prietest ECO

Biochemistry Analyser

USER MANUAL

ROBONIK®
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Navi Mumbai – 400 710(INDIA)
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Version No.: 01 **Page No. 1 to 46**
Effective Date: Dec, 2008

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Manufacturer:

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prietest ECO , Version -01

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/or 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 incidental expenses like travel and man-hour service charges 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. While asking for service, please refer to this manual, and report the printed serial no. on the identification label.

Only qualified technicians are entitled to fix the instrument; the user, as described in this manual, should carry out ordinary maintenance.

ROBONIK's technical service or an authorized service center with specialized technicians, with suitable instrumentation and original spare parts 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,
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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 ONLY.

- A qualified user has to make sure that the 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, the user 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 strictly prohibited. The user is liable and solely responsible for any improper modification to the instrument, and for the consequences derived as a result.***
- Should the instrument need extraordinary maintenance, contact ROBONIK service or an 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 ECO is a programmable Biochemistry analyzer. It measures the optical densities of samples and it uses algorithm to calculate results, which are used for biochemical investigations. It has a user friendly program and capacity of storing programmed analytical methods and QC results. It is intended for in vitro diagnostic use.

3.2. Special Features:

- Effective temperature regulation system for 12 position dry block incubator.
- Peltier controlled Cuvette block
- Versatile calculation option by factor or standard concentration.
- Extensive programming modes.
- Latest technology with battery back up for 100 test, calibration graph and 10 QC results per test.
- Robust in built 20 Column Thermal Printer with 384 stationary heads.
- Unique circuitry for long lamp life.
- 500 µl Cuvette volume
- Built in stabiliser
- Ability to run multi standard in all modes
- QC with Levey-Jennings Graph

3.3. Specifications:

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
Cuvette Volume	500 µl
Temperature of cuvette Block Method Temperature	 By Peltier Control 37^0 C
Dry Block Incubator Number of cuvettes Temperature	 12 Cuvettes 37^0 C
Light Source	Tungsten Halogen, 6 V / 10 W
Warm up time	90 Sec
Display	Four Line LCD, back lit, 4 X 20 Characters
Printer	Built – in thermal printer 20 columns
Memory	32 KB Non volatile RAM Battery backup, 100 Open tests, with 10 QC results/test
Analysis Mode	Absorbance Fixed Time End Point Kinetic Multi-Standard Differential Ratio PTT
Concentration Calculation	By factor or by Standard
RS232 Serial port	2400 baud, 1 start, 8 data, 1 stop, no parity bits
Power Wattage Voltage	 50 Watts 115 – 230 Volts ± 10%, 50/60 Hz
Operating Position	On horizontal flat, rigid & vibration free surface
Operating Conditions Temperature Relative Humidity	 From + 18^0 C to 35^0 C Up to 85 %
Storage Conditions Temperature Relative Humidity	 From – 10^0 C to 50^0 C Up to 85 %
Enclosure	ABS Fire retardant
Size (cm)	30 X 38 X 13.5 (l X b X s)
Weight (Approx)	5 Kgs.

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 it is to be transported or shipped by courier or other means.
- To pack the instrument follow the instructions as below described:
- Decontaminate the instrument as explained in chapter No. 13 (Decontamination) of this manual.
- Place 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 the instrument:

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

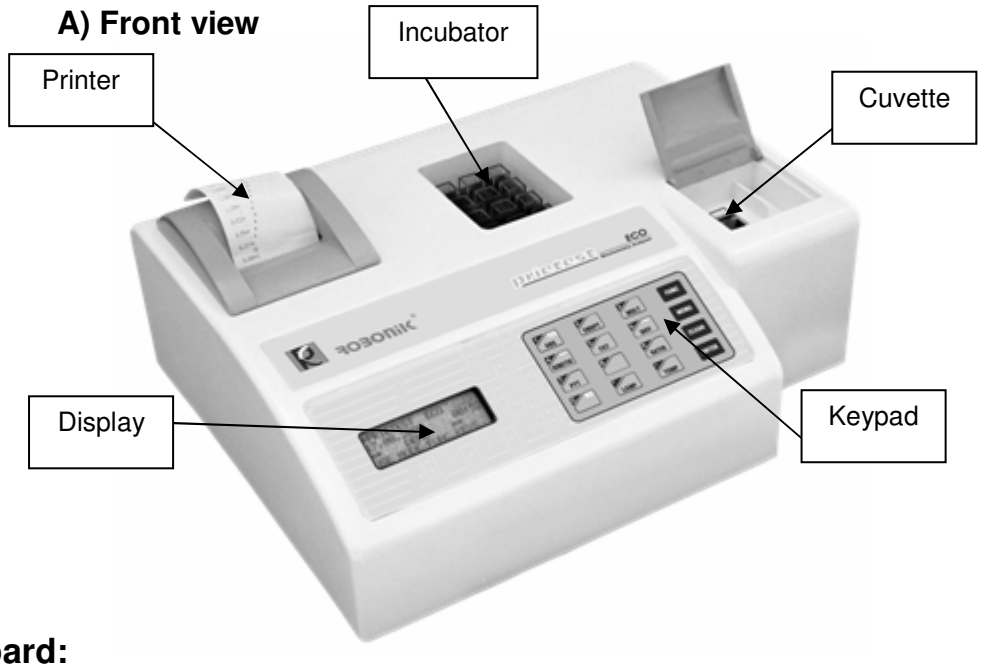
Relative humidity has to be less than 85%, and temperature between 0ºc and 50ºc.

5. INSTRUMENT DESCRIPTION

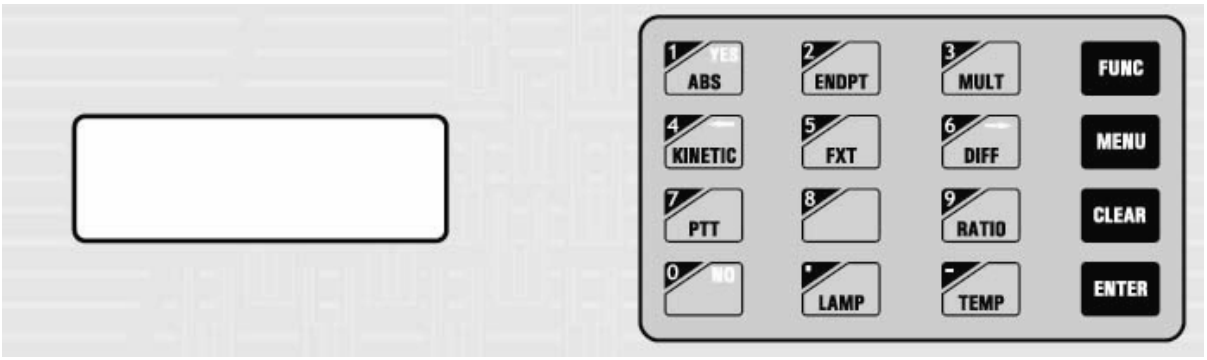
Components of different views of the below pictured instrument:

5.1. Perspective View:

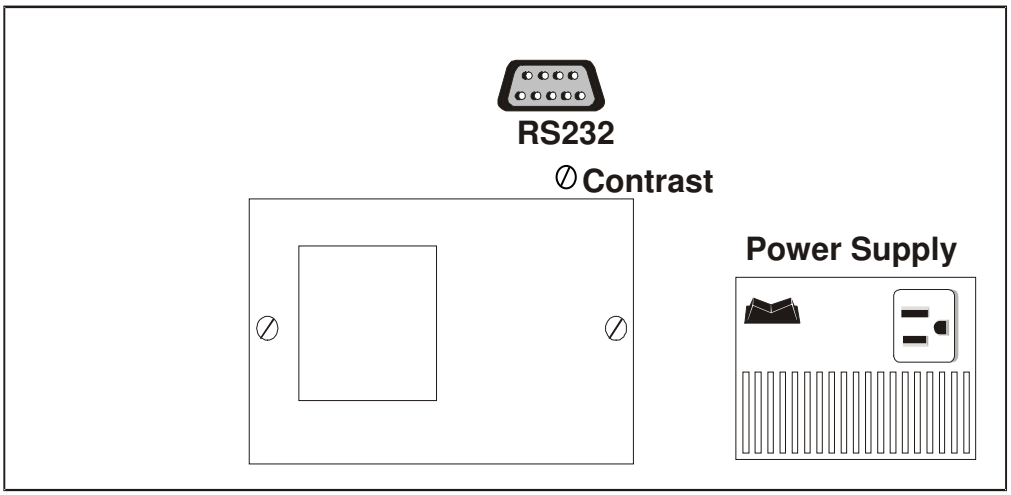
A) Front view



B) Keyboard:



C) Rear View

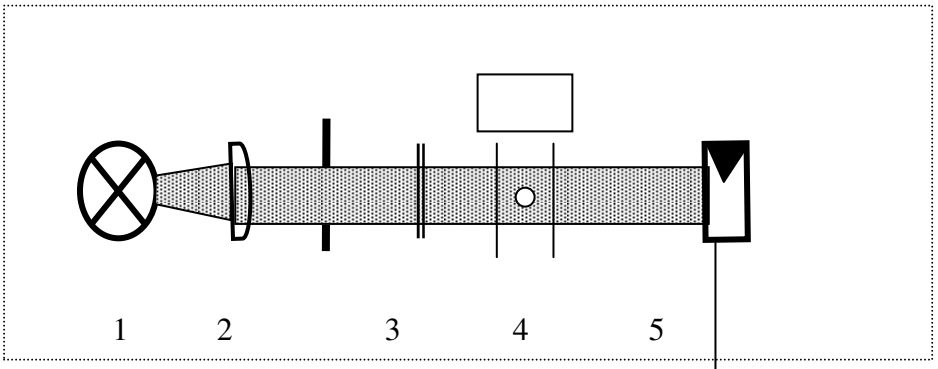


5.2. Instrument working principle:

Instrument functional sequence:

- Switch on and program the instrument
- Start the test
- The measures and the calculations are carried out according to the assay method
- At the end of the cycle the results are printable and at the same time they are available at the RS232 serial port output.

