prietest eXP

Biochemistry Analysers

User Manual

Version : 4.0

ROBONIK (INDIA) PVT. LTD.
Plot No.:A-374, TTC, MIDC Industrial Area,
Mahape, Navi Mumbai – 400 710. (INDIA)
Tel.: +91 (22) – 67829700, Fax : +91 (22) – 67829701
Email-sales@robonikindia.com
Website-www.robonikindia.com

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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
Fax: +91-22-67829701

Email: sales@robonikindia.com
Website: www.robonikindia.com

European Authorized Representative

Obelis s.a
34, Av. de Tervuren, bte 44
B-1040 Brussels, BELGIUM
Tel: (32) 2. 732.59.54
Fax: (32) 2.732.60.03
E-Mail : mail@obelis.net

CE

2. GENERAL SAFETY WARNINGS

2.1. Danger – warnings symbols

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

This is a symbol of 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 makes use of chemical reagents and other dangerous (Corrosive, irritant, or harmful) CHEMICAL SUBSTANCES, which can cause damage to people or materials. When this label is found, pay attention to the manufacturer's recommendations.

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 heeded

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

This symbol indicates a Protective Earth or Ground terminal.

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 special maintenance, contact MANUFACTURER service or authorized service centre. 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 eXP is a programmable Biochemistry Analyzer, embedded with power of desktop computing on to a biochemistry analyser. It measures the optical densities of samples and uses algorithm to calculate results, which are used for biochemical investigation. It has a photometer operating in the visible range. It is an open system facilitate user to select the reagents of their choice. Its user-friendly program navigates comfortably for running tests on samples. Large semiconductor memory is used for storing Reagent programs, QC results, and patient data results. It is intended for in vitro diagnostic use.

3.2. Features

- Reagent Data Management
- Patient Data Management
- Simplified Test Run Mode
- Q. C.
- Online Reaction Graph
- Patient Report
- Memory
- Power supply with built-in stabilizer.
- Dual system Flow Cell / Cuvette.
- Multi standard run up to 12 standards in all modes.
- Monochromatic and Biochromatic Measurement.
- Auto Stand by.
- Built in Incubator.
- Maintenance free Peristaltic Pump.
- Easy load Thermal Printer.
- Option to connect any Deskjet / Inkjet / Laserjet Printers.

3.3. Technical Specifications

Human Machine Interface	Keyboard and Mouse
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
Photometric Linearity	2.2 A
Drift	< 0.007 A/hr.
Light Source	Tungsten Halogen
Optical measurement	Photodiode
Filters • Filter Type • Wave Lengths • Half Bandwidth • Filter Selection	 Interference 340,405,510,546,578,630 nm & Two Optional 10nm ± 2nm Automatic by Stepper motor.
Cuvette/ Flow cell	Supports both Cuvette and Flow cell
Cuvette Volume	500 µl
Flow cell • Flow cell Volume • Sipping Volume • Sipping	 18µl 300 to 1000 µl Automatic by Specially designed Peristaltic Pump
Temperature of Cuvette Block • Method • Temperature	 By Peltier effect 25ºC, 30ºC and 37ºC
Dry Block Incubator • No of Positions • Temperature	 15 Test tubes 37ºC
Warm up Time	90 sec.
Analysis Mode	ABSORBANCE , ENDPOINT , FIXEDTIME , DIFFERENTIAL KINETIC , RATIO
Concentration Calculation	By factor or by Standard
No Of Tests	> 500
No. Of results	> 10000
No. Of Qc results	Up to 50 each (both Normal & Abnormal control)
Computer Interface	By USB – Pen drive
Hardware	Embedded
Display	In built Swivel, large size LCD colour ,800 x 600 pixels Optional Colour Monitor (external)
Printer	On board thermal 20 column printer, maintenance free. Optional external printer
Software Interface	Copyright of **Microsoft ® Windows ® XP**
Memory Capacity	1 GB - Non volatile RAM
Power • Wattage • Voltage	 50 watts 115 /230 Volts ± 10%, 50/60 Hz
Operating Position	On horizontal, flat, rigid and vibration free surface
Operating conditions • Temperature • Relative Humidity	 From 18 to +35º C Up to 85%
Storage condition • Temperature • Relative humidity	 From 10º C to +60 º C Up to 85%
Enclosure	ABS Plastic.
Size (cm)	30 x 36 x 18 (l x b x h)
Weight	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. DESCRIPTION

5.1. Screen

prietest eXP comes with color TFT LCD screen with 800x600 pixels for smooth and pleasant display. Mounted on swivel, for convenient docking inside the housing for transportation. Using smartly designed mechanically arm, screen angle can be adjusted for comfortable use.

Standard External monitor can be connected for comfortable viewing display.

5.2. HMI Interface

Standard IBM compatible Keyboard, PS2 or USB Mouse could be used for navigating user-friendly software.

5.3. Conducting tests on samples

Samples can be assigned only with reagents, which are prepared and ready with calibrator values and graph. User can prepare/select patients database and assign tests from the reagent table. *Prietest eXP* **compiles** all the data and sorts tests on reagents for batch processing the samples. Required reagent volume for all the selected tests is calculated and displayed to optimise the operator's valuable time.

5.4. Preparing reagents

All required Reagents could be programmed and saved for future use. Un-calibrated reagents are coloured for easy identification. All calculated reagent parameters like reagent volumes, calibrator values, are refreshed whenever edited or newly created.

5.5. Aspiration Switch and Probe

Mechanically Guided Teflon probe aspirates the sample into the flow cell by pressing ASPIRATION Switch when prompted

5.6. Peristaltic pump

Specially designed Peristaltic pump with planetary rollers are used for aspirating controlled volume of samples and washing solution. Pump is conveniently located on the back panel for easy replacement and maintenance

5.7. Thermal printer

prietest eXP **prints** all readings on built in 384 stationary thermal head, Easy load Thermal Dot matrix printer. Easy to use assembly reduces the valuable time of user for paper loading. and has long life compared to moving head printer. For better performance and longer life following tips should be followed

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

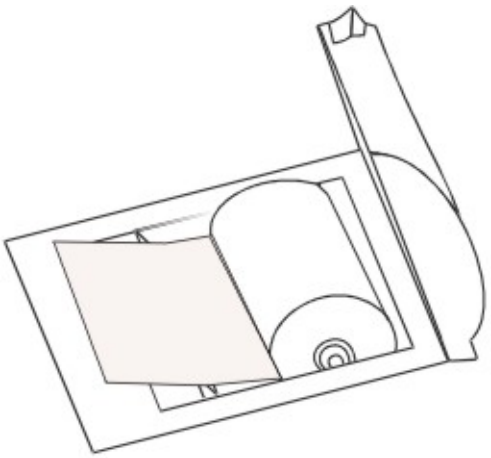
prietest eXP gives line feed automatically wherever it is necessary for clear reading like

a. While powering on
b. In between character lines

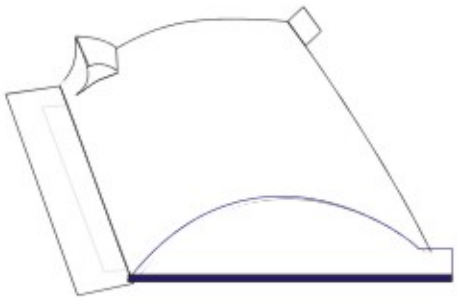
How to insert the paper

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



5.8. Instrument working principle

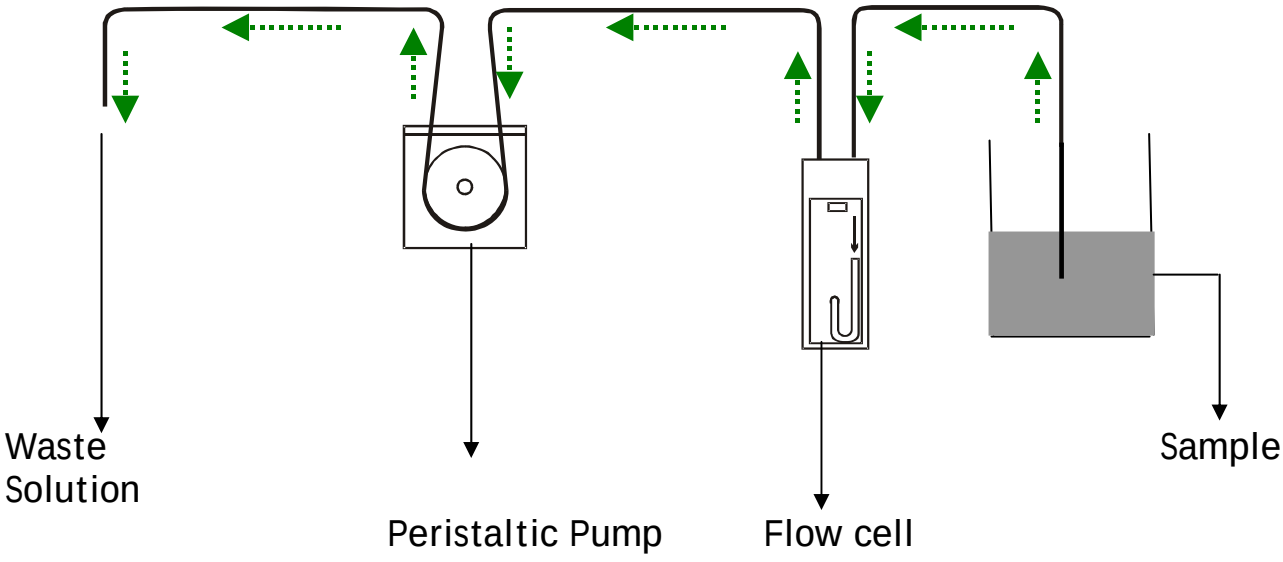
prietest eXP **is** a powerful embedded computer with high speed CPU and 1GB Secondary memory and 256MB RAM. User friendly software works in background and manages data and operation flow to optimize the resources and minimizes operator requirements.
Following sequence of operation are required for preparing to run the test on samples

1) Create/Prepare reagent Ref : sec. 8.4.1
2) Calibrate reagents if required Ref : sec. 9.1
3) Create/select patient name Ref: sec. 8.5.1
4) Assign tests required to be performed on sample Ref : sec. 8.5.1
5) Run tests on sample Ref : sec.9.3
6) Print the report Ref : sec.8.5.3

The Result of the samples is stored are viewed by clicking sub menu "Patient result" of Patient Data. Report of the patient can be previewed and edited for results from other Machines. Colorful reports on Laboratory letter head can be printed on any standard printer compatible to Windows XP.

Fluidic flow diagram

Following is the diagram representing the fluid system of the instrument. Sample is aspirated through flow cell by peristaltic pump when button near the probe is pressed.

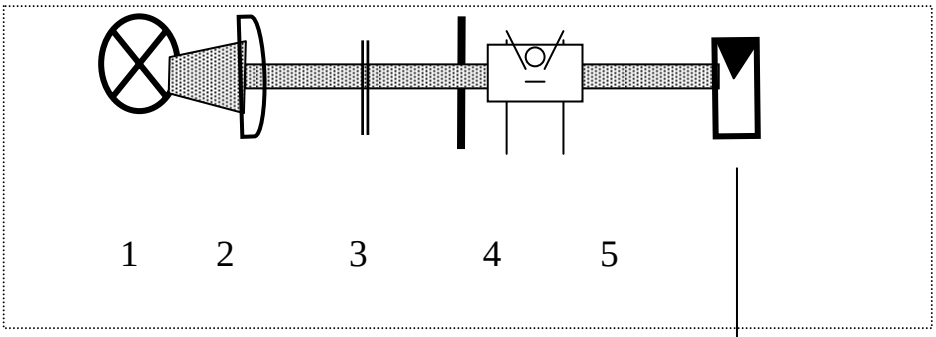


Direction of Arrows represents liquid flow

Principle of working of Optical block

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

The diagram below represents 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. Then the monochromatic light is passes through the sample, during this some part of 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 analogue signal which transformed into digital count. Microprocessor reads this count and calculates the optical density, taking in account of the blank and Bio chromatic selection



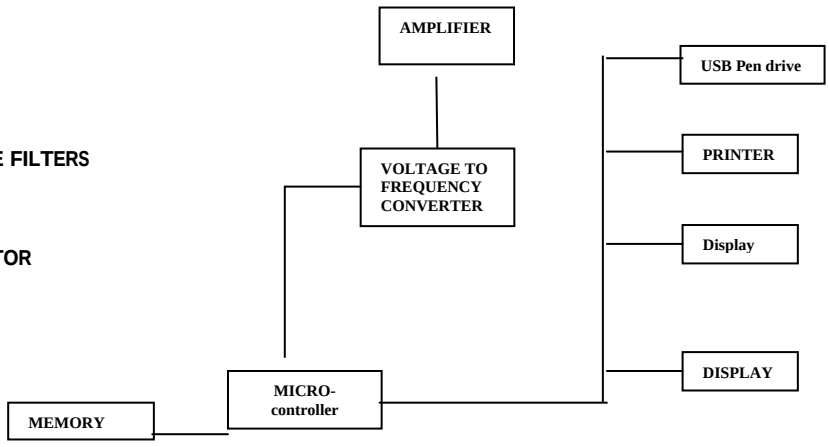
1 LAMP

2 LENS

3 INTERFERENCE FILTERS

4 FLOW CELL

5 PHOTODETECTOR



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

Procedure
1. Switch on the instrument.
2. The instrument initializes all the parameters internally, and carries out a power on self-test and prints the date and clinic name on printer

3. Halogen Lamp used in optical block is switched ON and it requires around 90 Sec. of warm up time for stability.
4. *prietest eXP* with its powerful language option enables operator select the languages. Soft keyboard displayed on screen maps itself to selected language. Menus can select by mouse or keypad

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 Cuvette 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

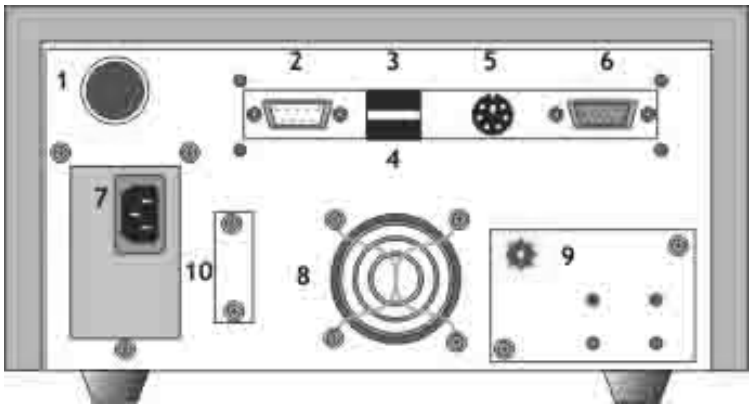
- λ Do not switch OFF the instrument directly, switch it off by shutting down from file menu.
- λ Allow time interval of minimum 1 min between Power OFF & Power ON.
- λ Before inserting USB drive(PEN Drive)in the instrument scan it for Virus

8. INSTRUMENT DESCRIPTION

8.1. Perspective View & Rear View

1: Printer
2: TFT monitor
3: Incubator
4: Aspiration Tube
5: Aspiration Switch

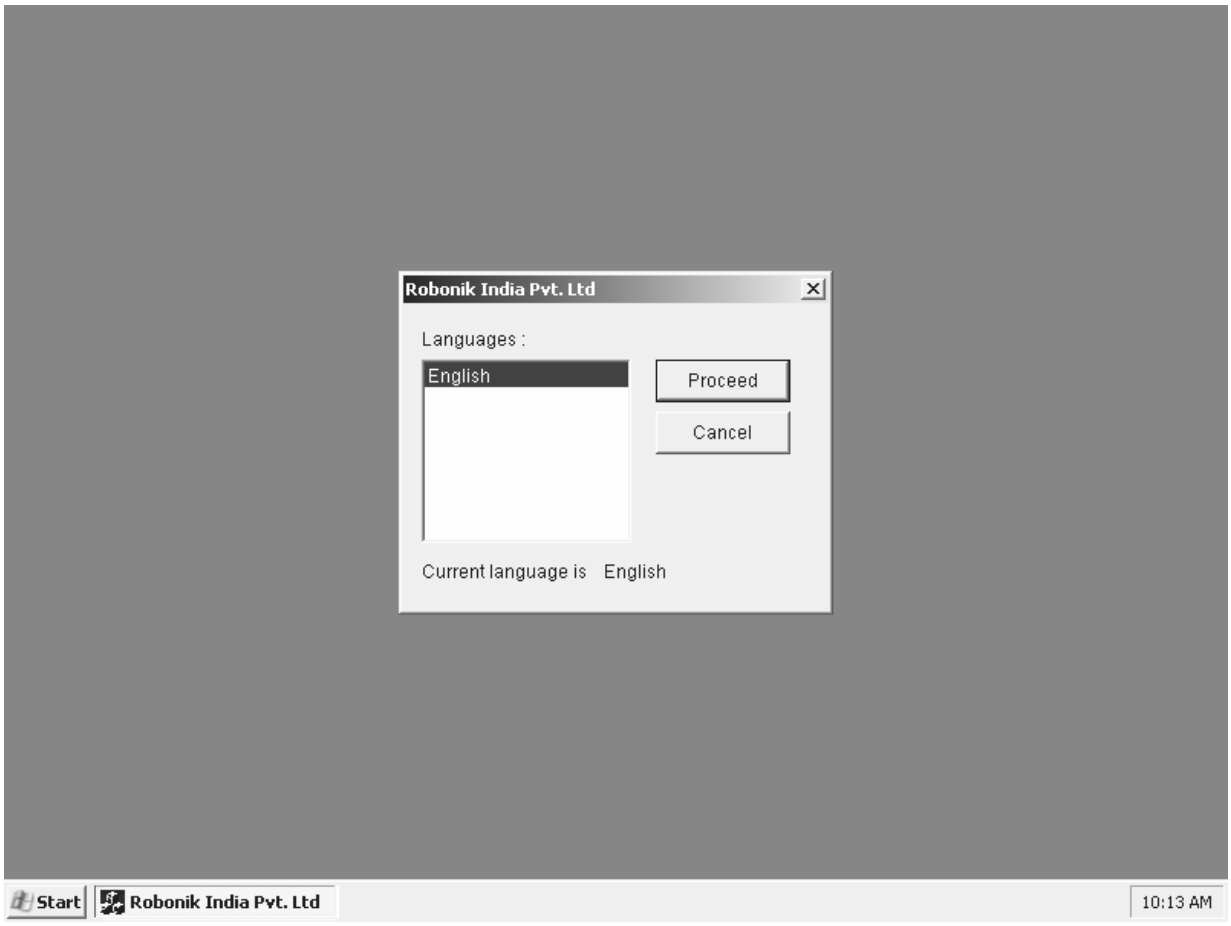
REAR VIEW



1: Push to ON Switch
2: RS 232
3: USB connector 1 for USB Drive/PEN Drive
4: USB connector 2 for External printer
5: Mouse & Keyboard connection
6: External monitor connection
7: SMPS
8: Fan
9: Waste Outlet
10.USB Drive

8.2. Instrument Description

When the system is switched on Language options screen is displayed
On the monitor

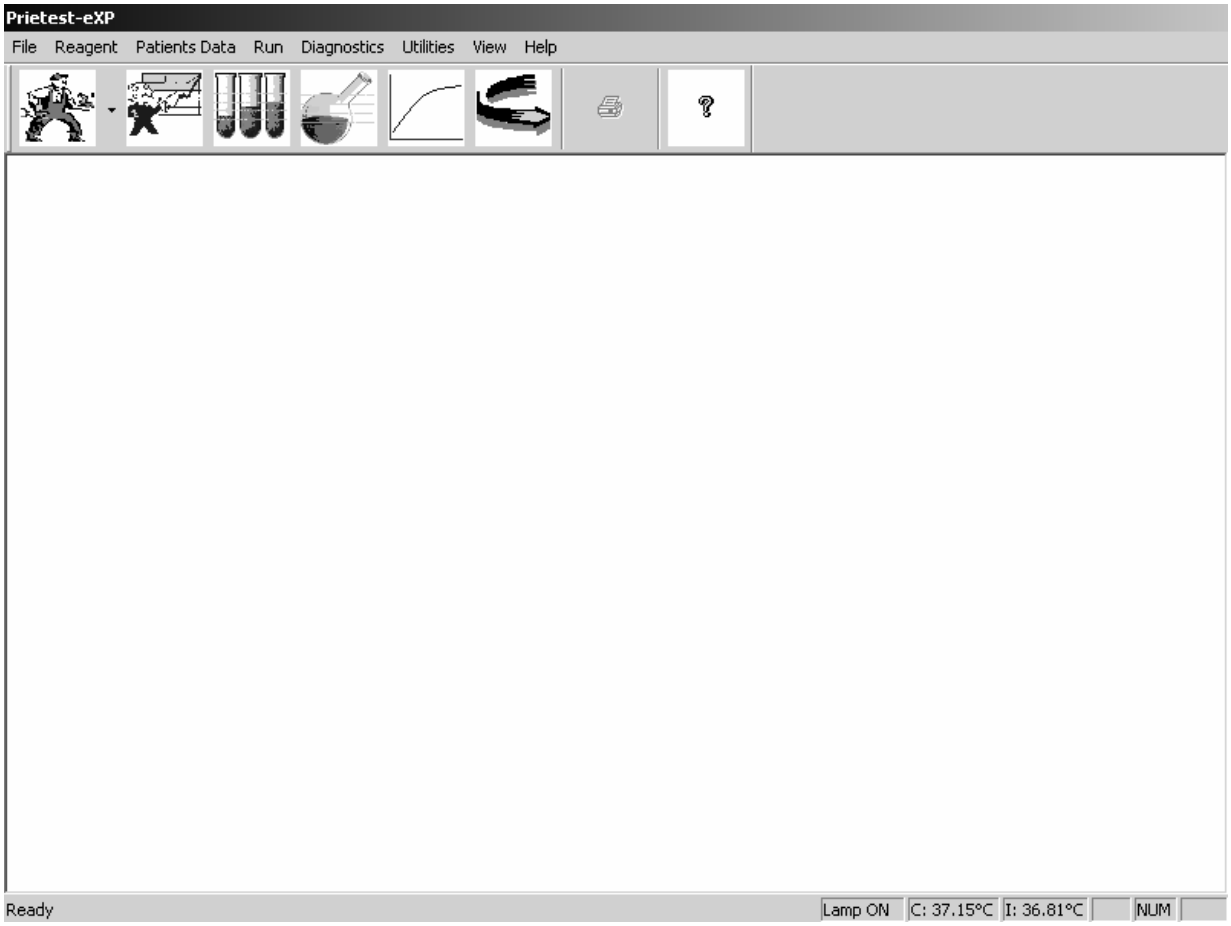


After selecting the language, click on proceed.

When proceed is clicked instrument is initialised & displays the screen shown below.

From this screen menus displayed can select by keypad or mouse.

8.3. Screen after initialization

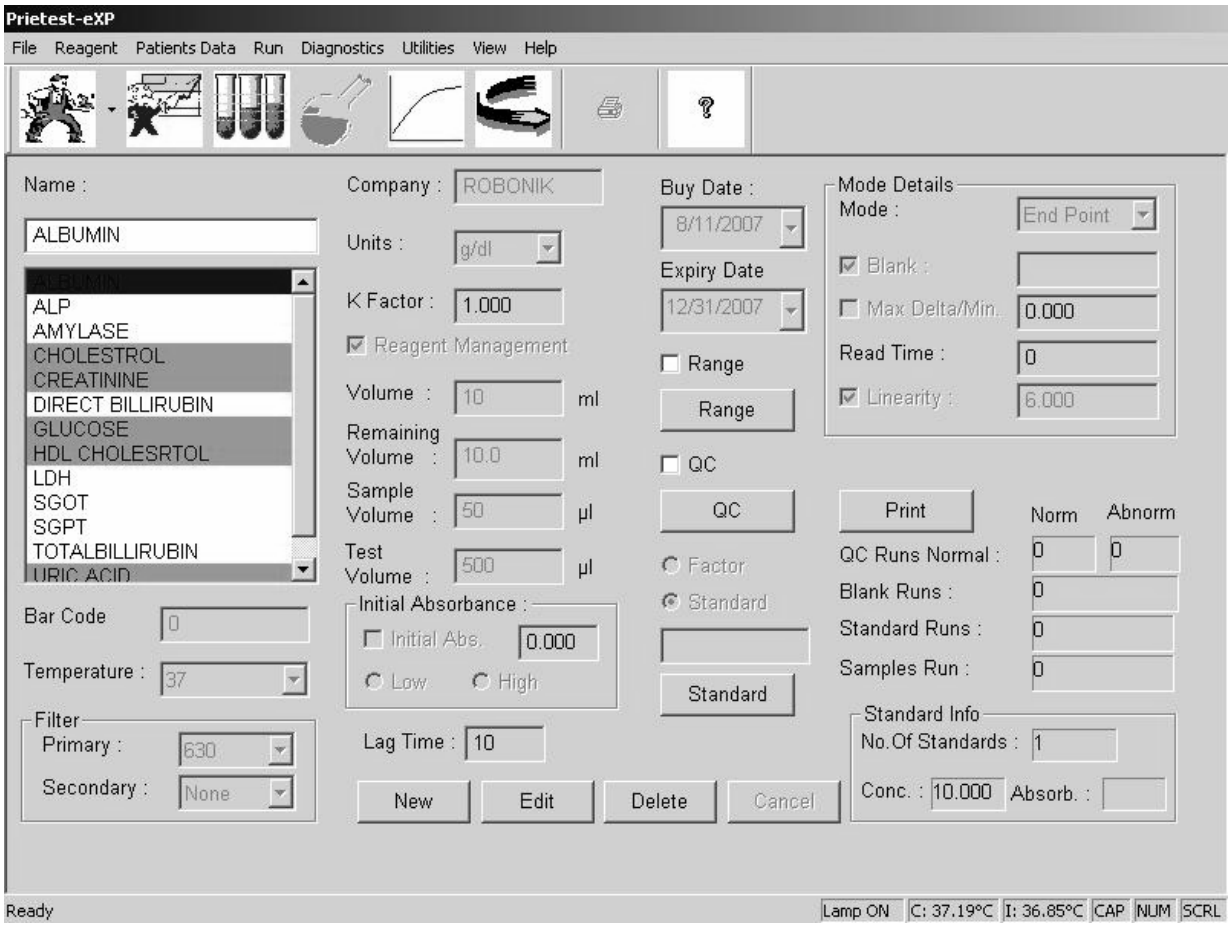


Description of different symbols in screen after initialisation

	This is Diagnostics menu for detail refer sec. 8.7
	When click on this one can get patient report refer sec. 8.5.3
	When click on this one can enter Patient details refer sec. 8.5.1
	When click on this one can get reagent details refer sec. 8.4.1
	When click on this QC Graph can be viewed refer sec.9.4
	When click on this one can run the test refer sec. 9.3
	Prints the patient report when selected.

8.4. Reagent Menu

8.4.1. Reagent Data



When clicked on the reagent data following screen appears.

Following Function can perform in this screen:

1) To create and program new reagent data (click at NEW).
2) To edit existing reagent data (select the reagent to be edited & click at EDIT).
3) Delete existing reagent (select the reagent to be deleted & click at DELETE).

Description of the fields in Reagent screen.
(Compulsory entries are given in *Italic Bold* in following description).
Note: To carry out the entries one has to first bring the curser at that location.

1) *Name:*
   Enter the reagent name by keyboard.
   Name can be up to maximum 21 alphanumeric characters.
2) List is displayed with reagents name.
   Select the reagent by clicking to view its contents.
   Selected test can then edit or delete.

3) Temp:
25^0C, 30^0C or 37^0C can enter.

4) *Filter Primary:*
By clicking at arrow one can select primary filter.

5) Filter Secondary:
By clicking at arrow one can select secondary filter.

6) *Company:*
Name of the Reagent Supplier / manufacturer can enter.

7) Units:
By clicking on arrow one can scroll the available units & select the required unit.

8) K factor:
It is the Kelvin factor to be entered (as per given in kit).
Instrument is provided with default K- factor 1.00.
Note: If K- factor is not given then keep it 1.000

9) Reagent Management:
Enable this to maintain the reagent consumption statistics.

9.1 Volume	:	Total volume of the reagent purchased in ml.
9.2 Sample volume	:	Sample volume in µl.
9.3 Test Volume	:	Volume of reagent required for the test in µl.

10) Buy Date:
Date of Purchase of reagent.

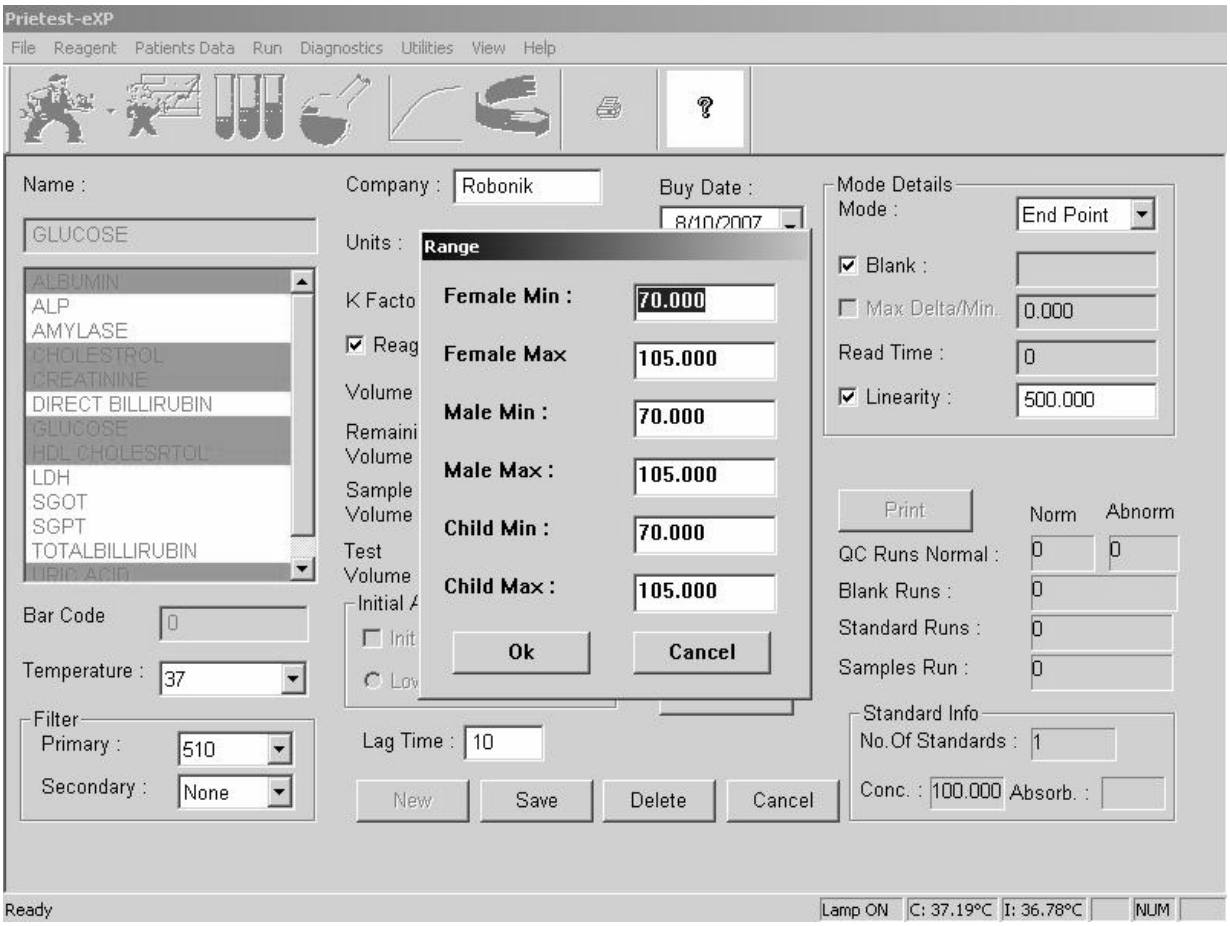
11) Expiry date:
Reagent expiry date. Validate the expiry of kit.
Instrument will give message to the user if the reagent is expired
When that particular test is selected for run.

12) Initial Absorbance:
(Applicable only for Kinetic & fixed time).
One can enter the initial absorbance along with High or Low selection
Depending on initial absorbance H or L flags gets displayed & printed
Along with initial absorbance.

13*) Lag Time:*
Minimum Lag Time is 5 secs.
(In case of differential mode test instrument displays two lag times one for sample blank & one for sample).

14) Normal Range:

When clicked on range following screen appears



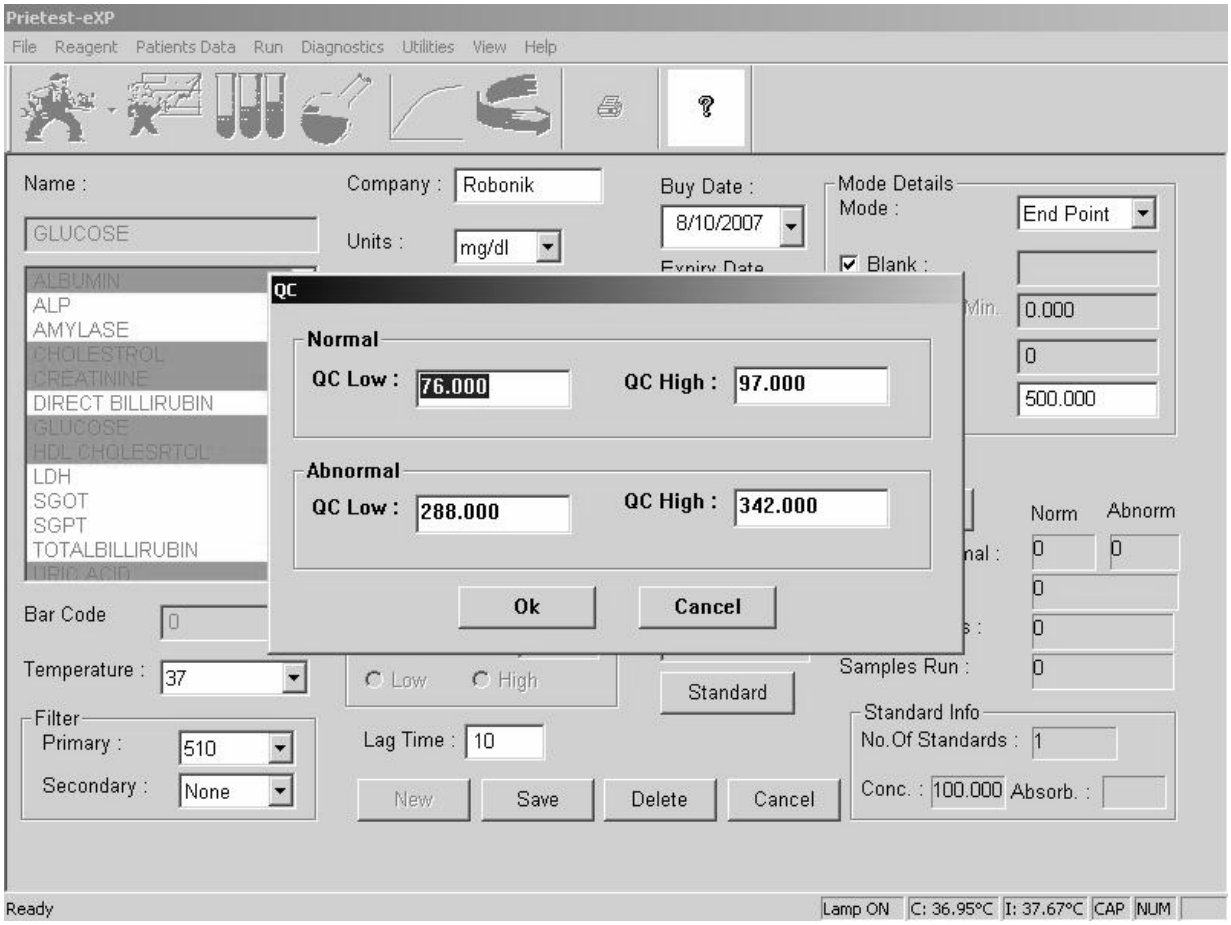
The normal range for the concentration or the activity of the assay can Enter here .If a test result is out of this range, the result will be flagged with L or H.

