch. The instrument aspirates the sample and displays the readings/results.
To continue reading more samples do the same.
(Note :At this stage the operator can enter the Patient Identification .To enter Patient ID ,touch" ***PID****". Entering PID is optional.)*

9.5. DIFFERENTIAL

Differential of Sample and Sample Blank is taken. Concentration is calculated either from the factor fed by using standard.

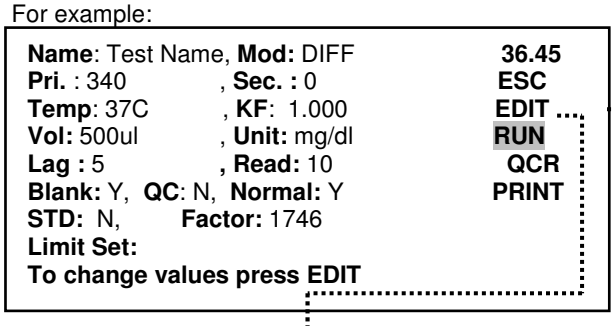
PROGRAMMING / ADDING a NEW TEST (Refer chapter 8)



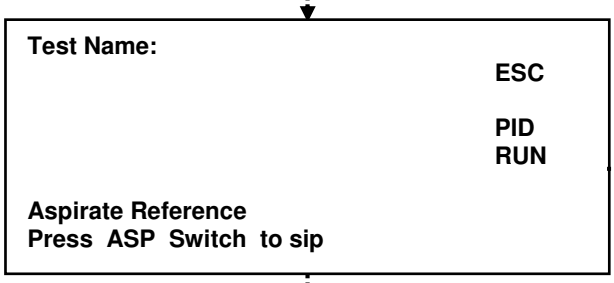
DIFFERENTIAL Mode screen before programming would look like the above screen
Refer chapter11 for entering the test parameters .On completion ,touch "SAVE" to save the programmed test.

Recalling /Running (Operating) a pre-programmed test .(Refer chapter 8)

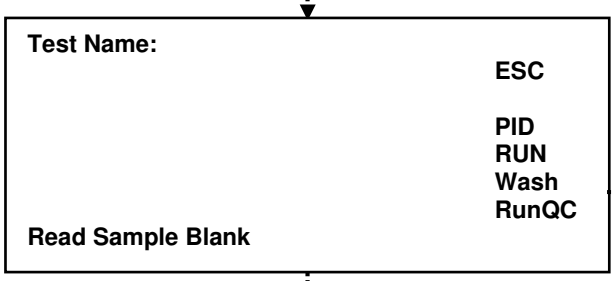
For example:



DIFFERENTIAL Mode screen (After recalling a saved test.)
To change values ,touch" **EDIT**"
To run the programmed test, touch "**RUN**"
To print , touch **"PRINT"**(Printing is optional)
To escape ,touch "**ESC**"

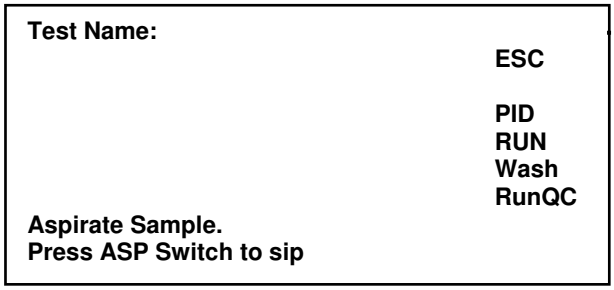


At this stage, the analyser will wait till the temperature of cuvette reaches the set temperature. The instrument prompts for REFERENCE, and prompts the user to place the reference solution (distilled water) below the tube and to press the aspiration switch. The instrument aspirates the solution and automatically adjusts the reference.
*(Note :To abort temperature setting, touch "***ESC***" once)*
(In cuvette mode when the instrument prompts reference "close the lid and Press RUN" before inserting sample cuvette)



The user has to place the "sample blank" solution below the tube and press the aspiration switch. The instrument aspirates the sample ,displays the "sample blank" absorbance .
*(Note :At this stage the operator can enter the Patient Identification .To enter Patient ID ,touch" **PID**". Entering PID is optional.)*

.



The user has to place the "sample" solution below the tube and press the aspiration switch. The instrument aspirates the sample ,displays the "sample absorbance" and computes the result.

9.6. RATIO

PROGRAMMING / ADDING a NEW TEST (Refer chapter 8)

Name:	, **Mod:** RATIO	**36.54**
Pri. : 340	, **Sec. :** 0	**ESC**
Temp: 37C	, **KF**: 1.000	
Vol: 300ul	, **Unit:** No –Unt	**ADD**
Lag : 0	**, Read:** 0	
Blank: N, **QC**: N, **Normal:** N		**SAVE**
STD: N, **Factor:** 0.000		
Limit Set:		**PRINT**

RATIO Mode screen before programming would look like the above screen
Refer chapter11 for entering the test parameters .On completion ,touch "SAVE" to save the programmed test

Recalling /Running (Operating) a pre-programmed test .(Refer chapter 8)

For example:

Name: Test Name, **Mod:** RATIO		**36.54**
Pri. : 340	, **Sec. :** 0	**ESC**
Temp: 37C	, **KF**: 1.000	**EDIT**
Vol: 500ul	, **Unit:** mg/dl	**RUN**
Lag : 5	**, Read:** 10	**QCR**
Blank: Y, **QC**: N, **Normal:** Y		**PRINT**
STD: N,	**Factor:** 1746	
Limit Set:		
To change values press EDIT		

RATIO Mode screen (After recalling a saved test.)
To change values ,touch" **EDIT**"
To run the programmed test, touch "**RUN**"
To print , touch **"PRINT"**(Printing is optional)
To escape ,touch "**ESC**"

Test Name:	**ESC**
	PID
	RUN
Aspirate Reference	
Press ASP Switch to sip	

At this stage, the analyser will wait till the temperature of cuvette reaches the set temperature. The instrument prompts for REFERENCE, and prompts the user to place the reference solution (distilled water) below the tube and to press the aspiration switch. The instrument aspirates the solution and automatically adjusts the reference.
*(Note :To abort temperature setting, touch "***ESC***" once)*

Test Name:	**ESC**
	PID
	RUN
	Wash
	RunQC
Read Sample A.	

The user has to place the "Sample A" solution below the tube and press the aspiration switch. The instrument aspirates the sample and displays the "Sample A" absorbance.

*(Note :At this stage the operator can enter the Patient Identification .To enter Patient ID ,touch" **PID**" . Entering PID is optional.)*

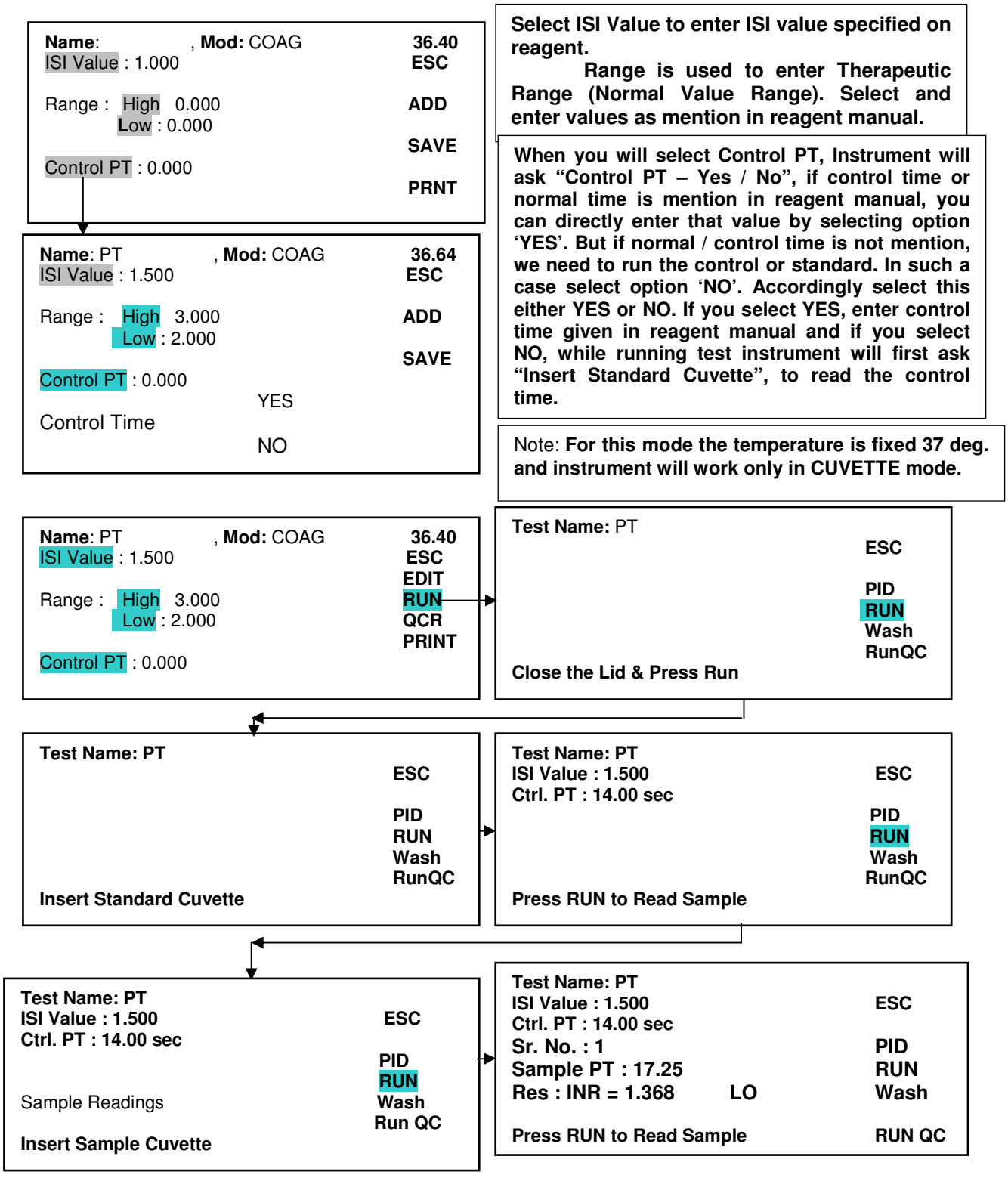
Test Name:	**ESC**
	PID
	RUN
	Wash
	RunQC
Aspirate Sample B	
Press ASP Switch to sip	