The diagram representing the main functional elements of the instrument.



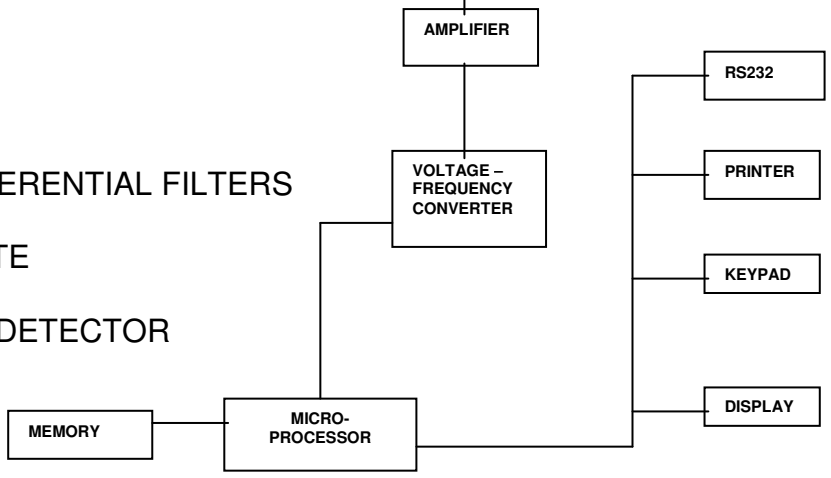
1 LAMP

2 LENS

3 INTERFERENTIAL FILTERS

4 CUVETTE

5 PHOTODETECTOR



White light produced by the lamp is focused into a beam by the lens. It is passed through the Interference filter to get monochromatic light. This further passes through the sample. Part of the light is absorbed by the sample, the remaining light 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.

6. Installation procedure and verification criteria

6.1. Unpacking instructions:

Check accessories as per packing list

Kindly store all packing materials so as to use it to repack and ship for maintenance or servicing.

6.2. Placing the instrument:

- The instrument has to be placed on a level bench.
- Room temperature has to be between 10 and 35ºC with a relative humidity below 85%.
- Protect it from direct sunshine

6.3. Power supply requirements:

Once the instrument has been placed, plug it into a power source by the locally available approved plug-in cable. Power cord should be CE, CSA, and UL marked.

115 - 230 Volts ± 10V, 50-60 Hz

6.4. Protective Grounding:

Warning: Please make sure that electrical power source is properly grounded.

6.5. Thermal printer:

Internal Printer **(Thermal Printer)**

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

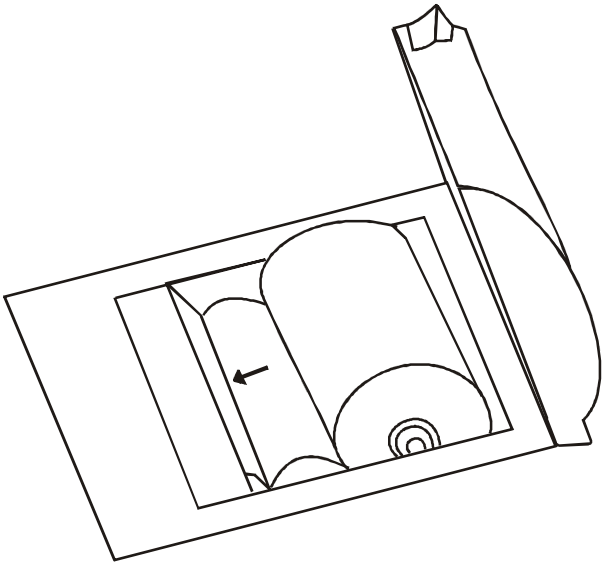
a. **While powering on**
b. **In between character lines**

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

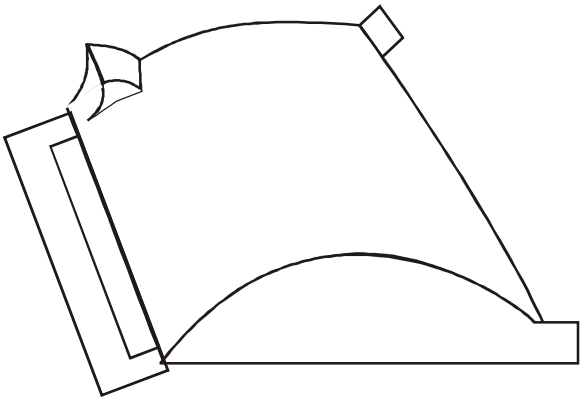
How to insert the paper

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



6.6. Start up Instructions:

- Switch on the instrument. The instrument will display the model name
- The instrument initializes all the parameters internally, and carries out a power on self-test. It then displays 'model name "and the time indicating that initialization is complete. If a printer is enabled, model name, the time, and the date will be printed.
- If the correct date and time are not displayed, switch off the instrument and switch on again.
- Once initialization is over, a lamp located within the instrument will glow. This lamp requires 90 seconds for stabilization.

The instrument is now in IDLE mode, and ready for use.

6.7. Printer setting operations:

Press MENU key under Programming Mode.

In case of any problems in thermal printer, following message will displayed

"SET PRINTER PR ENTER"
"SKIP PRINTER PR YES"

User may operate the instrument by disable the printer.

To Set Printer

- Press **FUNC** key
- Delete test Y/N
- Press **NO** key
- Set time Y/N
- Press **NO** key
- Set printer Y/N
- Press **YES** key
- Printer on? Y/N
- Press **NO** key to switch off the printer, press **YES** key to switch On the printer

6.8. Keyboard check:

Check key board by pressing MENU key first and all other keys later, one should get a beep and either alpha numerical or numerical should appear on display

6.9. Setting Date and Time:

Setting of date and time can be done with the help of FUNC key

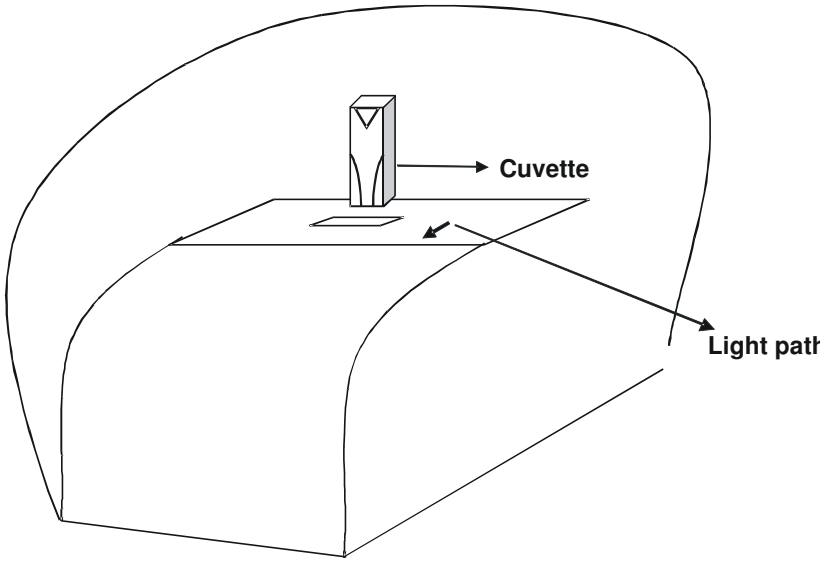
- Press **FUNC** key
- Delete test Y/N
- Press **NO** key
- Set time Y/N
- Press **YES** key
- The instrument displays DATE DD.MM.YY
- Enter date month and year in the same format
- Press **ENTER** key
- The instrument displays TIME HH.MM.SS
- Enter hour, minutes, and seconds in 24 hr format.
- Press **ENTER** key
- The instrument goes back to idle position

6.10. To Enter Clinic Name:

- Press **MENU** Key
- Choose Test
- Enter **205** press **ENTER** Key
- Clinic Name Y/N
- Press **YES** key
- ABCDEFGHIJKLMN
- Select the characters using arrow keys, key no **4** and **6**, confirm by pressing **ENTER** on blinking character. Conclude by pressing **ENTER** key twice at the last character, a maximum number of 15 characters can be entered.

6.11. Cuvette insertion procedure:

Optical path direction is as shown in the diagram below; Cuvette should be inserted with V notch facing the operator.



Front View Section

6.12. Check lamp amplitude:

- Press **MENU** key
- CHOOSE TEST
- Press **201** and press **ENTER** key.
- The instrument shall print lamp amplitude in the following format

340 Amplitude **405** Amplitude
545 Amplitude **510** Amplitude
578 Amplitude **630** Amplitude

The amplitude should be in the range of 3.000 to 11.000 without cuvette.

After printing amplitude press **FUNC** key once the instrument shall display SAVE TEST Y/N. press **CLEAR** key twice to go back to idle position.

6.13. Temperature check:

Press **TEMP** key the shall display the set temperature on display, by default set temperature is 37 degree centigrade.