Also in Patient Report results are printed in red colour if they are out of range.

Normal range for male, female & child can be entered separately.

Click **Ok** for instrument to accept the ranges enter.
Click **Cancel** for instrument not to accept the ranges enter.

15) QC Range:
When clicked on QC following screen appears



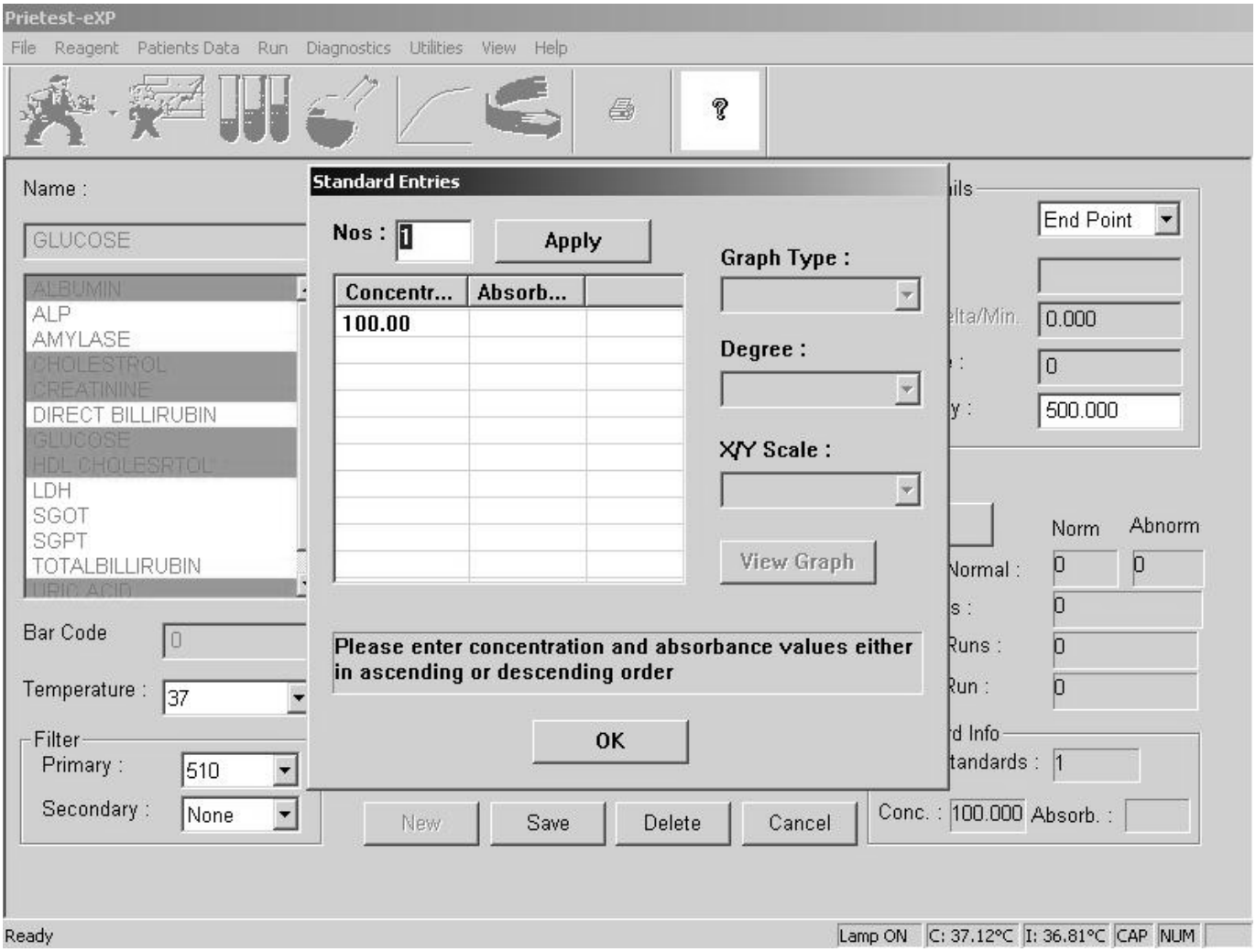
One can enter lower & higher limits for normal & abnormal controls in this screen.

Click **Ok** for instrument to accept the ranges enter
Click **Cancel** for instrument not to accept the ranges enter.

16) Factor/ Standard entry

16.1 Factor Entry : Click on radio button before factor.
One can then enter the factor value in the block provided.

16.2 Standard Entry: After Clicking on radio button before standard one can enter standard concentrations, for that click on standard button
When clicked on standard following screen appears.



Maximum 12 standards can be entered.
Graph of multistandard can be viewed in two types
Point To Point or Linear. (Type of graph can be selected by clicking at arrow in graph type).

Out of factor or standard any one is Compulsory.

17 Mode Details

17.1 Mode

One can program the reagent in following five modes:

I. End Point
II. Kinetic
III. Fixed Time
IV. Differential
V. Ratio

17.2 Blank

I. If selected in kinetic reaction instrument performs kinetic reaction on blank solution.
II. if selected in differential reaction instrument performs differential reaction on blank.

17.3 Max delta/min (can be entered)

I. In case of kinetic Max delta/min.
II. In case of Fixed Time Max delta.
III. In case of Differential Max diff.
IV. In case of Ratio Max Ratio.

17.4 Read Time

Total read time required for test.

17.5 Linearity

It is the maximum value up to which reagent action is linear.

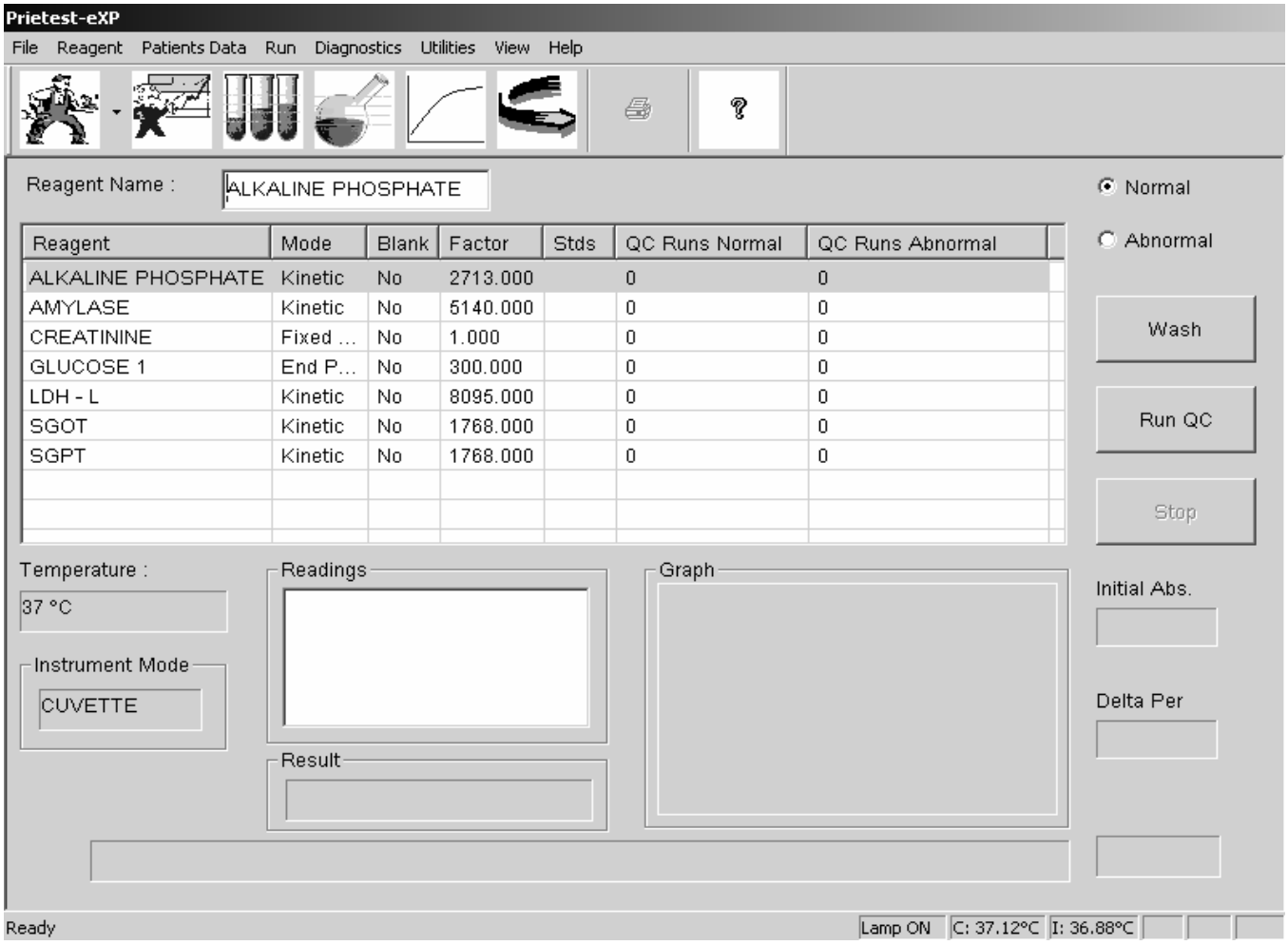
18) Run information:

This section provides the following information.

9.1 QC Runs Normal : Displays the no. of QC normal control run.
9.2 QC Runs Abnormal : Displays the no. of QC abnormal control run.
9.3 Blank Runs : Displays the no. of times blank is run for that test.
9.3 Standard Run : Displays the no. of times standards are run.
9.4 Samples Run : Displays the no. samples run.

8.4.2. QC Run

When clicked on the QC Run following screen appears.



Used to run control samples (Normal /Abnormal) to analyse the QC result by plotting standard deviation graph. Refer section 9.4 for standard deviation graph.

Click on Normal / abnormal to select control to be run.

QC Run table provides following information

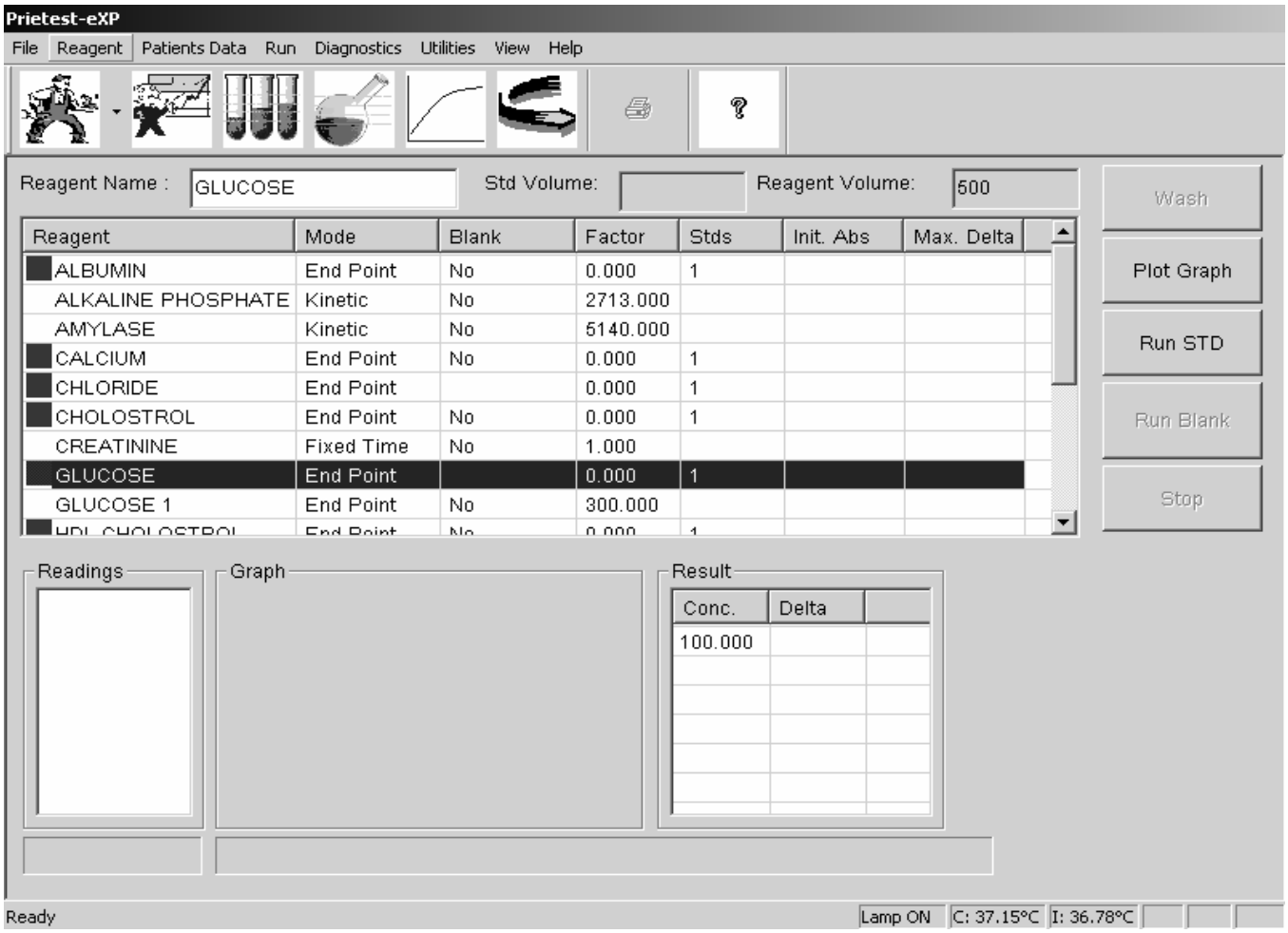
- The results of blank, factor calculated in case of single standard.
- No. of standards run.
- No. of QC samples (Normal / Abnormal) run.

Running QC Samples

Refer to section 9 Test Operations for steps to run QC Samples

8.4.3. Standard Run

When clicked on the Standard Run following screen appears.



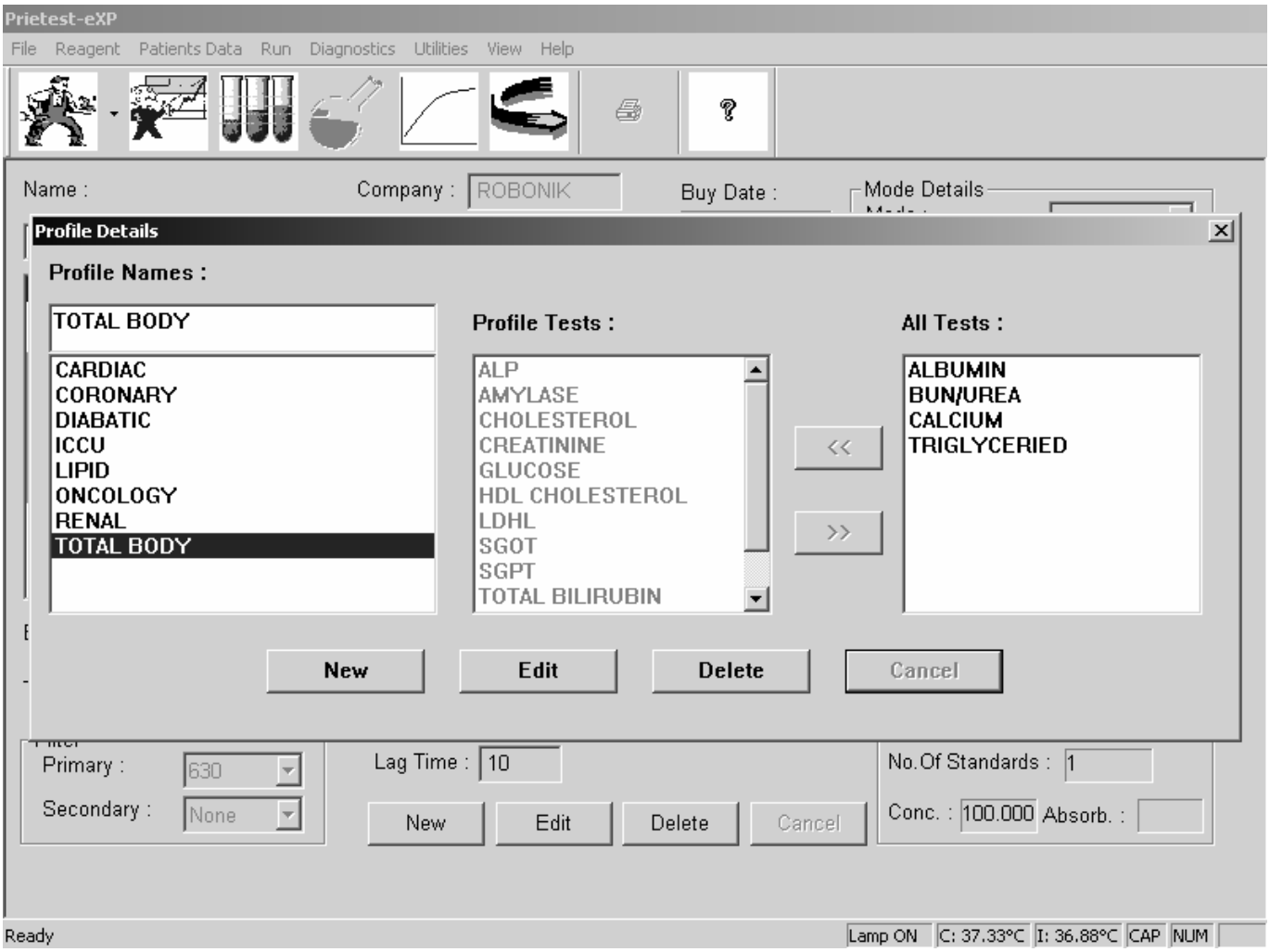
One can run blank & standard programmed for the reagents.
The test for which standard is to be run is highlighted by red colour block.
& the tests for which only blank (for tests with blank & factor) is to be run is highlighted by blue colour block.
Standard Run table provides following information.

- The results of blank & factor calculated (in case of single standard).
- No. of standards to be run.
- Initial abs., max delta entered in case of Fixed time reaction.
- Init abs., max delta/min entered in case of Kinetic reaction.
- Max.Diff.in case of Differential Mode.
- Max.Ratio in case of Ratio Mode
- One can plot the standard graph by selecting the reagent for which standards are already run.
  For that first select the reagent for which standard graph is required.
  Then click on Plot Graph.
  Instrument will display the graph for the standards run.

Running Blank/Standard.

Refer to section 9 Test Operations for steps to run actual Blank or standard.

8.4.4. Profile Creation



When clicked on profile following screen appears.

This screen is used for following Function:

- To create user defined profiles.
- To edit or delete existing profiles.

Steps to create new profile:

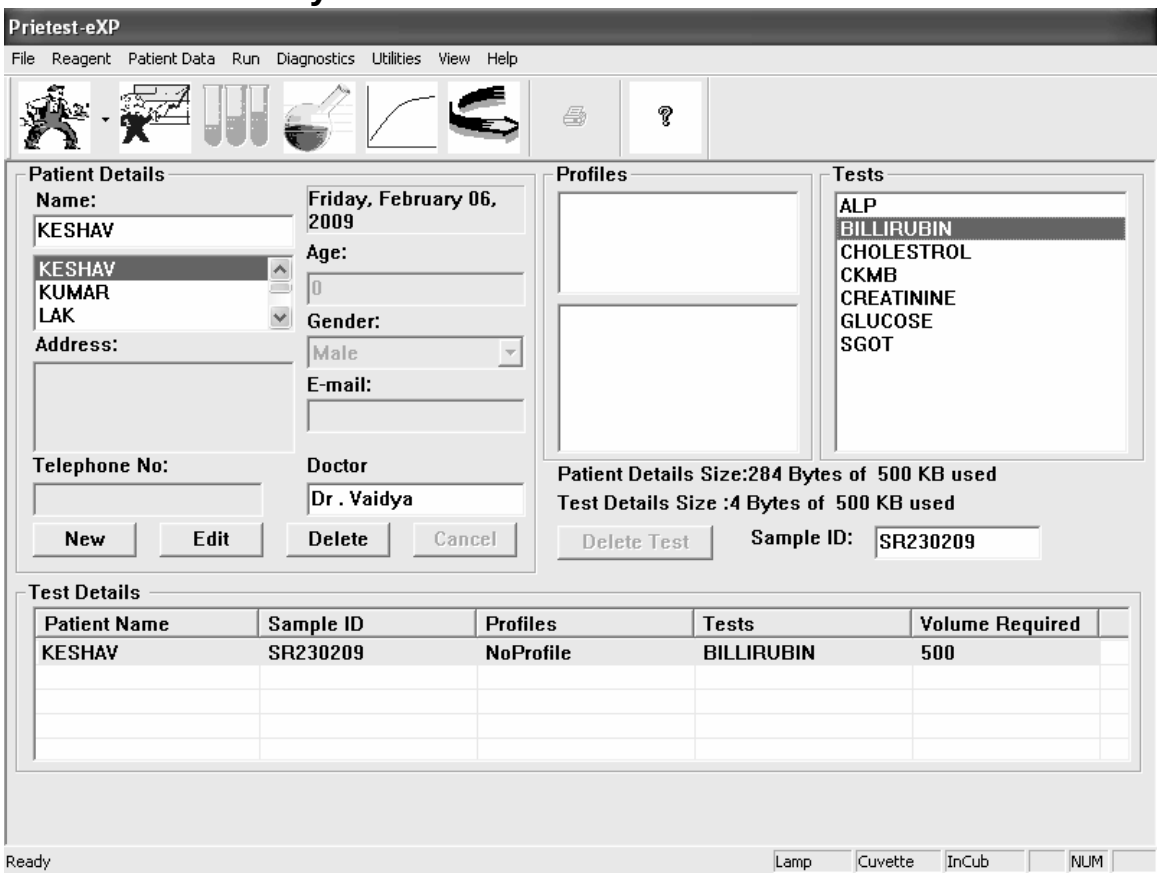
- Click on new, profile name block will become blank.
- Enter the profile name.
- Select the test from All Tests, which are required in profile.
- Click on arrow << this will transfer that particular test in profile & gets displayed in Profile Tests.
- Click on save this will save the profile programmed & same will get displayed in Profile Names.

Steps to edit a profile

- Select the Profile form Profiles displayed under Profile names.
- Click on Edit to edit the profile.
- If test is to be removed from profile select the required test From Profile tests click on arrow >> to remove the selected test from profile.
- If test is to be added in the profile Select the test from All Test which is required in profile, Click on arrow << this will transfer that particular test in profile & gets displayed in Profile Tests.
- Click on Save this will save the profile edited one can view the tests added or removed.

8.5. Patient Data

8.5.1. Patient Entry



One can perform following functions in this menu.

- To assign tests or profiles to particular patient.
- To edit existing patient.

Steps to assign tests / profiles to patient.

- Click on new, Name block will become blank - enter the patient name. Enter all other details like – Address, Telephone no., age, gender, e-mail address.
- Click on save to save the particular patient.
- One can view the patient entered in patient list below the block provided for patient name.
- Once the patient is saved instrument will automatically generate the unique sample id for that patient.

To assign tests/ profiles:

- Select the patient for which tests are to be assigned.
- Enter Doctor's name.
- Double click on required test / profile to assign it to the selected patient.
- One can get the details – sample id, profiles / tests selected for the patients programmed along with the volume required for the particular test.

To edit existing patient.

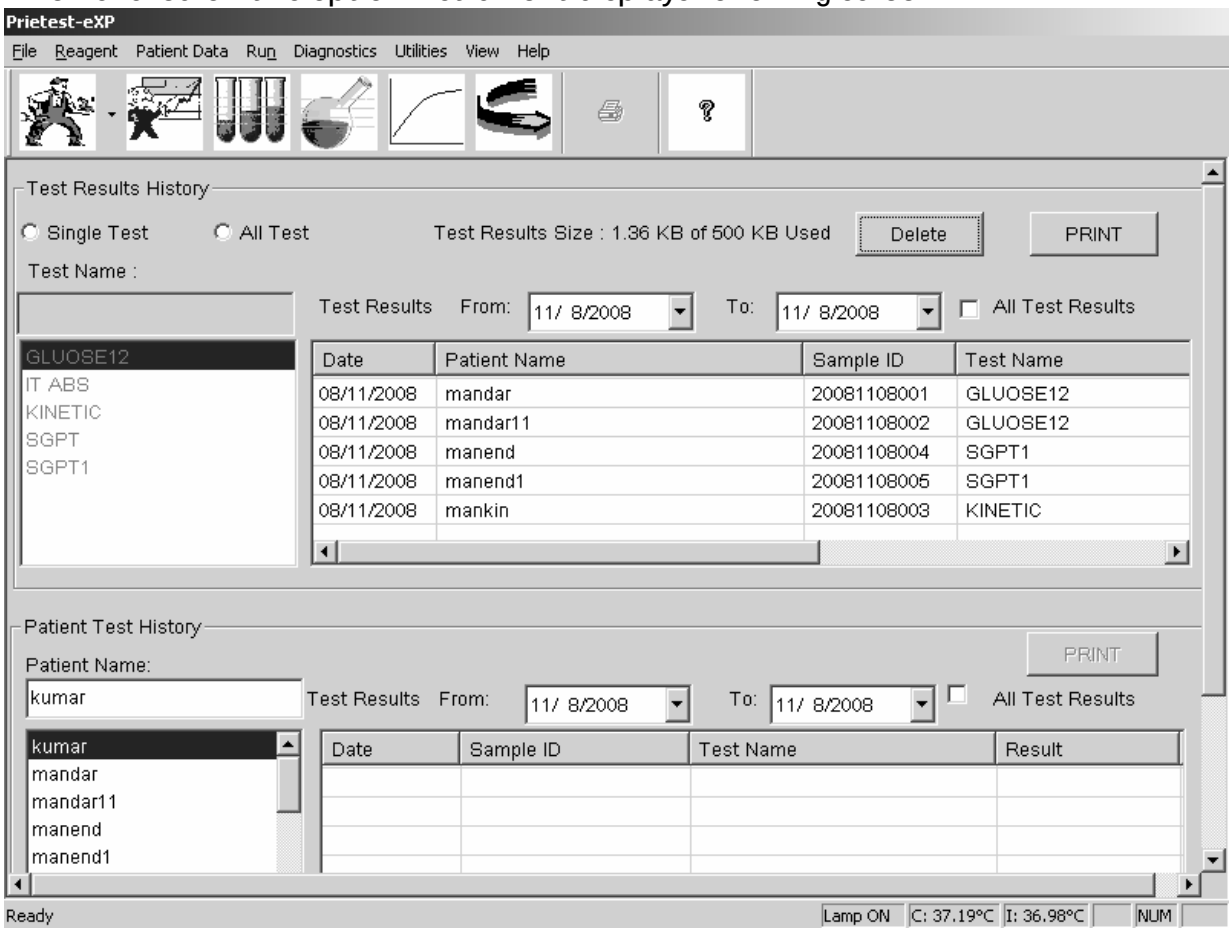
- One can add or remove tests / profiles by this option.

Steps to edit existing patient.

- Select the patient for which tests / profiles needs to be added.
- Double click on required test / profile to be added to the selected patient.
- Click on save to save the selected patient.

8.5.2. Patient Results

When clicked on this option instrument displays following screen



From this screen print out can take by following option.

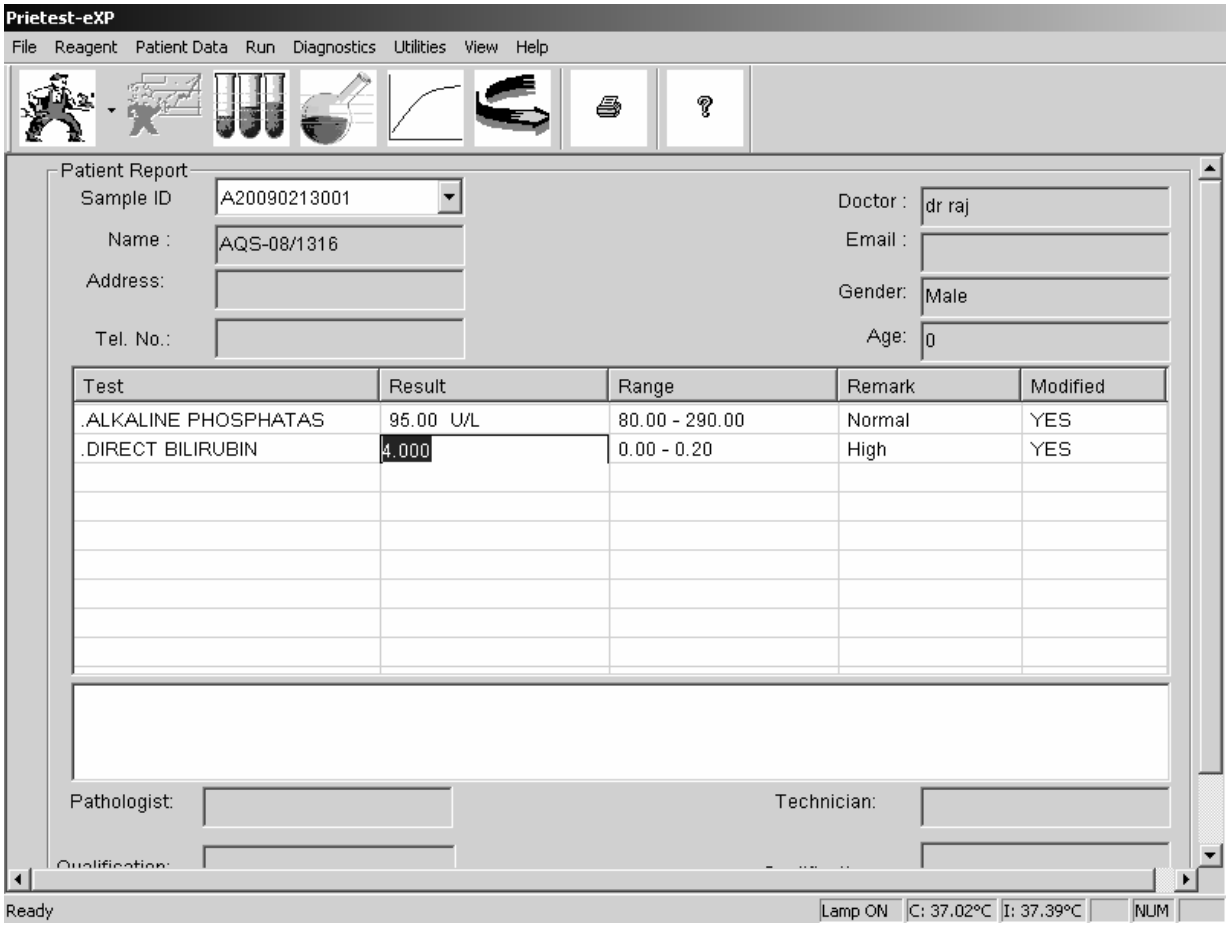
1 By Patient Wise

3. By test wise.

4. Whole result

8.5.3. Patient Report

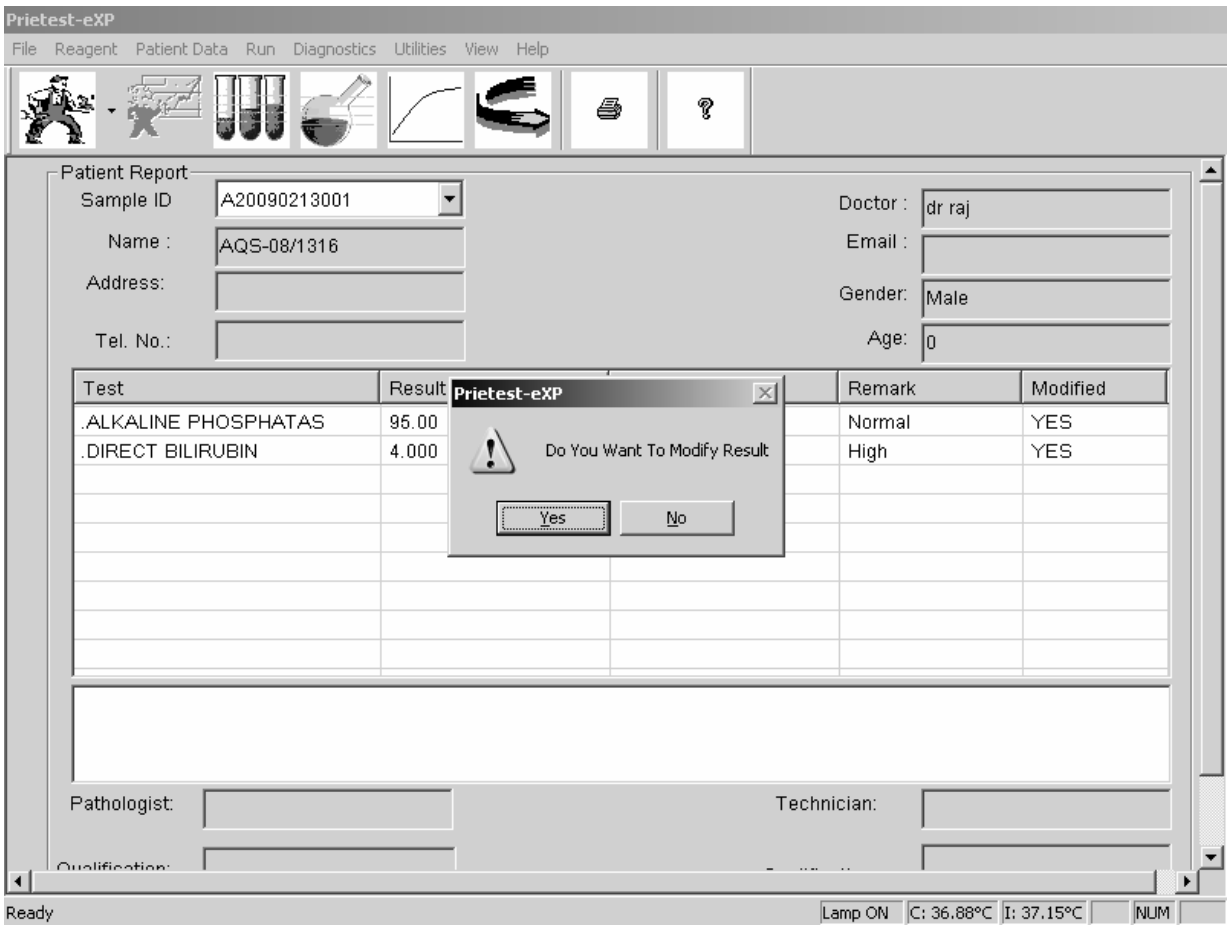
One can get the patient report in following format when clicked on Report in Patient Data menu.