The user has to place the "Sample B" solution below the tube and press the aspiration switch. The instrument aspirates the sample , displays the "Sample B" absorbance and computes the result.

9.7. COAGULATION

This mode is used to report the Prothrombin Time (PT) results based on the ISI (International Sensitive Index) of the thromboplastin reagents and INR (International Normalised Ratio). The INR is calculated using formula INR = $R^{(ISI)}$, where ISI = Lot specified ISI value of reagent and R= Patient PT/ Normal PT. Normal PT is also known as Control PT or Standard PT.

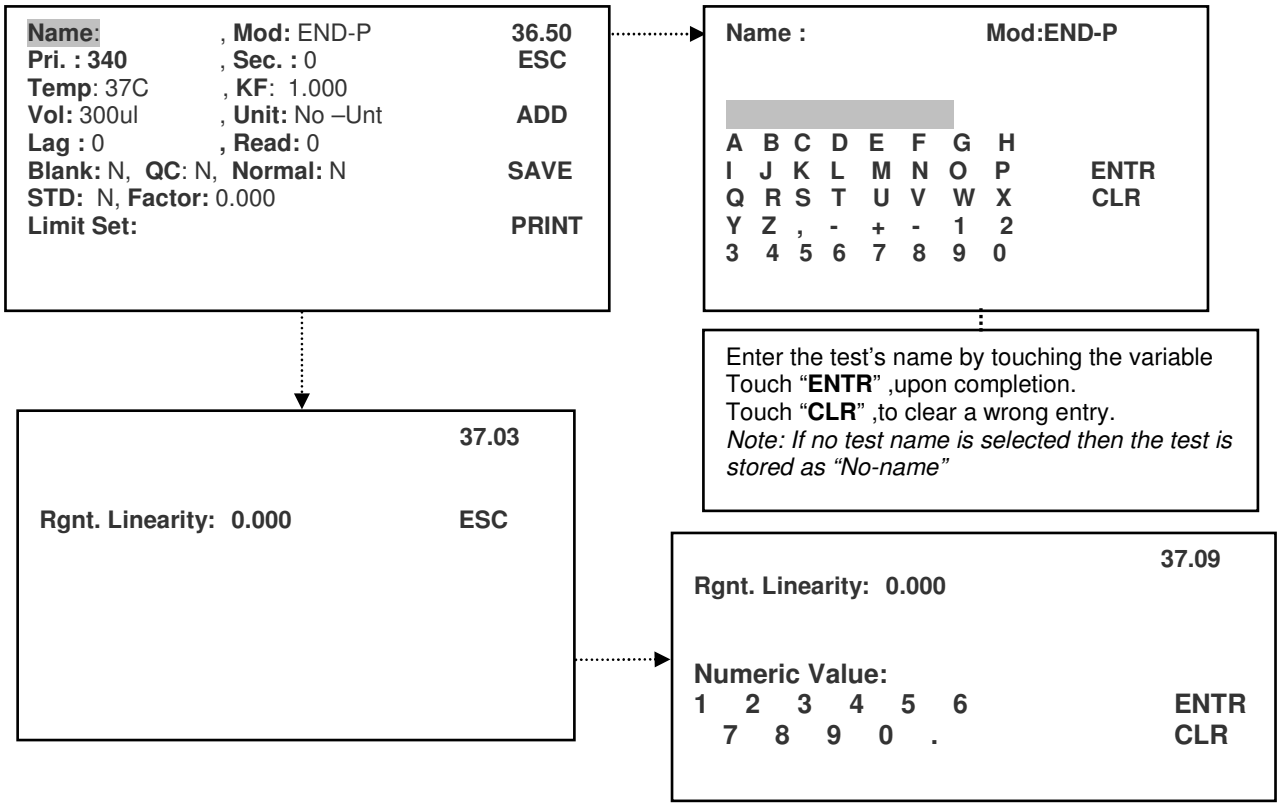
PROGRAMMING / ADDING a NEW TEST



10. General Functions

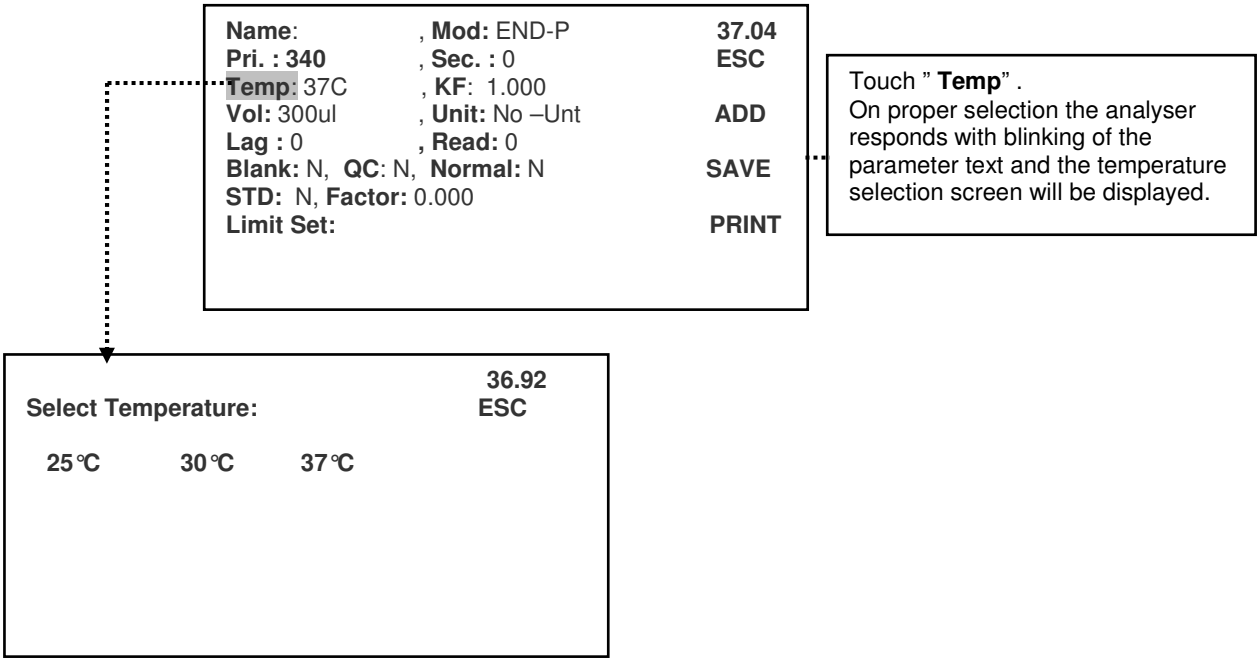
10.1. Enter Test Name

Touch" Name" under the selected mode on the Test Screen.
For example :In **ENDPOINT** mode