6.14. Readings check:

Checking of readings should be done through controls. Reading should be with range specified in data sheet of controls (care should be taken while preparing and pipetting controls and reagents, reagent and control expiry dates need to be checked.)

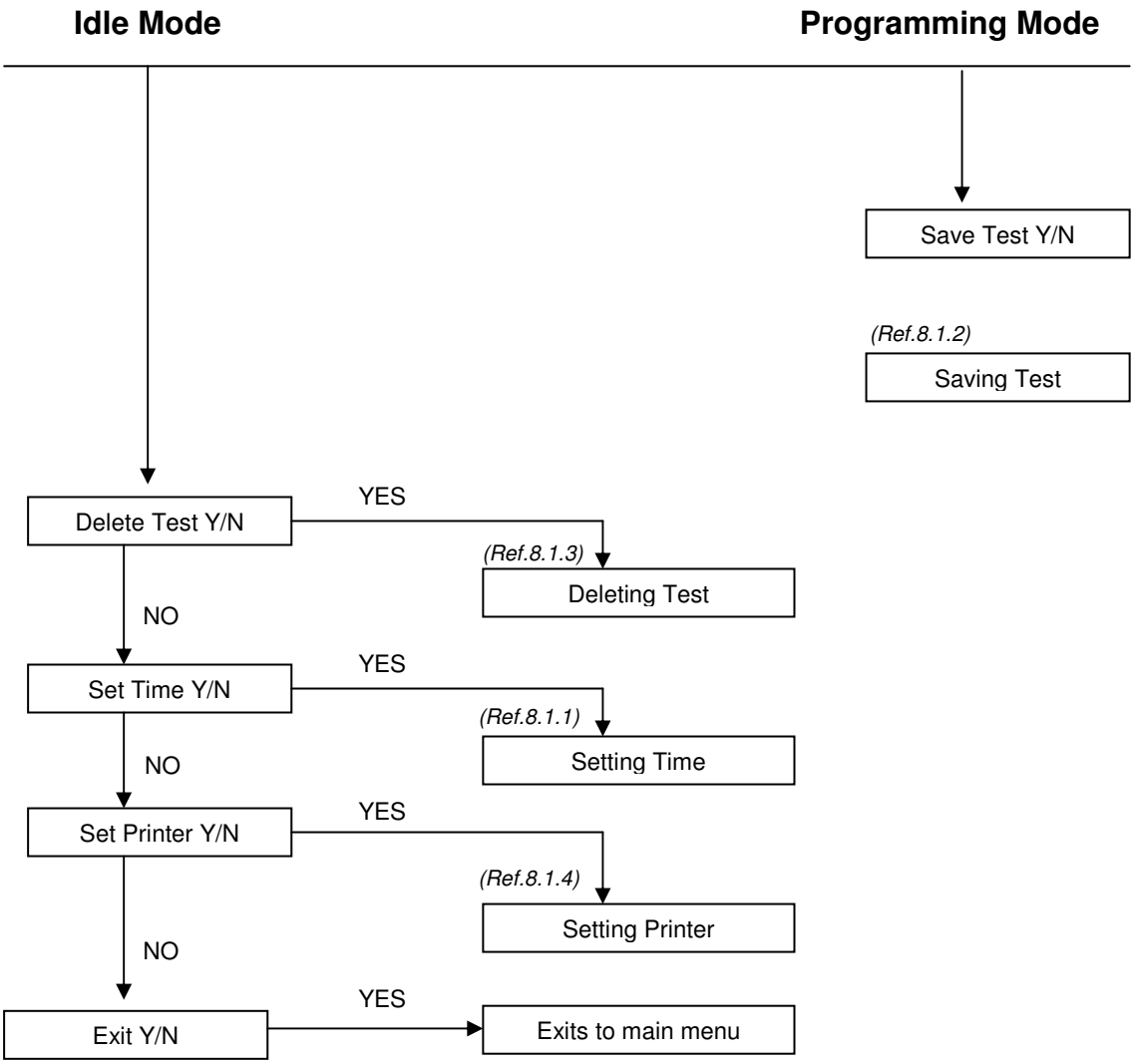
7. PRECAUTIONS

Precautions:

- Keep the place dry and clean.
- Check all the grounding wires properly.
- Repeat the readings, if Absorbance is more than 2.0 A.
- Use original packaging for transportation.
- Use clean Cuvettes. Check the blank absorbance of the cuvette at regular intervals to check the absorbance of the blank cuvette.
- Check the temperature of cuvettes block at regular intervals especially before running kinetic and fixed time.
- Check the linearity of the instrument at regular intervals using standards.
- Do not take reading when the lid is open.
- Incubate the reagents at set temperature for at least 30 minutes before using
- Normally, avoid reading HIGH OD samples immediately after referencing.
- Use 1ml cuvette for Coagulation test.

8. GENERAL KEY OPERATION

8.1. FUNC KEY: FUNC



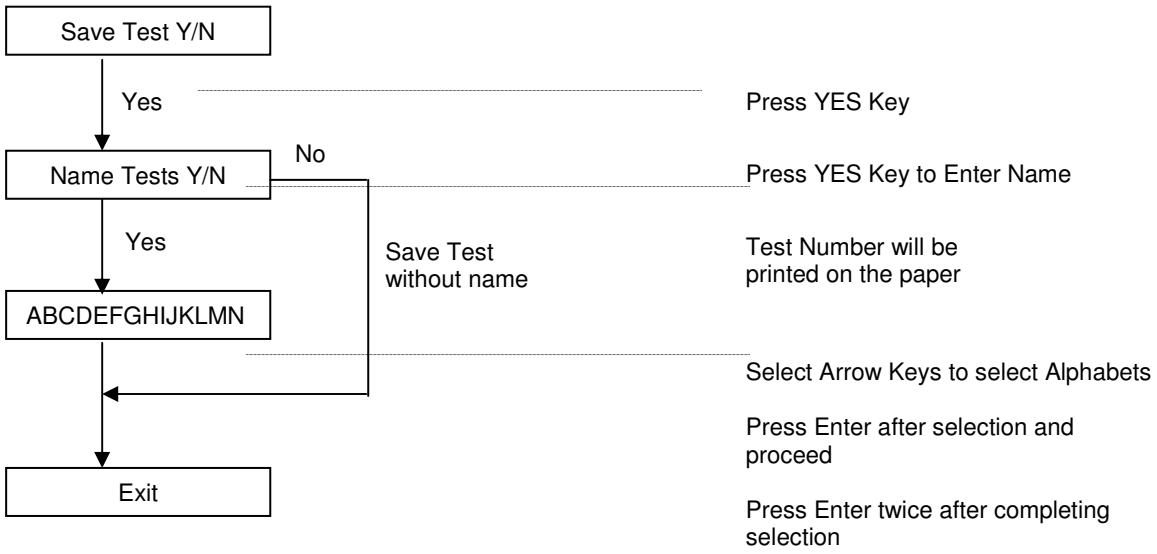
8.1.1. Setting Date and Time:

(Please refer point No. 6.9)

8.1.2. Saving Test:

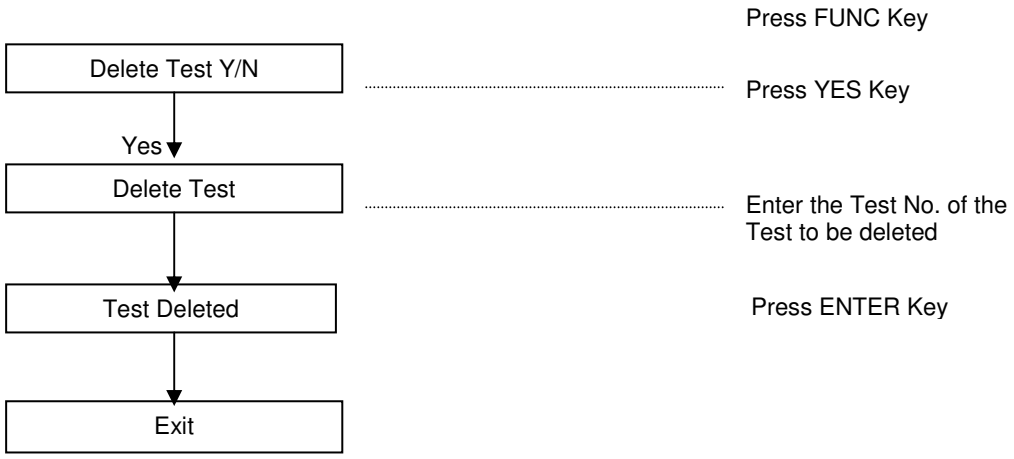
To save the programmed test under any programming Mode

Display **How to operate**



8.1.3. Deleting test:

Display **How to operate**



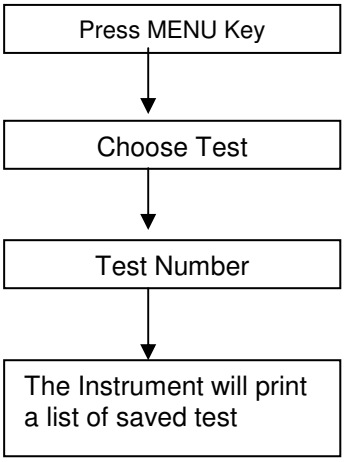
8.1.4. To Set Printer:

(Please refer point No. 6.7)