The print out of the above report can be taken on USB printer attached to the instrument (if installed).

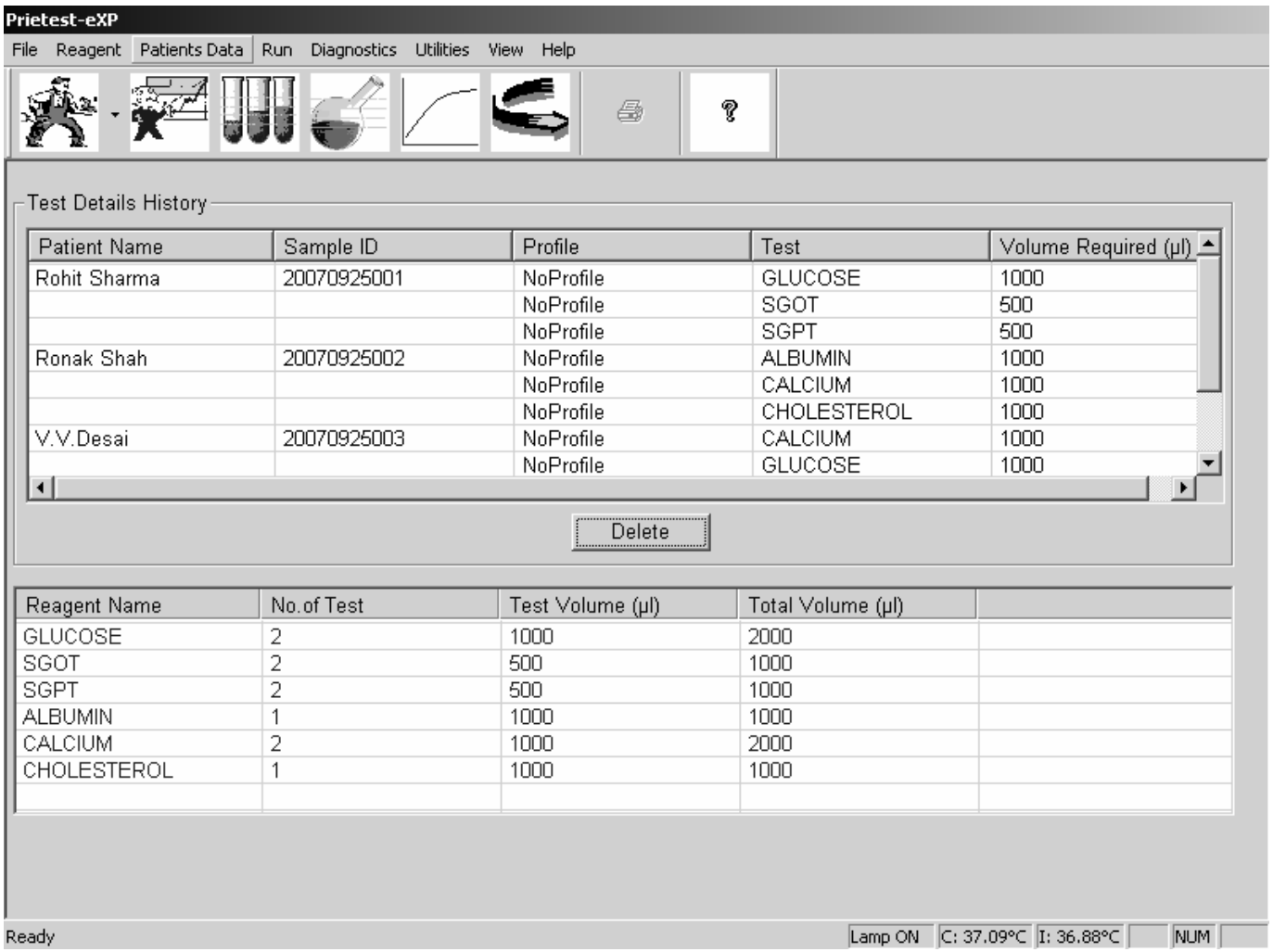
8.5.4. Editing of patient result

- Click on the result to be modified as shown above
- Delete the old result and type the new result in the column and press enter key.
- The message box will come in the screen as shown below.
- Confirm the result by clicking on “Yes” button.



8.5.5 Test details

When clicked on this option instrument displays following screen



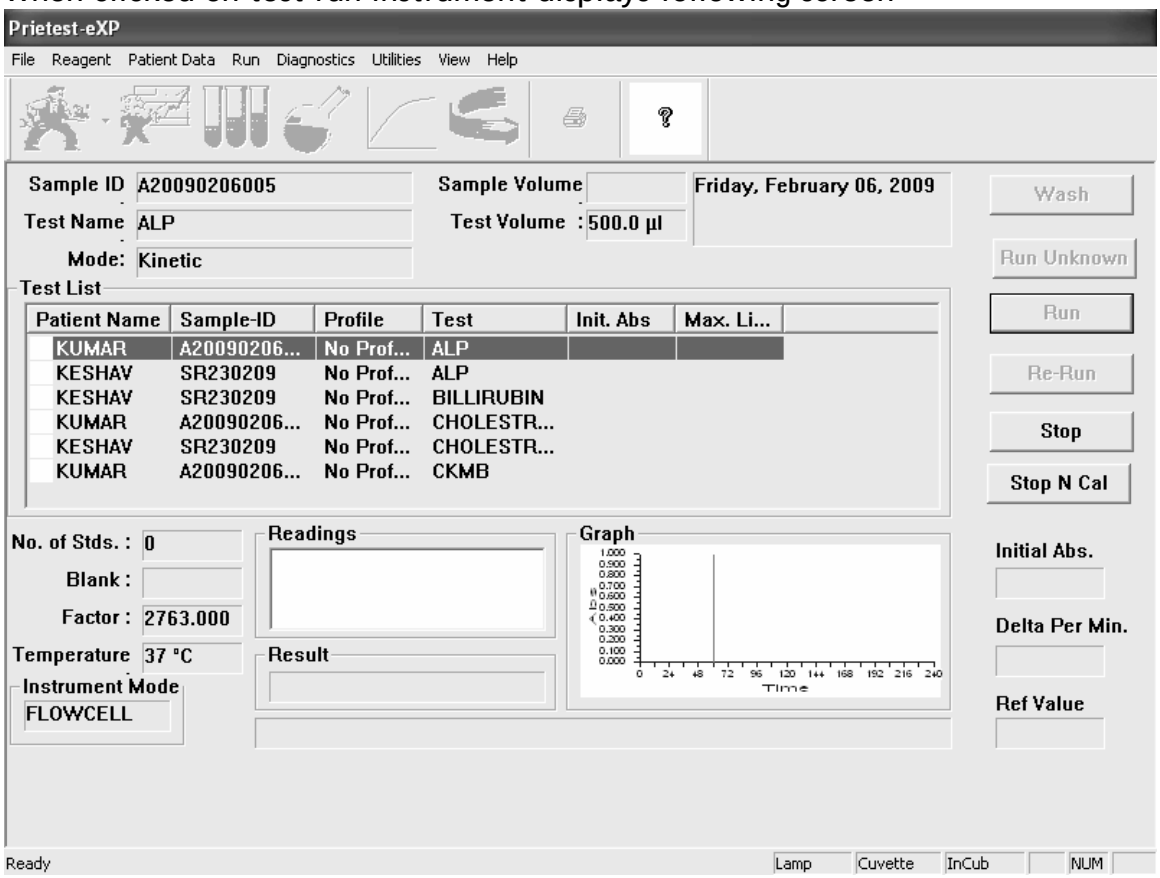
This screen provides requirement of reagent to user in following two ways.

- Per patient how many tests are programmed along with reagent required for each test.
- Total reagent consumption per test along with the no. of tests to be run.

8.6. Run

8.6.1. Test Run

When clicked on test run instrument displays following screen



This screen provides user following information

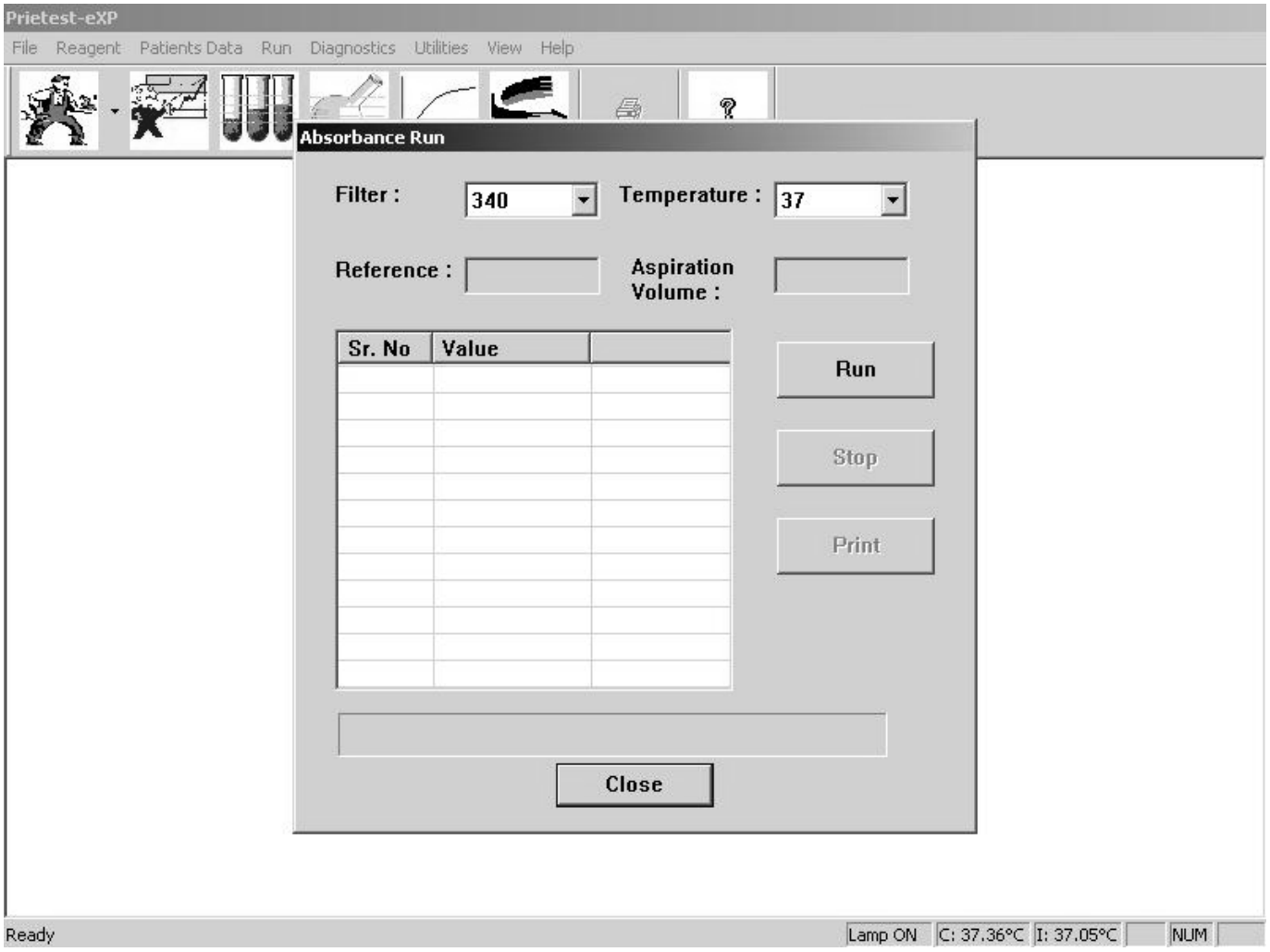
- Test wise separation for the patient samples to be run.
- On line graph of the reaction in case of kinetic & fixed time reactions.
- Sample volume (if entered) & test volumes required for a selected test.
- In this screen if the test is run then that particular test is highlighted by green colour.

Running Samples in Test Run

Refer to section 9.3 Running Samples in Test Run Mode in Test Operations for steps to run actual sample run.

8.6.2. Absorbance Run

When clicked on absorbance run instrument displays following screen.



This screen helps user to check absorbance (O.D.) of reagent.
One can select the filters available by clicking on arrow in the filter block

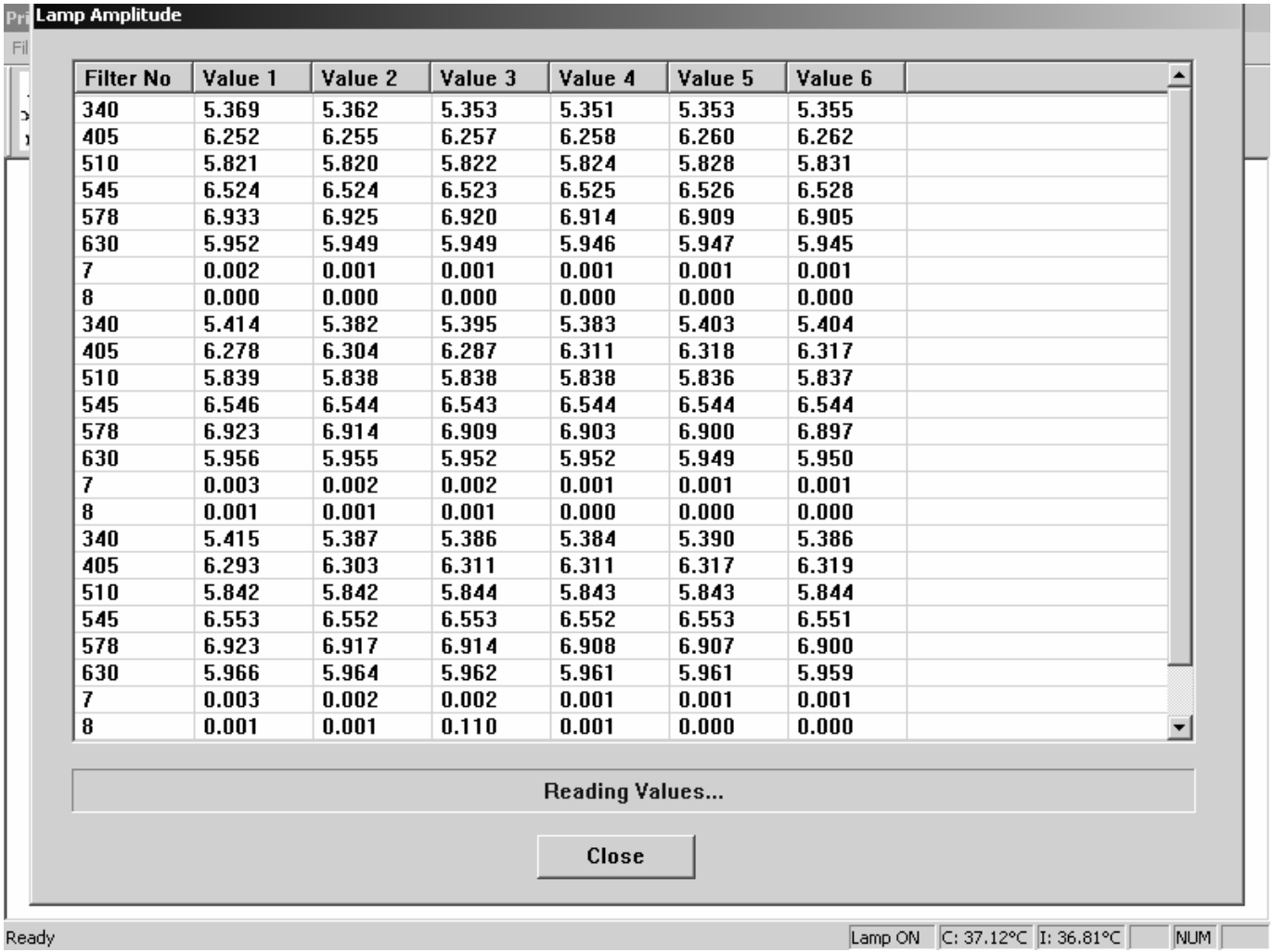
8.7. Diagnostics

8.7.1. Filter Home

When selected brings filter wheel to the home position.

8.7.2. Lamp Amplitude

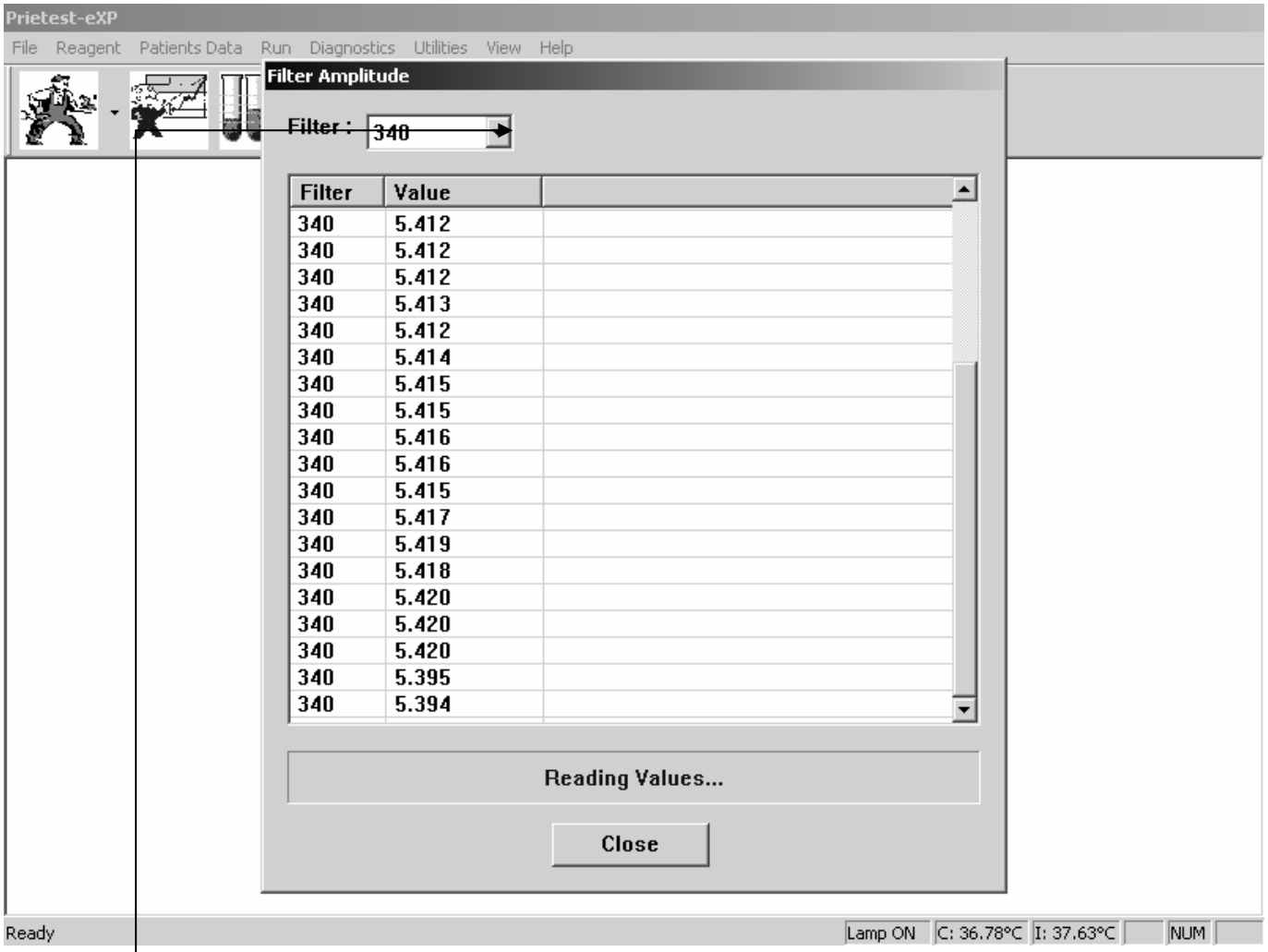
When selected displays & prints amplitude for all the filters.
(Ref. following screen)



Filter No	Value 1	Value 2	Value 3	Value 4	Value 5	Value 6
340	5.369	5.362	5.353	5.351	5.353	5.355
405	6.252	6.255	6.257	6.258	6.260	6.262
510	5.821	5.820	5.822	5.824	5.828	5.831
545	6.524	6.524	6.523	6.525	6.526	6.528
578	6.933	6.925	6.920	6.914	6.909	6.905
630	5.952	5.949	5.949	5.946	5.947	5.945
7	0.002	0.001	0.001	0.001	0.001	0.001
8	0.000	0.000	0.000	0.000	0.000	0.000
340	5.414	5.382	5.395	5.383	5.403	5.404
405	6.278	6.304	6.287	6.311	6.318	6.317
510	5.839	5.838	5.838	5.838	5.836	5.837
545	6.546	6.544	6.543	6.544	6.544	6.544
578	6.923	6.914	6.909	6.903	6.900	6.897
630	5.956	5.955	5.952	5.952	5.949	5.950
7	0.003	0.002	0.002	0.001	0.001	0.001
8	0.001	0.001	0.001	0.000	0.000	0.000
340	5.415	5.387	5.386	5.384	5.390	5.386
405	6.293	6.303	6.311	6.311	6.317	6.319
510	5.842	5.842	5.844	5.843	5.843	5.844
545	6.553	6.552	6.553	6.552	6.553	6.551
578	6.923	6.917	6.914	6.908	6.907	6.900
630	5.966	5.964	5.962	5.961	5.961	5.959
7	0.003	0.002	0.002	0.001	0.001	0.001
8	0.001	0.001	0.110	0.001	0.000	0.000

8.7.3. Filter Amplitude

When selected displays & prints amplitude for selected filter.
(Ref. following screen)



One can change the filter by clicking at arrow.

Caution:
While taking amplitude in Cuvette mode, remove the Cuvette from Cuvette block if it is there.

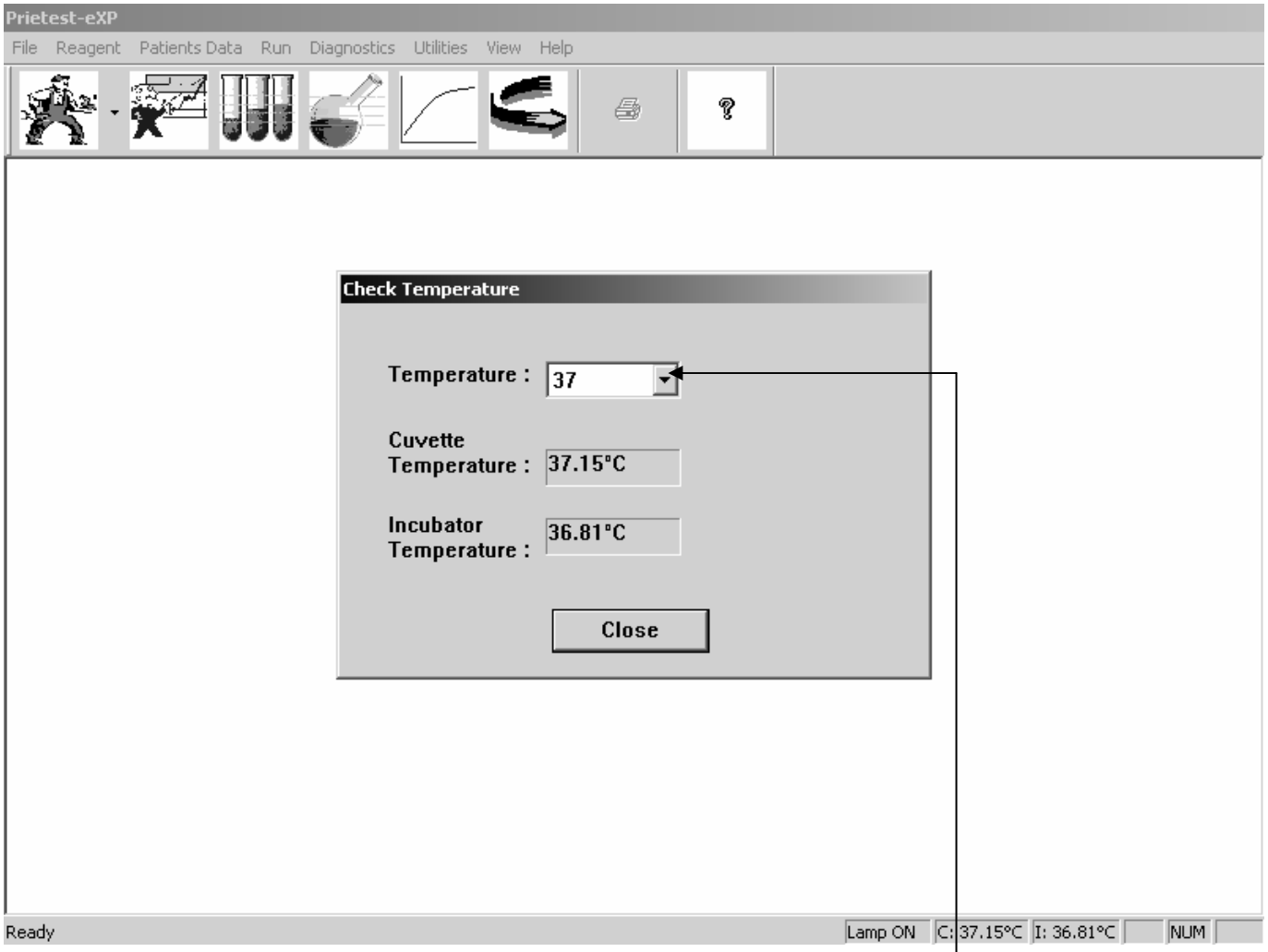
While taking amplitude in flow cell mode, perform wash operation with Distilled water four to five times.

Refer section **8.8.8** for wash flow cell.

8.7.4. Temperature

When selected displays the Cuvette block & Incubator Temperature

(Ref. following screen)

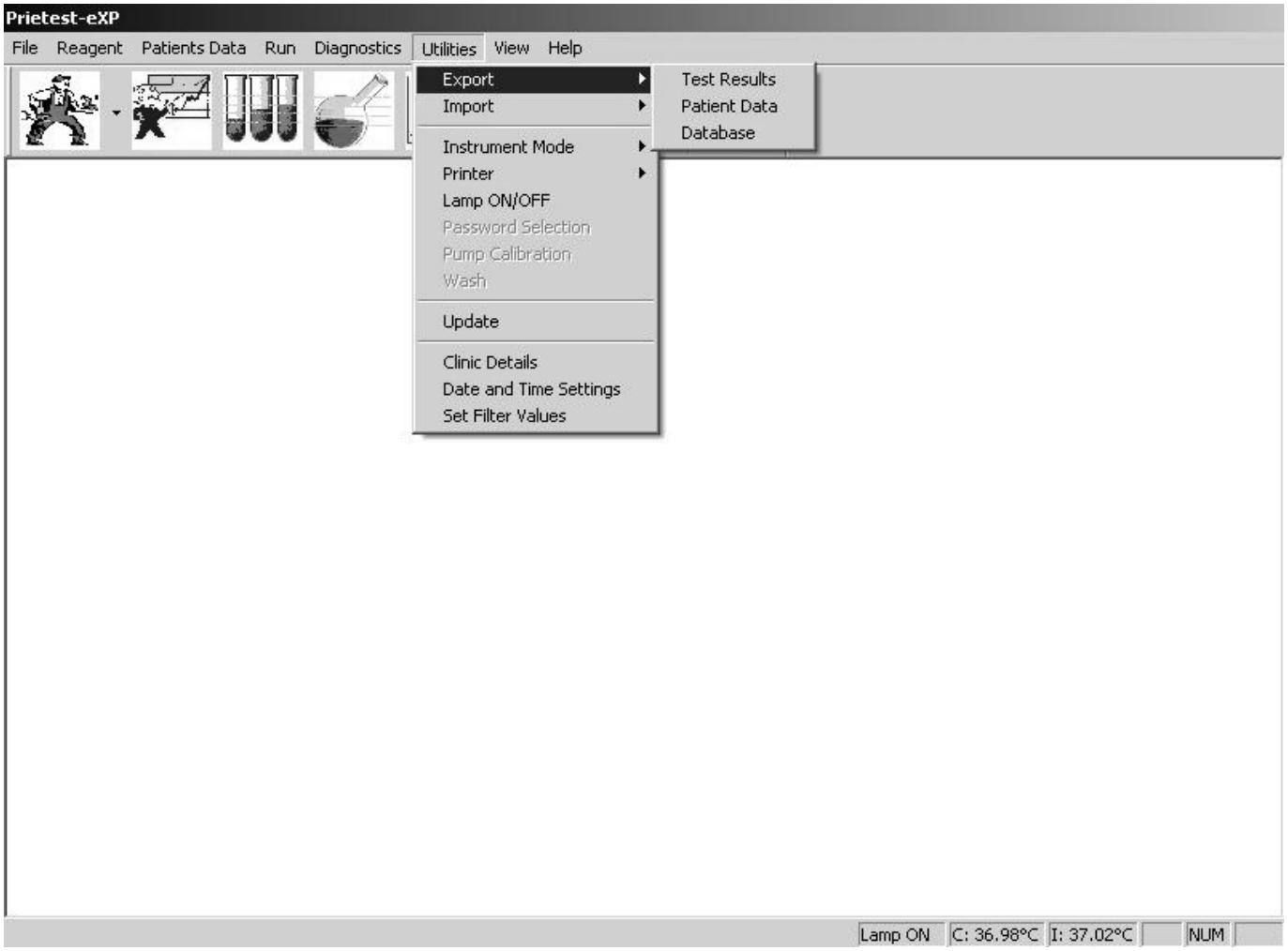


By clicking at arrow one can monitor 25^0c, 30^0c temperatures.

8.8. Utilities

8.8.1. Export

When clicked on Export instrument displays following screen



One can transfer Test Results, Patient data & Data Base to the Pen Drive connected to the USB Port.

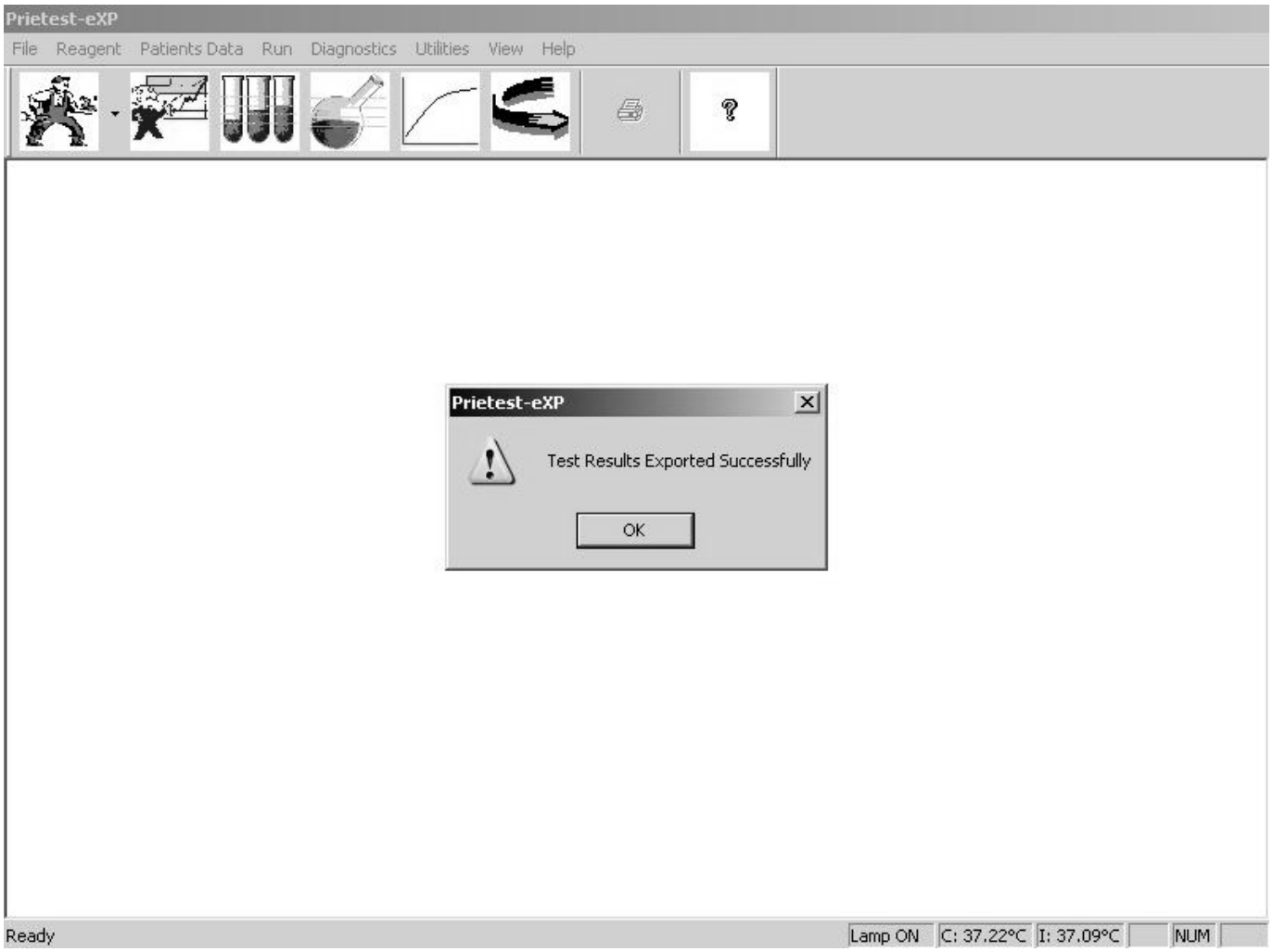
Steps to Transfer data from Instrument to Pen drive.

- Insert Pen drive in to USB terminal
- Click on Utilities.

Test Results Transfer:

- Click on Test Results

When selected transfers test results to USB Drive or PEN Drive in excel format.
After completion of data transfer instrument will display following screen.