10.2. Temperature selection

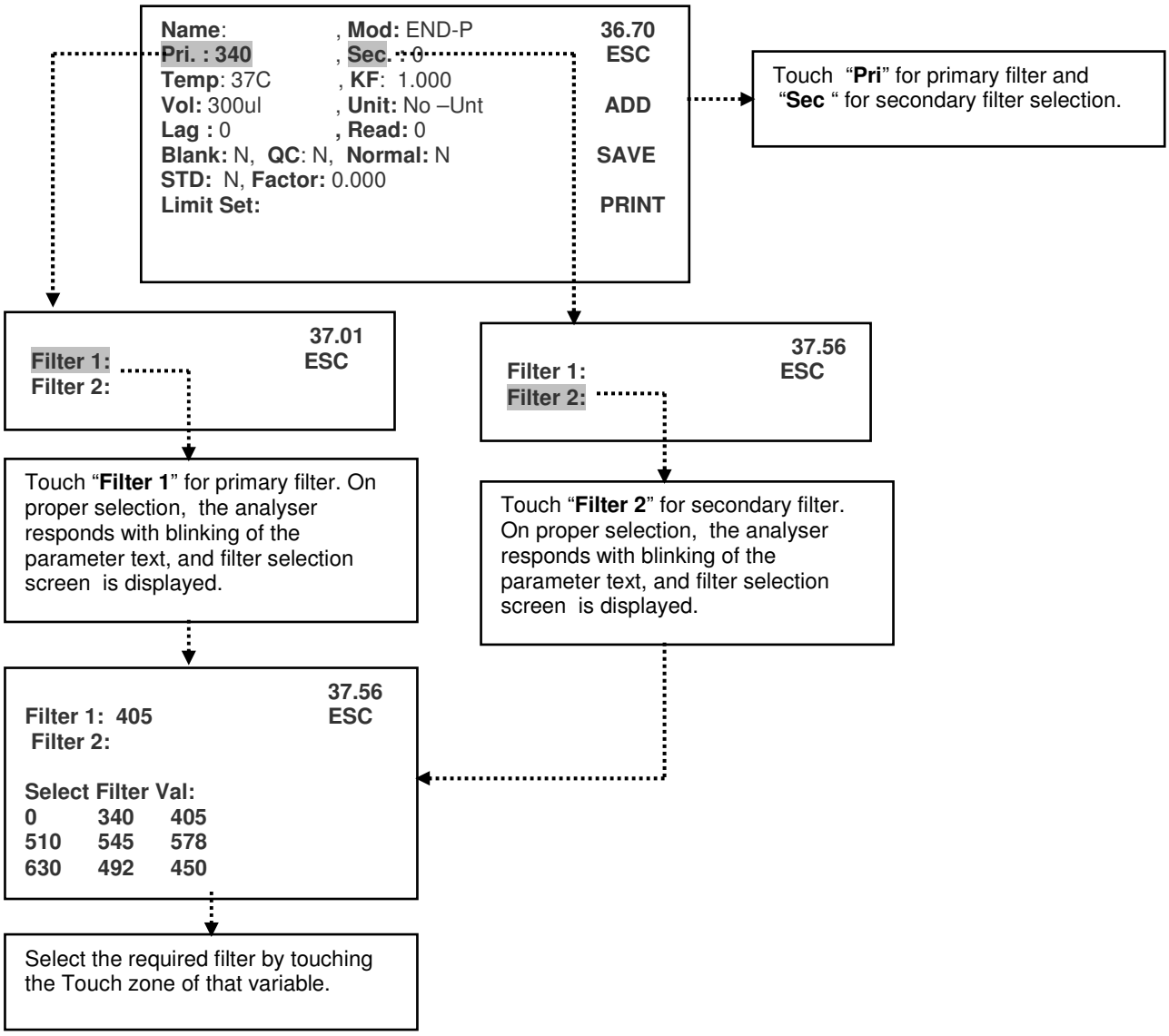
For example :In **ENDPOINT** mode.



10.3. Filter selection.

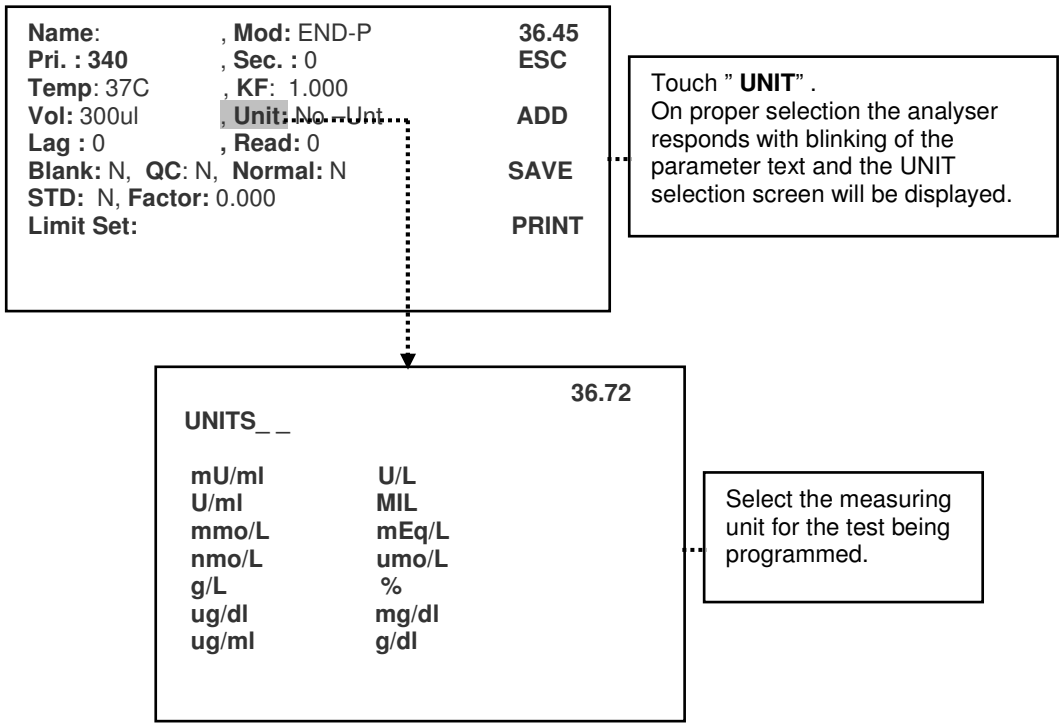
To select the interferential filter required for the test being programmed.

For example :In **ENDPOINT** mode.



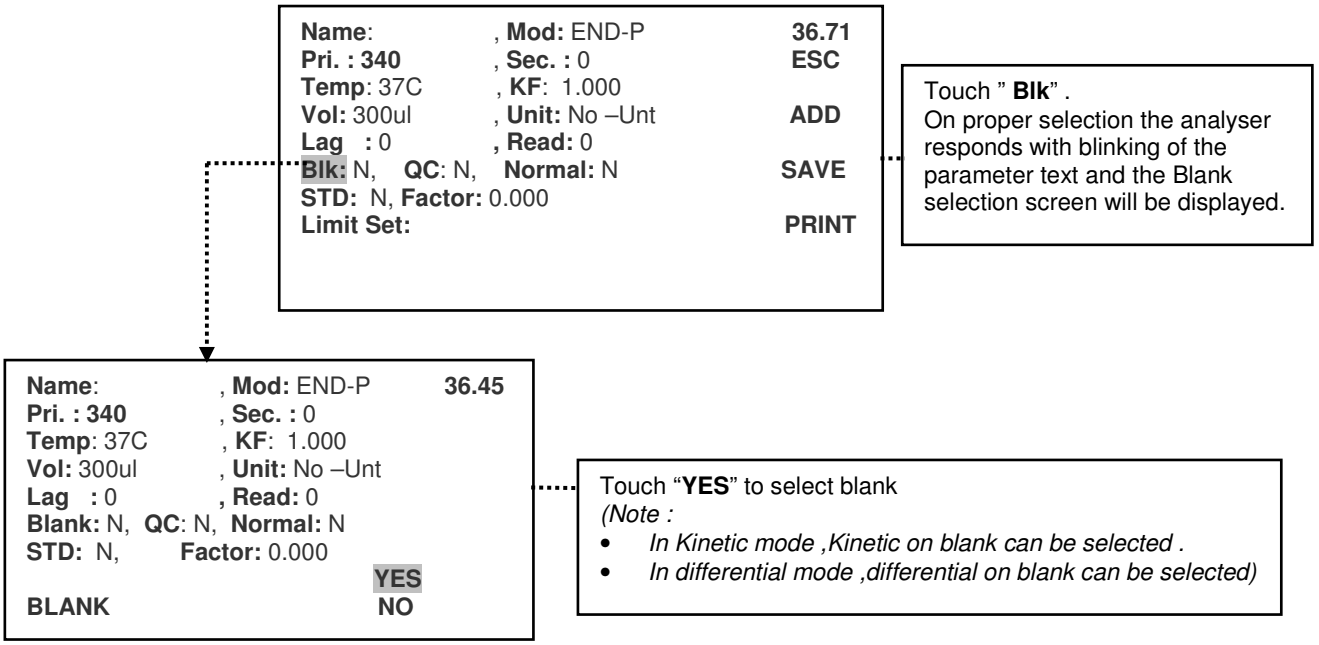
10.4. Selection of Units

For example :In **ENDPOINT** mode.