8.2. Menu Key: MENU

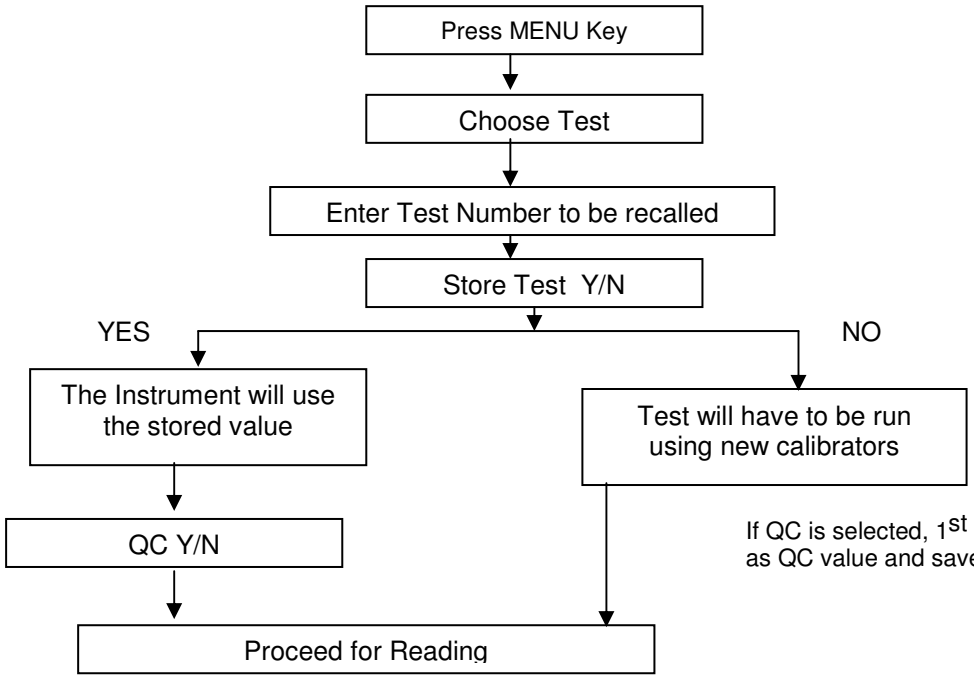
This key is used to select the saved tests

8.2.1. Listing of saved test:



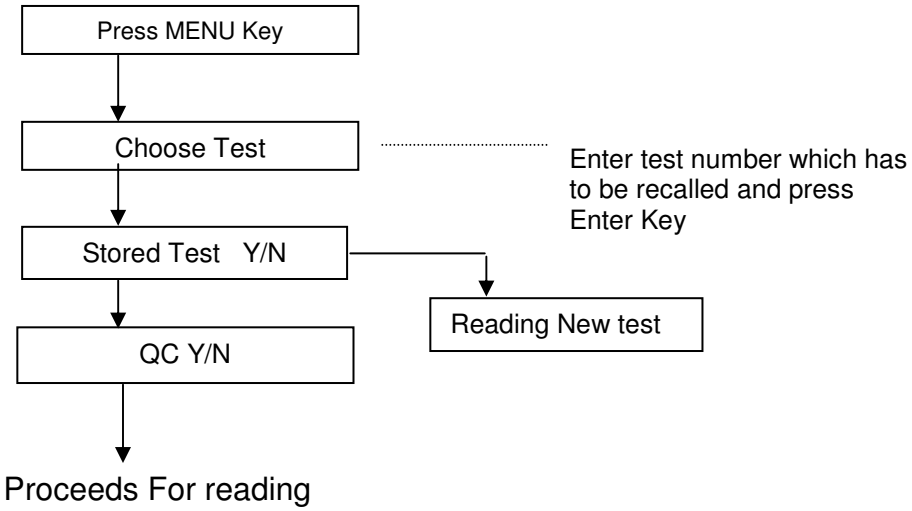
Enter 202 and press Enter

8.2.2. a) Recalling of Saved Test in Standard Mode:



If QC is selected, 1st sample run, will be treated as QC value and saved under the test,

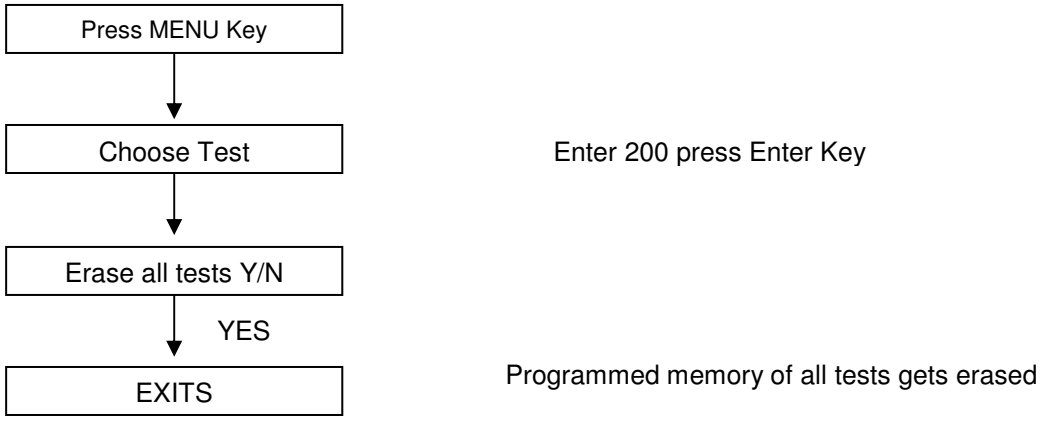
8.2.2. b) Recalling of Saved Test in Factor Mode:



8.2.3. To Enter Clinic Name:

(Please refer sub point No. 6.10 of point No. 6)

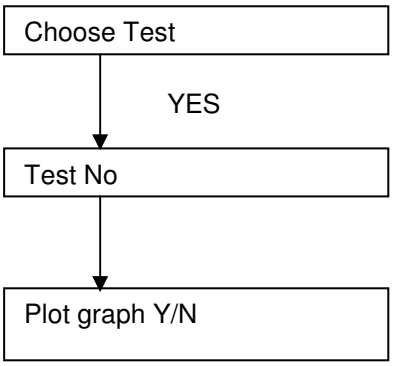
8.2.4. Deleting all Tests:



8.2.5. QC Recall:

It is advisable to run Quality control at regular intervals. By analyzing the quality control graph user can determine the stability of the instrument as well as the reagents.

Operation



Enter 240 to select the Quality control analysis.

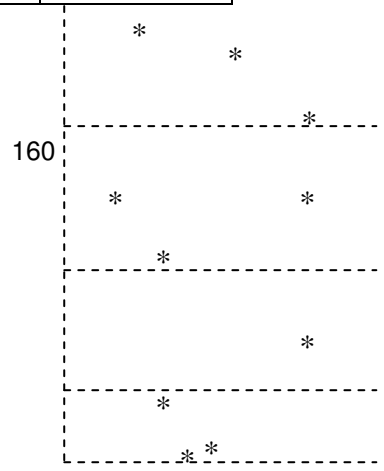
Enter the test Number whose quality control data to be analyzed.

Prietest ECO Prints the stored QC values on the printer

Press YES To plot Graph

Example Printout:

Test No	1
1	115.483
2	142.033
3	220.433
4	42.033
5	20.733
6	23.249
7	102.533
8	126.466
9	180.666
10	59.733



8.3. TEMP Key: 

Display	How to operate
Displays the cuvette temperature and exits	Press Temp Key

8.4. LAMP Key: 

It is a toggle key to switch the lamp on and off.

8.5. CLEAR Key: 

Press twice to initialize the instrument. Under data entry mode it will clear the entered data while pressing once.

8.6. ENTER Key: 

To complete the command / data entry.

9. GENERAL FUNCTIONS

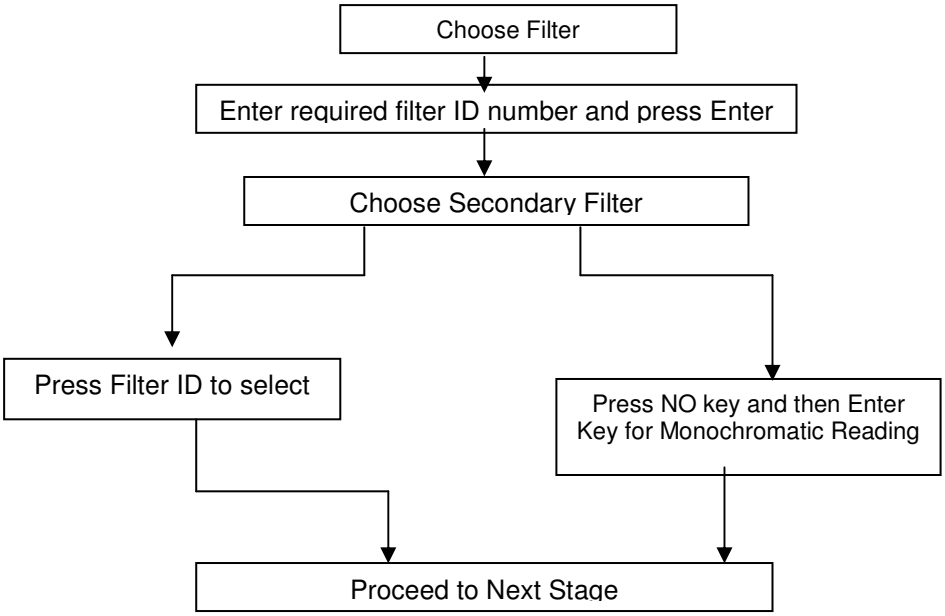
9.1. Selecting Primary and Secondary Filters:

The instrument asks the operator to select the primary and secondary filters. Select the filter using identification number given below. In all modes the operation begins by asking the filter to be selected. The following 6 filters have been provided.