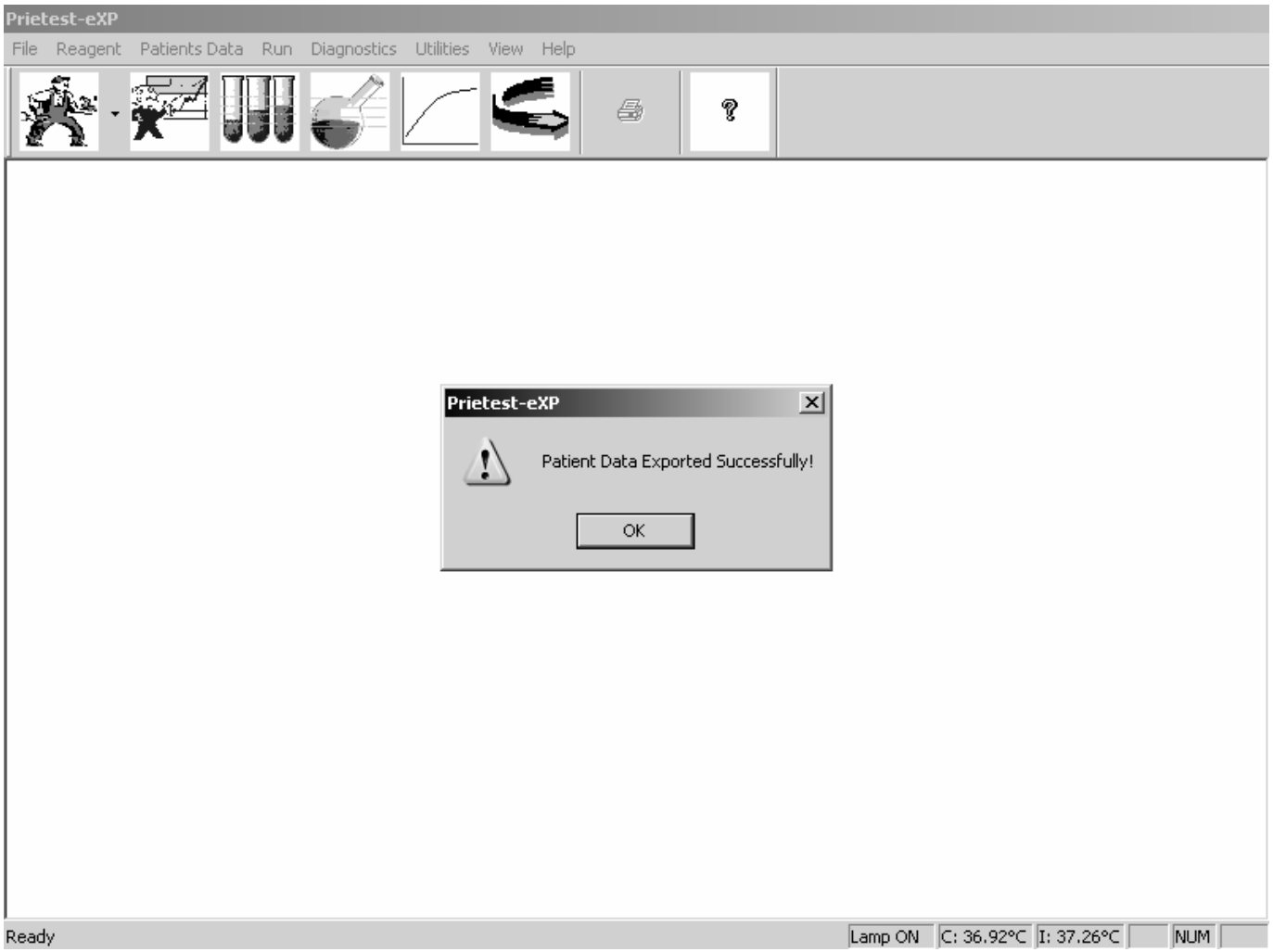


Click on OK to complete the data transfer.

Patient Data Transfer:

- Click on Patient data

When selected transfers Patient data to USB Drive or PEN Drive in excel format. After completion of data transfer instrument will display following screen.



Click on OK to complete the data transfer.

To view the excel format of the Test Results & Patient Data ON Computer follow following steps.

- Insert Pen drive in to USB Terminal of computer.
- Locate the folder in format of YY/MM/DD
  i.e. 20070928
- By opening the folder one can find two excel sheets
  Patient Data
  Test Results

(Ref.sec.8.8.3 for excel format of Patient Data & Test Results).

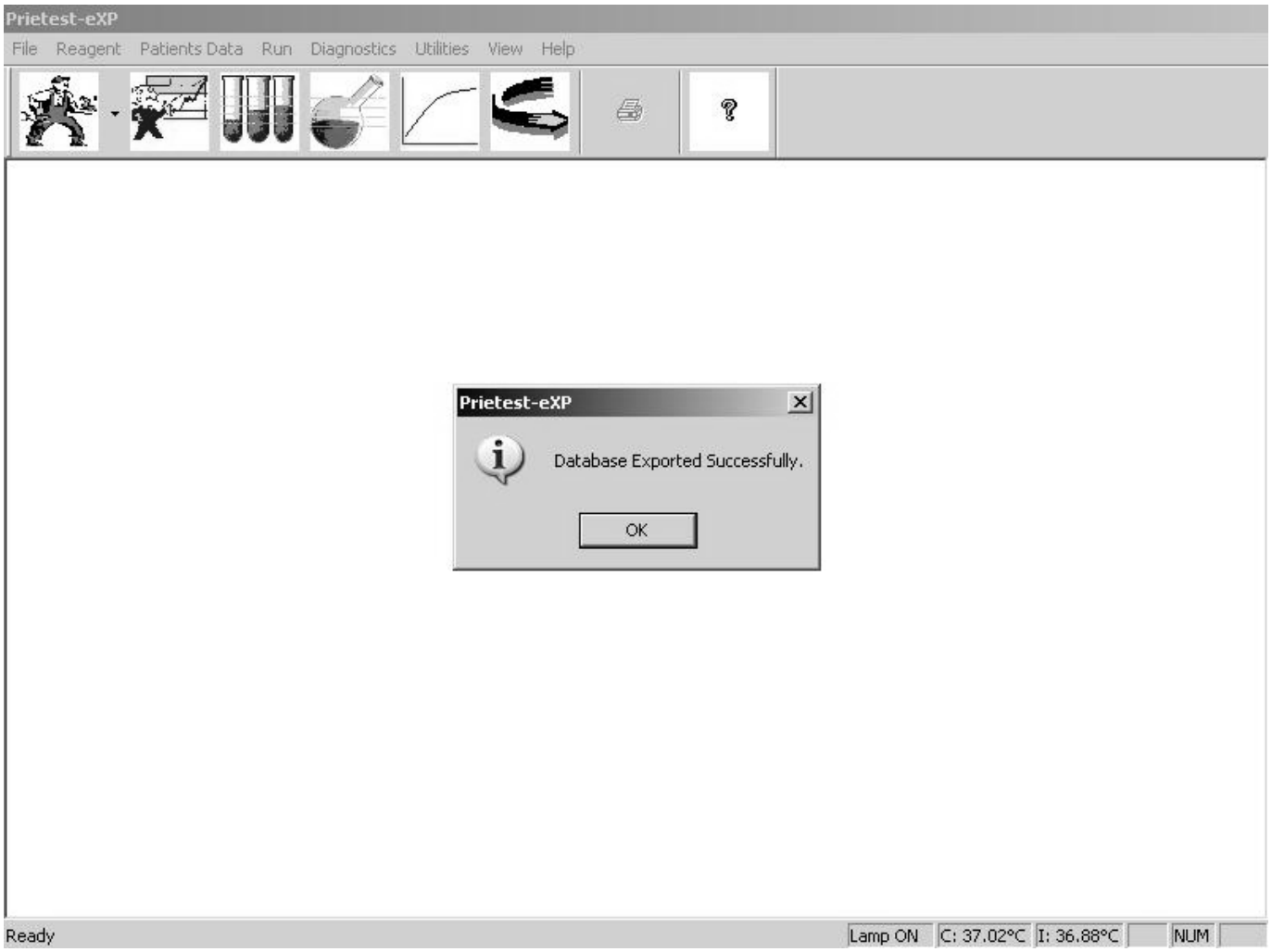
Data Base Transfer:

When selected transfers complete data base i.e.
Reagent Details
Profiles
QC run results - Normal, Abnormal.
Test Details.
Test Results.

From instrument to Pen drive connected to USB terminal.
Steps to perform Data Base transfer from instrument to PEN Drive.

- Click on Data Base

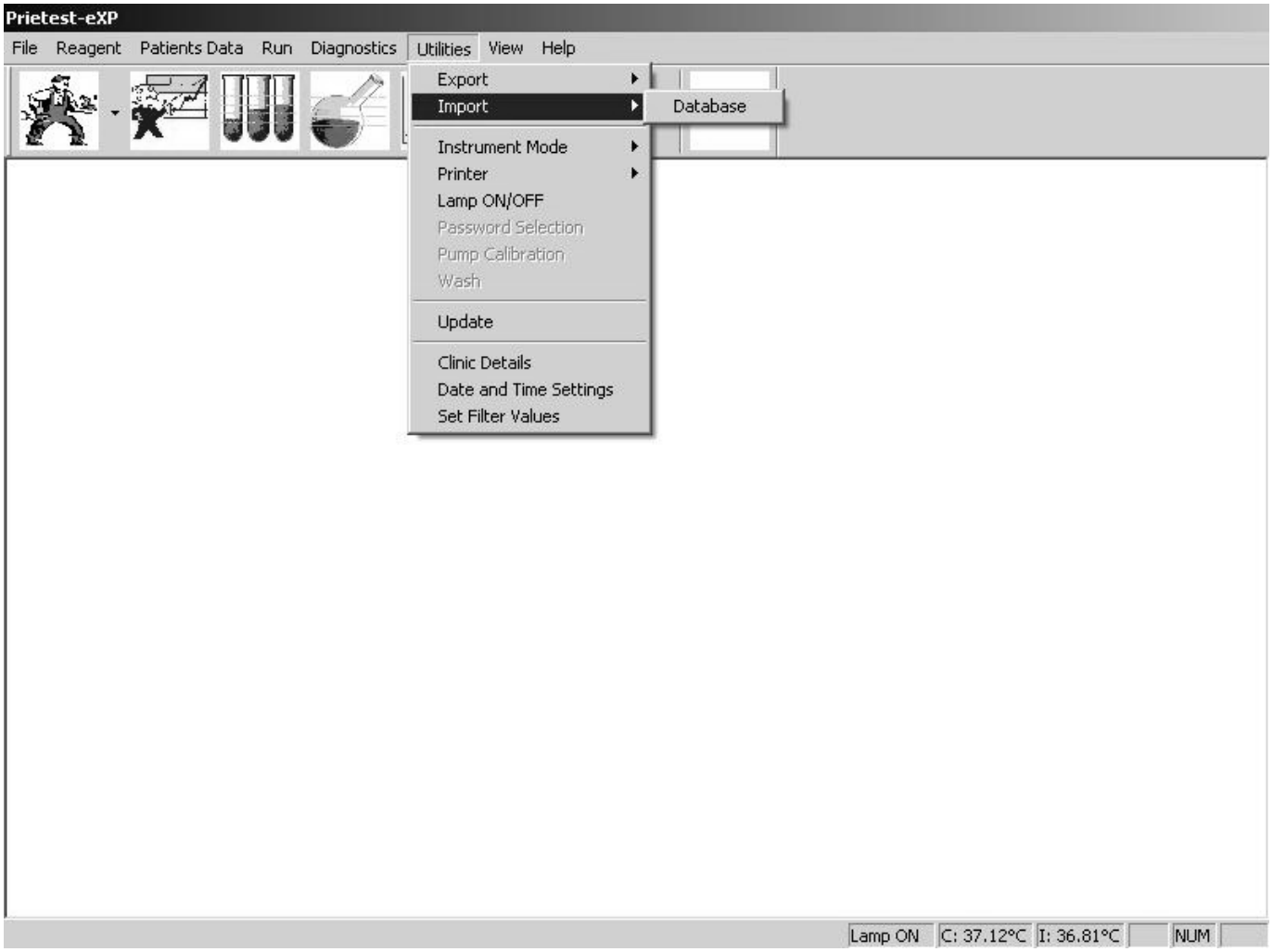
After completion of data transfer Instrument will display following screen.



- Click on OK to complete the transfer operation.

8.8.2. Import

When clicked on Import instrument displays following screen.



Data Base:

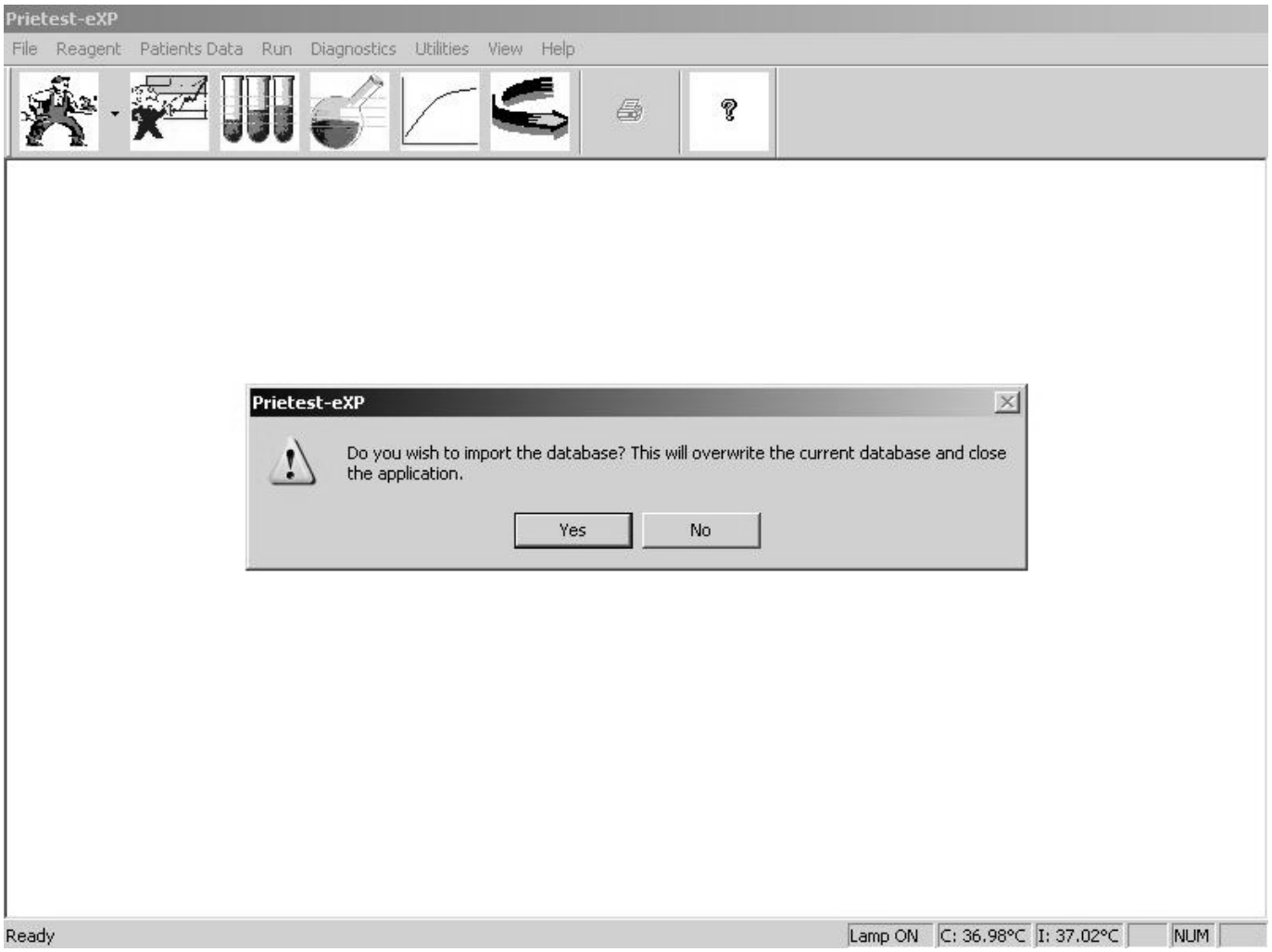
When selected transfers complete data base i.e.
Reagent Details
Profiles
QC run results - Normal, Abnormal.
Test Details.
Test Results.

From PEN Drive connected to USB terminal to Instrument data base.

Steps to Transfer Data Base from Pen drive to instrument.

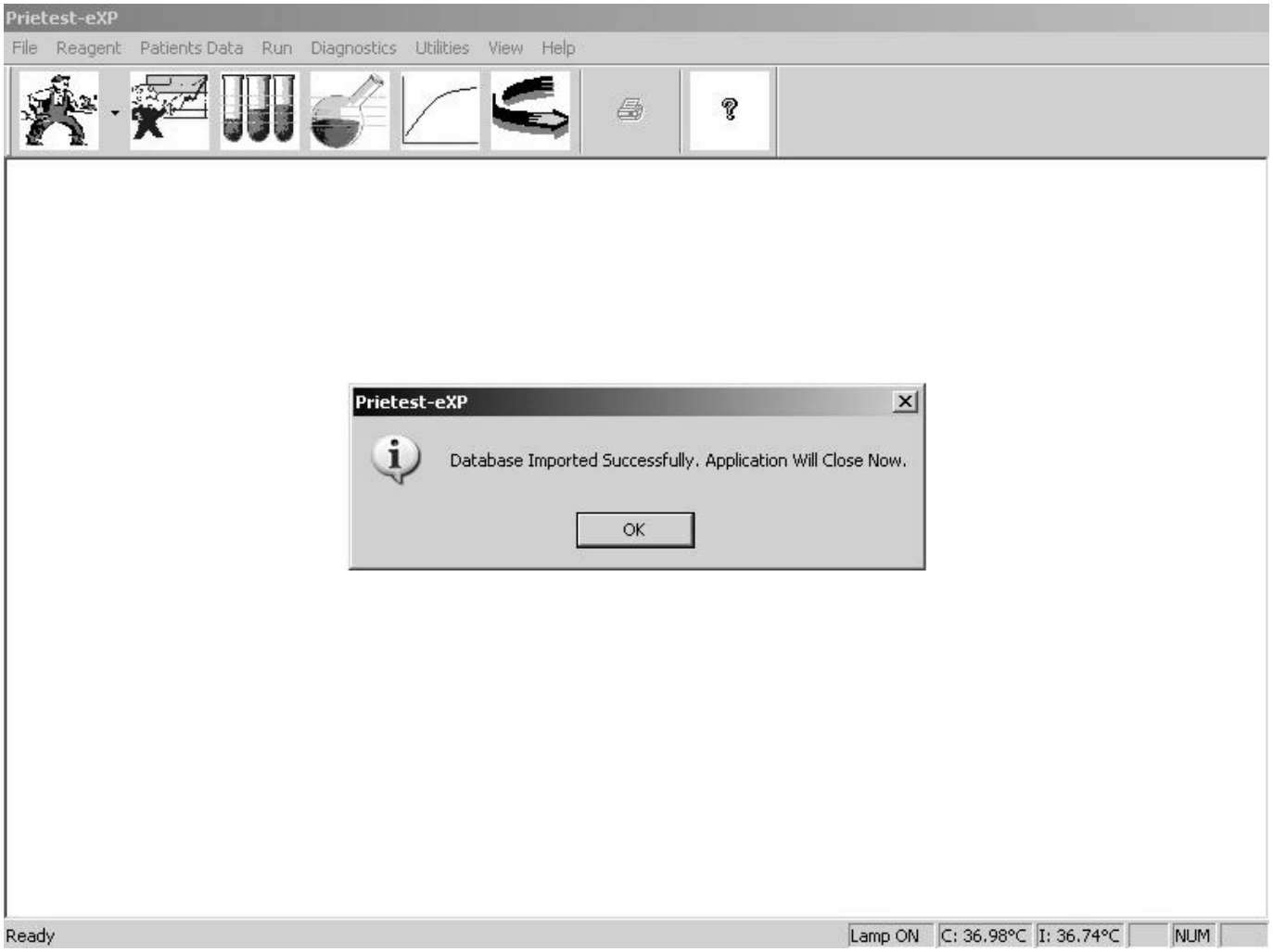
- Insert Pen drive in to USB terminal
- Click on Utilities.
- Click on Import.
- Click on Data Base.

When clicked on Data Base instrument displays following screen.



Click on YES to start transfer of complete data base from PEN drive to instrument.

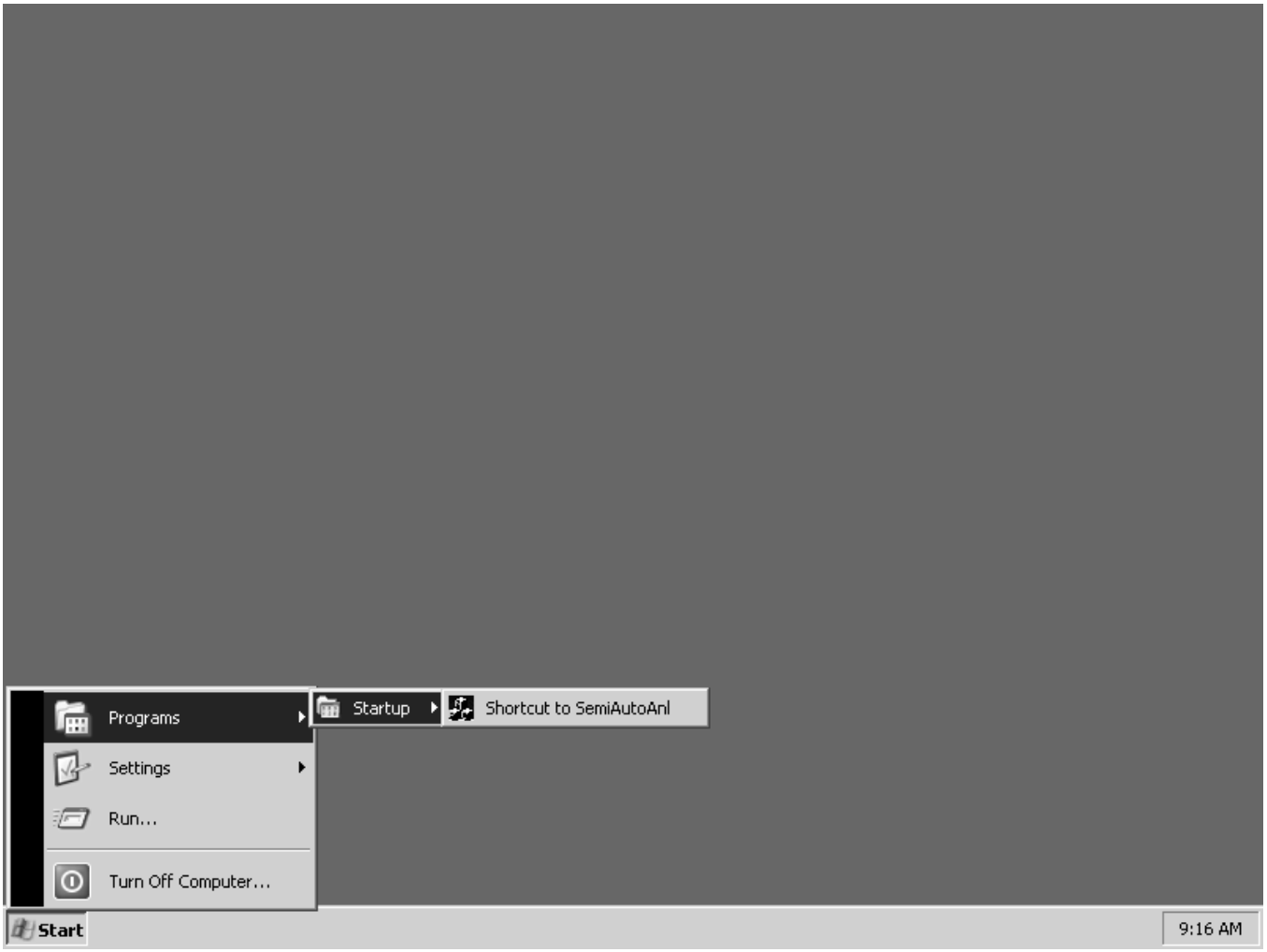
Instrument will display following screen after complete data base is transferred.



- Click on OK.

This will complete the data transfer from PEN drive to instrument.
After clicking OK instrument one has to restart the instrument once again.

For that click at Start.
Instrument will give following screen.



Click at Shortcut to SemiAutoAnl.

One can get screen given in **sec.8.2**

8.8.3. Excel Formats for Patient Data & Test Results

XL Format For Patient Data

Name	Address	Email	Telephone No.	Age	Gender
Rohit Sharma	34, Vihr Complex. Lahari Road, Vile Parle (W.).	rohit@yahoo.com	26542318	45	Male
Ronak Shah	45, Shakti Complex Surya Nagar Andhari (E)	ronak@rediffmail.com	28234567	45	Male
V.V.Desai	54, Anand Vihar Laxmi Complex Virar (W)	v_desai@yahoo.com	9820045673	45	Female
Varun	32, Shiva Complex Gandhi Nagar Mahim (E).	varun@yahoo.com	9823167679	56	Male

Excel Format for Patient Data :

Excel Format for Test Results :

XL Format For Test Results

Name	Sample ID	Test	Result
V.V.Desai	20070925003	GLUCOSE	98.57mg/dl
Rohit Sharma	20070925001	GLUCOSE	98.95mg/dl
Ronak Shah	20070925002	CHOLESTEROL	21.24mg/dl
Rohit Sharma	20070925001	SGOT	31.5U/l

8.8.4. Instrument Mode

Instrument is provided with two modes

1. Cuvette
2. Flow cell

One can select the mode by clicking on it.

8.8.5. Printer

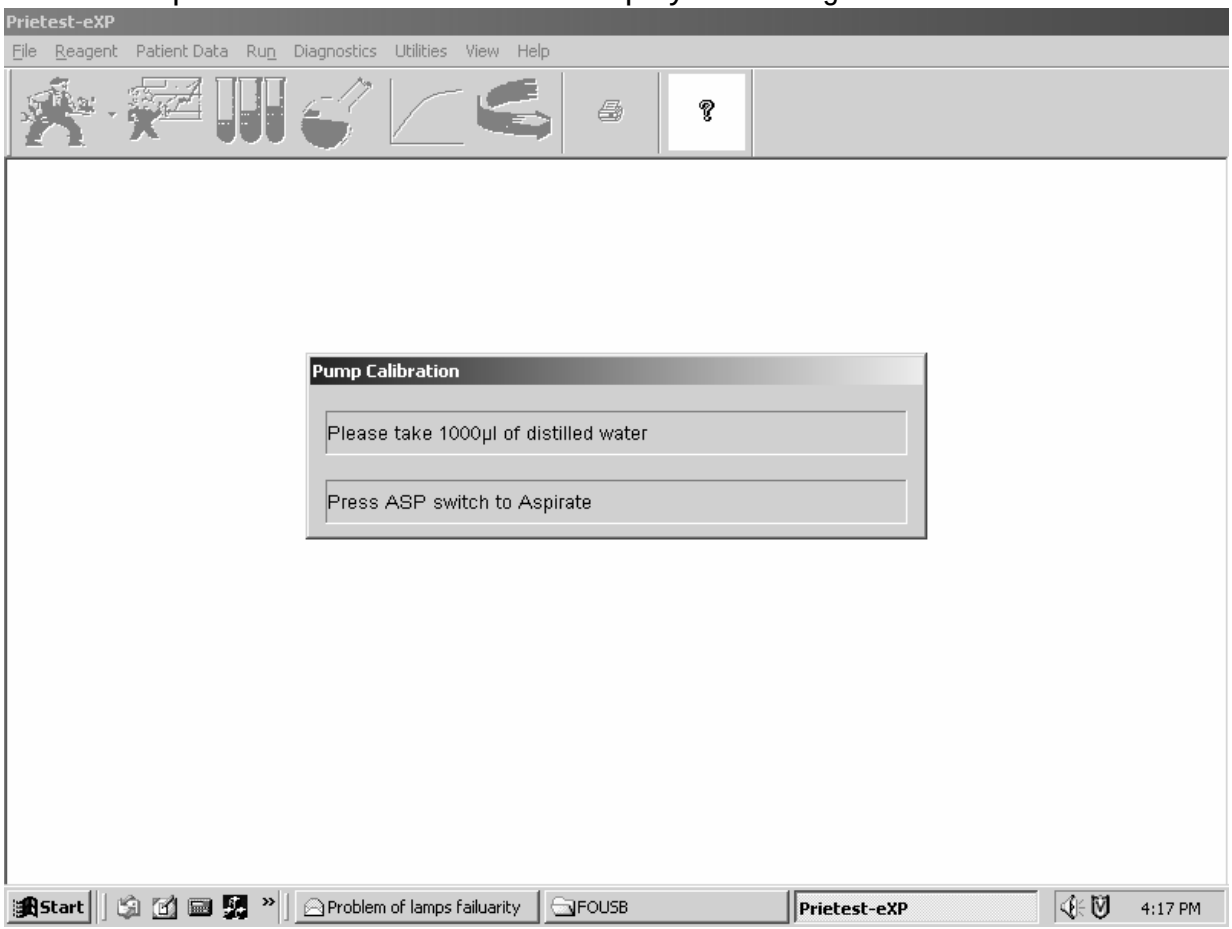
Internal printer provided can be turned ON or OFF by clicking on the option.

8.8.6. Lamp ON/OFF

Lamp can be turned ON or OFF by using this options.

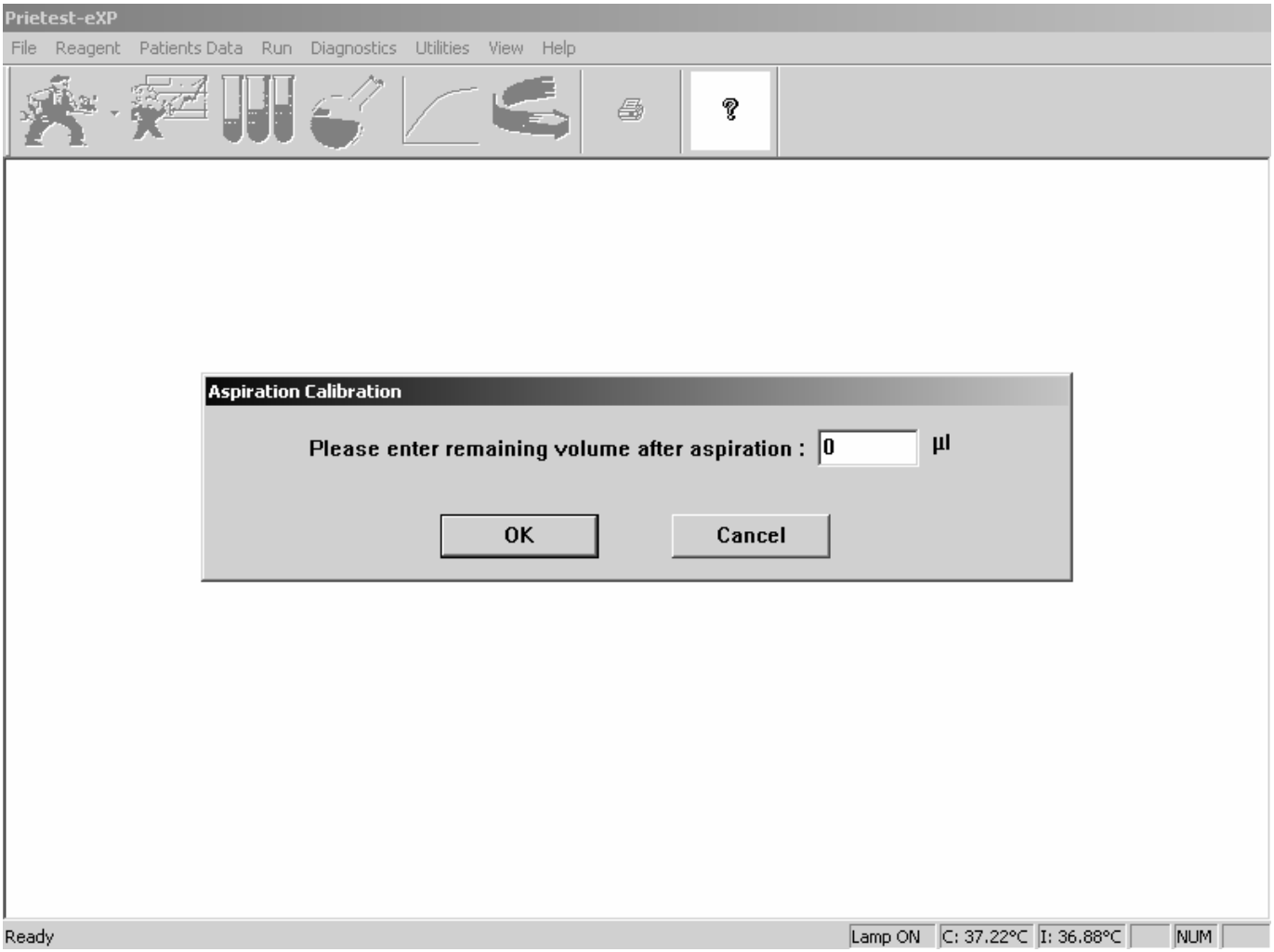
8.8.7. Pump Calibration

When this option is selected instrument displays following screen



Before starting Pump Calibration ensures that there should be no water in Flow cell. For that perform wash operation 3 to 4 times (w/o distilled water)
Ref. **Sec. 8.8.8** for wash operation.

Take 1000ul of distilled water and press the aspiration switch.



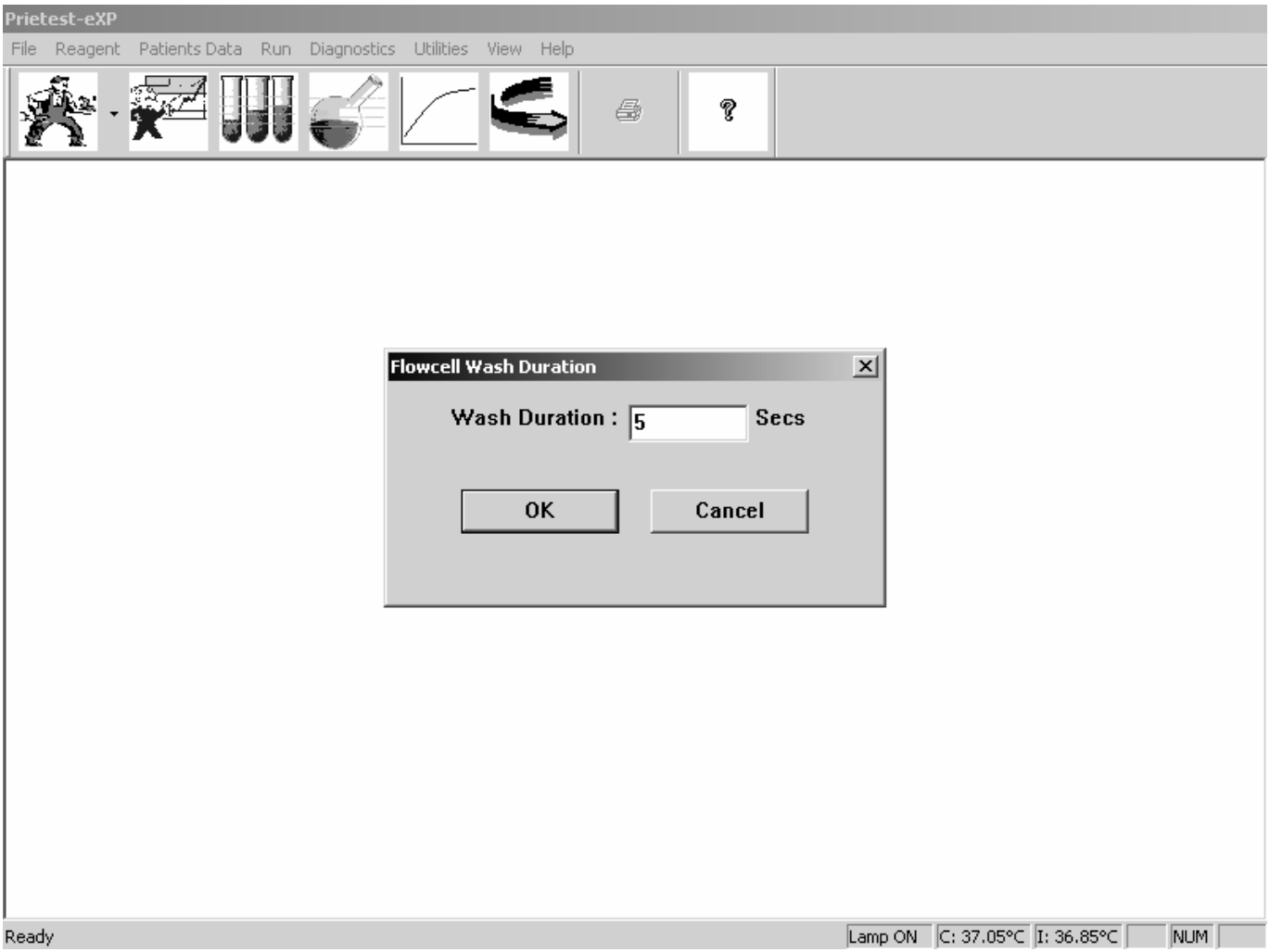
- Enter the remaining volume & click OK.