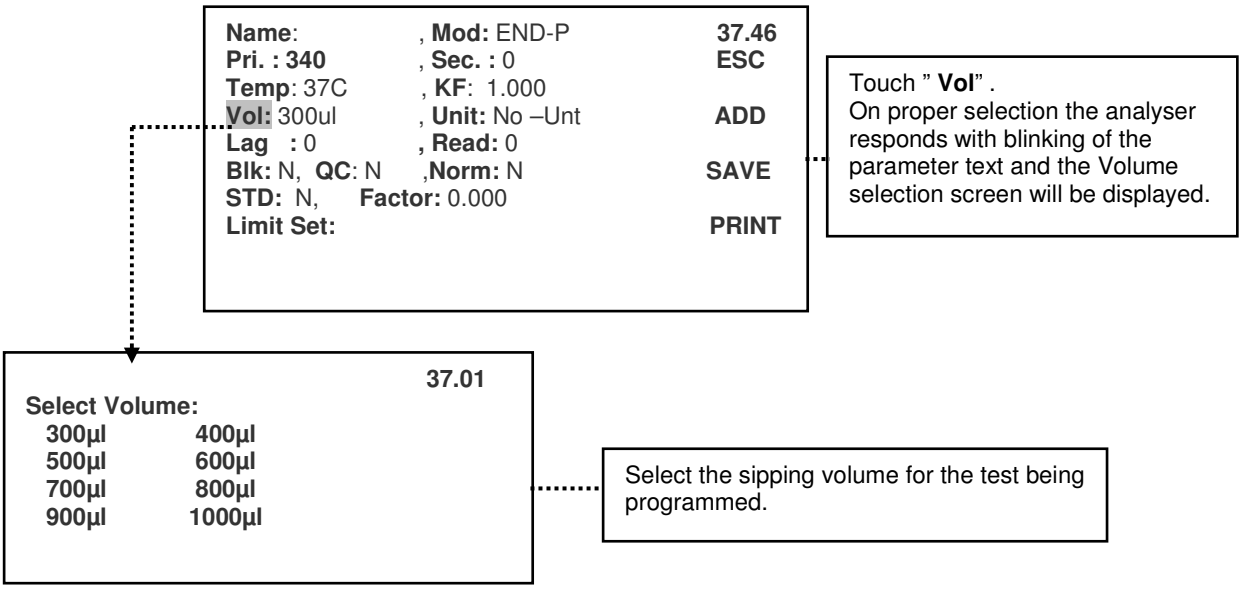
10.5. Blank Selection

For example: In **ENDPOINT** mode.



10.6. Selection of Aspiration/Sipping volume

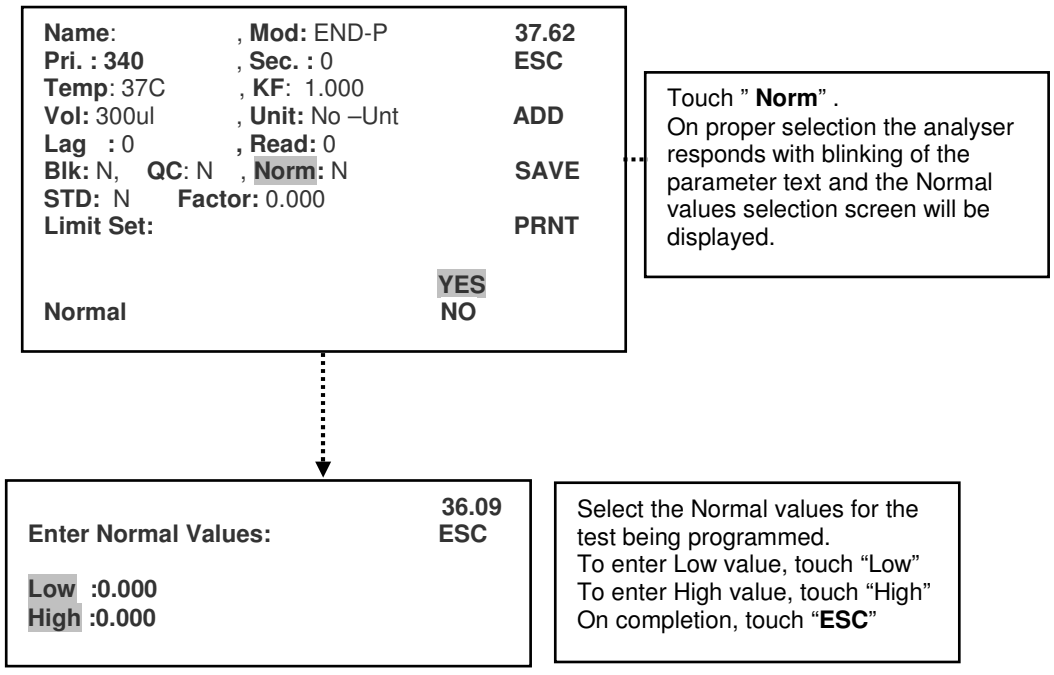
For example: In **ENDPOINT** mode.



10.7. Normal Value selection

Normal Values :The normal range for the concentration or the activity of the assay can be entered .If a test result is out of this range, the result will be flagged with L or H.

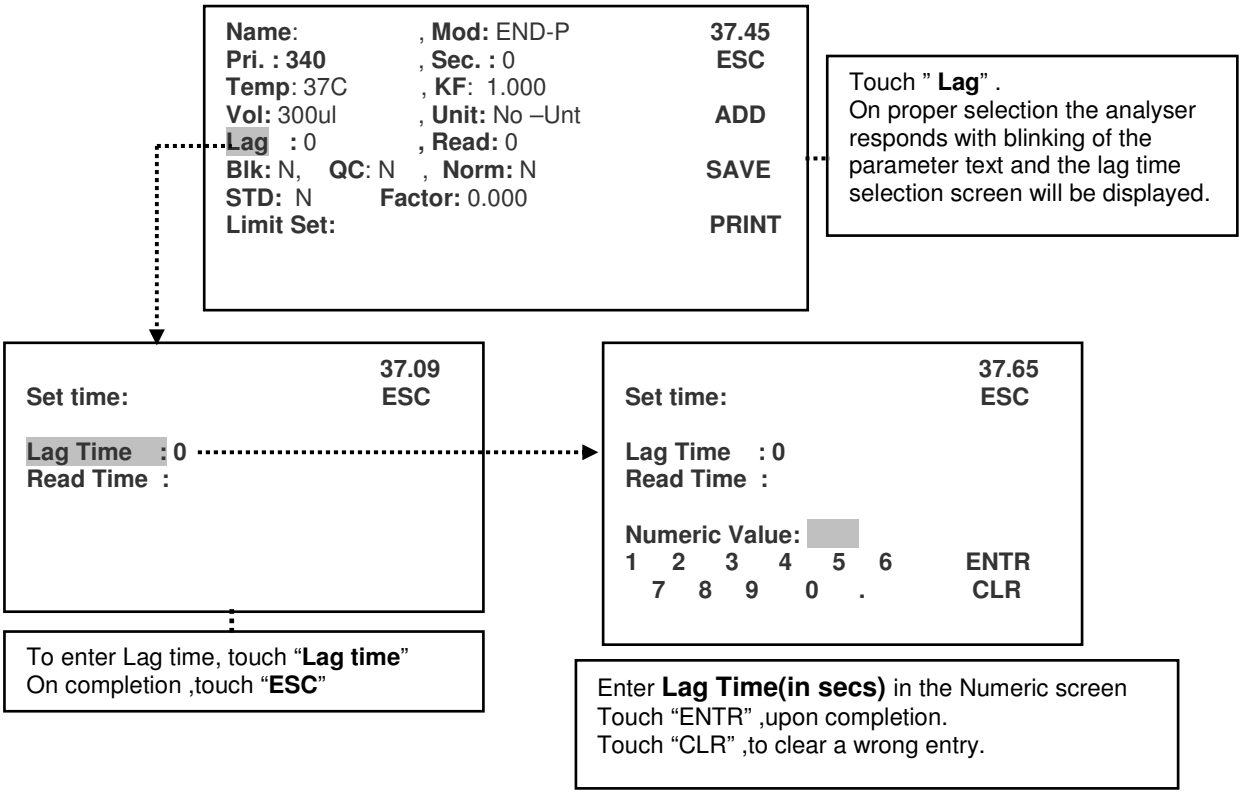
For example :In **ENDPOINT** mode.