Filter Identification Key No.	Filter Wavelength
1	340 nm
2	405 nm
3	510 nm
4	546 nm
5	578 nm
6	630 nm

Operation

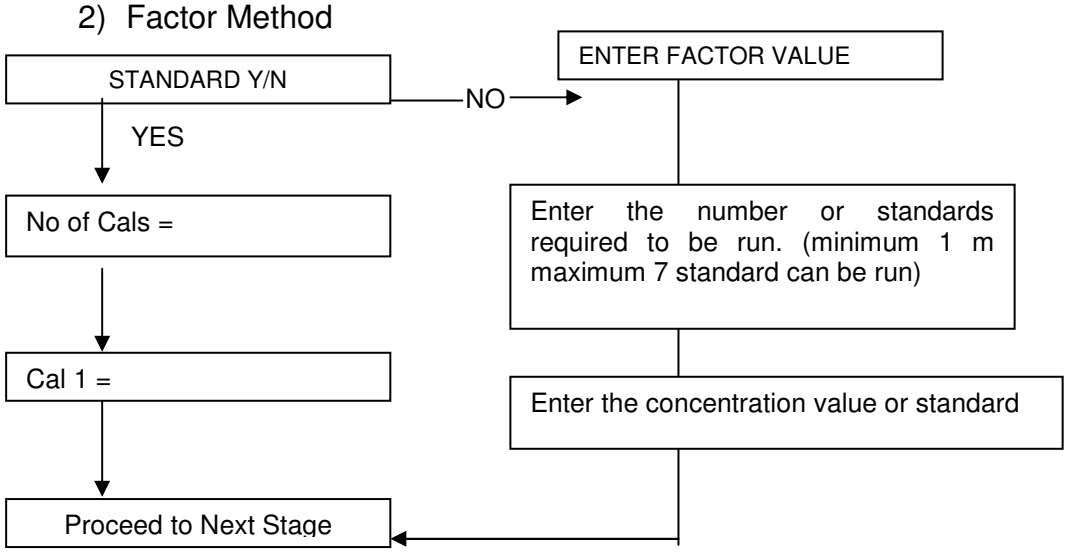
After selecting programming mode instrument prompts for filter selection



9.2. Selection of Standard or Factor:

Prietest ECO has the flexibility to calculate the results by

1) Standard concentration method
2) Factor Method



9.3. Units:

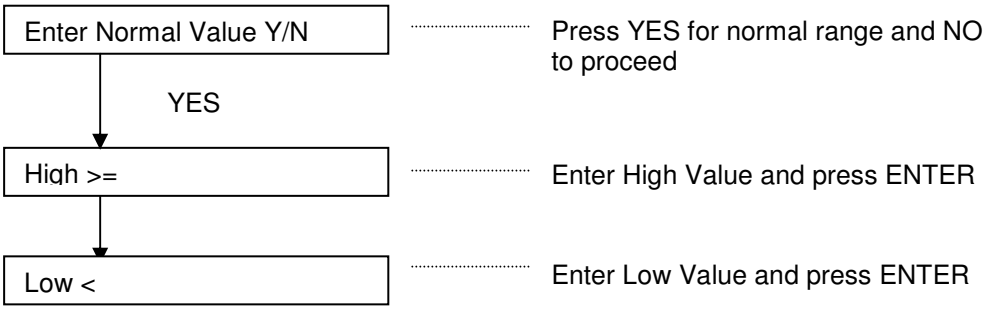
Units can be selected by using the corresponding number key

UNIT KEY NO.	Unit
1	U/L
2	U/ml
3	mU/ml
4	mEq/L
5	MIL
6	mmo/l
7	umo/L
8	nmo/L
9	%
•	ug/mL
—	g/dL
10	G/L
11	Mg/dl
12	Ug/dl
13	G/dl
14	Ug/ml

9.4. Normal Value Selection:

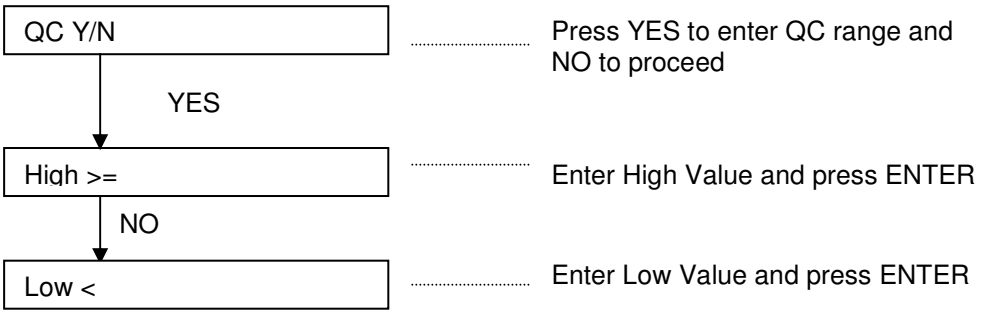
Enter the Normal range of the test

Prietest ECO calculates the results and validates with normal ranges and flags the remarks accordingly



9.5. QC Range Selection:

Quality control is selected by default. Under this option only range is entered for LEVY- JENNINGS graph. With out feeding high and low QC values graphs will not be plotted



9.6. Base Line referencing:

After the lamp warm up, instrument prompts for REFERENCE, indicates the user to remove the cuvette from optical path, if any & close lid. The instrument reads air as reference and automatically adjusts the reference. Now instrument is ready for reading samples.

10. PROGRAMMING MODE

10.1. Absorbance: 

The instrument reads and prints the monochromatic and Bichromatic Absorbance at the user selected wavelength.

OPERATION

Press ABS key to enter the mode

Display	How to operate
Choose Filter	Ref. 9.1
Referencing	Ref. 9.6
Read Sample	Displays/Prints the Absorbance value along with Sample numbers. Continue till all samples are read.

Sample Printout:

```
 ABSORBANCE
Filters 340      nm
 37 DEGREE
S.No    ABS   REM    CON
……..

S1   1.160
S2   2.173
TEST CLEARED
```

10.2. End Point:

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

OPERATION

Press END PT key to enter the mode

Display	How to operate
Select Filter	Ref. 9.1
Blank Y/N	If YES, blanking need to be done, before running Standard or Factor
YES / NO	
Select Standard or Factor	Ref. 9.2
Unit Selection	Ref 9.3
Normal Value Selection	Ref. 9.4
QC Selection	Ref. 9.5
K Factor	(Available only if factor is selected)
Referencing	Ref. 9.6
Read Blank/Standard/ Sample	

Sample Print out:

WITH FACTOR

```
END POINT
Filters 340      nm
FACTOR            100.0
UNITS             U/L
HIGH>              300.0
LOW<               100.0
QC HIGH =         300.0
QC LOW =           100.0

S.No   ABS  REM  CON
……..
BL1    0.215                  0.0
S  1    0.943       LOW     94.3
S  2     1.947      NORM194.7
S  3>    3.00       HIG     349.0
 TEST CLEARED
```

WITH STANDARD

```
END POINT
Filters 340      nm
CALS               200.0
UNITS             U/ml
HIGH>              300.0
LOW<               100.0
QC HIGH =         300.0
QC LOW =           100.0

S.No   ABS  REM CON
……..
BL1    0.210
0.0
 C 1    1.961
200.0
FACTOR
101.96
S1      0.948      LOW
96.6
S2      1.965      NORM
200.3
S3>    3.00        HIG
356.0
TEST CLEARED
```

10.3. Kinetic Rate Mode:

Multiple readings (maximum 15) are taken at set temperature at regular intervals and change in absorbance per minute is calculated. Concentration / Activity of enzyme is calculated from the factor fed by the user or by using calibrator.

OPERATION

Press KINETIC key to enter this mode.

Display	How to operate
Select Filter	Ref. 9.1
Blank Y/N	If YES, blanking need to be done, before running Standard or Factor
YES / NO	
Select Standard or Factor	Ref. 9.2
Unit Selection	Ref. 9.3
Normal Value Selection	Ref 9.4
Select the Lag time in secs	Select Corresponding Number Keys (min. 3 Seconds)
Select the Total Read time In secs	Select Corresponding Number Keys
QC Selection	Ref. 9.5
High Initial ABS Y/N	Press YES to enter Initial Absorbance and NO to proceed
YES	