  Instrument will give message
  Pump calibration done successfully

- Click OK; this will complete the pump calibration

8.8.8. Wash

When selected instrument displays following screen



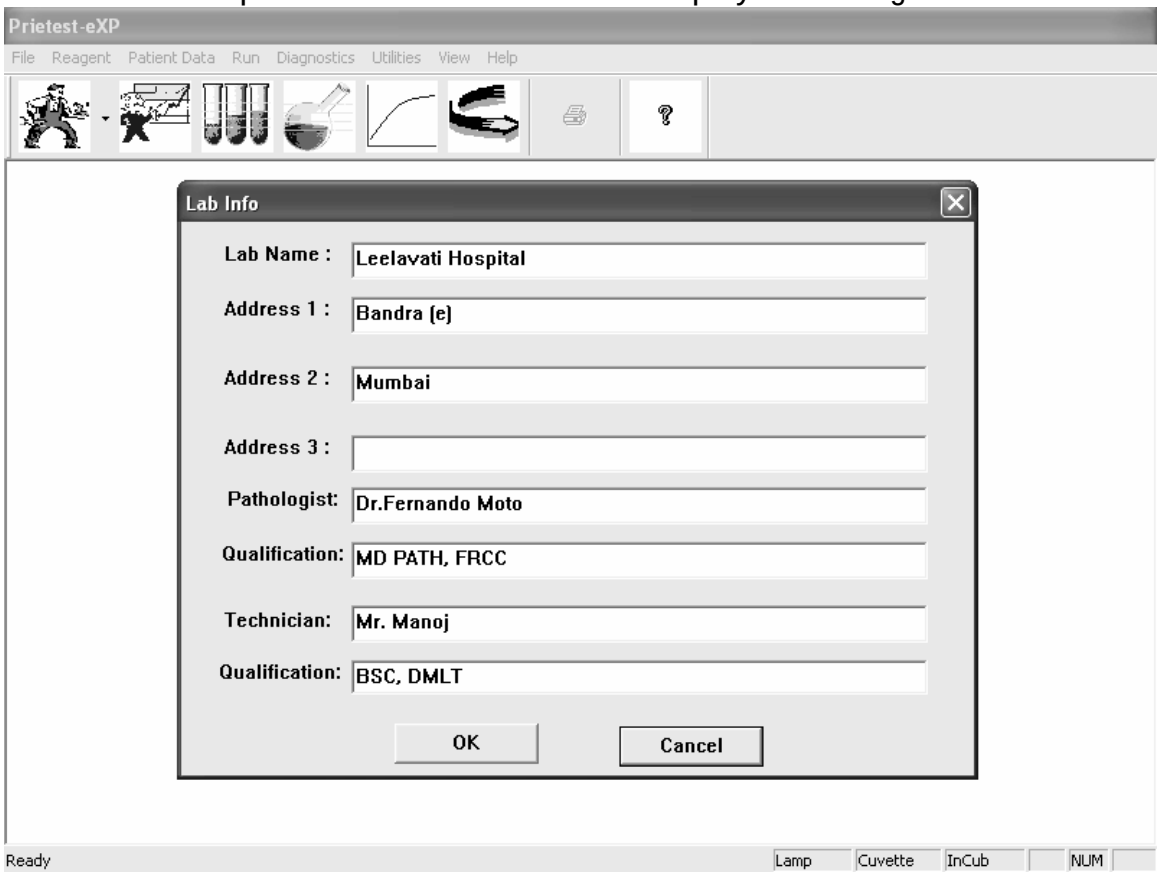
Instrument will wash the flow cell for the time (in seconds) entered at wash duration.

8.8.9. Update

When this option is performed software of the instrument will get updated through USB drive connected.
Refer to section 11 for detailed procedure of updating.

8.8.10. Clinic Details

When this option is selected instrument displays following Screen.



We can store the following details in this screen.

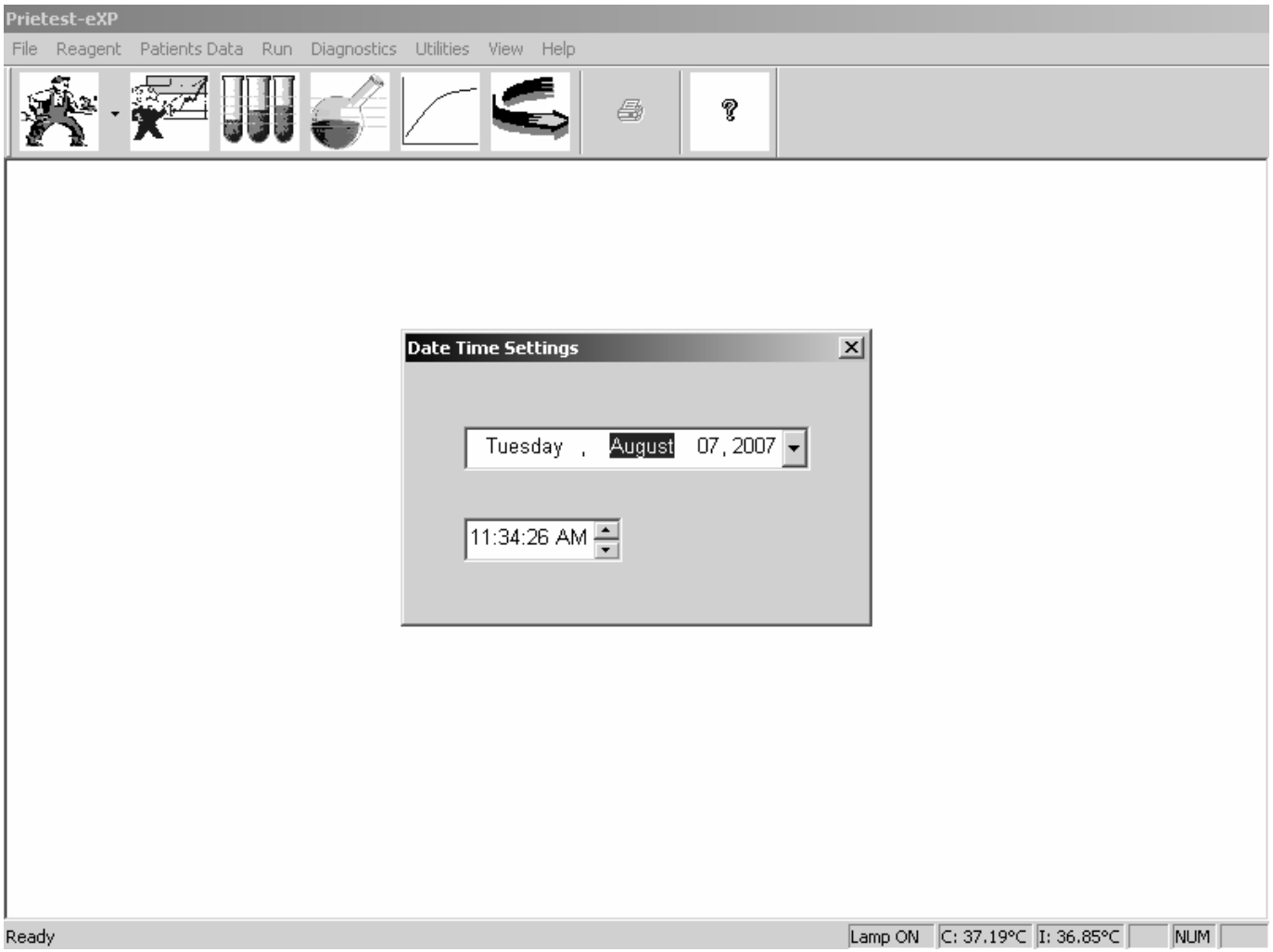
1. Lab name:
2. Lab address
3. Pathologist Name
4. Pathologist Qualification
5. Technician's Name
6. Technician's Qualification.

*This Data will be available during patient Report printing

- Click OK after completion of address entry.
- Click cancel to come out without doing any changes.

8.8.11. Date & Time Settings

When selected instrument displays following screen.



By using arrow keys one can set the current date & time.

8.8.12. Set Filter Values

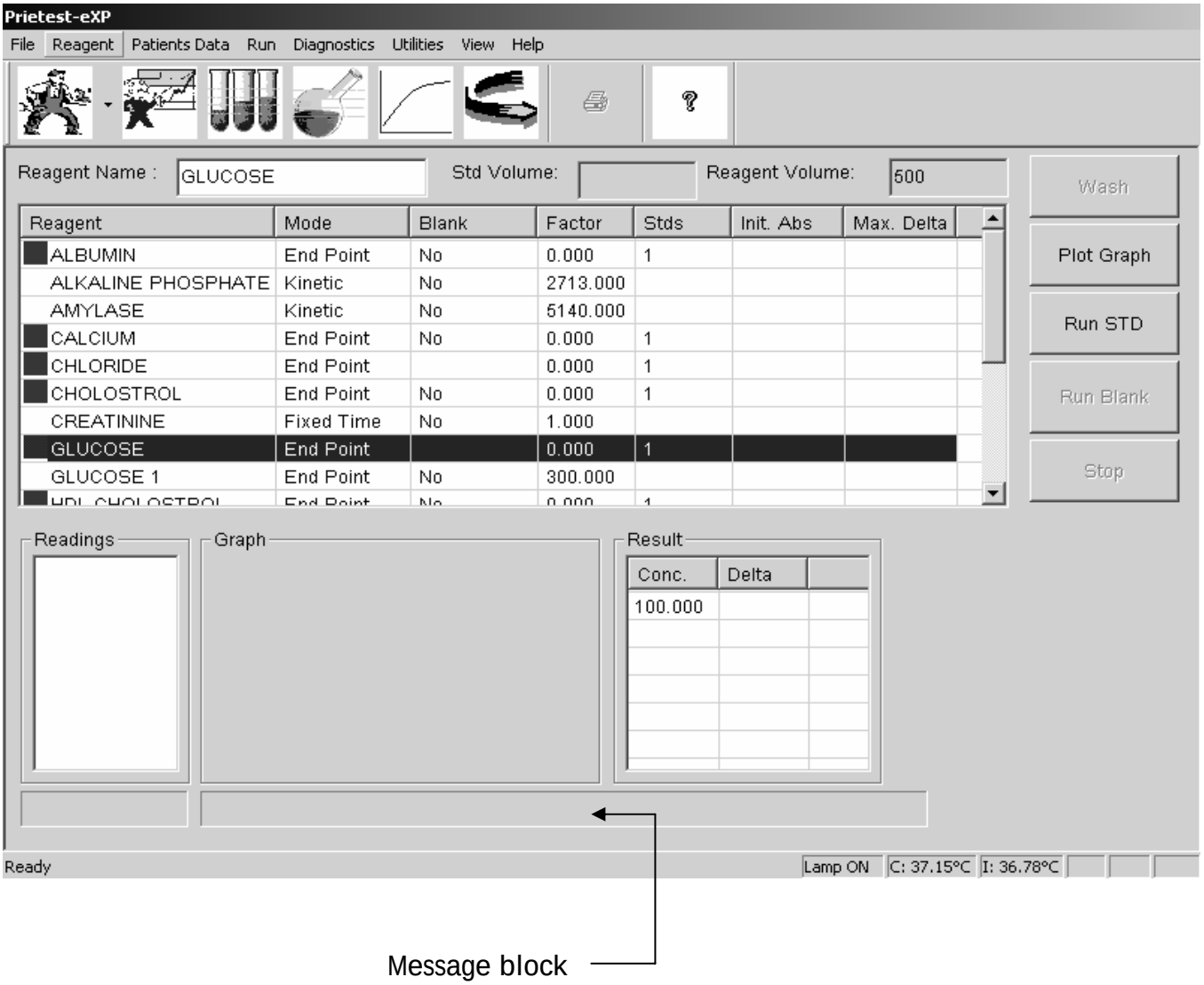
By this values of additional filters inserted can be entered.

Note: Normally instrument is provided with 6 filters this option is used only if additional filter is used.

9. TEST OPERATIONS

9.1. Running Blank / Standard

Click on Standard Run in Reagent Menu instrument displays following screen.

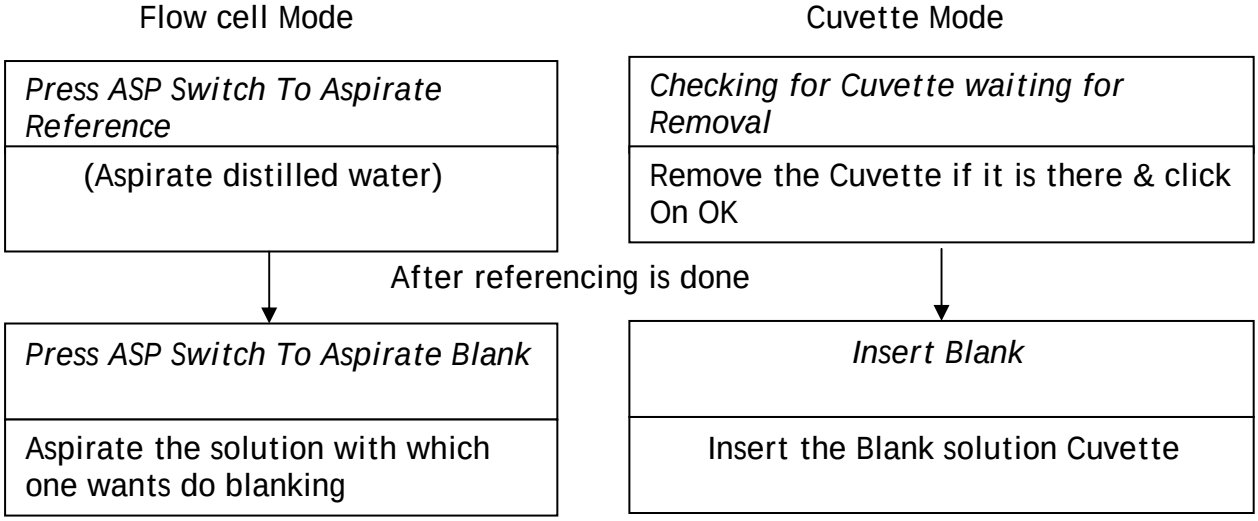


In this screen one can run

- The Blank solution for the tests having factor & blank : By clicking on Run Blank
- Blank & Standard solution for the tests having blank & standard: By clicking on Run Standard.

Steps to run Blank

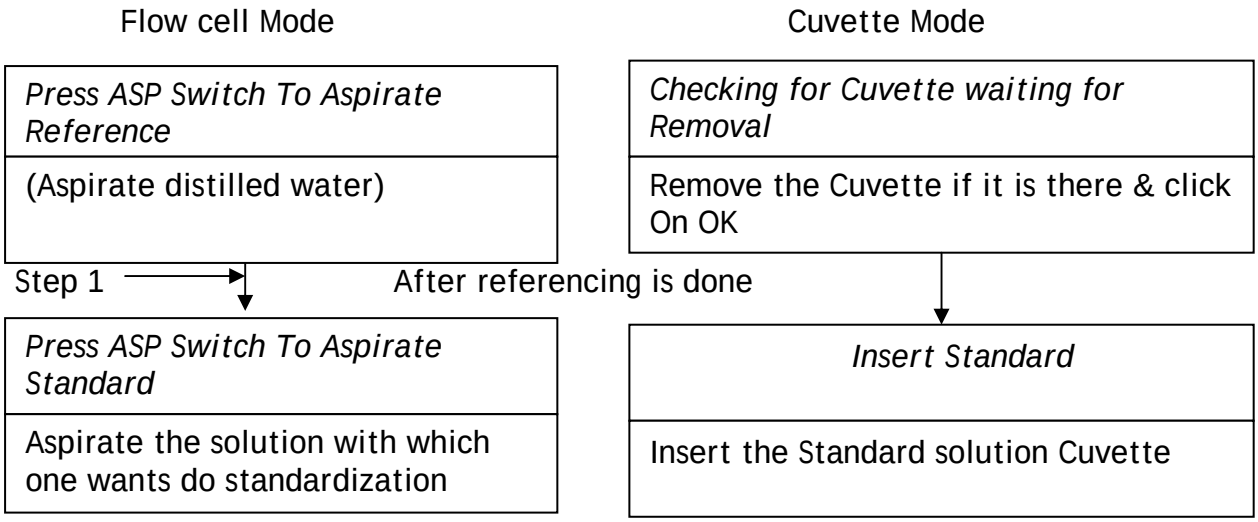
- Select the test for which blank needs to be run by clicking on it.
- Click on Run Blank Instrument displays messages given in Italic in message block



Instrument will wait for lag time & then reads the absorbance of the blank solution.
After reading is done instrument displays message remove blank Cuvette
This completes the blank running.

Steps to run Standard

- Select the test for which standard needs to be run by clicking on it.
- Click on Run STD Instrument displays messages given in Italic in message block



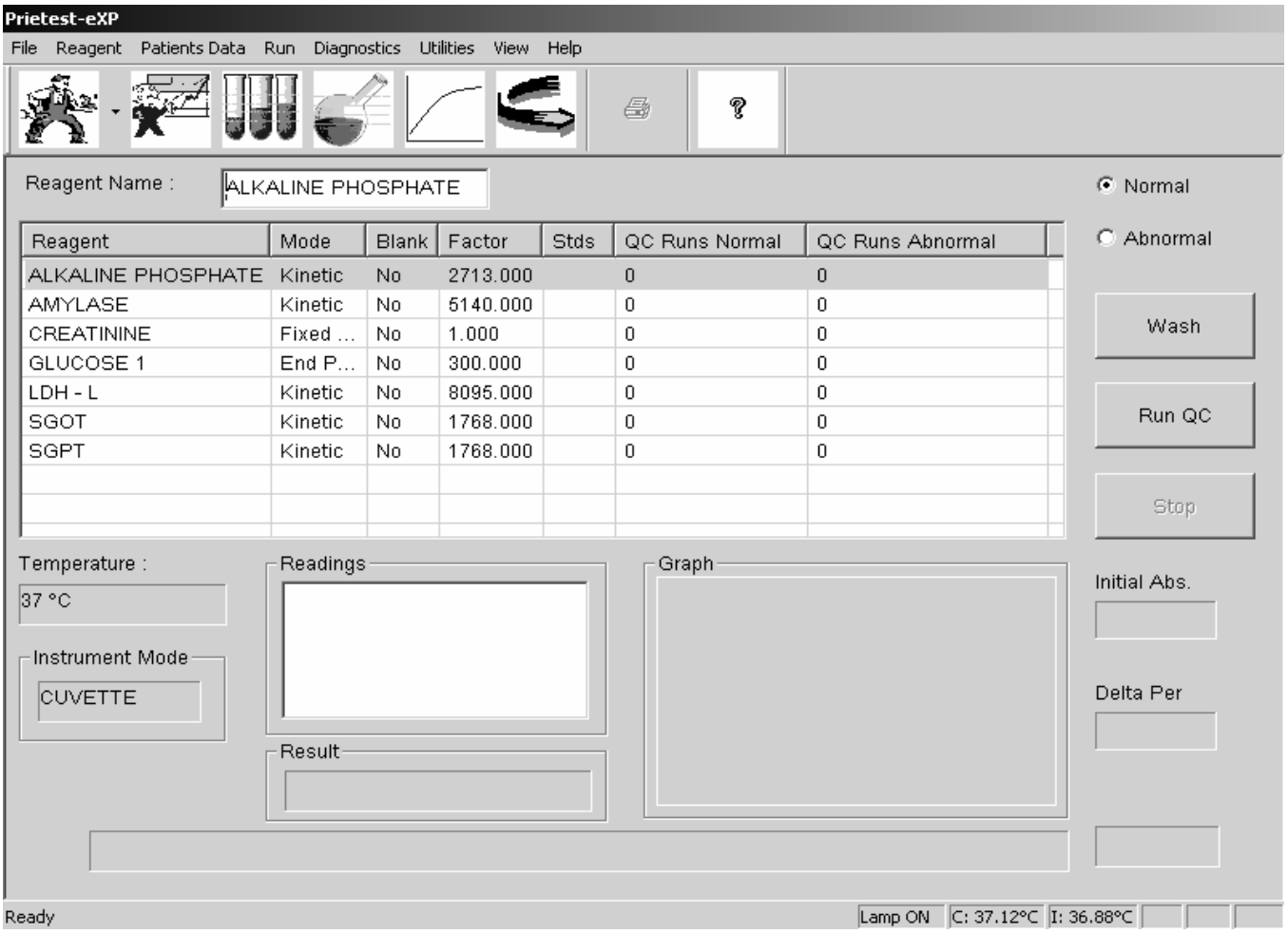
Instrument will wait for lag time & then reads the absorbance of the Standard solution.
After this instrument will ask whether to rerun the standard or not

- If YES is clicked then instrument will repeat the standard run procedure from step 1 for that standard.
- If NO is clicked then instrument will displays as well as print the factor in case of single standard or ask for next standard run in case of multistandard.

The values of Blank run & factor calculated from single standard run are get displayed in the standard run table.

9.2. Running QC Samples

Click on QC Run in Reagent Menu instrument displays following screen.



Steps to run QC Samples

- Select the test for which QC Samples needs to be run by clicking on it.
- Select type of QC Sample Normal / Abnormal by clicking in the radio button before it.
- Click on Run QC

Instrument displays messages given in Italic in message block

Flow cell Mode	Cuvette Mode
Press ASP Switch To Aspirate Reference	*Checking for Cuvette waiting for Removal*
(Aspirate distilled water)	Remove the Cuvette if it is there & click On OK
↓	After referencing is done ↓
Press ASP Switch To Aspirate Sample	*Insert Sample*
Aspirate the QC Sample	Insert the QC Sample Cuvette

Instrument will wait for lag time & then reads the absorbance of the sample solution.

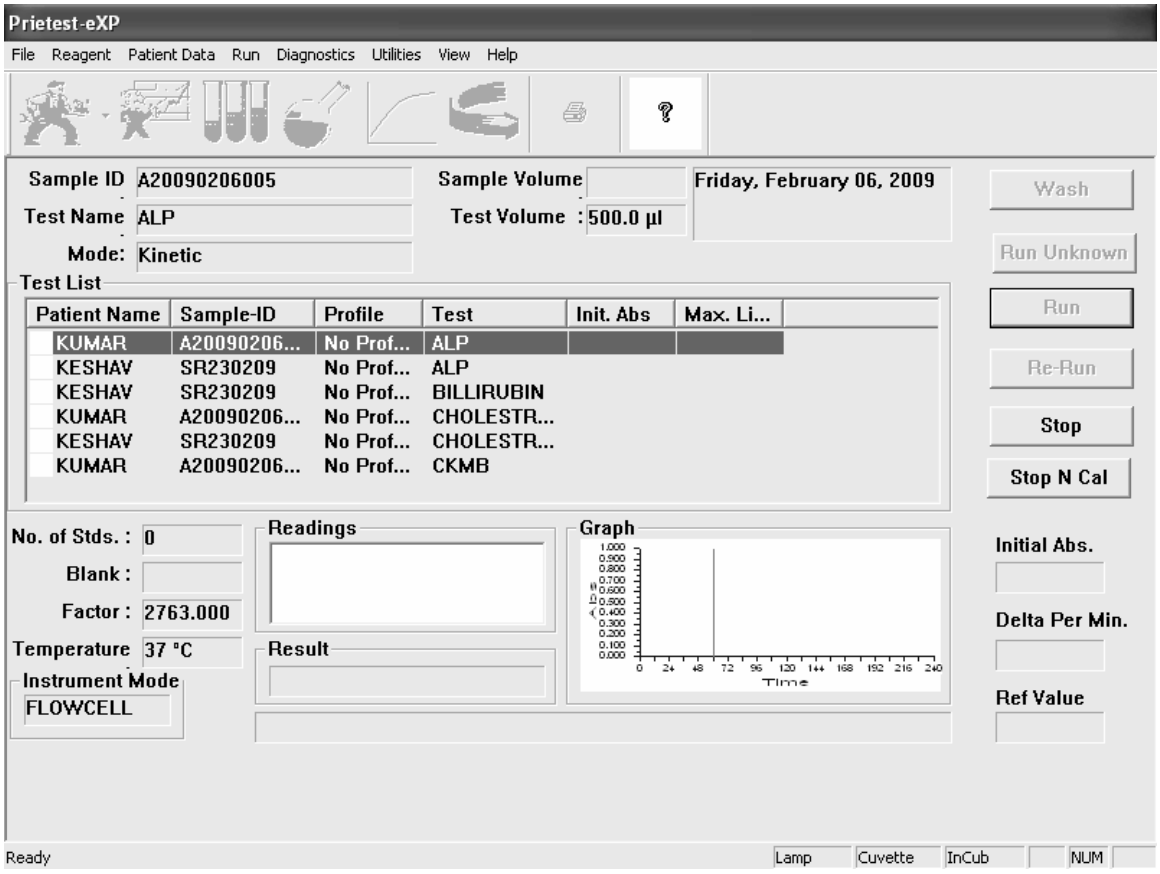
9.3. Running Samples in Test Run Mode

One can run the samples in two ways

- Patients for which information is known.
  If one knows the details for the patient then the details can be enter in Patient entry sec.8.5.1
- Patient for which information is not known.

9.3.1. Running Sample for Patients for which information is known.

When clicked on Test Run Instrument displays following screen containing test details for each individual Patient.



Steps to run Samples.

- Select the Patient whose Samples needs to be run by clicking on it.
- Click on RUN.

Instrument displays messages given in Italic in message block

Flow cell Mode

Press ASP Switch To Aspirate Reference
(Aspirate distilled water)

↓

Press ASP Switch To Aspirate Sample
Aspirate the sample solution for the patient selected.

Cuvette Mode

Checking for Cuvette waiting for Removal
Remove the Cuvette if it is there & click On OK

After referencing is done

↓

Insert Sample
Insert the Sample solution Cuvette for the patient selected.

Instrument will wait for lag time & then reads the absorbance of the sample solution.
It will then calculate the result of the sample run.
Displays & Prints following
Sample ID
Patient name
Sample Absorbance
Result of the sample run
Status

When printing of the results is over curser will automatically move to next patient for the same test & gives messages as below.

Press ASP Switch To Aspirate Sample
Aspirate the sample solution for the patient selected.

Insert Sample
Insert the Sample solution Cuvette for the patient selected.

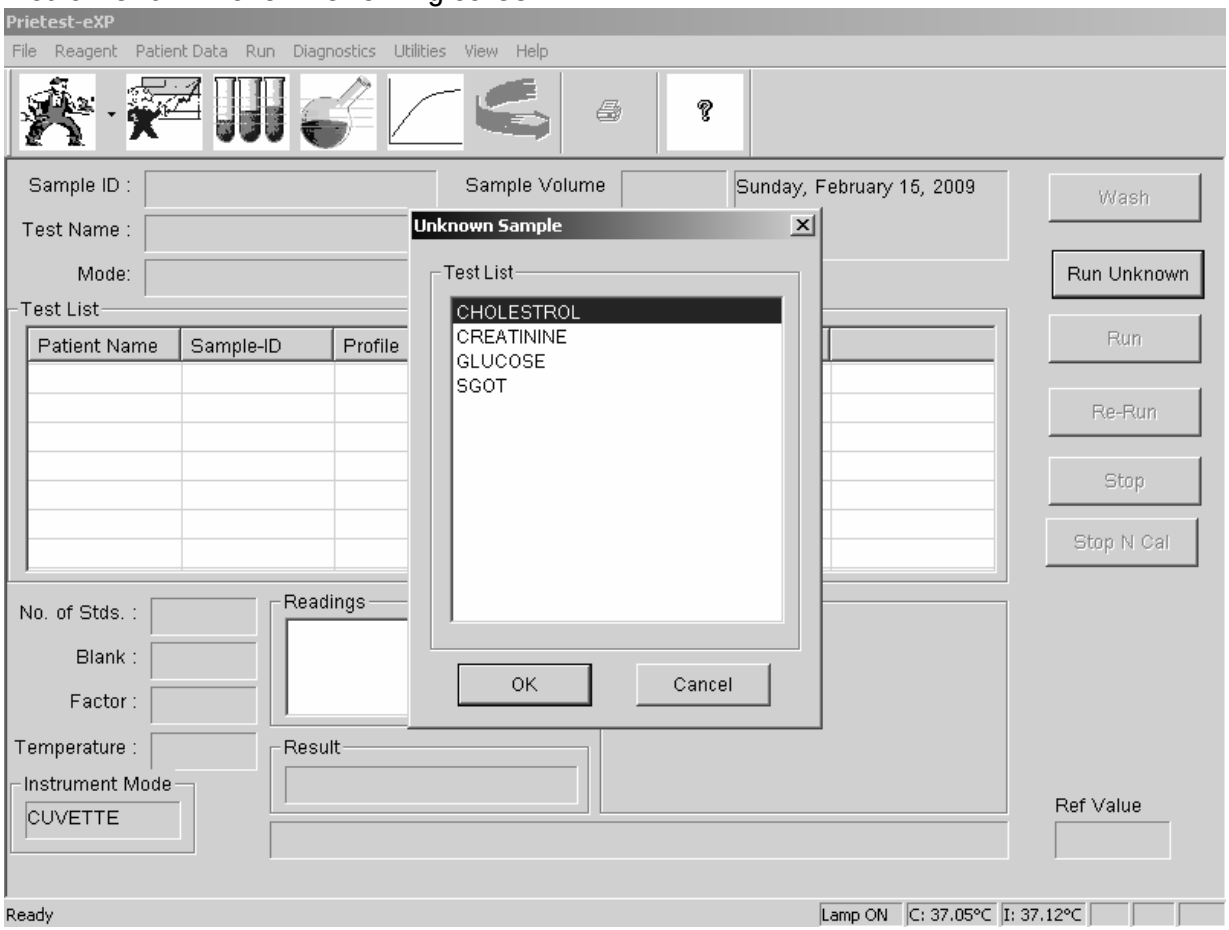
Instrument will continue running samples till one clicks on stop button.

9.3.2. Running Sample for Patients for which information is not known.

Steps to run Samples.

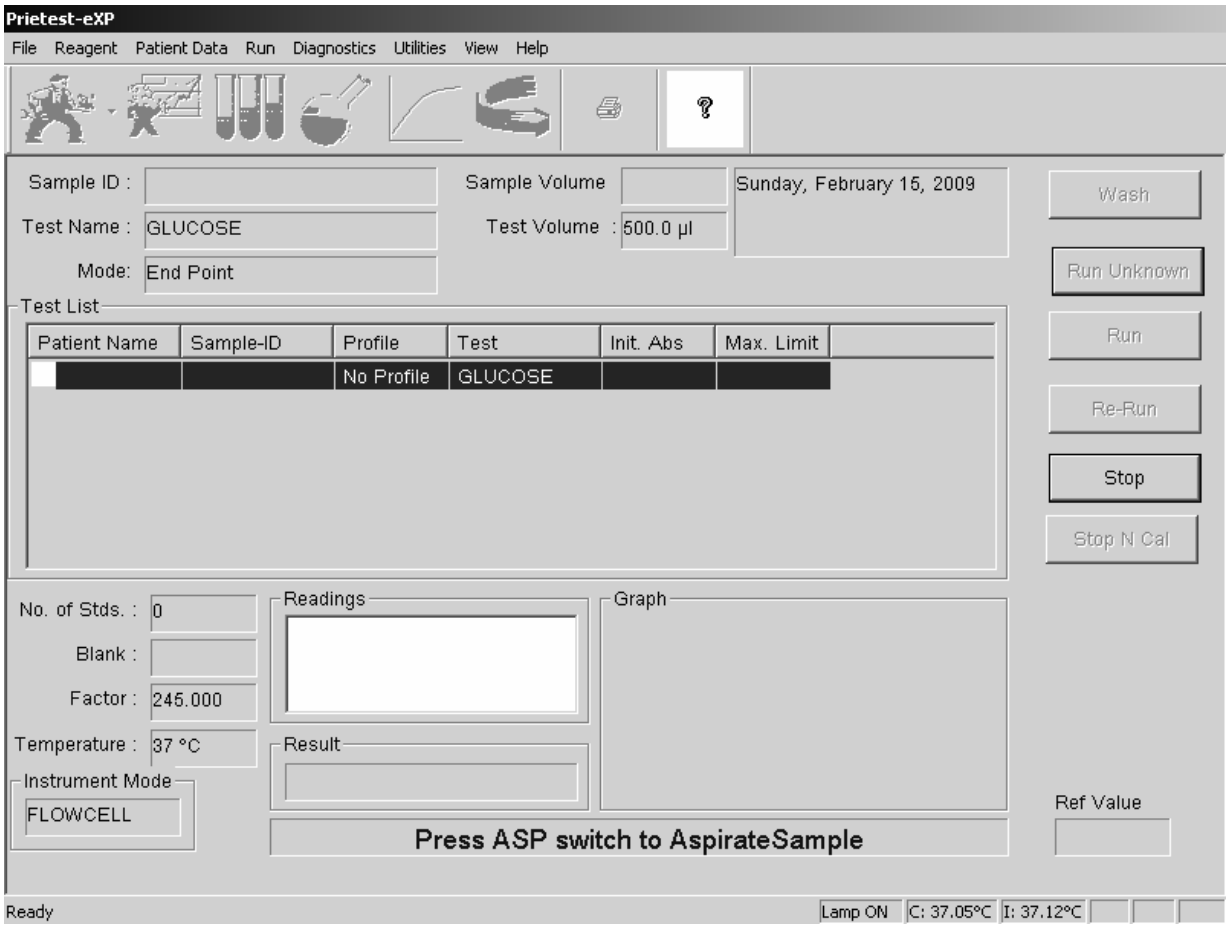
- Click on Run Unknown.

Instrument will show following screen



- Select the test which one wants to run for the patient & click OK .
  e.g. consider GLUCOSE test is selected.

When OK is clicked instrument will display following screen.