10.8. Lag time

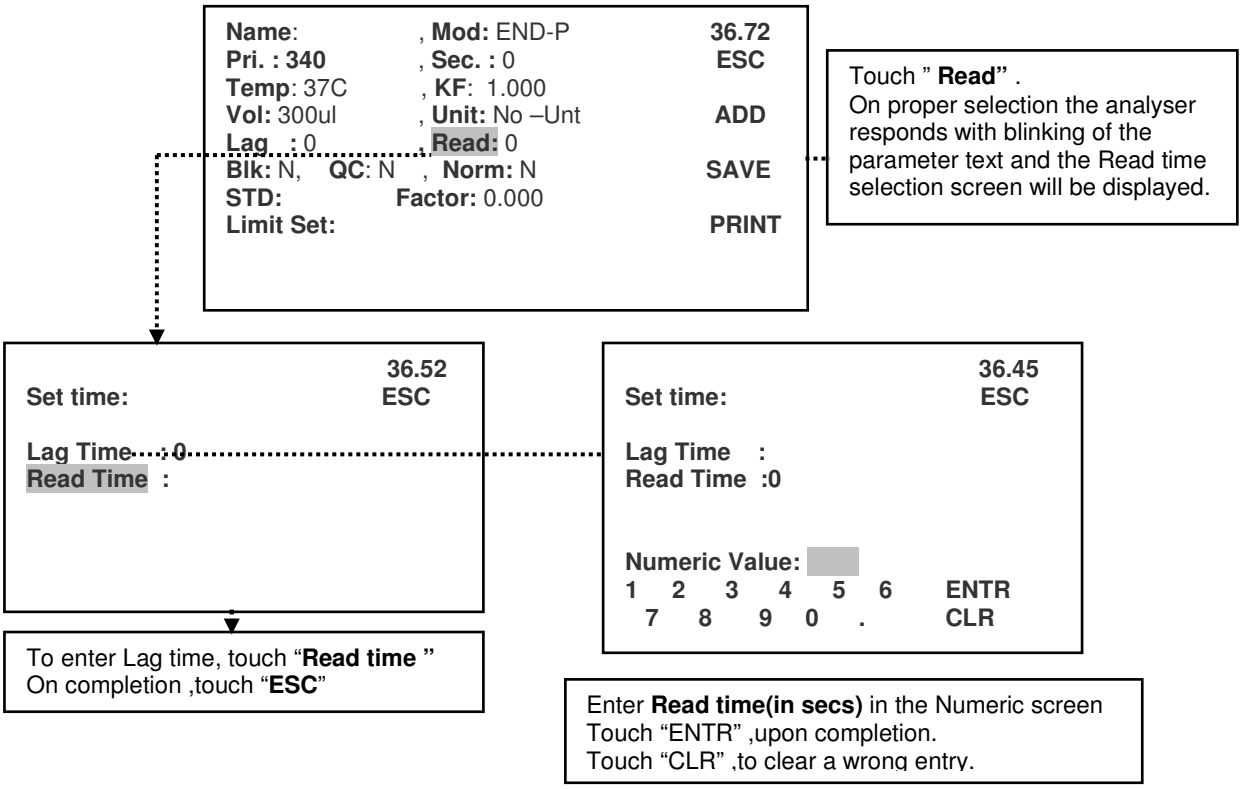
Delay interval (in seconds) before readings are executed.

For example :In ENDPOINT **mode.**

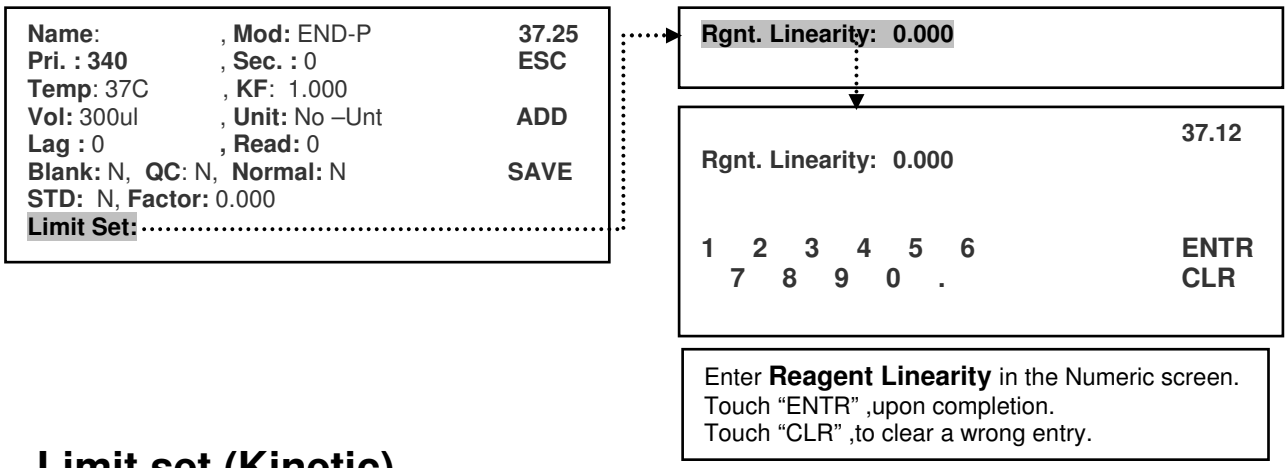


10.9. Read time

Time interval (in seconds) between subsequent readings.(For kinetic and fixed time mode)
For example :In **FIXED TIME** mode.

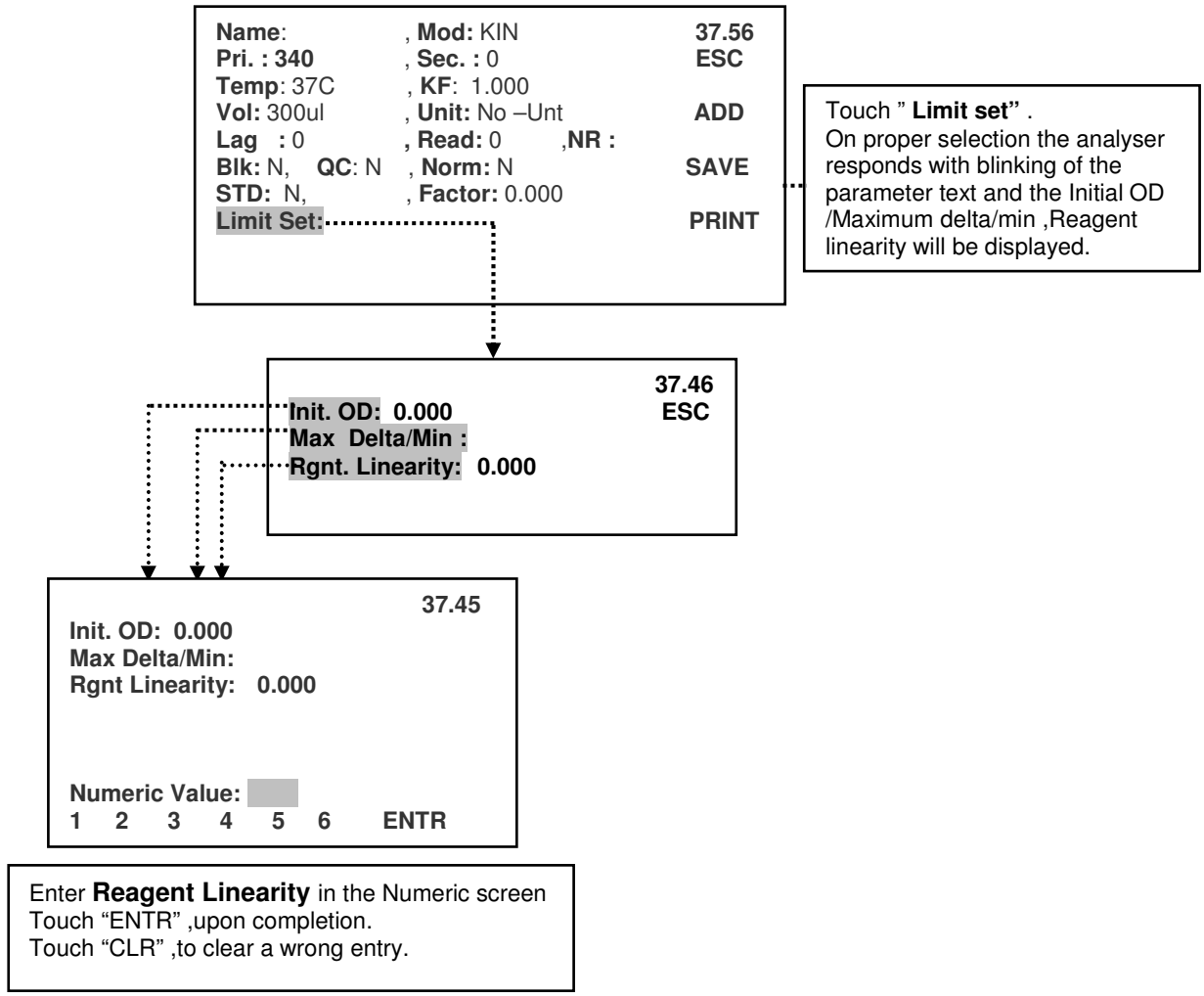


10.10. Limit set (End Point, Differential & Ratio)



Limit set (Kinetic)

Init O.D : High or low absorbance level. This limit is entered for those samples which may exceed the limits of the reagent system.
Max Delta/min :Upper limit for the Delta/min
Max Delta :Upper limit for the Delta
Rgnt. Linearity: as per given in a reagent kit.
For example :In **KINETIC** mode.