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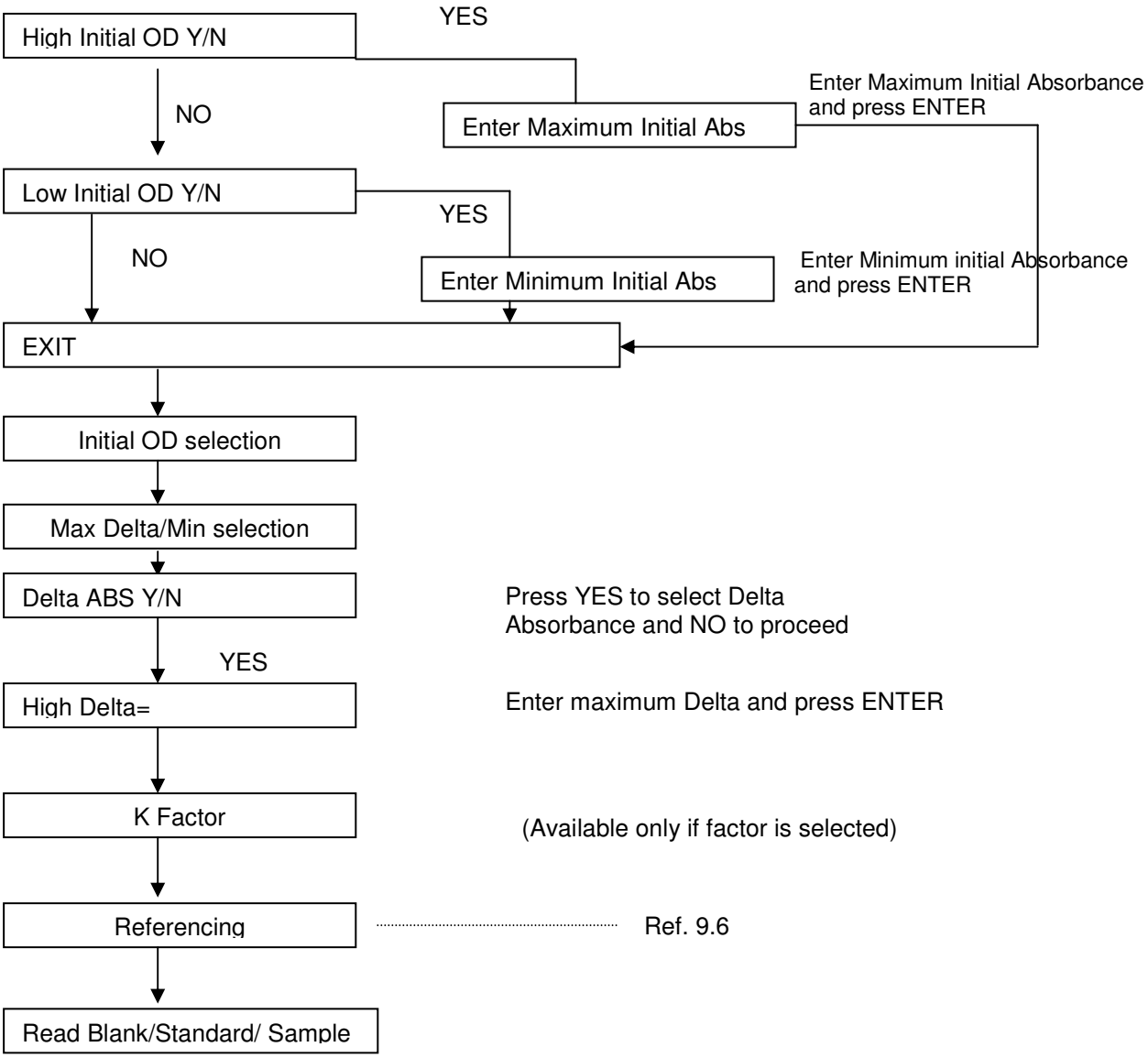

- Instrument will wait till the temperature of cuvette reaches the set temperature. After this Test can be saved at any time (Ref. 8.1.2).
- Instrument will read the absorbance and calculate concentration and then displays / prints in following format.

Sample Printout:

```
KINETIC RATE
Filters 510     nm
FACTOR          100.0
UNITS         mEq/L
HIGH>           200.0
LOW<            100.0
LAG TIME    10
RD TIME     10
#  OF RD     3
QC HIGH =       200.0
QC LOW =        100.0
HIGH INIT ABS <=
I ABS  =        1.000
DEL/M=          1.600
S.No   ABS  REM CON
.....
BL1     0.028
S  1    1.019
D  1B   0.171
D  1C         0.118
 DELTA/MINUTE=
  RES  0.870   LOW   87.0
S  2    0.804
D  2B   0.330
D  2C         0.052
DELTA/MINUTE=
  RES  1.147  NORM 114.7
S  3    0.834
D  3B   0.501
D  3C         0.333
DELTA/MINUTE=
  RES  2.503  HIG 250.3
TEST CLEARED
```

```
KINETIC RATE
Filters 510     nm
CAL1            150.0
UNITS         MIL
HIGH>           250.0
LOW<             50.0
LAG TIME    10
RD TIME     10
#  OF RD     3
QC HIGH =       250.0
QC LOW =        100.0
HIGH INIT ABS <=
I ABS  =        2.000
DEL/M=          0.800
S.No   ABS  REM CON
.....
BL1     0.058
CALS  0.770         150.0
D  2B   0.268
D  2C         0.131
DELTA/MINUTE=
HIGH DELTA
CALS  1.197         150.0
FACTOR          125.26
S1      0.762
D  1B   0.336
D  1C         0.298
DELTA/MINUTE=
HIGH DELTA
CALS  1.902    NORM238.3
S2      0.768
D  2B   0.037
```

10.4. Fixed Time Mode: 

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.

OPERATION

Press FXT key to enter this mode.

Display	How to operate
Select Filter	Ref. 9.1
Blank Y/N	If YES, blanking need to be done, before running Standard or Factor
YES / NO	
Select Standard or Factor	Ref. 9.2
Unit Selection	Ref. 9.3
Normal Value Selection	Ref 9.4
Select the Lag time	Enter Selecting the Number Keys
Select the Read Interval time	Select Corresponding Number Keys (min. 3 Seconds)
QC Selection	Ref. 9.5
Initial OD selection	
Initial ABS Y/N	
YES	YES

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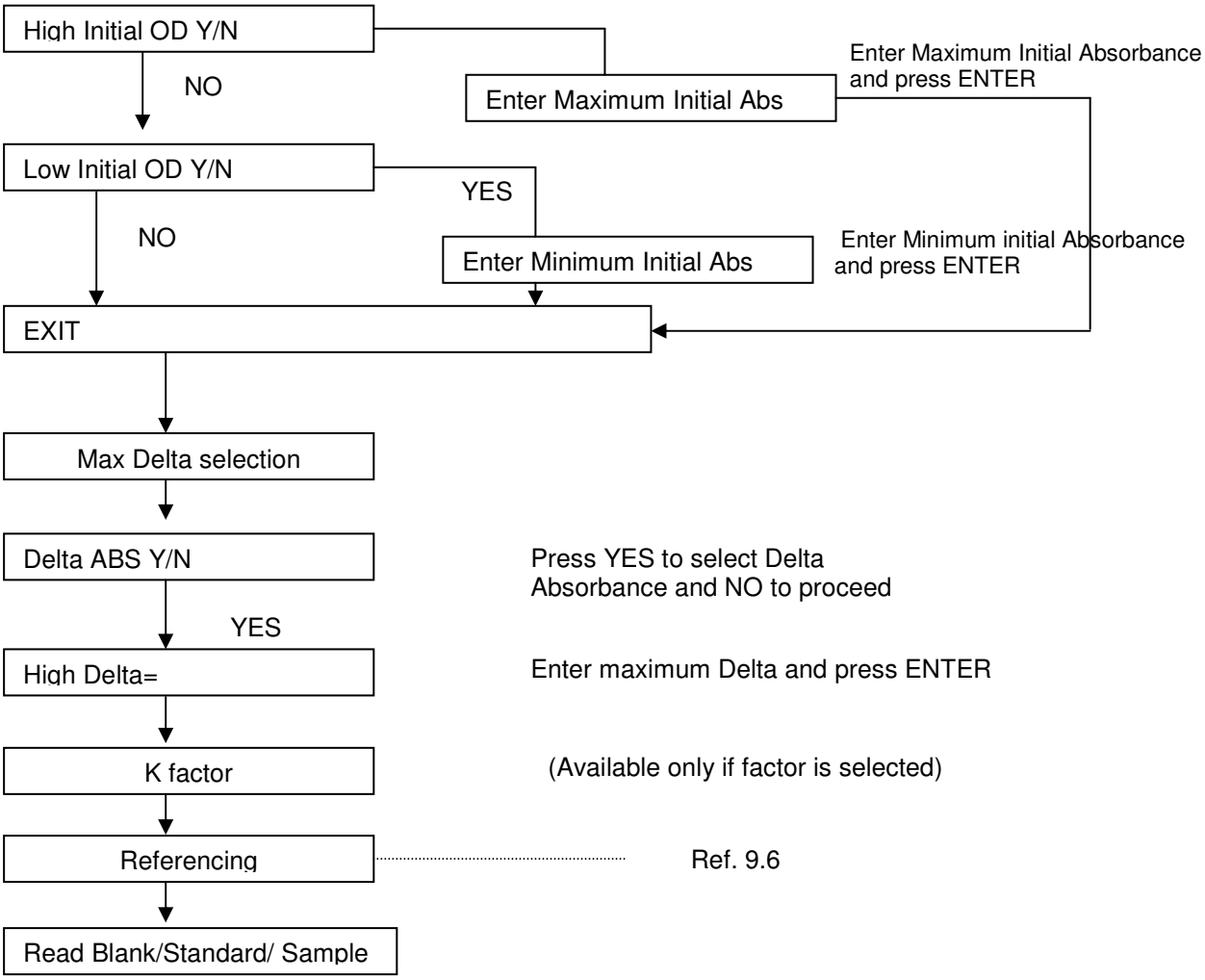


- Instrument will wait till the temperature of cuvette reaches the set temperature. After this Test can be saved at any time (Ref. 8.1.2).
- Instrument will read the absorbance and calculate concentration and then displays / prints in following format.