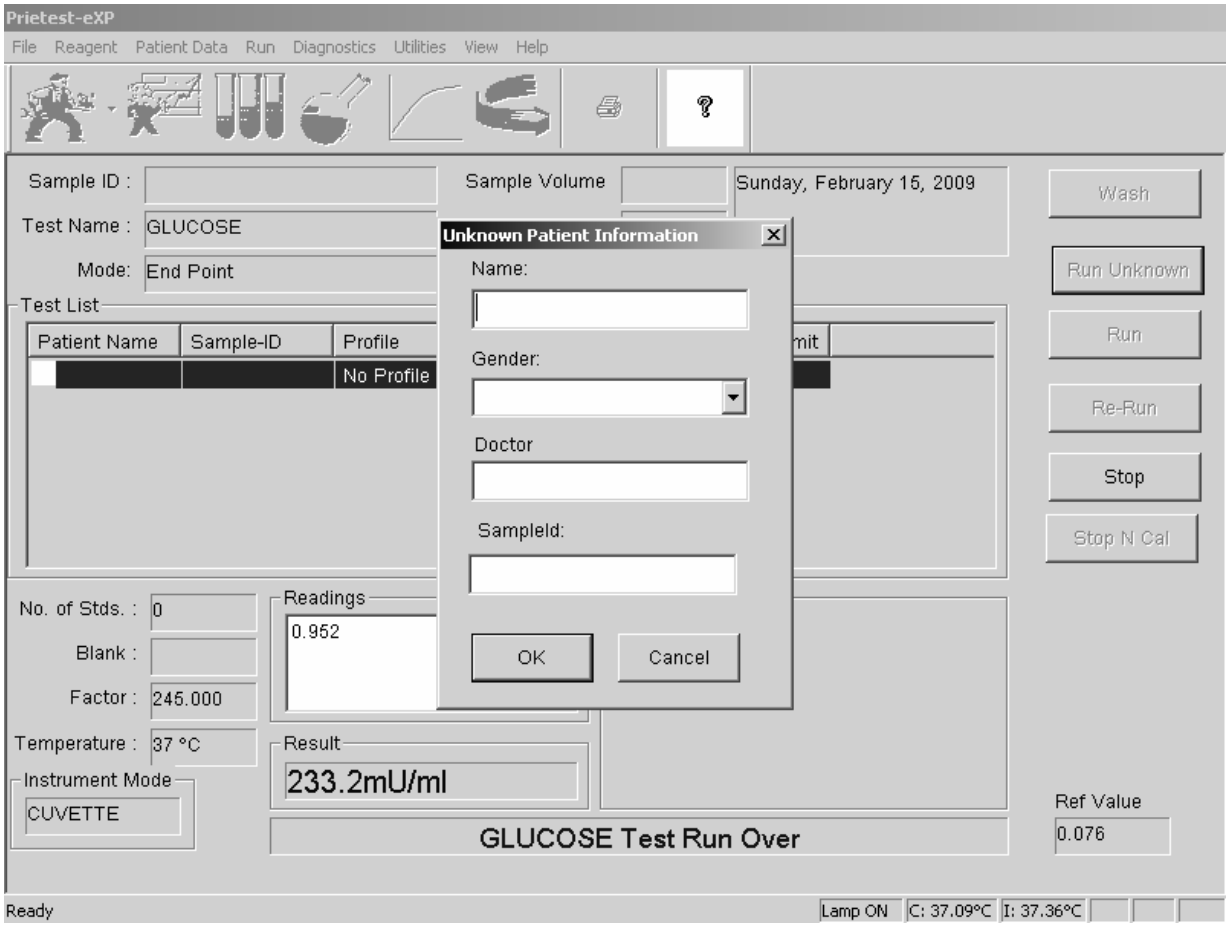


Initially it will add only test w/o name & displays messages in message block as per mode selected.

Instrument displays messages given in Italic in message block

Flow cell Mode	Cuvette Mode
Press ASP Switch To Aspirate Reference	*Checking for Cuvette waiting for Removal*
(Aspirate distilled water)	Remove the Cuvette if it is there & click On OK
↓	↓
After referencing is done	
Press ASP Switch To Aspirate Sample	*Insert Sample*
Aspirate the sample solution for the patient.	Insert the Sample solution Cuvette for the patient.

Instrument will wait for lag time & then reads the absorbance of the sample solution.
It will then calculate the result of the sample run.
Instrument Displays the result of the sample run & displays following screen.



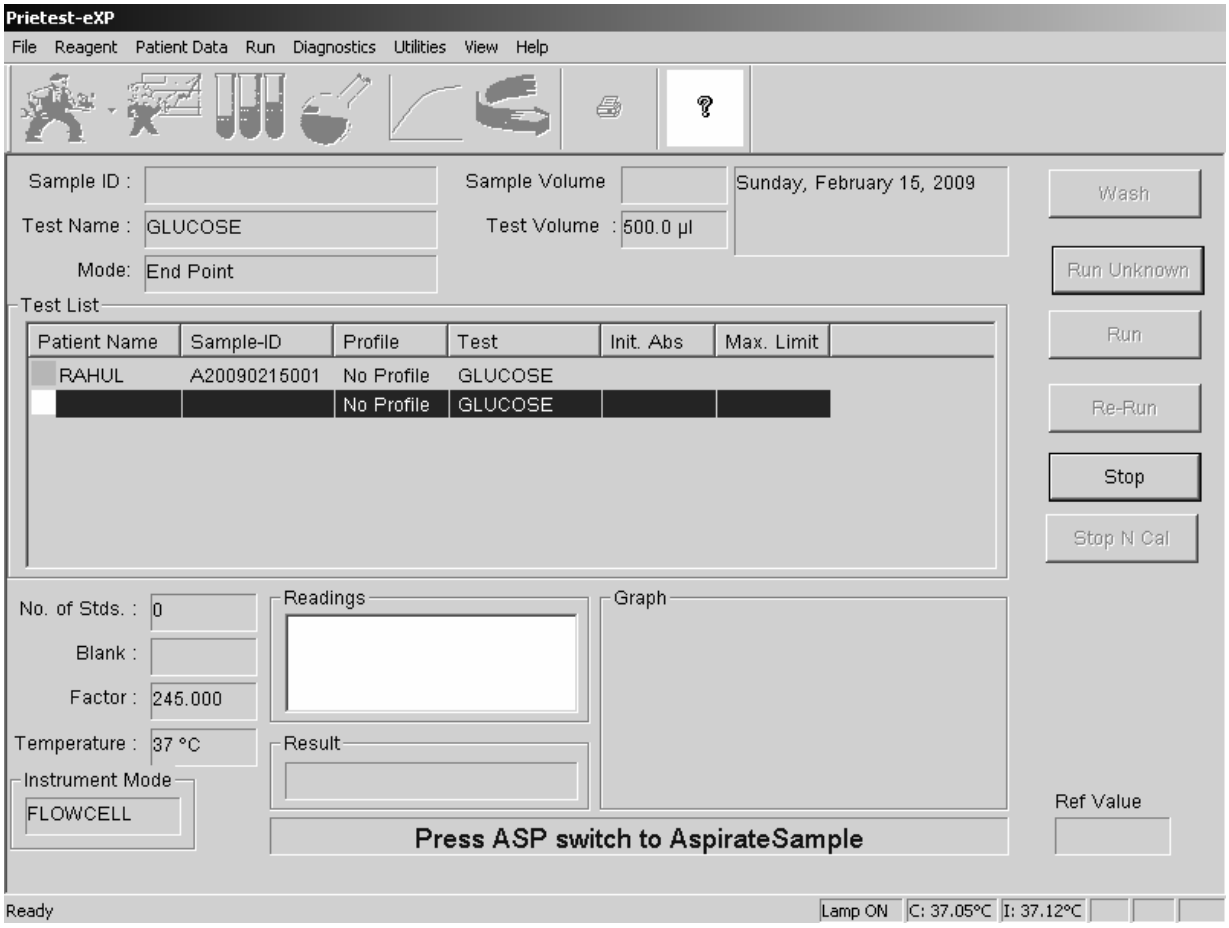
In this screen one has two option

- Save the results of the sample run.
- Not to save the results of the sample run.

To save the results of the sample run.

- To save the results of the sample run one has to enter Patient Name, Gender & click OK.
- In the above entries Doctor Name and sample ID is not compulsory entry.
- If sample ID is not entered manually instrument will automatically assign sample id to the patient with prefix A.

When OK is clicked instrument will display following screen.



Instrument will print

Sample ID
Patient name
Sample Absorbance
Result of the sample run
Status

Instrument will continue running samples till one clicks on stop button.

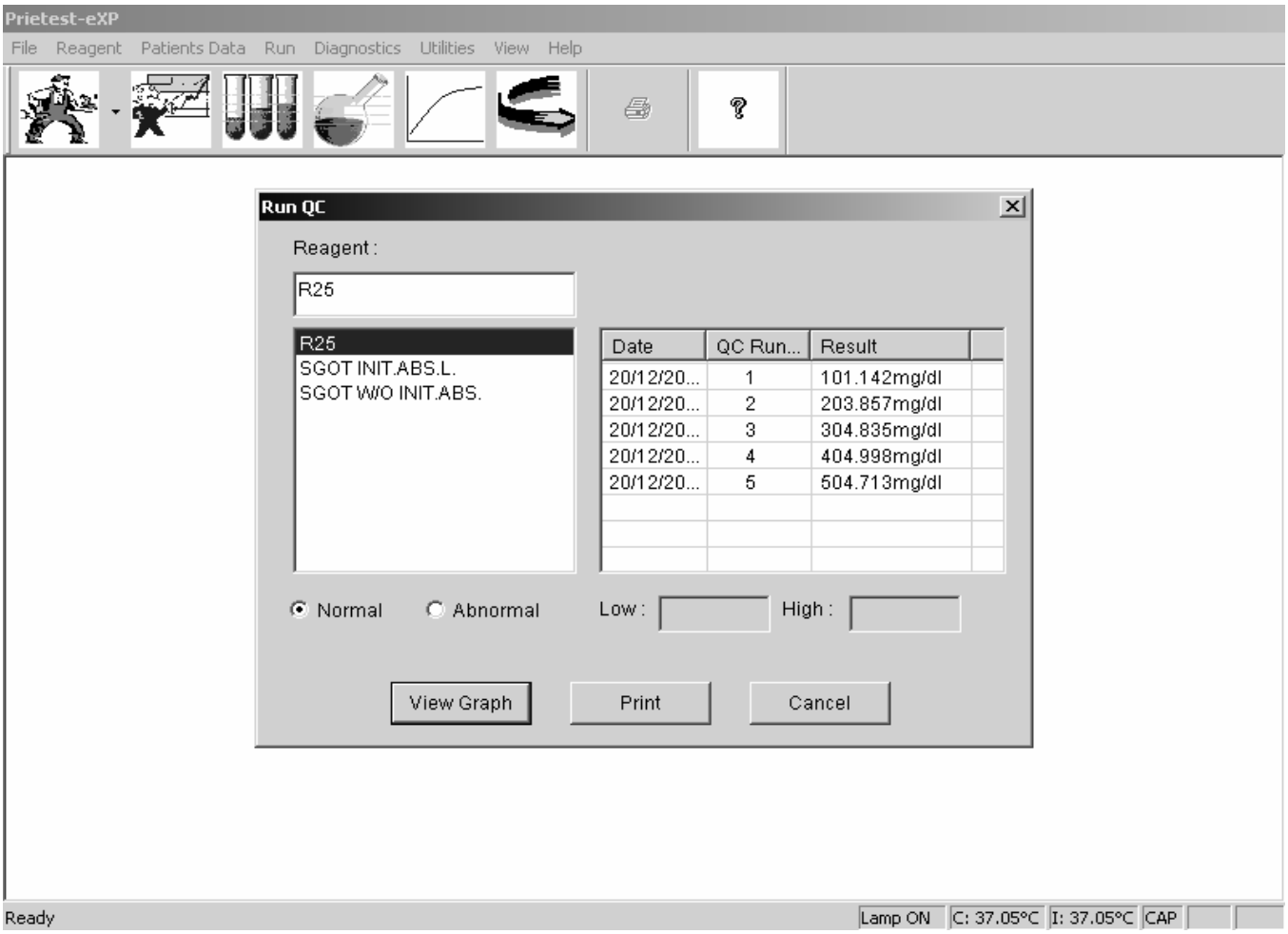
Not to save the results of the sample run.

- If one doesn't want to save the results of the sample run then click cancel. If cancel is clicked instrument will not print the results.

Instrument will continue running samples till one clicks on stop button.

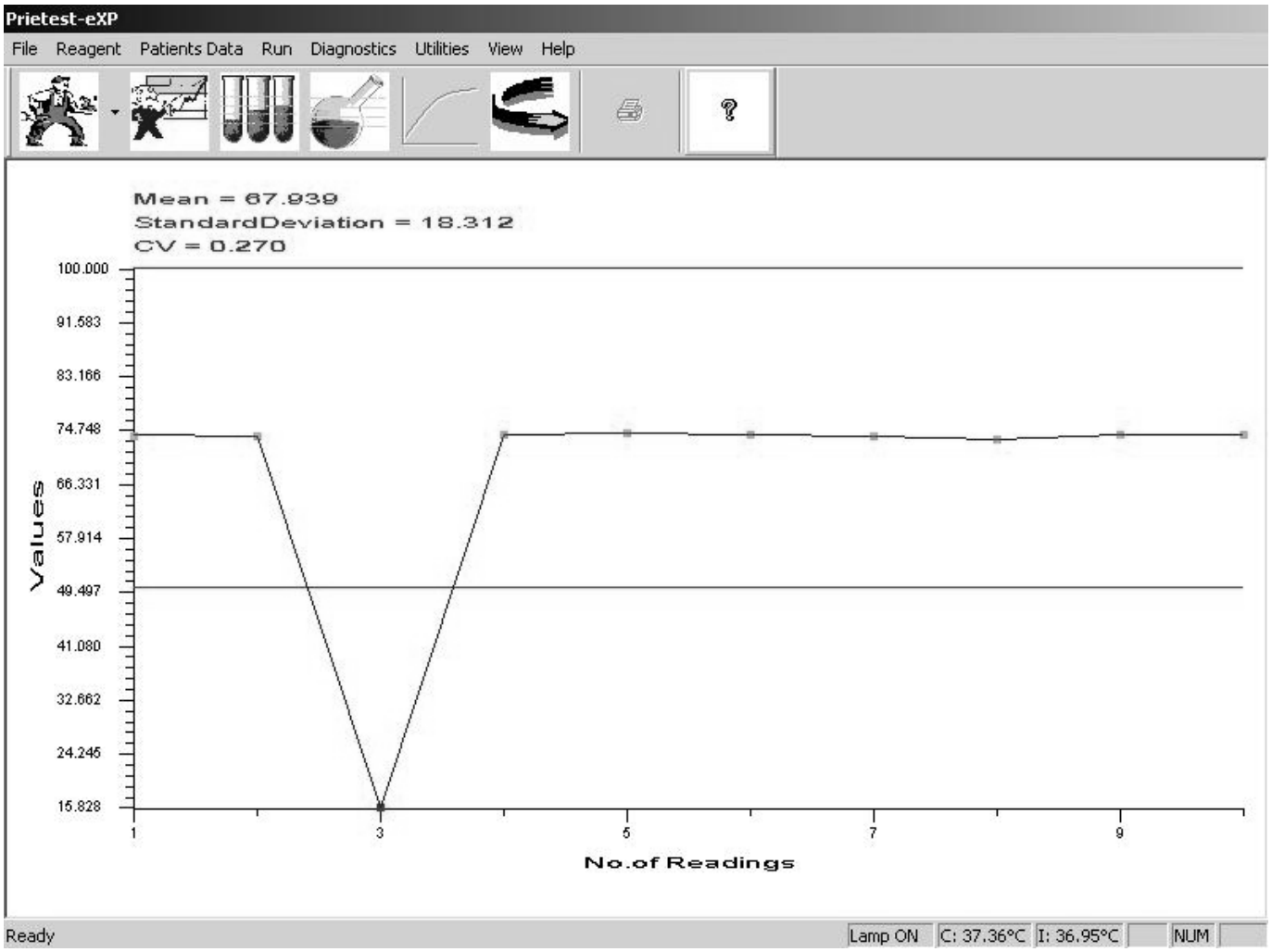
9.4. Standard Deviation Graph

When clicked on Graph option instrument displays following screen



Steps to view the standard deviation graph.
Click on reagent for which QC graph is required.
Select normal or abnormal by clicking on it instrument will display the no of QC Samples run till date.
Click on View Graph this will display the QC graph as below

QC graph :


Prietest-eXP
File Reagent Patients Data Run Diagnostics Utilities View Help
Mean = 67.939
StandardDeviation = 18.312
CV = 0.270
100.000
91.583
83.166
74.748
66.331
57.914
49.497
41.080
32.662
24.245
15.828
Values
1
3
5
7
9
No.of Readings
Ready
Lamp ON
C: 37.36°C
I: 36.95°C
NUM

10. ADDING A EXTERNAL PRINTER

Using this one can add the required printer (USB compactable).

Steps to add the printer

Following are the two steps to add the printer.

10.1 Copying printer software in to USB drive (Pen Drive).
10.2 Printer Driver installations.

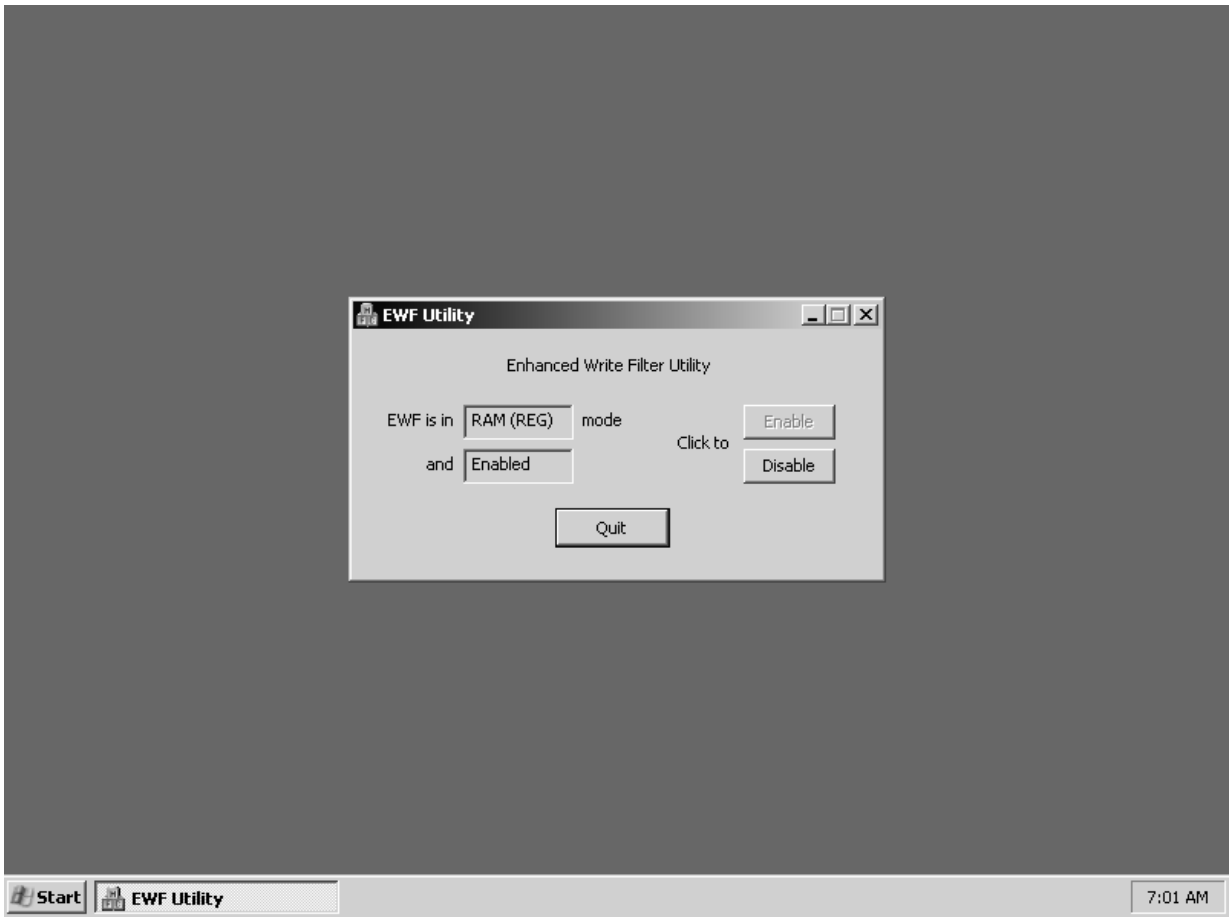
10.1. Copying printer software in to USB drive (Pen Drive)

Following are the instruction for copying files from Printer software CD into USB Drive (Pen Drive).

- Insert software CD that comes with your printer model into computer CD-ROM Drive.
- Open the CD and copy all the files from the CD.
- Insert USB drive into USB port of computer.
- Open removable disk and create a folder with name “Printer”.
  e.g. HP DESKJET 3840 in this case.
- Paste all the files copied from software CD of Printer into “Printer” folder.
- Close the removable disk drive and CD drive.
- Remove USB drive from USB port of computer.
- Now with this USB Drive, you can install printer driver for your Printer Model.

10.2. Printer Driver installation

- Initialise the Instrument & let the initial screen to come.
- Press window button on Keyboard.
- Click on Start.
- Click on Program
- Click on EWF Utility. & instrument will display following screen

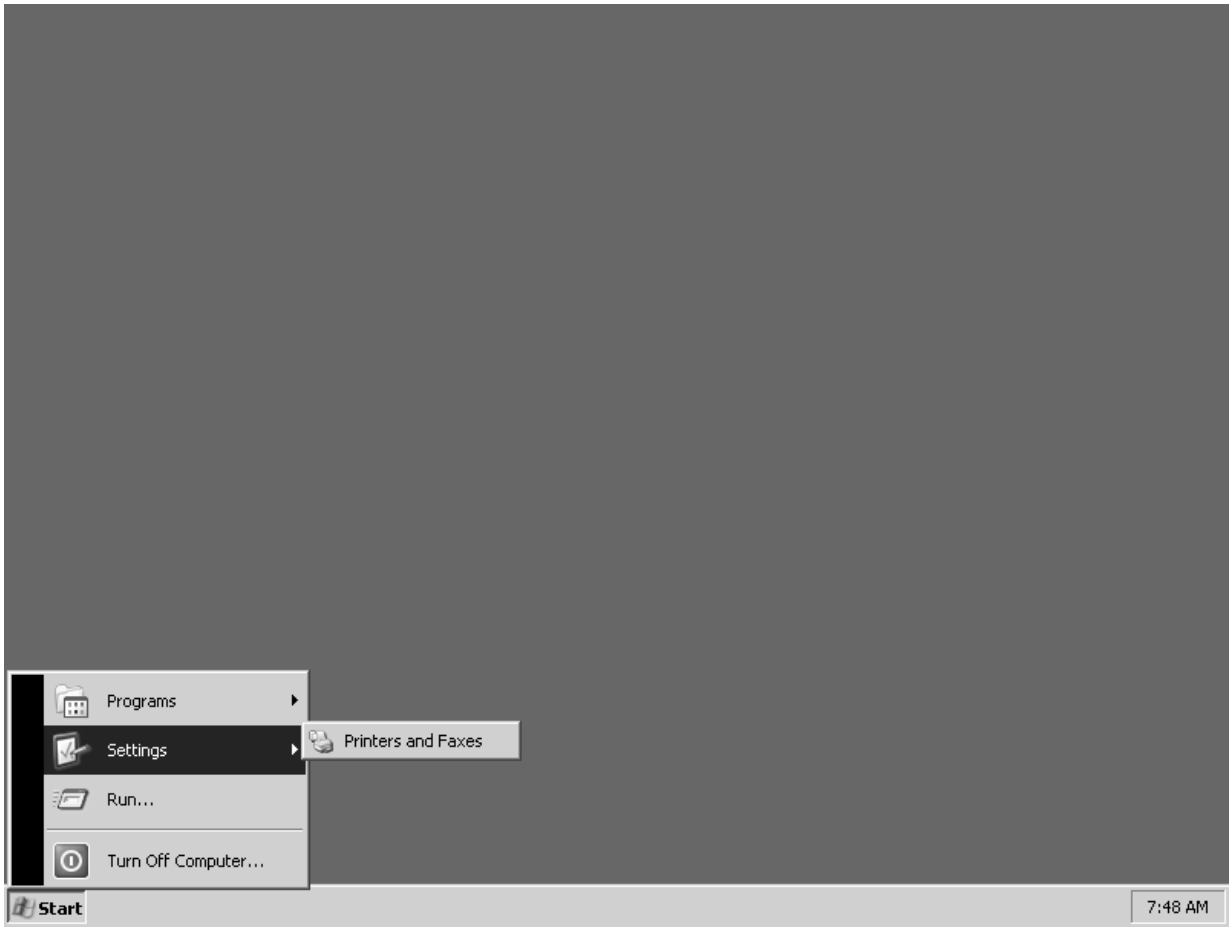


- Click on disable button. The system will now restart.
- Now system is ready to accept printer driver.

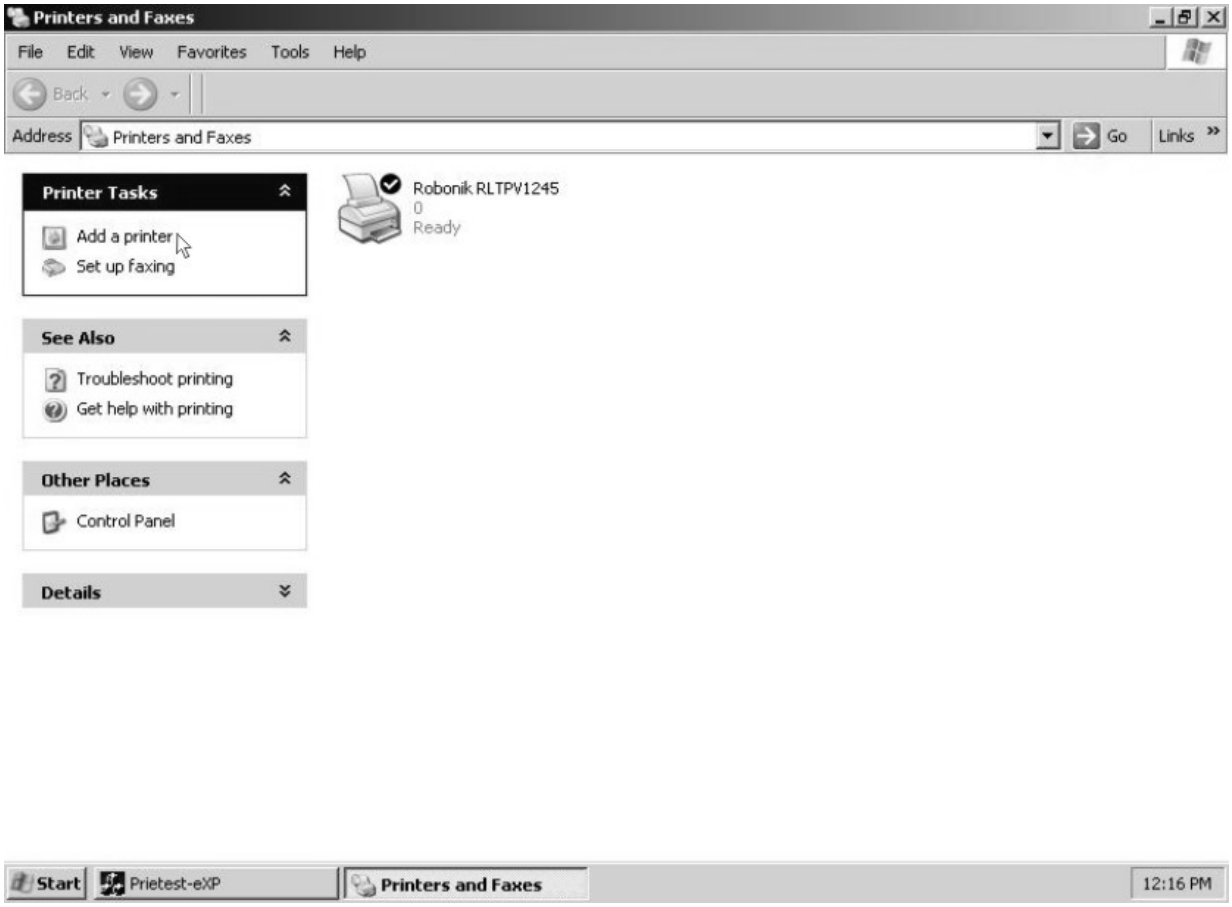
To add the external printer manually carryout following steps.

- Press window button on Keyboard.
- Click on Start.
- Click on Settings.
- Click on Printer and Faxes.

instrument will display Following screen:



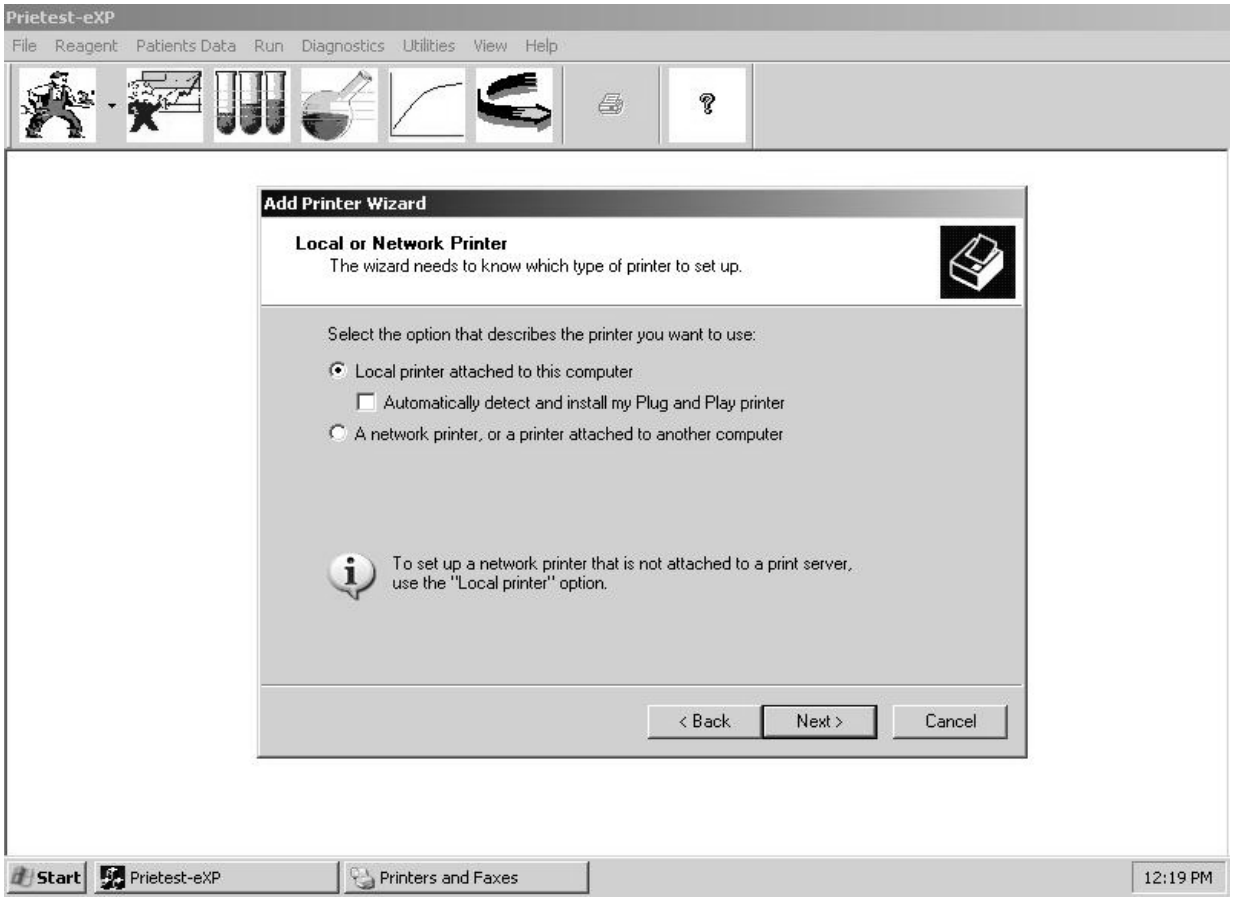
After clicking on Printer and faxes option following screen will appear.



- Click on “Add a printer” Option in screen, then “Add Printer Wizard” will appear on the screen.

- Click on “Next” Command button.
- Connect the pen drive in the second USB pot (Pen drive in which the printer installation software is loaded).

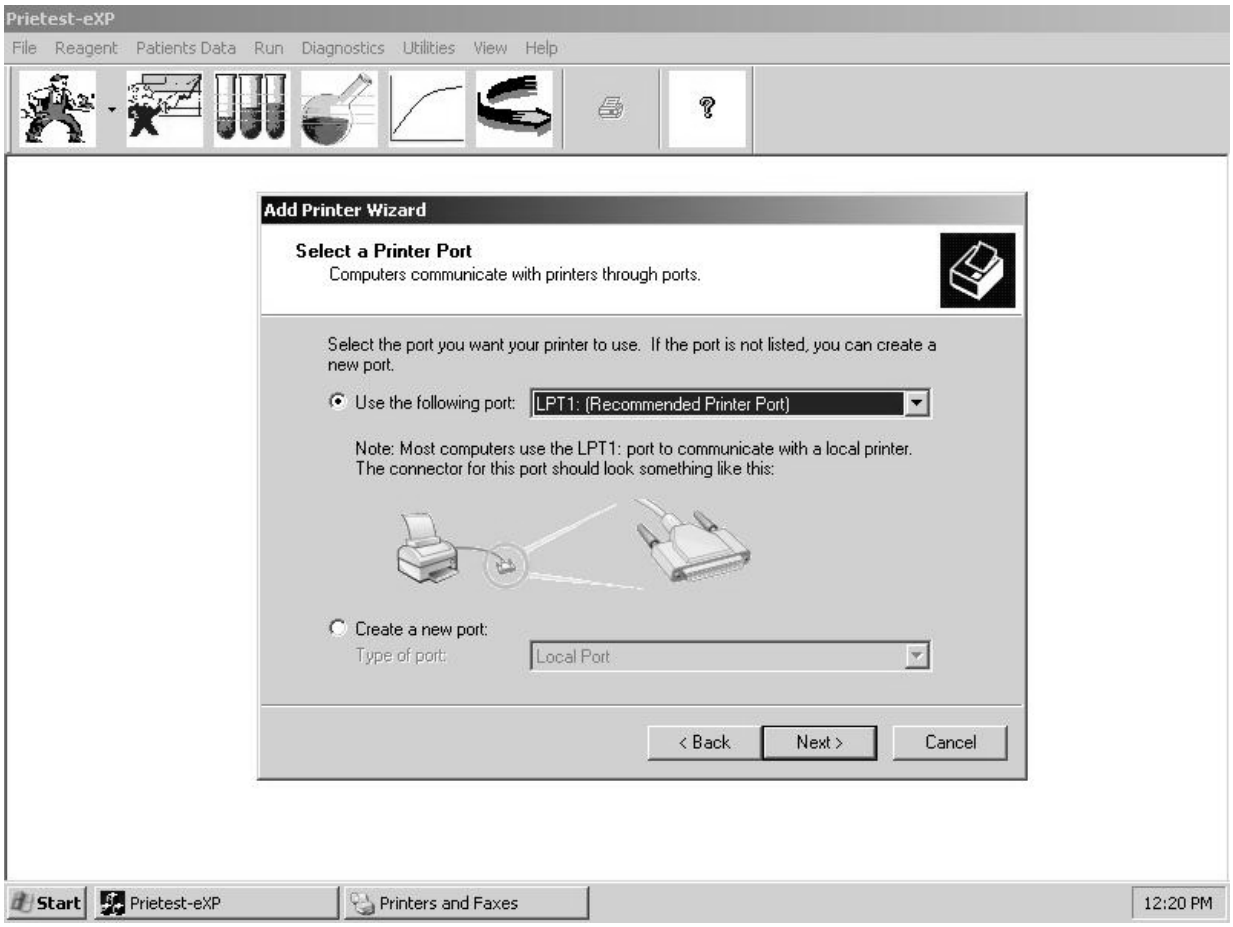
When clicked on Next command button following screen will appear.