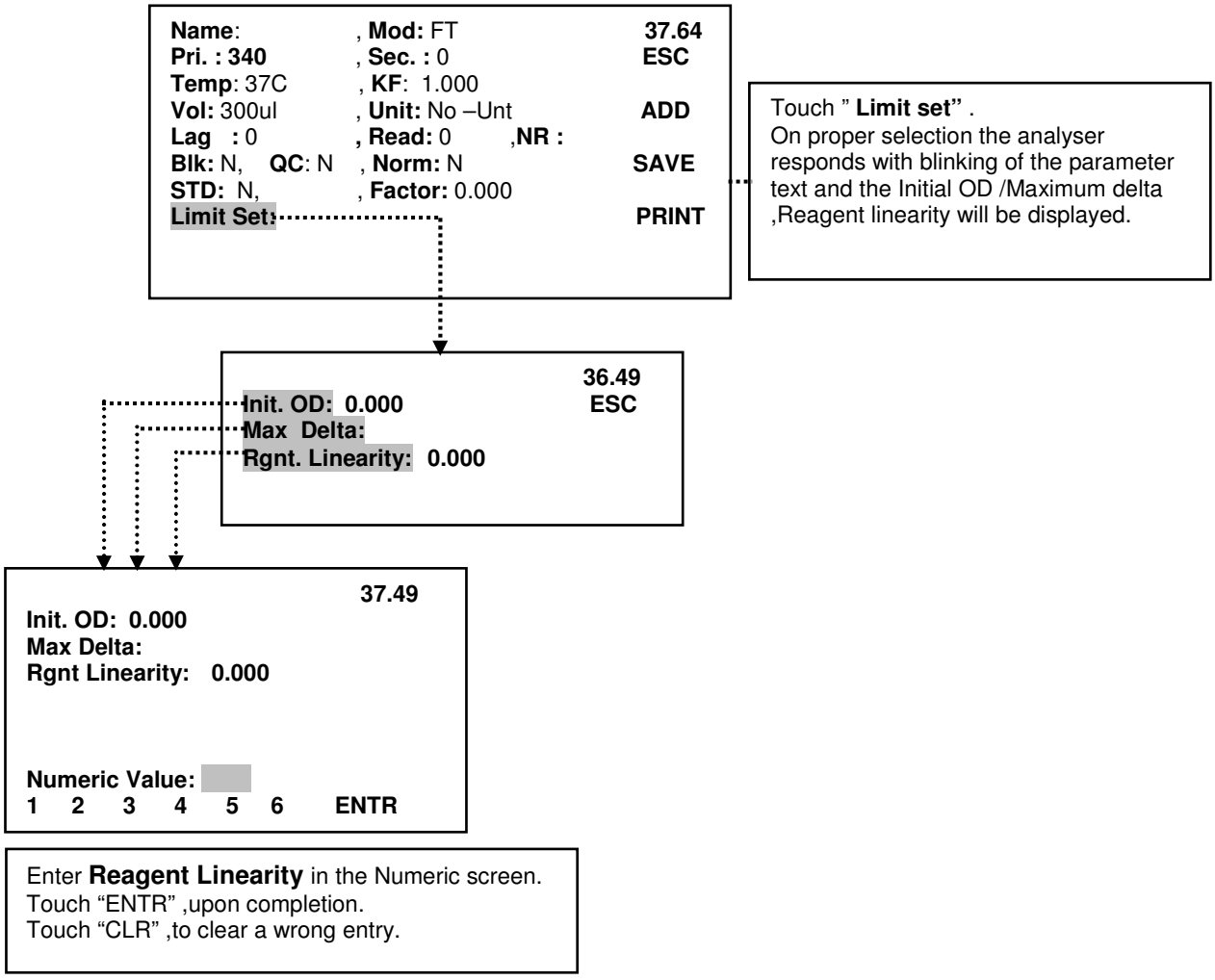


Limit set (Fixed Time)

Init O.D : High or low absorbance level. This limit is entered for those samples which may exceed the limits of the reagent system.

Max Delta :Upper limit for the Delta
Rgnt. Linearity: as per given in a reagent kit.

For example :In **Fixed Time** mode.



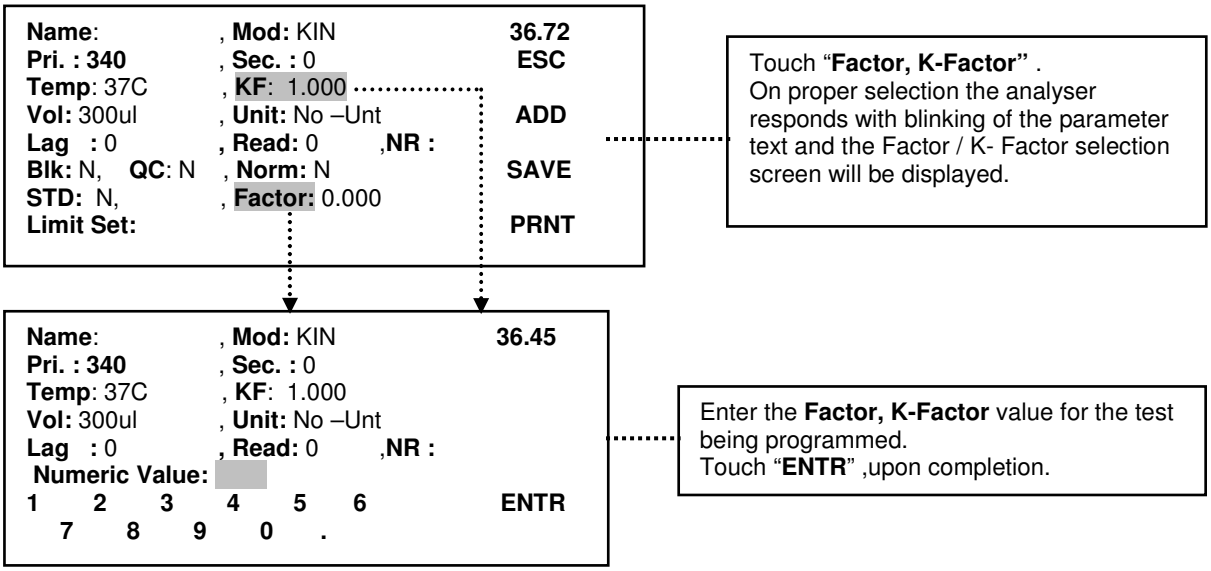
10.11. Factor / K-Factor / Standard selection

Selection of Standard or Factor

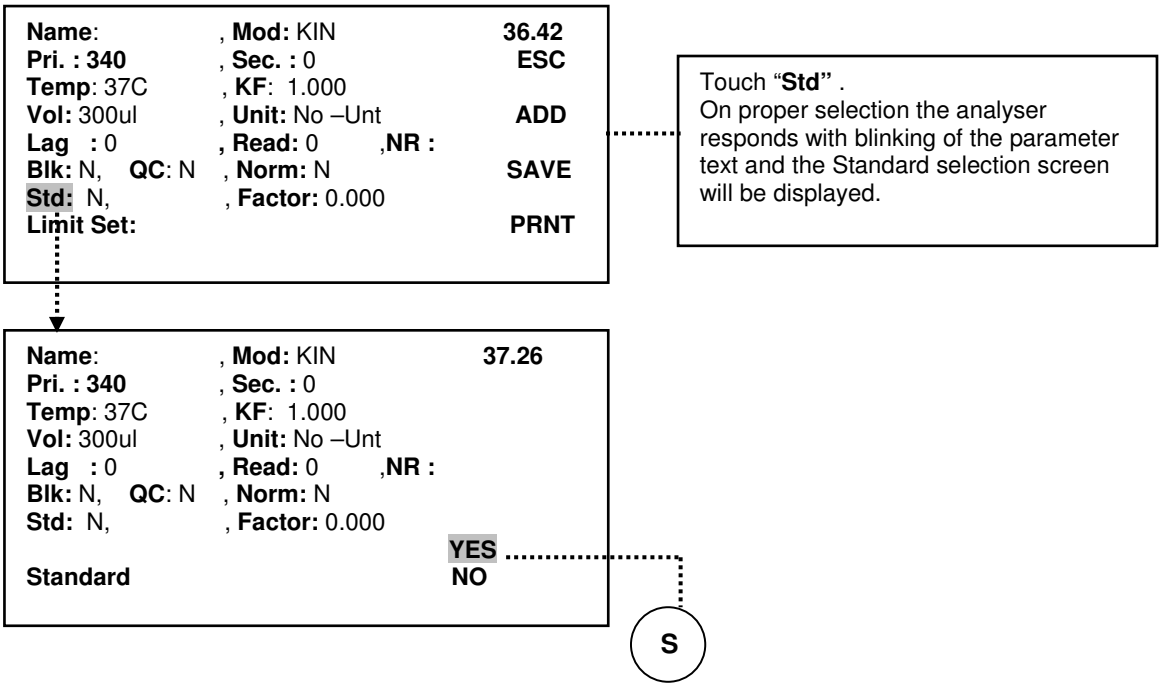
prietest TOUCH has the flexibility to calculate the results by