Sample Print out:

WITH STANDARD

```
 FIXED TIME
 Filters 630      nm
 FACTOR           100.0
 UNITS          mmo/L
 HIGH>            250.0
 LOW<              50.0
 LAG TIME    5
 RD TIME     20
 #  OF RD
 QC HIGH =        250.0
 QC LOW =          50.0
 HIGH INIT ABS <=
 I ABS  =         2.000
 DELTA=           1.500
 S.No   ABS  REM CON
.....................................
BL1     0.043
S  1    1.248
   2    1.308
 DELTA=
 RES  0.059 LOW   5.9
S  2    1.275
 3      1.732

DELTA=
 RES  0.456 LOW   45.6
S  3    0.129
 4      1.163
DELTA=
 RES  1.034 NORM  103.4
S  4    0.095
 5      2.846
DELTA=
 RES  2.750 HIGH  275.0
 TEST CLEARED
```

WITH FACTOR

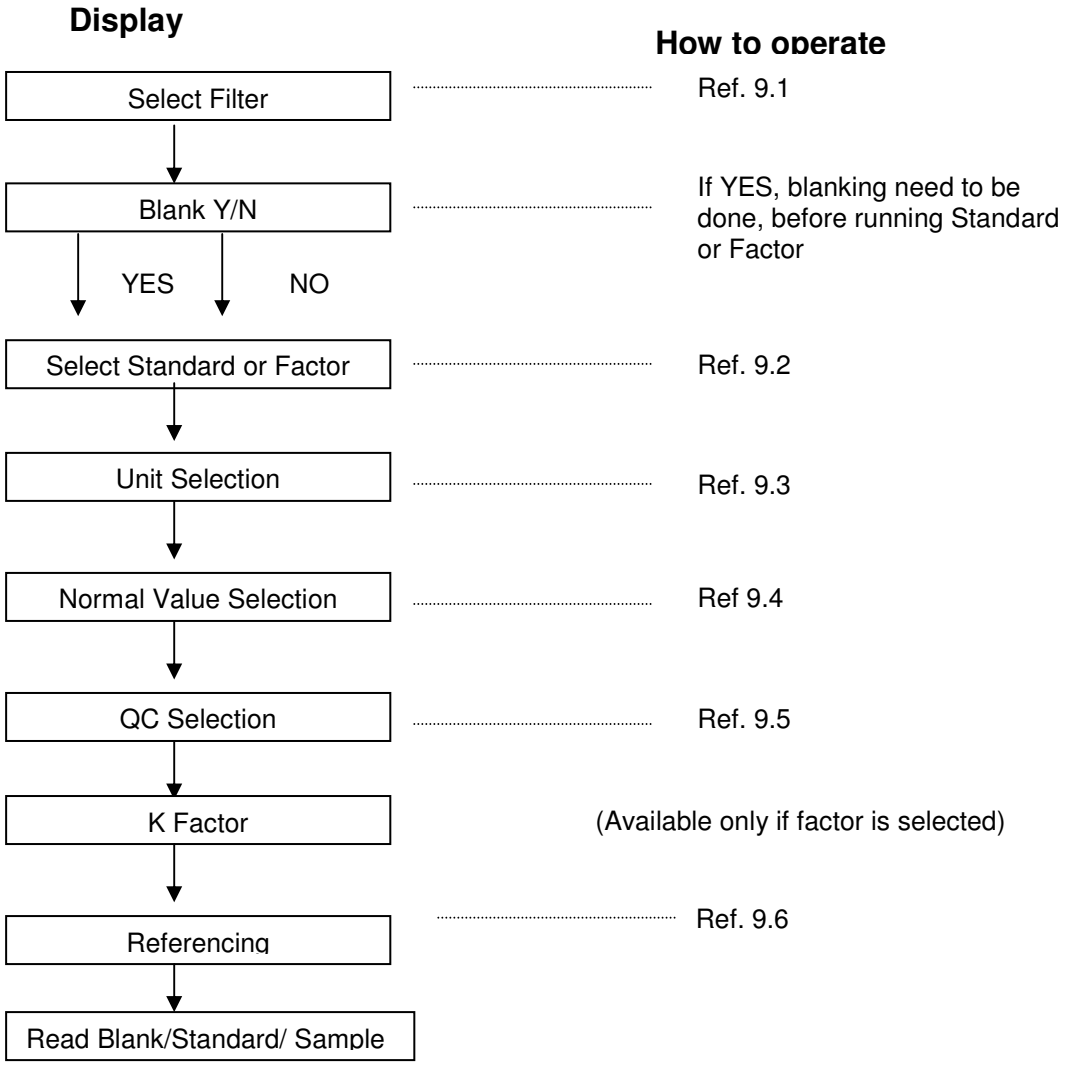
```
  FIXED TIME
Filters 630      nm
CAL1               50.0
UNITS           umo/L
HIGH>            300.0
LOW<              80.0
LAG TIME    5
RD TIME     20
 #  OF RD
 QC HIGH =       300.0
 QC LOW =        100.0
 HIGH INIT ABS <=
 I ABS  =         2.000
 DELTA=           2.000
 S.No   ABS  REM CON
.....................................
BL1     0.026
CALS  1.135       50.0
   1    1.311        1
DELTA=
CALS 0.176         0.0
FACTOR          283.82
S  1     1.159
   1     1.316
DELTA=
RES     0.157  LOW  44.7
S  2     1.167
   2     1.717
DELTA=
RES     0.55  NORM  156.2
S  3     0.108
   3     2.463
DELTA=
RES     2.355  HIG668.4
```

10.5. Differential Mode: 

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

OPERATION

Use DIFF key to enter the mode



- Instrument will wait till the temperature of cuvette reaches the set temperature. After this Test can be saved at any time (Ref. 8.1.2).
- Instrument will read the absorbance and calculate concentration and then displays / prints in following format.

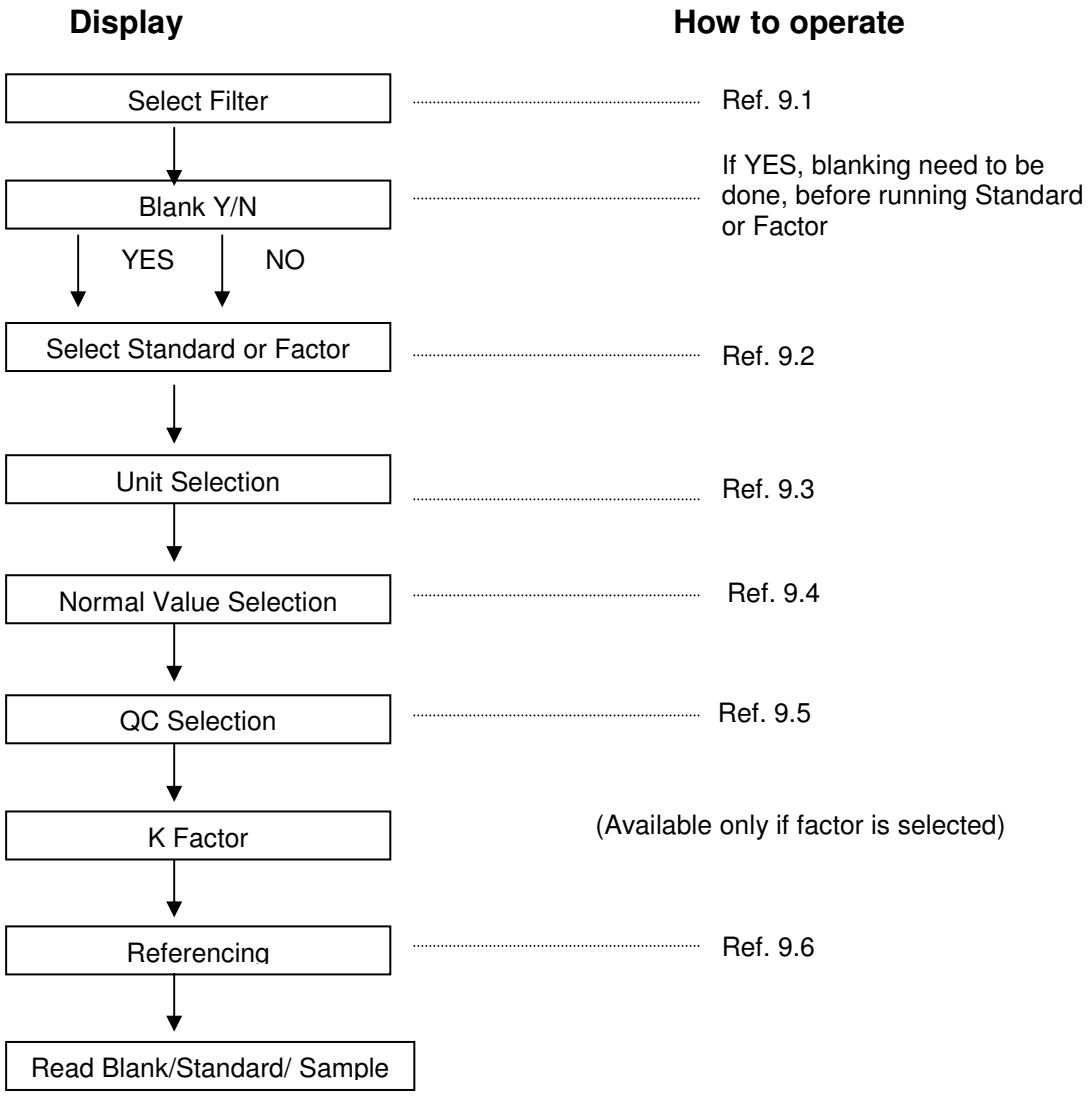
Sample Print out:

```
DIFERENTIAL
Filters340          nm
FACTOR              100.0
UNITS               nmo/L
HIGH>               200.0
LOW<                100.0
QC HIGH =           300.0
QC LOW =            100.0
S.No    ABS   REM    CON
 ……..
 BL1     0.184
 S  1    0.027
   2     0.964
DIFFERENCE   =
RES    0.936  LOW      93.6
S   2    0.969
   3      2.002
DIFFERENCE   =
RES    1.033 NORM   103.3
S   3    0.025
   4      3.525
DIFFERENCE   =
RES    3.00   HIGH350.0
 TEST CLEARED
```

```
DIFERENTIAL
Filters405          nm
CAL1                150.0
UNITS               nmo/L
HIGH>               300.0
LOW<                100.0
QC HIGH =           300.0
QC LOW =            100.0
S.No    ABS   REM    CON
 ……..
 BL1     0.068
 CALS-0.001          150.0
    1    0.224
 DIFFERENCE   =
 CALS 0.225            0.0
 FACTOR             664.69
 S  1    0.007
    1    0.508
 DIFFERENCE   =
 RES    0.501       HIG 333.3
S   2    0.446
   2      0.494
 RES    0.048       LOW 32.2
S   3    0.481
   3      0.757
RES    0.275      NORM103.3
 TEST CLEARED
```