In this screen by default "Local printer attached to this computer" is selected. If not

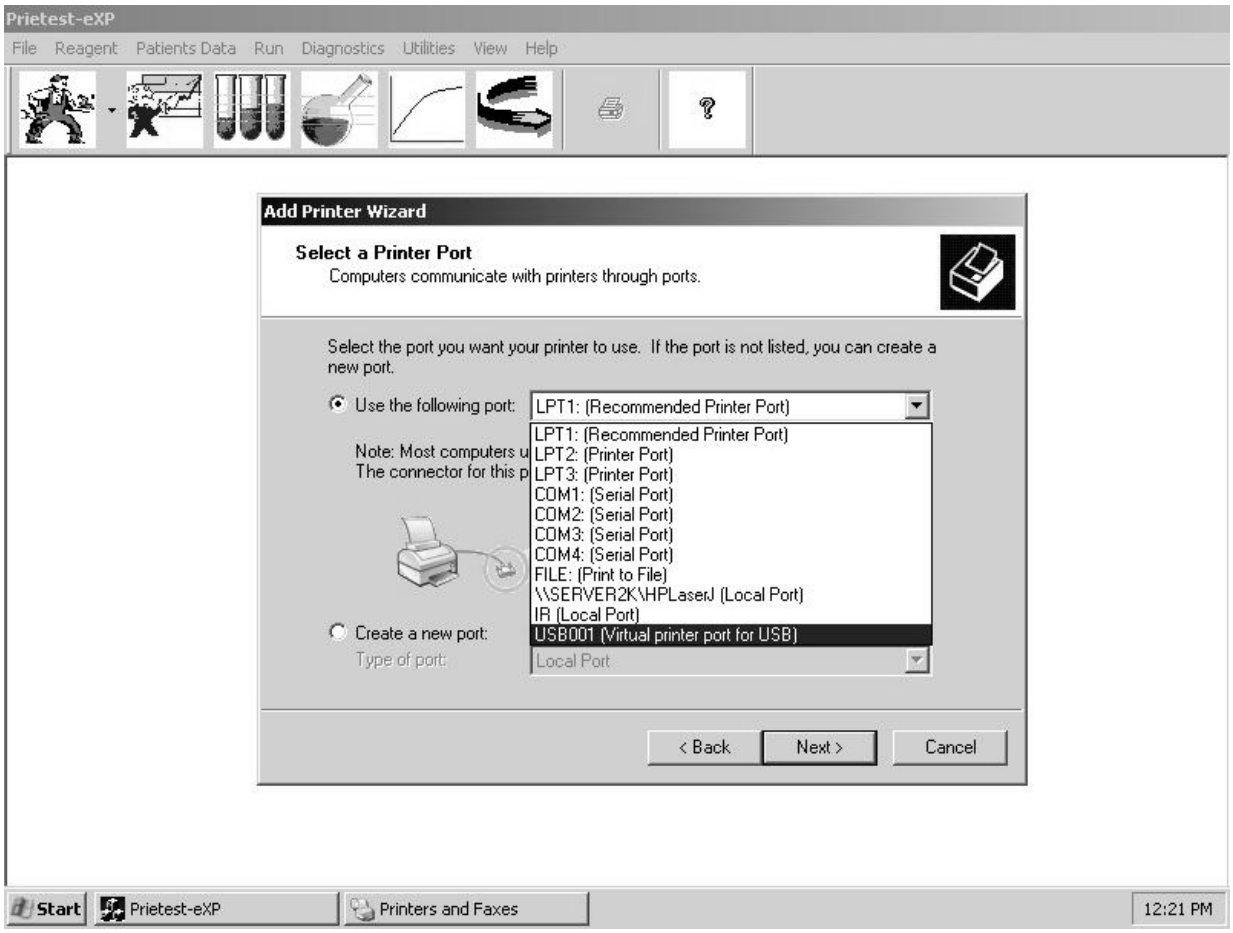
- Select "Local printer attached to this computer" by clicking on radio button (i.e. round before the heading).
- Proceed further by clicking "Next" Command button or Click "Back" to previous window.

After clicking on “Next”, following screen (Printer Port screen) will appear.



The radio button of “Use the following port” is active by default.
If not then select the “Use the following port” by clicking on radio button.

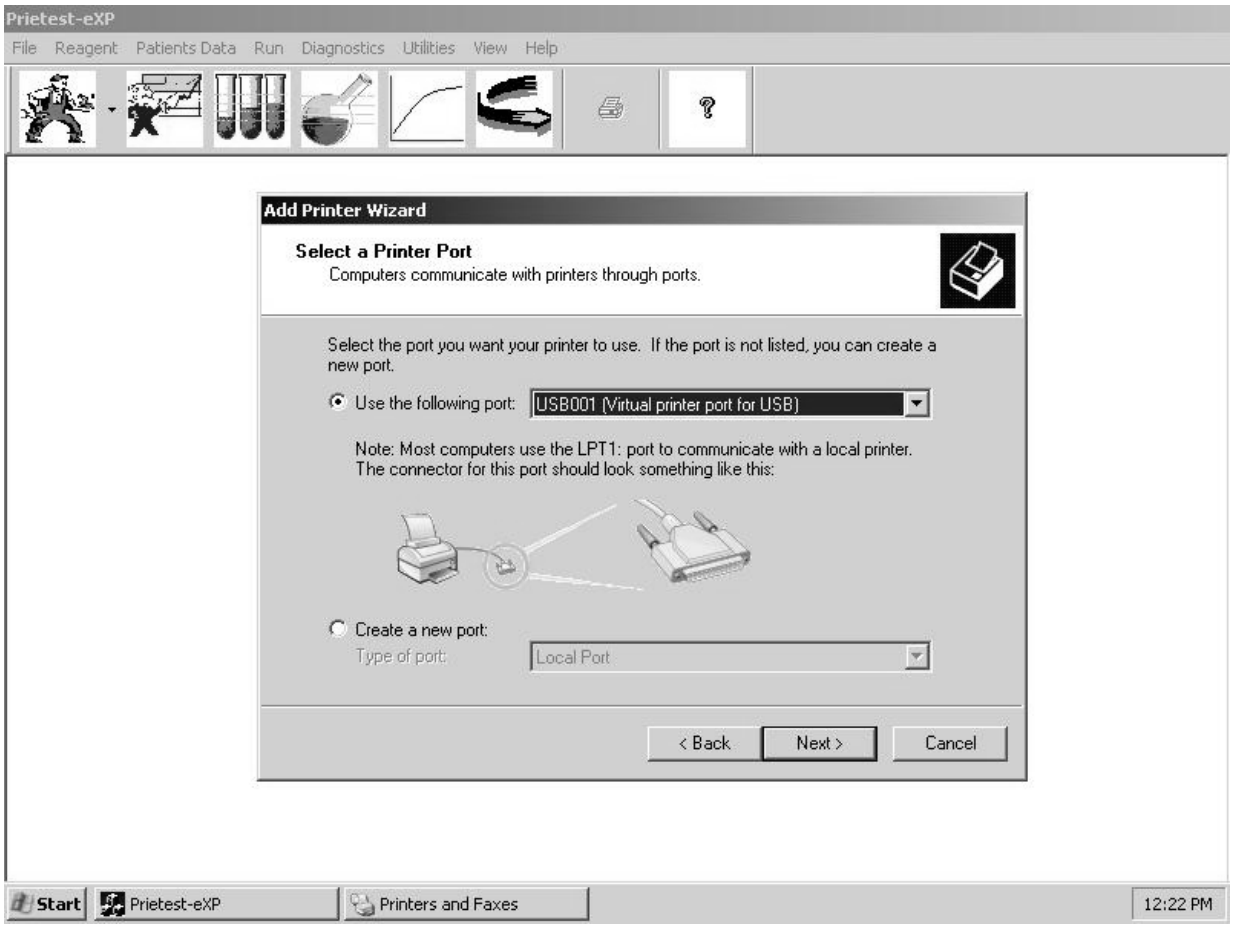
- Click on the down arrow to select the printer ports as shown in screen.



- Select the option of "USB001 (Virtual printer port for USB).

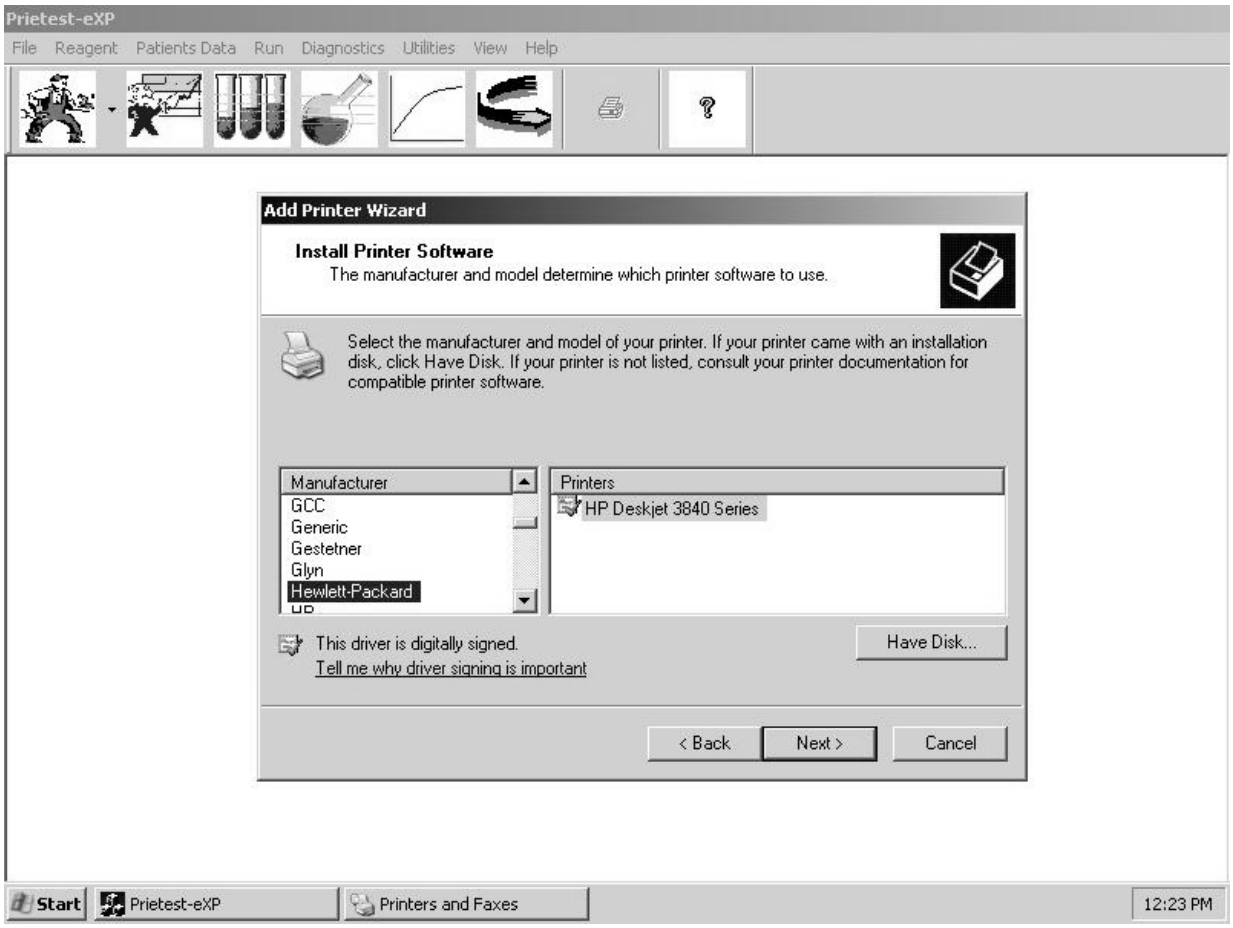
As Printer is connected to USB port of the instrument.

After selection of USB001 (Virtual printer port for USB), the following screen will displayed.



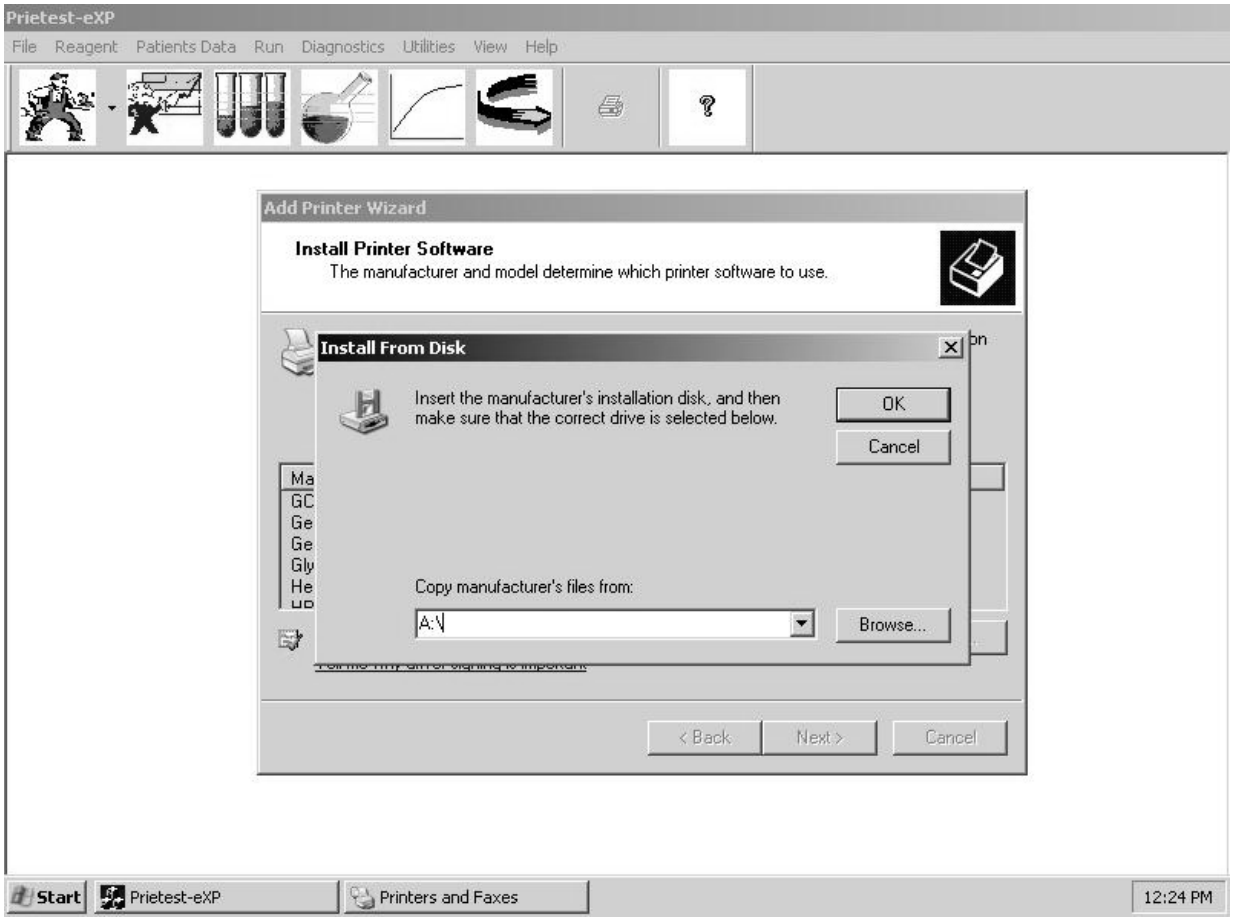
- Click on "Next" Command button to proceed or click "Back" to see previous window.

Then “Install Printer Software” wizard will appear as shown in screen.



- To proceed further, click the “Have Disk” Command button or click “Back” to see previous window.

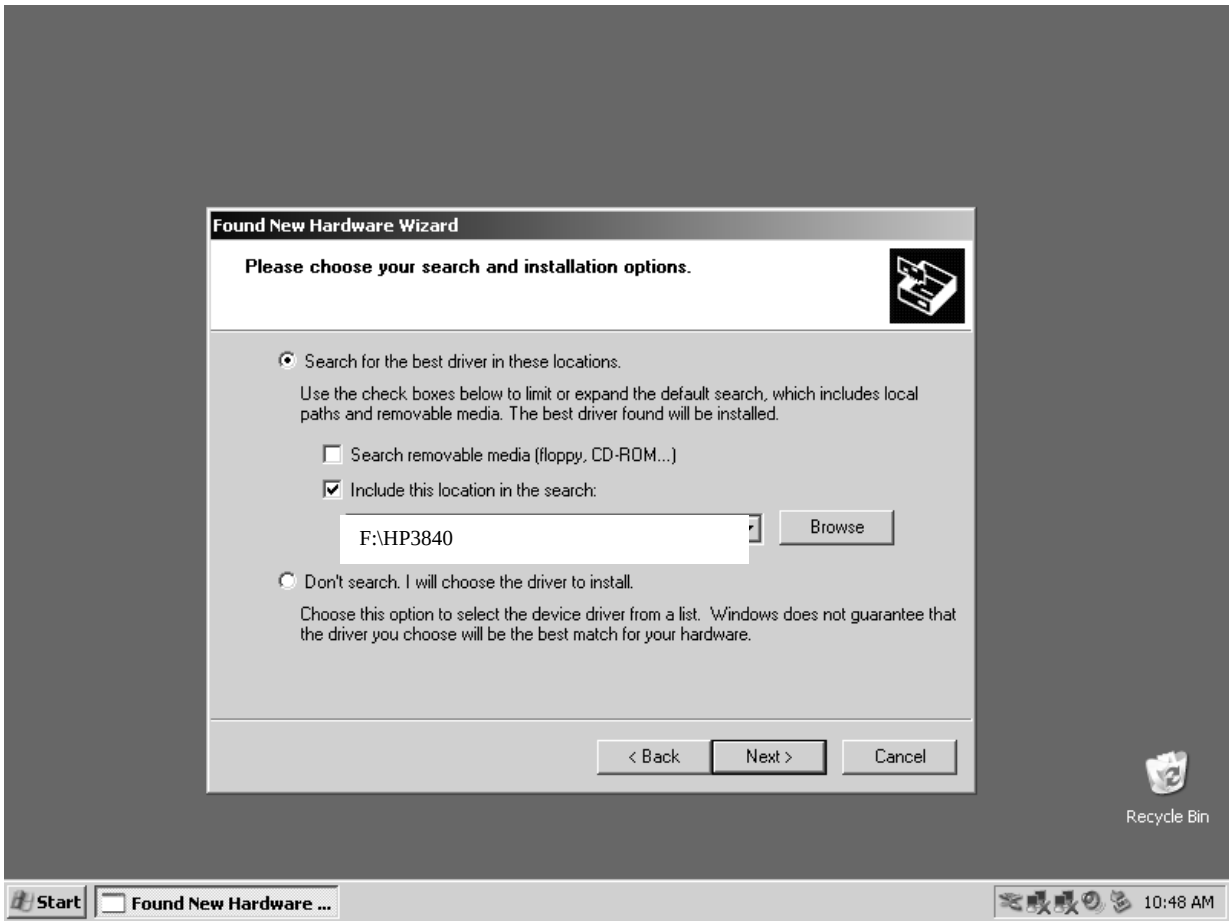
When clicked on “Have Disk” command the “Install from Disc” window will appear as shown in screen.



NOTE: The default drive selected is “A:\”.
As PEN Drive is connected to Drive is “F:\”

Following screen will appear

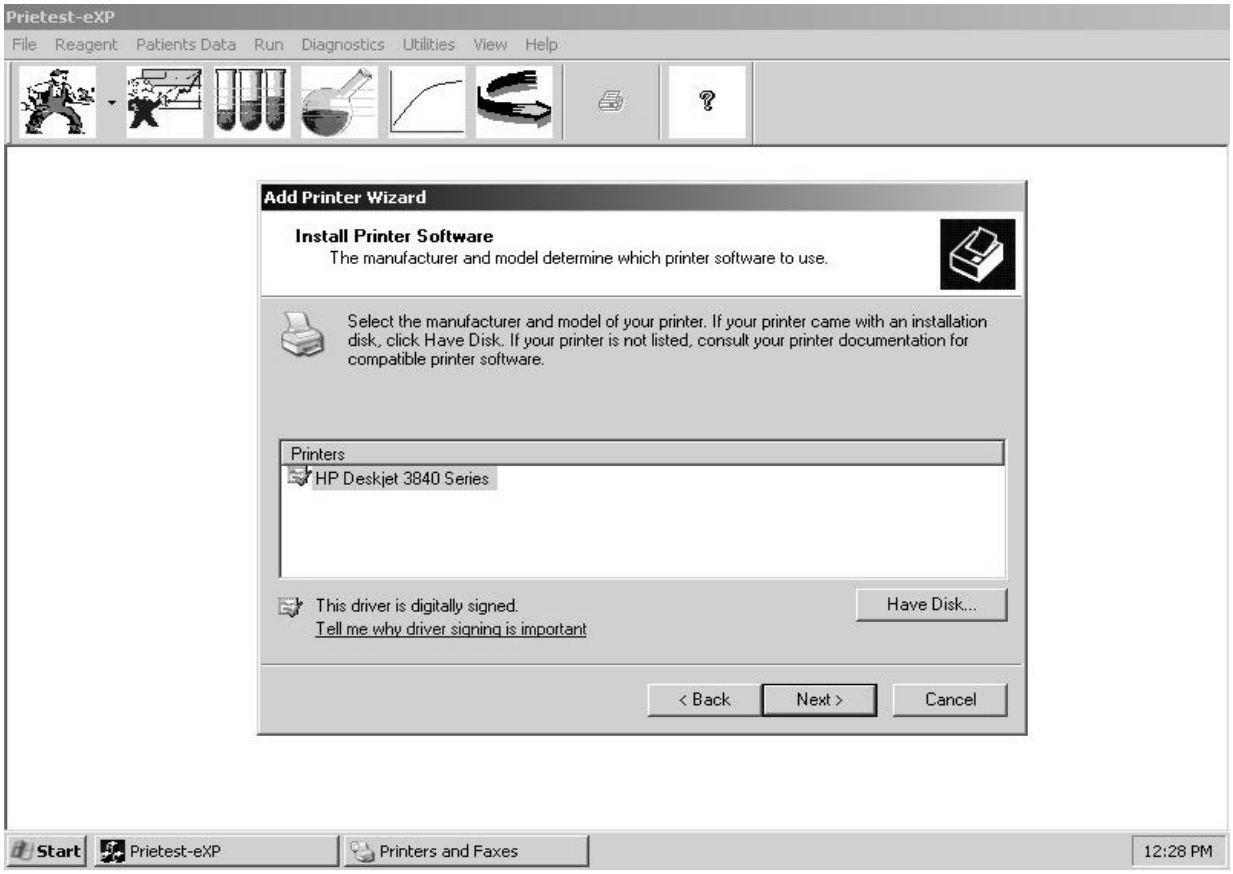
Hence for selecting the path of installation files, type "F:\(folder Name) in which the installation files are saved in Pen drive)".



- Then click on "OK" to proceed.

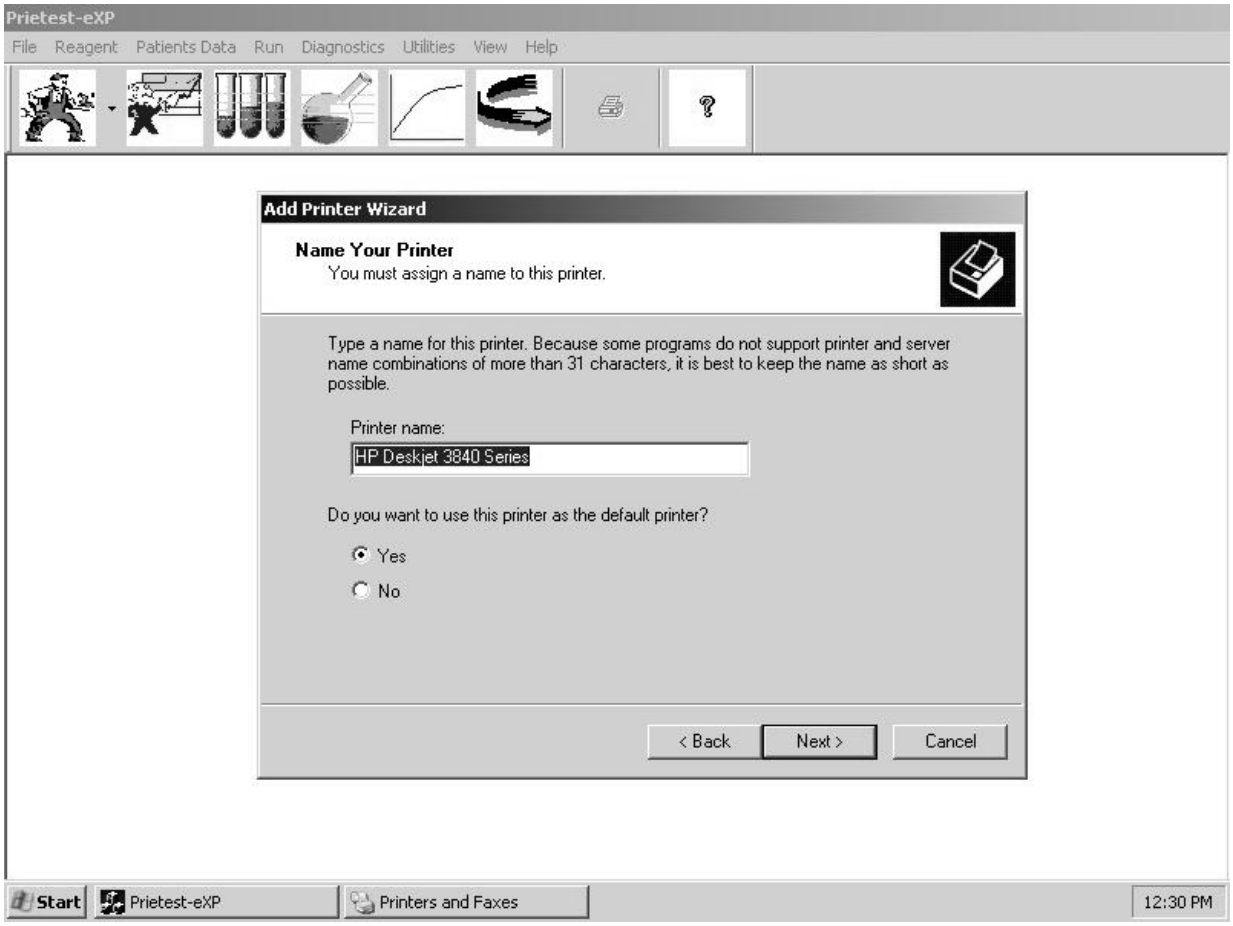
Note: Kindly ensure that the pen drive is plugged in USB drive before clicking "OK".

After clicking “OK”, Add printer wizard will show the printer name or printer series name.



- Then click “Next” to proceed with installation of external printer or click “Back” to see previous window.

After clicking on "Next", instrument will show the screen below.

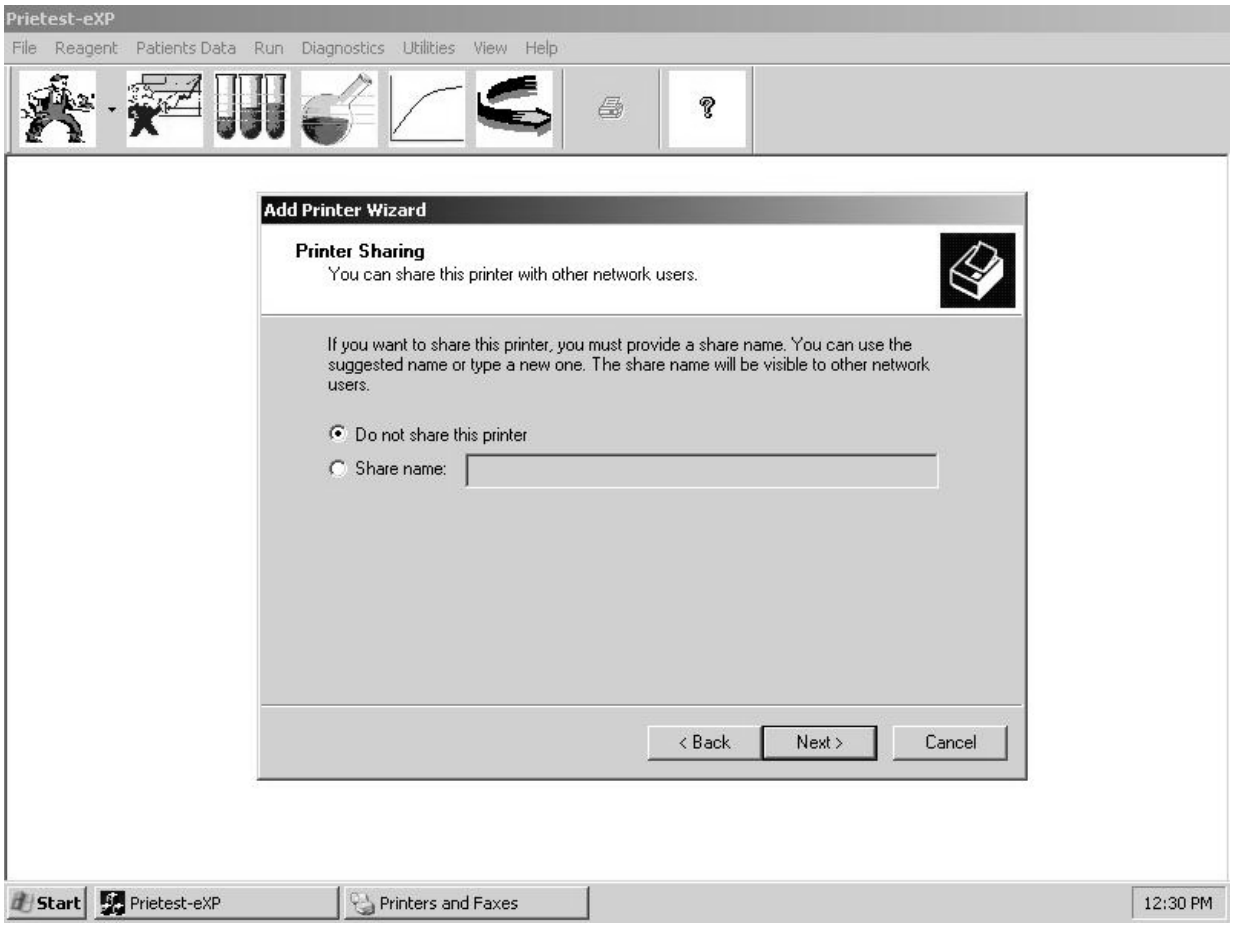


This wizard is for the assign a name for the printer installed on instrument. Then type the printer name in text box provided in the screen which is required to be displayed during printing.

NOTE: Type the printer name as short as possible.

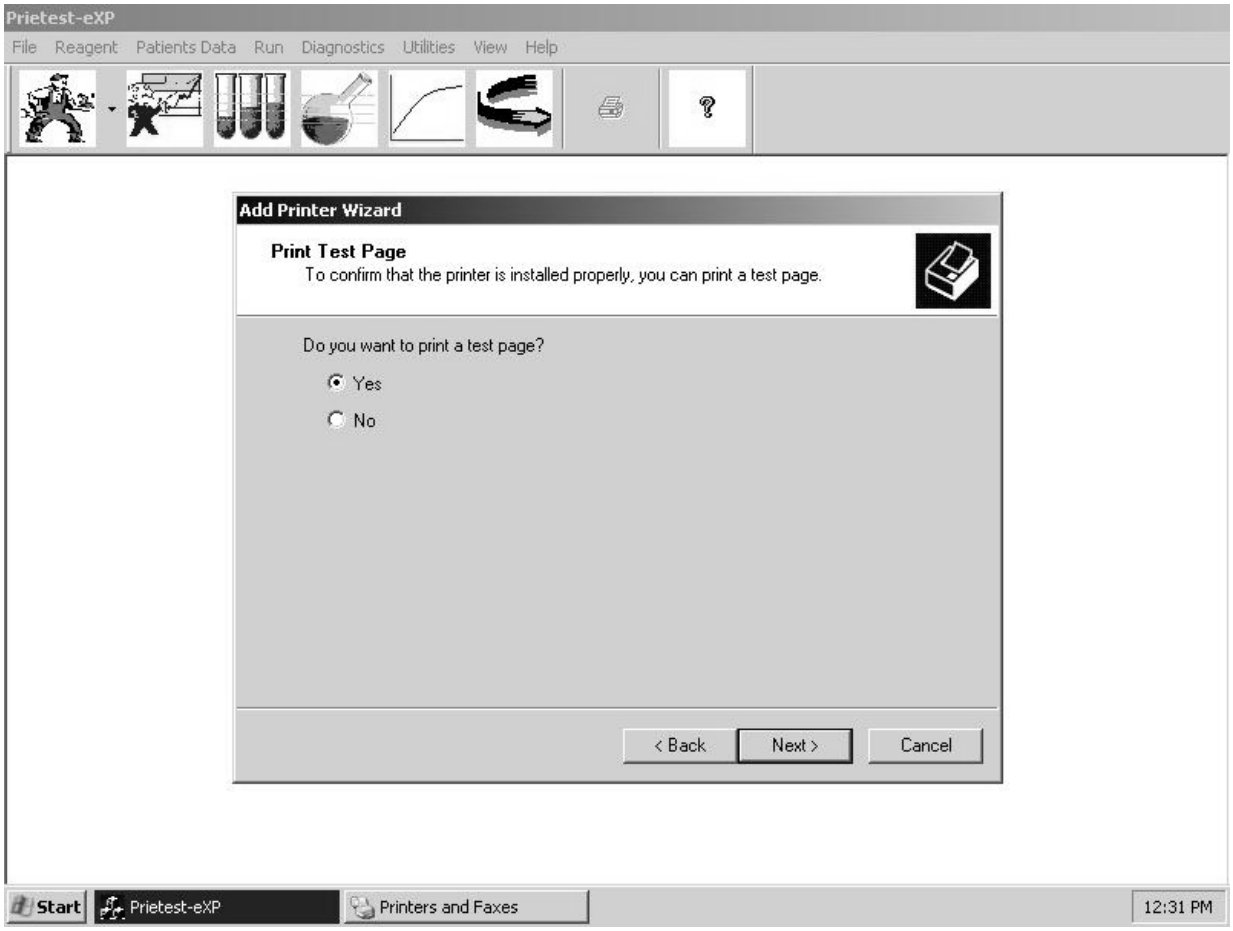
- Select "Yes" to select the installed printer as default printer or Select "No" to not to select installed external printer as default printer.
- Click on "Next" command button to proceed further or click "Back" to see previous window.