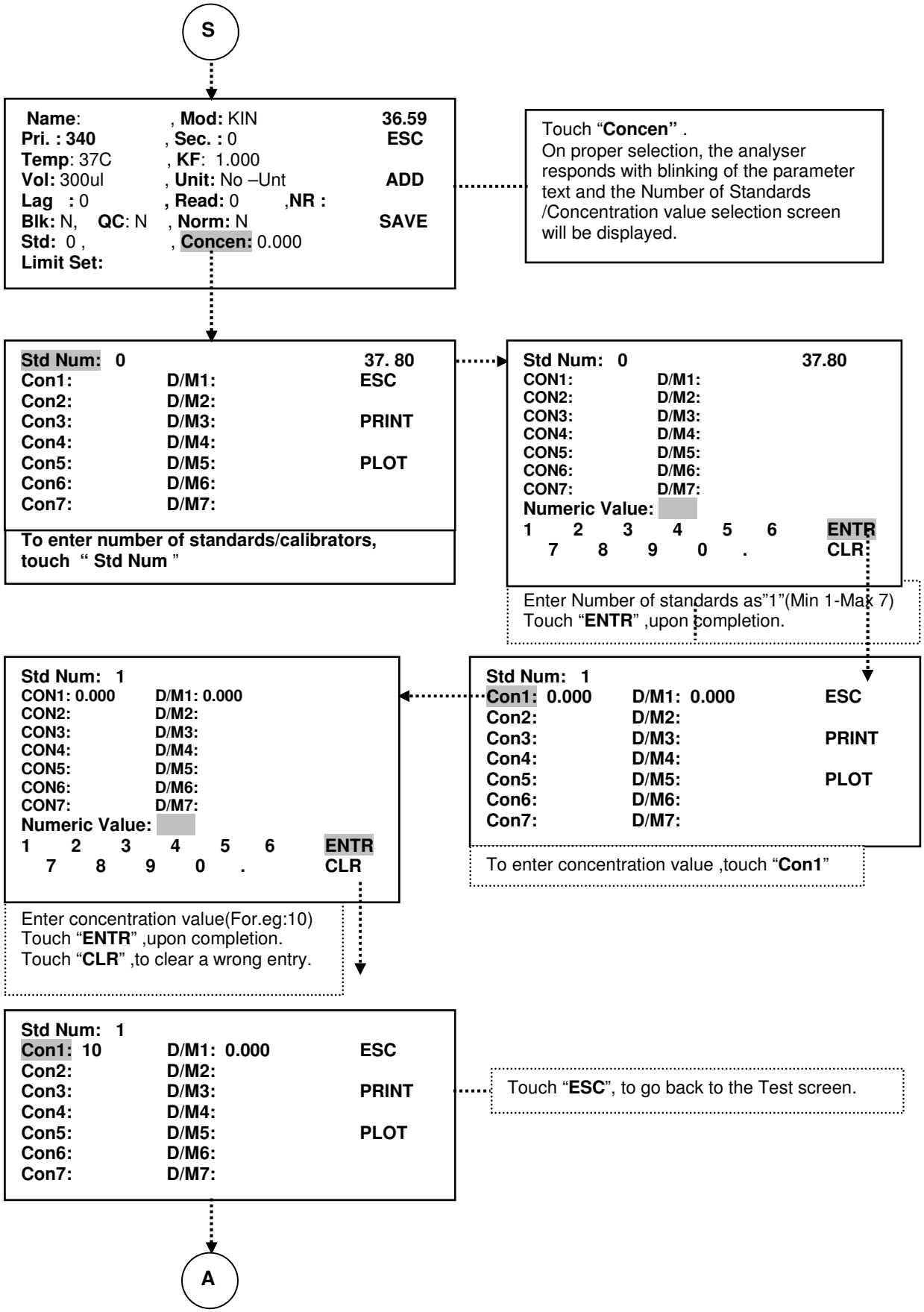
1) Factor Method
2) Single Standard/ Multi-standard

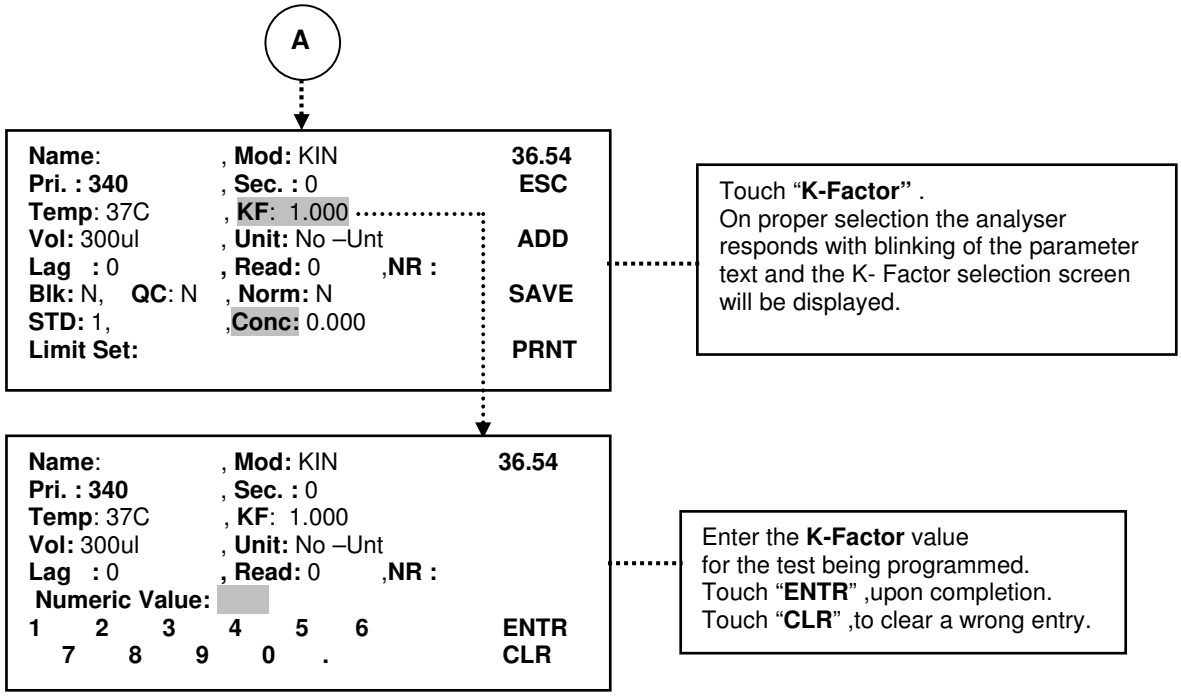
For example in kinetic mode,



Single Standard/ Multi-standard.




S
Name: , Mod: KIN 36.59
Pri. : 340 , Sec. : 0 ESC
Temp: 37C , KF: 1.000
Vol: 300ul , Unit: No –Unt ADD
Lag : 0 , Read: 0 ,NR :
Blk: N, QC: N , Norm: N SAVE
Std: 0 , , Concen: 0.000
Limit Set:
Touch "Concen" .
On proper selection, the analyser responds with blinking of the parameter text and the Number of Standards /Concentration value selection screen will be displayed.
Std Num: 0 37. 80
Con1: D/M1: ESC
Con2: D/M2:
Con3: D/M3: PRINT
Con4: D/M4:
Con5: D/M5: PLOT
Con6: D/M6:
Con7: D/M7:
To enter number of standards/calibrators, touch " Std Num "
Std Num: 0 37.80
CON1: D/M1:
CON2: D/M2:
CON3: D/M3:
CON4: D/M4:
CON5: D/M5:
CON6: D/M6:
CON7: D/M7:
Numeric Value:
1 2 3 4 5 6 ENTR
7 8 9 0 . CLR
Enter Number of standards as"1"(Min 1-Max 7)
Touch "ENTR" ,upon completion.
Std Num: 1
CON1: 0.000 D/M1: 0.000
CON2: D/M2:
CON3: D/M3:
CON4: D/M4:
CON5: D/M5:
CON6: D/M6:
CON7: D/M7:
Numeric Value:
1 2 3 4 5 6 ENTR
7 8 9 0 . CLR
Enter concentration value(For.eg:10)
Touch "ENTR" ,upon completion.
Touch "CLR" ,to clear a wrong entry.
Std Num: 1
Con1: 0.000 D/M1: 0.000 ESC
Con2: D/M2:
Con3: D/M3: PRINT
Con4: D/M4:
Con5: D/M5: PLOT
Con6: D/M6:
Con7: D/M7:
To enter concentration value ,touch "Con1"
Std Num: 1
Con1: 10 D/M1: 0.000 ESC
Con2: D/M2:
Con3: D/M3: PRINT
Con4: D/M4:
Con5: D/M5: PLOT
Con6: D/M6:
Con7: D/M7:
Touch "ESC", to go back to the Test screen.
A