10.6. Ratio Mode:

Ratio of sample 1 and sample 2 is taken. Concentration is calculated either from the factor fed by the user or by using standard.



- Instrument will wait till the temperature of cuvette reaches the set temperature. After this Test can be saved at any time (Ref. 8.1.2).
- Instrument will read the absorbance and calculate concentration and then displays / prints in following format.

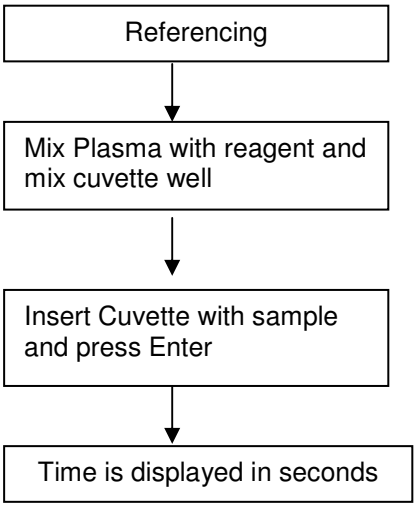
Sample printout

```
RATIO MODE
Filters545          nm
FACTOR              100.0
UNITS               G/L
 HIGH>              200.0
 LOW<               50.0
QC HIGH =           200.0
QC LOW =            50.0
S.No   ABS   REM   CON
 ……….
 BL1    0.031
 S  1   0.464
   2    0.839
RATIO =
RES   0.553 NORM 55.3
 S  2   1.044
   3    0.457
RATIO =
RES   2.283 HIGH  228.3
 S  3   0.456
   4    1.040
RATIO =
RES   2.283 LOW   43.8
TEST CLEARED
```

```
RATIO MODE
Filters578          nm
CAL1                200.0
UNITS               mg/dl
 HIGH>              250.0
 LOW<               100.0
QC HIGH =           250.0
QC LOW =            100.0
S.No   ABS   REM   CON
 ……….
 BL1    0.029
 CAL1   1.524          200.0
   1    0.790
RATIO =
 CALS  1.927           0.0
```

10.7. Prothrombin time Mode:

Use 1 ml cuvette for running this test.



Ref. 9.1

Prothrombin mode procedure and precautions to be taken while testing.

Please note as final reagent volume is 300 µl for Prothrombin, where as the instrument requires 500 µl minimum volume, kindly use 1 ml capacity micro cuvette for testing

Please note – cuvettes provided with the instrument are of 1.5 ml capacity.

Testing procedure

1. Press PTT key
2. Instrument will display close the lid and press ENTER KEY
3. Close the lid with empty cuvette slot and Press ENTER KEY
4. The instrument then displays mix sample. Press ENTER KEY
5. Insert cuvette with PTT reagent in cuvette slot, then pipette sample into the cuvette, and then Press ENTRE KEY
6. The instrument will then display prothrombin time in seconds
7. Note the time, time is also printed
8. Remove cuvette and then press ENTRE KEY.
9. The instrument then display mix sample, Press ENTER KEY
10. Repeat steps 5 to 7 read next sample.

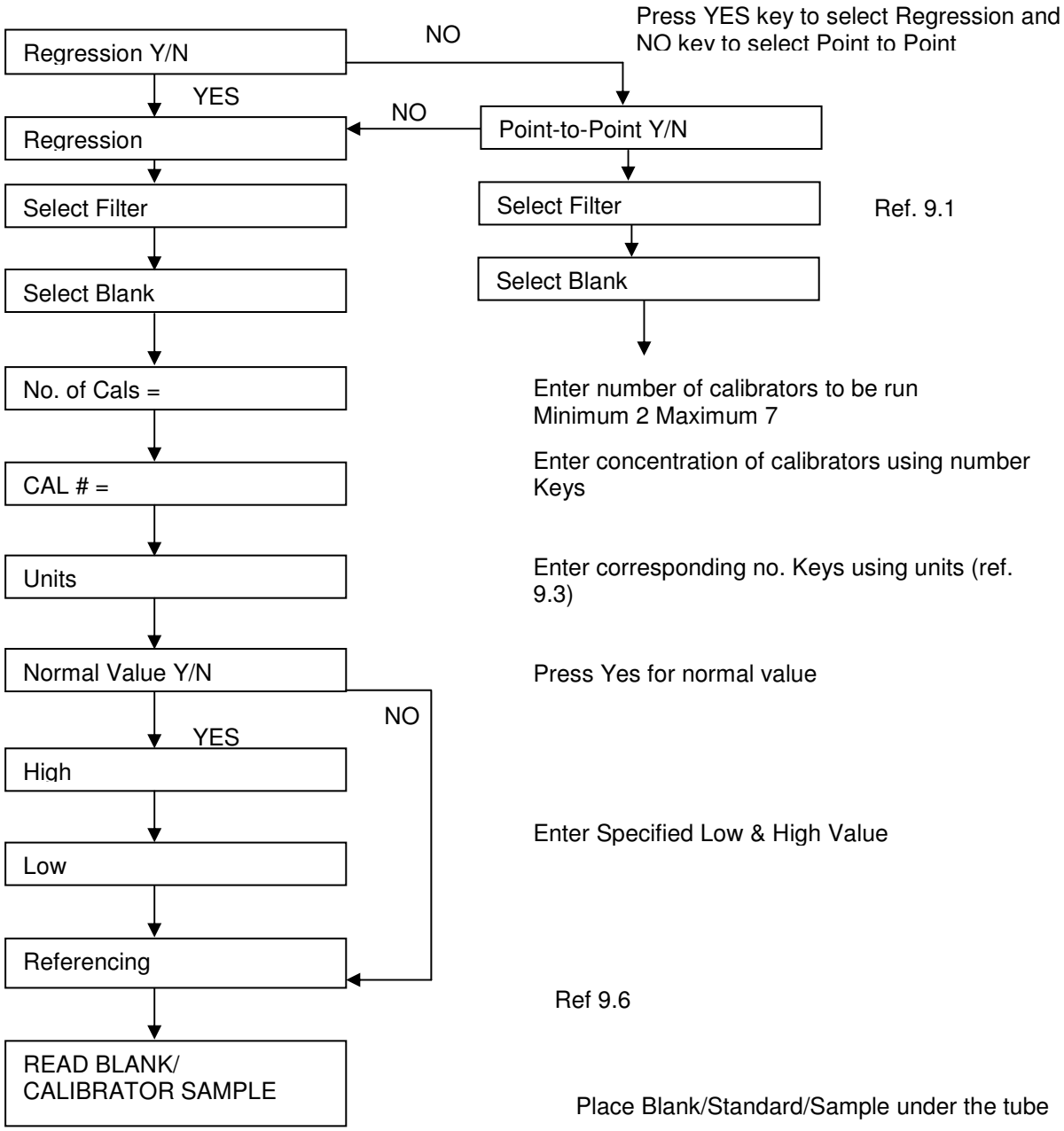
10.8. Multi Standard Mode:

The instrument accepts multiple calibrators (maximum 7) and plots the Graph based on

- Best-fit method
- Point to point method

Absorbance is plotted on Y-axis and concentration on X-axis.

How to operate



Instrument does lamp warm up and does the baseline referencing then, blank/calibrator to be once the calibrators are read, it calculates factor from the algorithm selected.

Calibrator should be read either in ascending or descending order else the instrument may reject the readings if it cannot fit a curve. Graph can be plotted. Graph may be saved or test can redone if readings are not acceptable. Readings will be displayed/printed in the following format.

11. TROUBLE SHOOTING

Trouble shooting:

ERROR MESSAGES	CORRECTIVE ACTION
Memory Full	If Number of saved tests exceeds 125 tests then delete the unwanted tests and save the test.
Clear Cuvette	This error will come in Cuvette mode while referencing. Remove the cuvette and press ENTER key.
Lamp Off press Enter	Incase Instrument remains idle for more than 10 minutes. The lamp is switched off automatically. Press ENTER key to proceed.
"SKIP PRIN. PR.YES" "SET PRI & PR.ENT "	Refer to "Chapter 6.5 thermal printer".

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 how to decontaminate 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 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 _____

_____