Then instrument will show the following screen for the printer sharing.



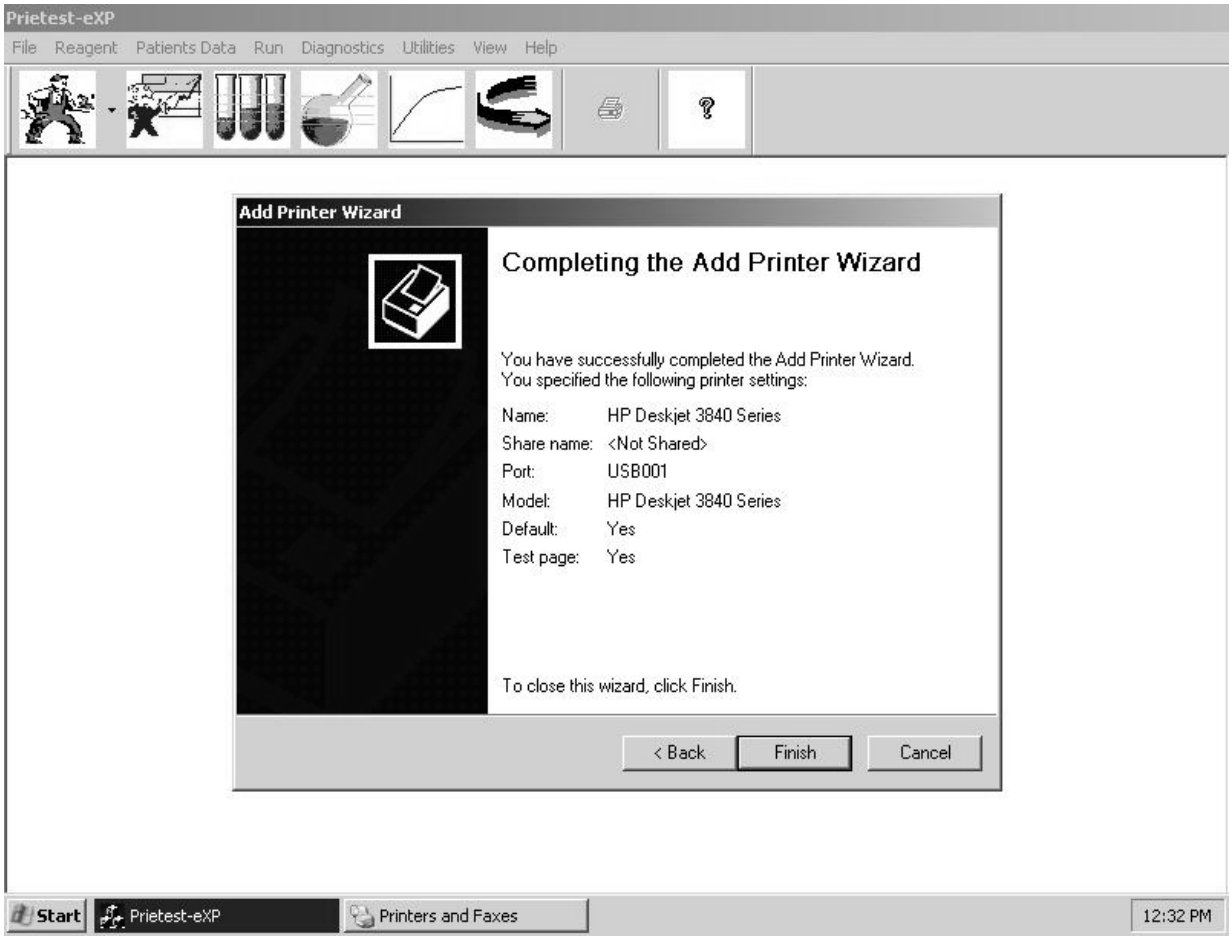
- Click on "Do not share this printer" and then click on Next Command button or click "Back" to see previous window.

Then instrument will show following screen regarding the “Print Test Page” window.



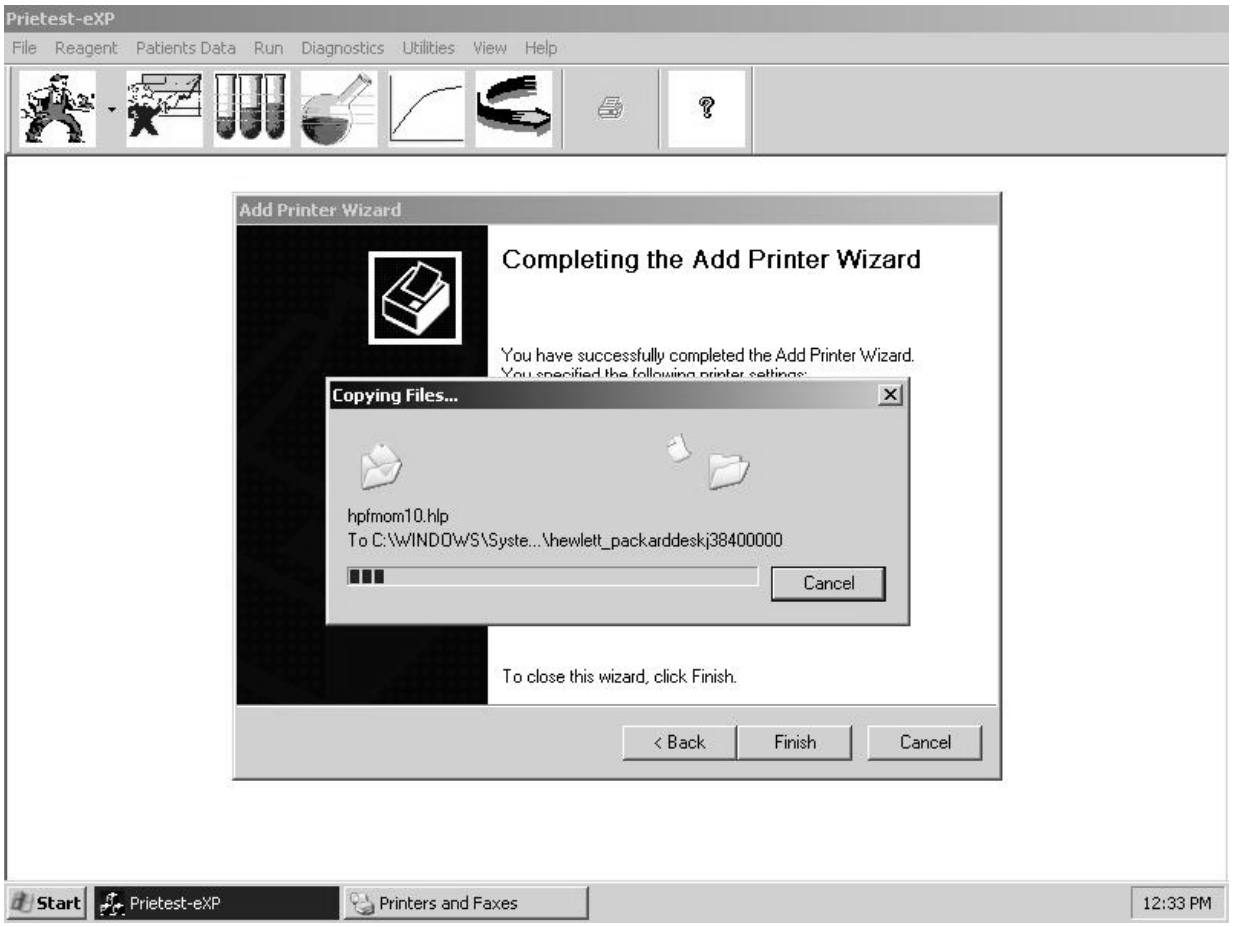
- Click “Yes” to print the test page.
- Click “No” to deny the printing of test page.
- Then click on “Next” command button to proceed further or click “Back” to see previous window.

Then instrument will show following screen regarding “Completing add printer wizard”.

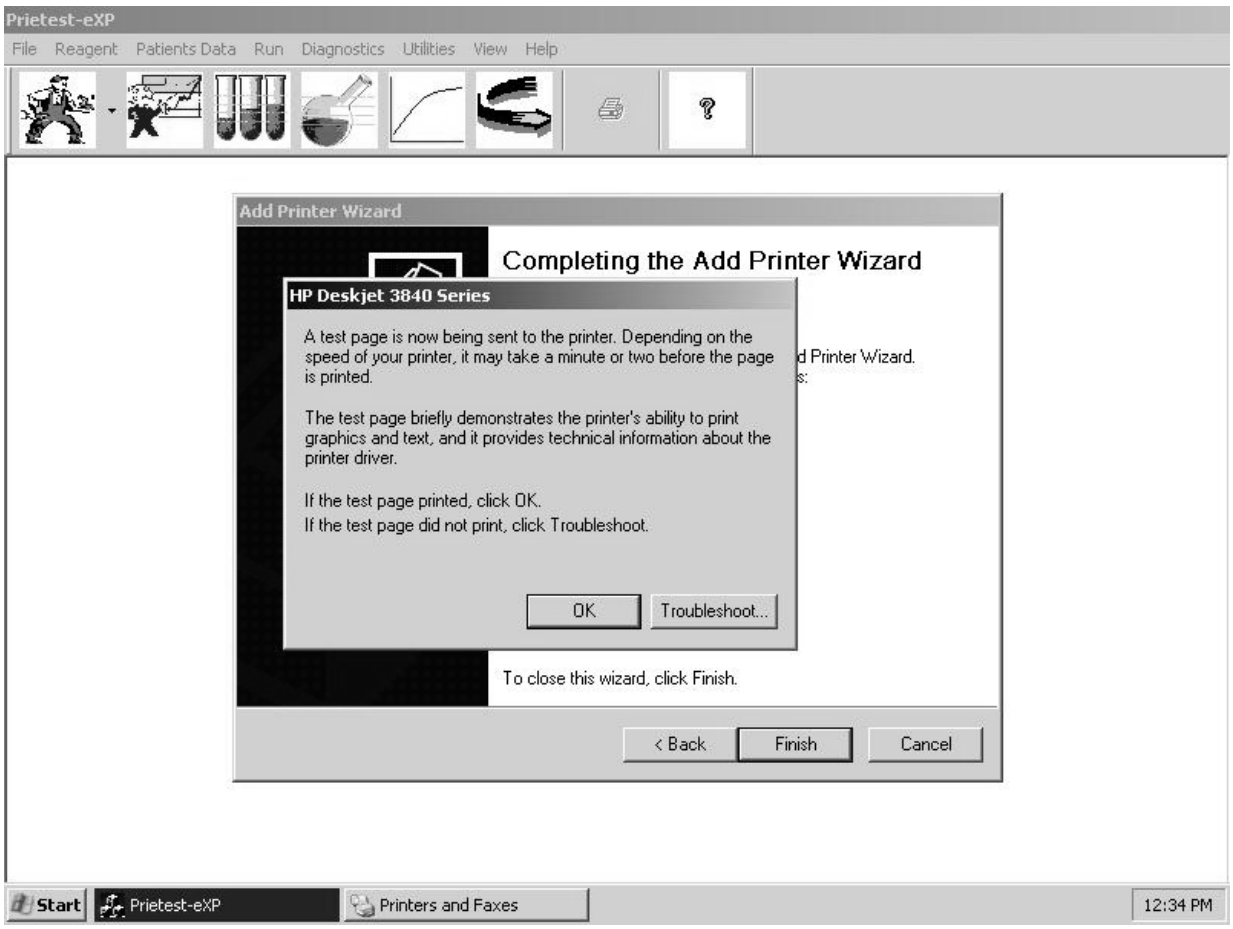


- Click on “Finish” to complete the add printer operation.
- Click “Back” to see previous window.

After clicking on “Finish” command button, driver installation will start and files will get copied from PEN Drive to instrument.
As shown below.



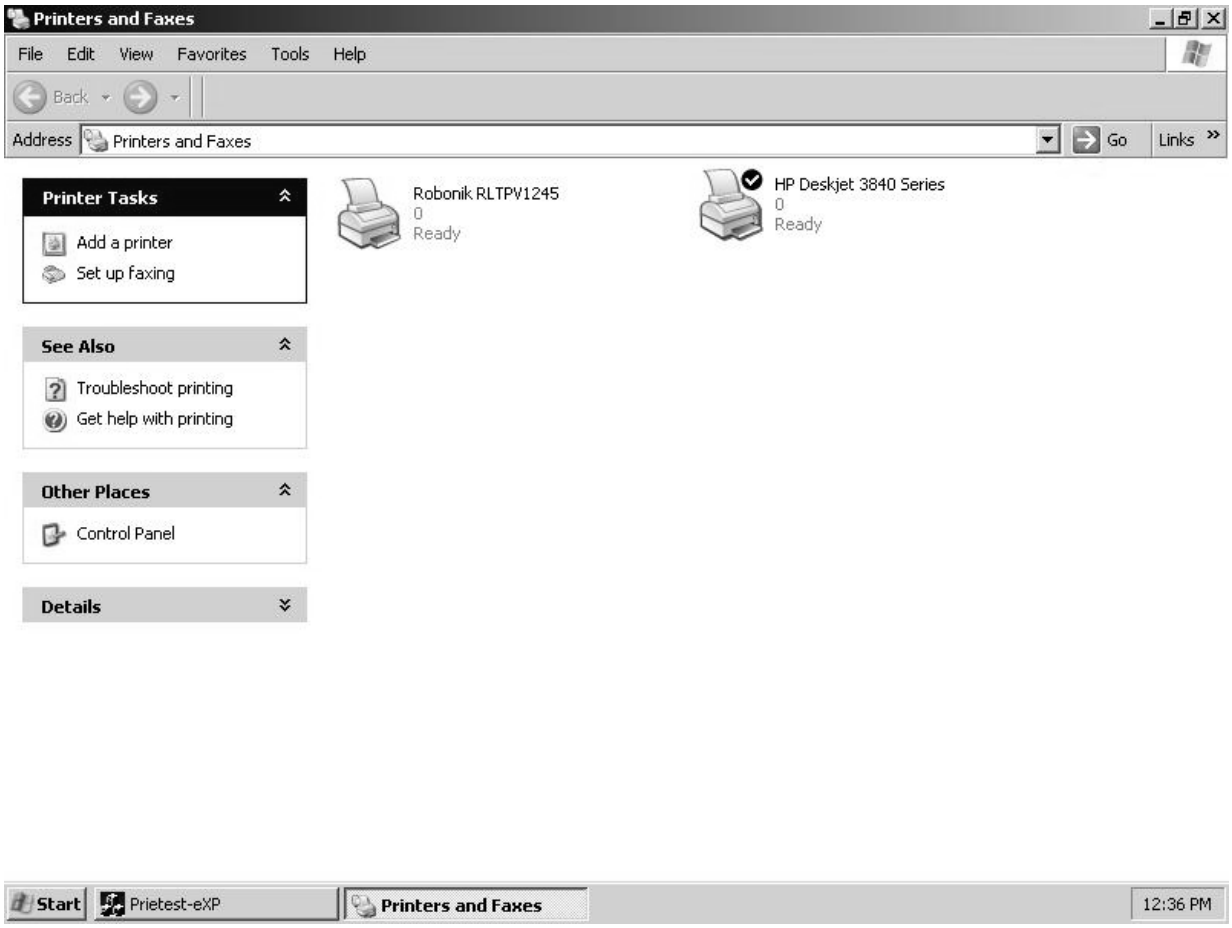
After complete file transfer is done following screen will appear.



- Click “OK” if the test print is printed.
- Click “Troubleshoot” if test page did not print.

After clicking on OK printer will print the test page indicating that printer installation is carried out successfully.

After printing the test page the screen will show the installed printer as shown below.



11. UPDATION OF SOFTWARE .

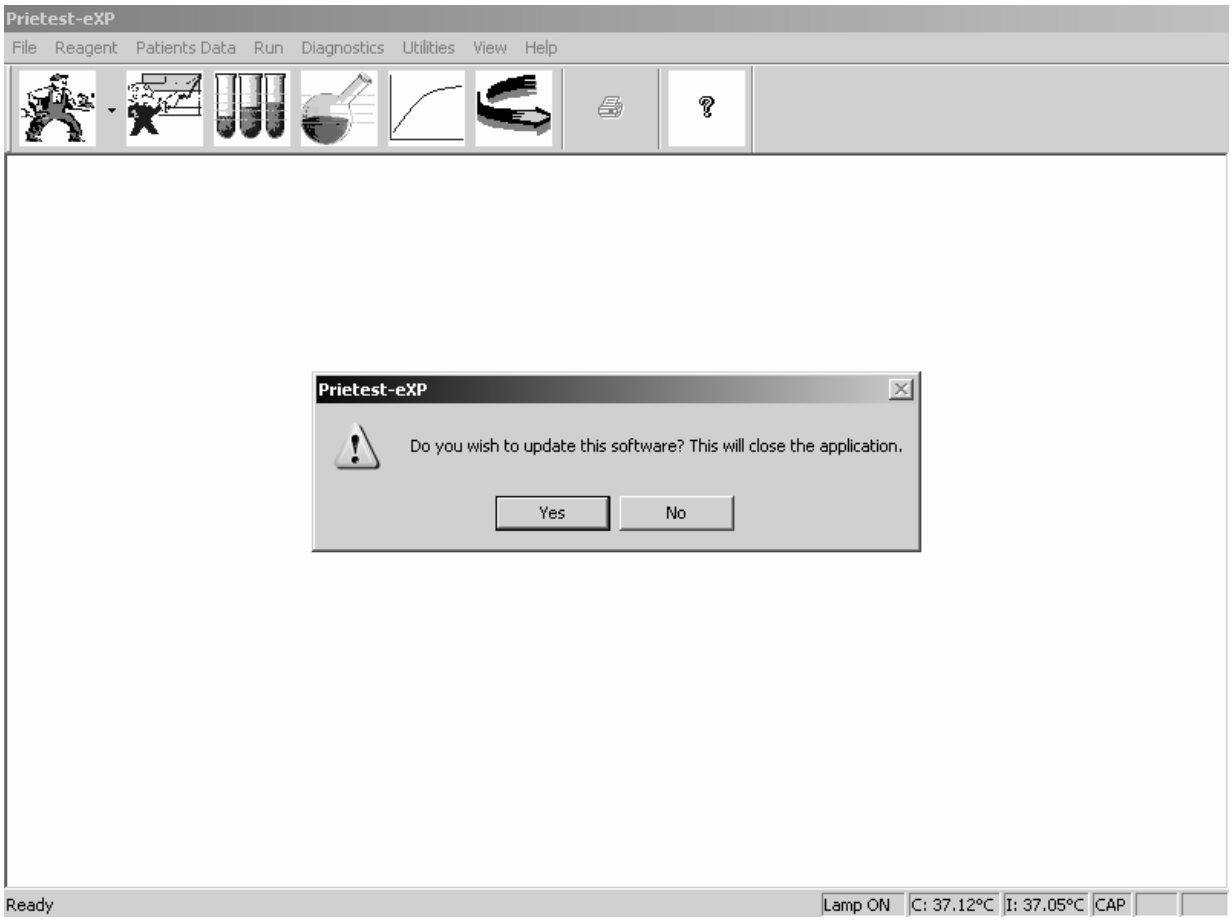
11.1. Procedure for Updating Application software :

Note : Before starting updation of software ensure

- *PEN drive is having application software with which one wants to Update the instrument.*
- *PEN drive is inserted in the USB drive of the instrument.*

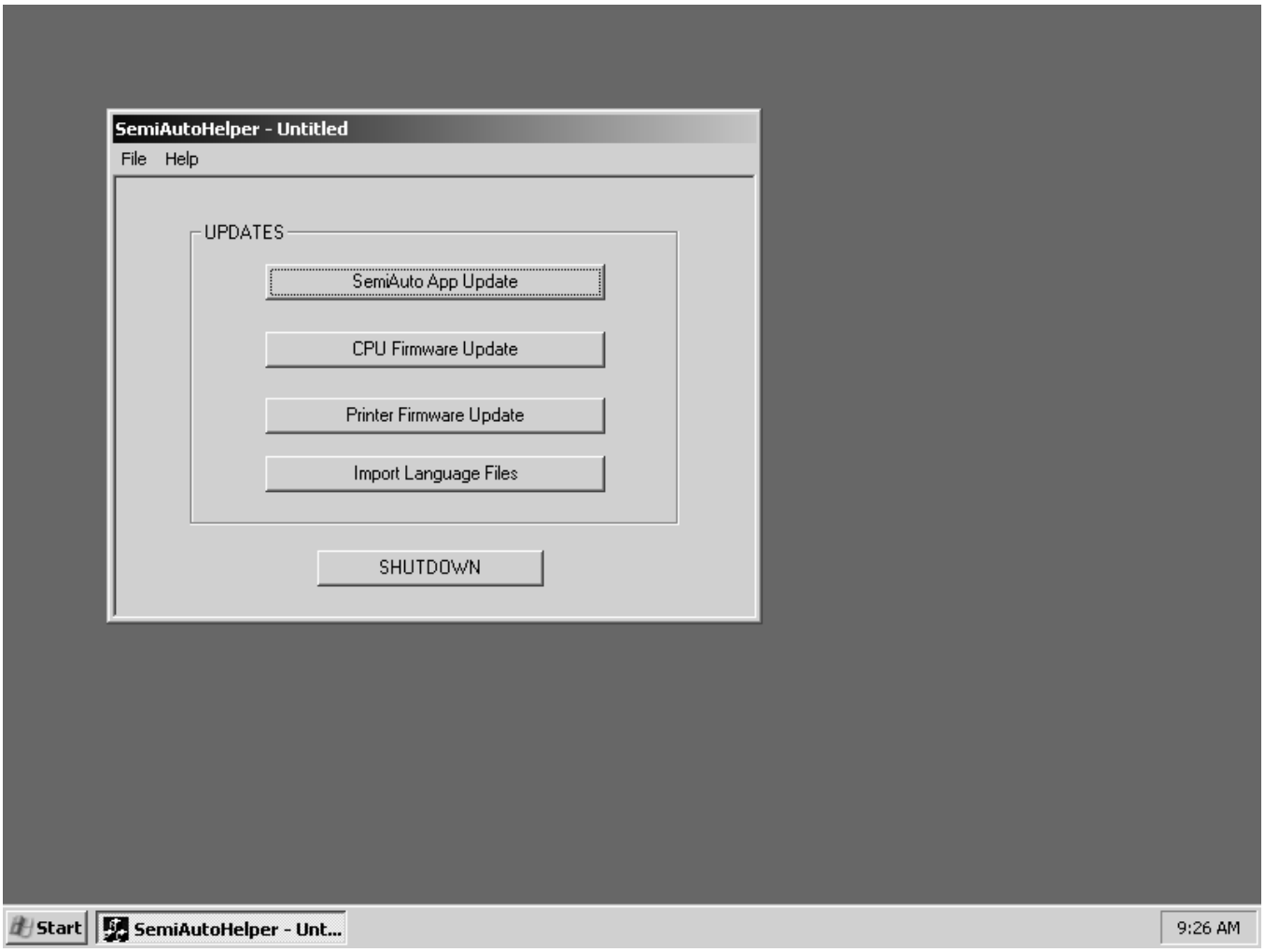
Carryout the following steps to update the software.

- Click on 'Utilities' menu from menu bar.
- Select 'Update' option. After selecting 'Update' option following screen will be displayed :

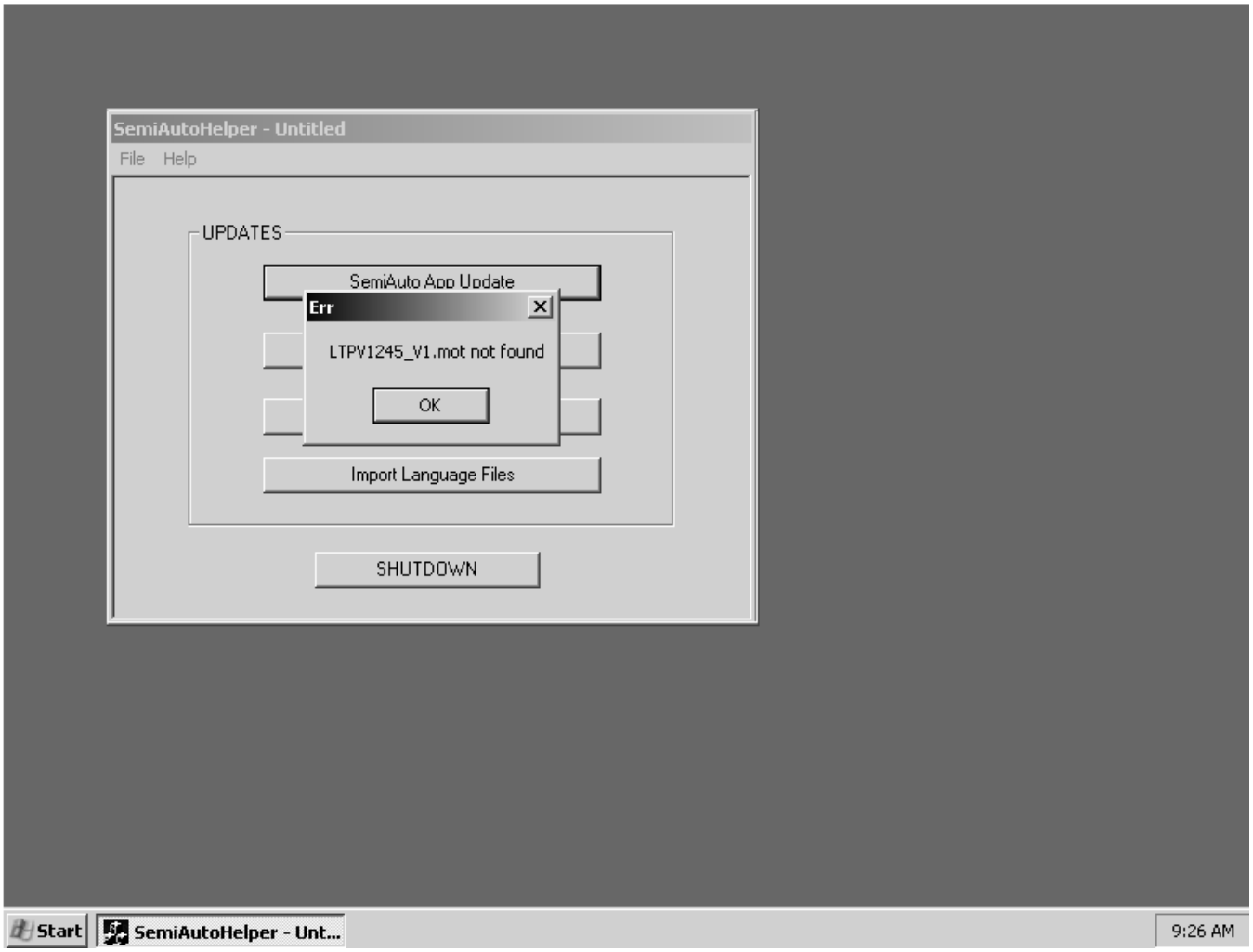


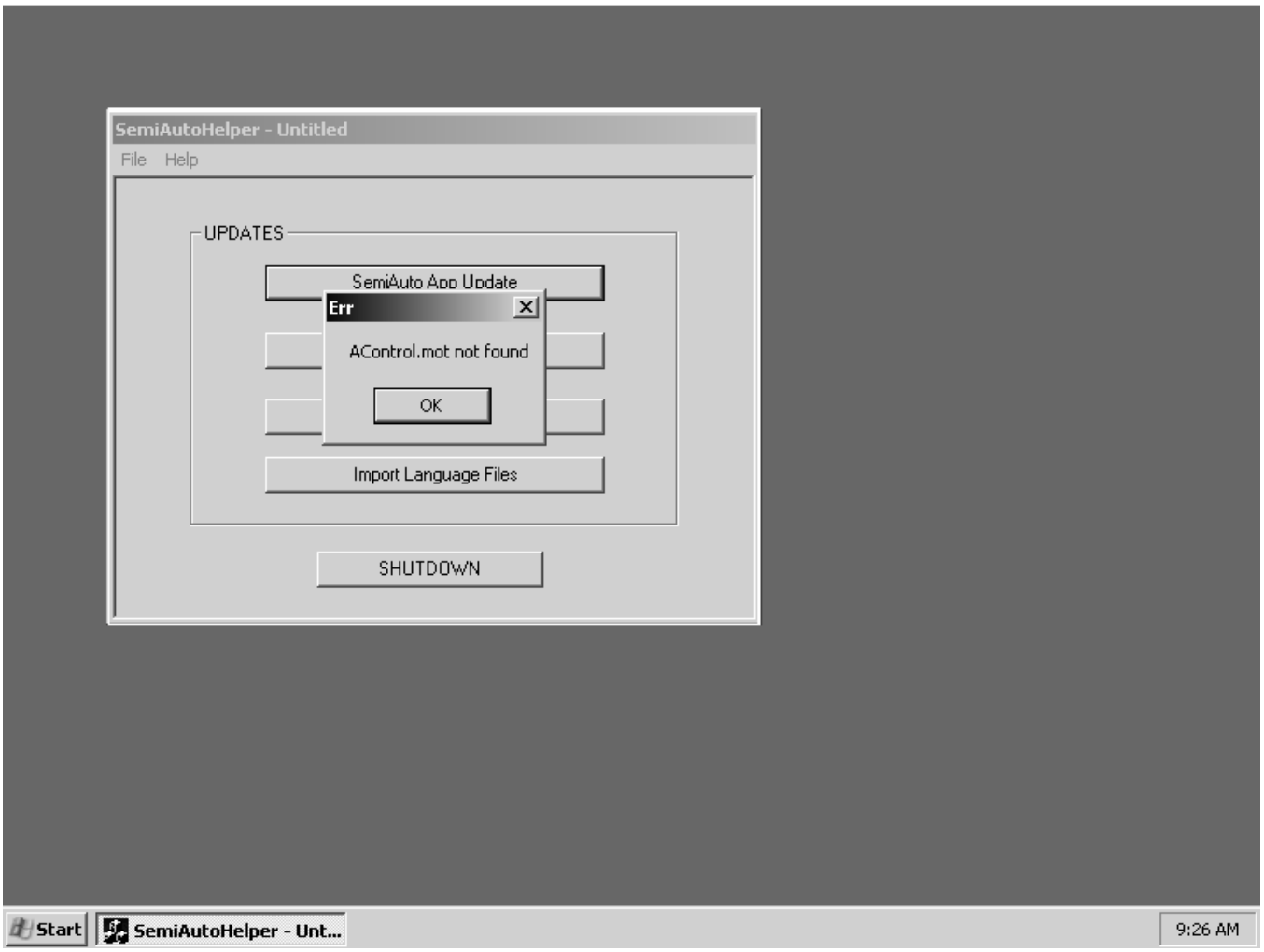
- Click on 'YES' button on the window.

- After clicking on YES button; application will get closed & following screen will pop-up on.

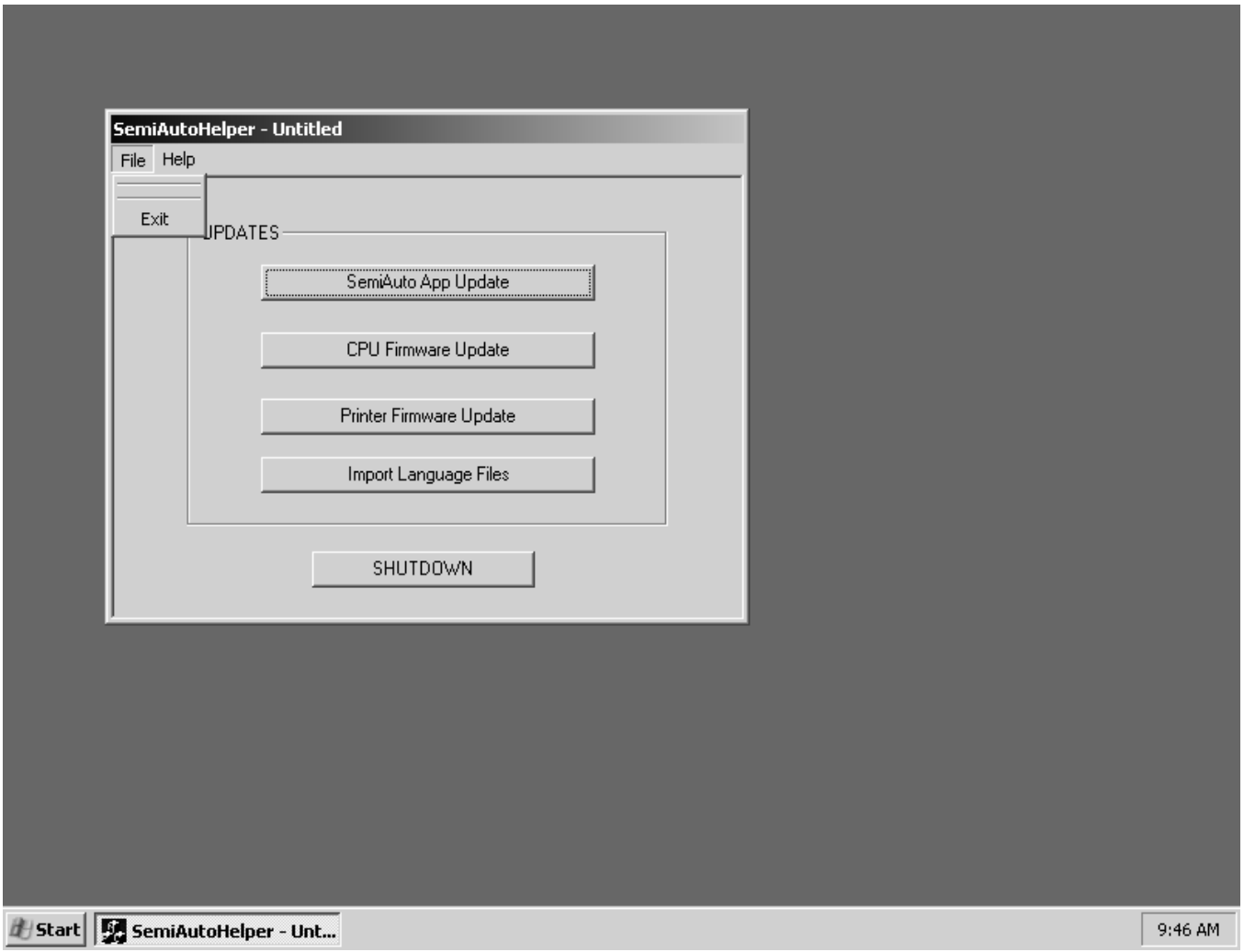


- Now click on ‘SemiAuto App Update’ button. Since we are not updating mot files for Printer & CPU, following message windows will be displayed. Please click on OK For both messages. After that Application gets updated.




SemiAutoHelper - Untitled
File Help
UPDATES
SemiAuto App Update
Err
AControl.mot not found
OK
Import Language Files
SHUTDOWN
Start
SemiAutoHelper - Unt...
9:26 AM

After clicking OK on both the messages instrument will display following screen.



- Click on 'Exit'.

After clicking on Start instrument will give option start menu from where one can start the application.

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

_____

_____