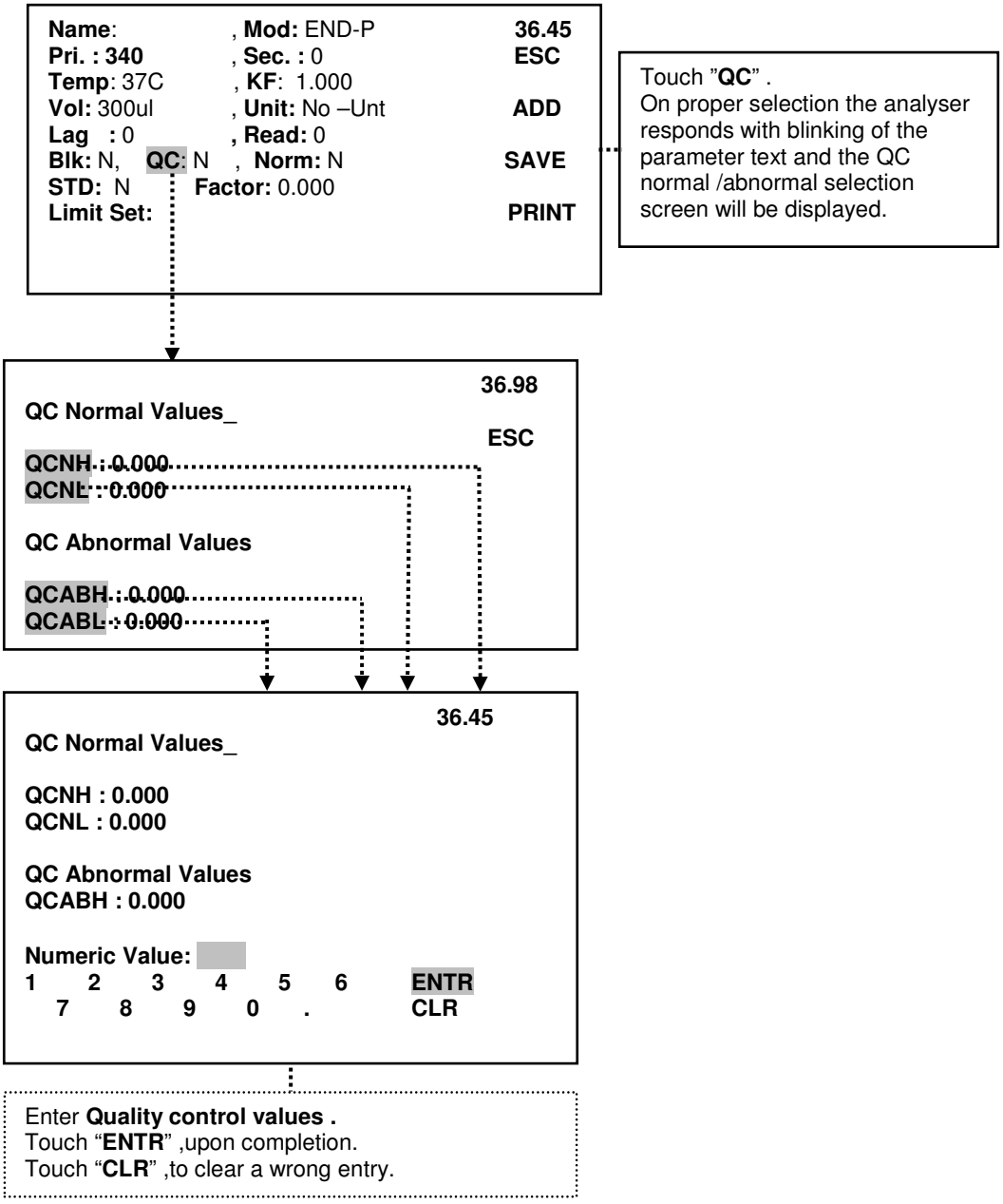

A
Name: , Mod: KIN 36.54
Pri. : 340 , Sec. : 0 ESC
Temp: 37C , KF: 1.000
Vol: 300ul , Unit: No –Unt ADD
Lag : 0 , Read: 0 ,NR :
Blk: N, QC: N , Norm: N SAVE
STD: 1, ,Conc: 0.000
Limit Set: PRNT
Touch "K-Factor" .
On proper selection the analyser responds with blinking of the parameter text and the K- Factor selection screen will be displayed.
Name: , Mod: KIN 36.54
Pri. : 340 , Sec. : 0
Temp: 37C , KF: 1.000
Vol: 300ul , Unit: No –Unt
Lag : 0 , Read: 0 ,NR :
Numeric Value:
1 2 3 4 5 6 ENTR
7 8 9 0 . CLR
Enter the K-Factor value
for the test being programmed.
Touch "ENTR" ,upon completion.
Touch "CLR" ,to clear a wrong entry.

10.12. QC Normal/Abnormal values

QC Normal Values
QCNH - Quality control Normal high value
QCNL - Quality control Normal low value

QC Abnormal Values
QCABH – Quality control Abnormal high value
QCABL – Quality control Abnormal Low value

For example :In **ENDPOINT** mode.



11. Trouble Shooting:

MESSAGES	CAUSE /CORRECTIVE ACTION
Disable Printer YES / NO ?	**Refer 5.8 "Thermal printer".**
Lamp Intensity is poor	**Clean the cuvette / Wash the flow cell thoroughly checks whether Instrument is aspirating the solution.**
Flow cell Missing	**This error will come in flow cell mode if Flowcell is not inserted or not inserted properly. Insert the flow cell properly.**
Remove Cuvette	**This error will come in Cuvette mode while referencing. Remove the cuvette.**
Invalid Assay	**In Multi standard mode if standard are not proper then this error will appear. Check the calibrators and rerun the test.**
Memory Full	**If Number of saved tests exceeds the memory limit then delete the unwanted tests and save the test.**
Filter Wheel Error	**During initializing, home filter wheel and during test run if there is any problem in rotation of filter wheel or IR LEDs, it will display and print the error message.**

12 Decontamination

12.1. Decontamination Procedure

- If the instrument is to be shipped after being exposed to potentially hazardous material, it should be decontaminated. The following procedure outlines the method of decontaminating the instrument before packaging and shipment.

12.2. Purpose of Decontamination

- Decontamination minimizes the risk to all who come in contact with the instrument during shipping, handling, and servicing.

12.3. General Considerations

- Any laboratory instrument that has been used for clinical analysis is considered a biohazard and should be decontaminated prior to handling. Intact skin is generally considered an effective barrier against infectious Organisms; however, small abrasions and cuts may not be always be visible. Prophylactic gloves must be worn when handling instruments that have not been decontaminated. Gloved hands should be considered contaminated at all times and must be kept away from eyes, mouth and nose at all times.

- Mucous membranes are considered prime entry routes for infectious agents. Wear eye protection and a surgical mask when there is a possibility of aerosols.

- Eating and drinking while decontaminating instruments is not advisable.

12.4. Procedure

- A solution of .5% Sodium Hypo Chlorite (NaOCL) solution (Bleach) is used. Commercial bleach is 5% NaOCL; household bleach is 3% NaOCL. When using commercial bleach, use a 10:1 mixture; if using household bleach, a 6:1 mixture is required. This is a caustic solution. It is important to wear gloves and eye protection when handling it.

- Wipe down the carrier and all exposed surfaces of the unit with the bleach solution. Remove the top shroud of the instrument and wipe down the top surface of the instrument base, as well as the inside of the top shroud.

- Reassemble the unit and discard the used gloves and towels.

13. SAFETY CLEARANCE CERTIFICATE

Please complete all information requests on this form prior to returning the instrument to the manufacturer or your local distributor for servicing, repairs or return. Thank you for your co-operation.

Customer _____ **Contact** _____

Address _____ **Position** _____

_____ **Dept** _____

_____ **Tel:** _____

_____

Country _____ **Fax:** _____

Post Code _____

Model No. _____ **Serial no.** _____

Accessories Returned _____

Date of Purchase (if known) _____

Complaint _____

_____

_____

_____

Has the equipment been exposed to any of the following: (*delete as applicable)

a) Blood, body fluids, pathological specimens ***YES/NO**
If YES, please specify _____

_____

b) Other Biohazard ***YES/NO**
if YES, Please specify _____

_____