

# Operator Manual

## For

### Automated Clinical Chemistry Analyzer

#### Model: EM 200

**IMPORTANT!**  
Read and understand this manual before operating  
the equipment. Keep this manual in an easily  
accessible place.

**Document Version: 2011.01**

**IMPORTANT!**

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- 3. The contents of this manual are correct to the best of our knowledge. Please inform us of any ambiguous or erroneous descriptions, missing information, etc.**

## Foreword

The Analyzer is a fully automated, discrete, random access, Computerized Clinical Chemistry Analyzer. It is intended in Vitro diagnosis of wide range of Analytes in various body fluids.

This operator's manual is an instructional aid to perform various operations and general maintenance of the analyzer. It contains detailed description of the analyzer features and specifications. The analyzer is used with operational PC and Printer, and can interact with the host computer. The operational PC consists of the application software for the user to operate the analyzer.

All the samples and reagents for measurements including samples obtained from patients are controlled by barcodes enabling the analyzer to perform the entire process of the analysis automatically. Use of the analyzer with proper knowledge will ensure quality test results and trouble free analyzer operation and performance.

This operator manual is prepared based on the assumption that the user has knowledge of clinical examination. The user:

1. has read the Operator Manual.
2. is trained by authorized personnel.
3. is familiar with the operation of the analyzer.

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## Document Conventions

Before reading the manual, please get familiarized with the following icons used in this manual.

Icons	Warning About
	Bio-hazard
	Electric Shock
	High Temperature
	Injury
	Warnings and Caution
	Notes, Usage, Tips, and Additional information

# 1. Safety Information

The user is requested to read the safety information in the manual before installing the analyzer.

## 1.1. Safety Instructions

	During operation, do not touch auto sampler unit, reagent container unit, nozzles and any other moving mechanical parts in the analyzer. During operation, shut cover all the time.
	Never touch patients' samples with bare hands to prevent operator from possible infection. Handle Sample and Reagent (SRPT) arm probe, reaction cells, wash nozzles, waste nozzles and Stirrer paddle in the same way. Wear medical rubber gloves to keep skin from direct contact with patients' samples.
	Give special consideration to keep skin and mucous membrane from contact with reagents to prevent operator from possible infection. Wear medical rubber gloves, goggles, etc. to keep skin and mucous membrane from contact with reagents.
	The contact with the wastes such as used reaction cells and solutions may cause infection. Handle them with gloved hands without exception. Follow the national or local laws and rules when they are thrown out. There are two kinds of liquid wastes drained from this analyzer, i.e. high- and low-concentrated wastes.
	The access to the conductive parts within the analyzer may cause serious electric shock. When removing parts, make sure to shut off the power supply. Leave any maintenance and repair of electrical parts inside the equipment to qualified service personnel.
	Never leave reagent bottles on the working table (upper surface inside the analyzer). Careless handling of reagent bottles may cause tumble and leak. Read the statements of virtues that came with reagents prior to their use. Do not make a modification to the analyzer.
	Exchange the halogen lamp for a new one after a lapse of 30 minutes since the power switch of the analyzer is turned off to avoid danger of burns.

## 1.2. Warning Labels

The following warning labels are affixed on the analyzer on different places that are potentially hazardous.

LABELS	PLACES
	On the 4-piece Top Cover Plates
	On the 4-piece Top Cover Plates
	On the Bio-hazardous waste can (10 Lt.)
	On Waste Can (20 liter)
	On Cleaning Solution Can (10 liter)
	On DI Water Can (20 liter)

## 2. Introduction to Analyzer

### 2.1. Introduction

The analyzer, designed with the needs of modern clinical laboratories in mind, easily fits into any laboratory environment. It is a fully automated, random access, time optimized, and patient sequential discrete computerized chemistry analyzer. Once programmed, it is a walk-away system.

The analyzer features user-friendly operation with minimum operator intervention. It is a highly sophisticated system and therefore it is of utmost importance that the operator and service personnel read the instructions and becomes familiar with the operation theory.

The analyzer comprises of a state of the art Photometer and sophisticated robotics combined with an Operating Console and Data Processing Unit (DPU).

The DPU in the analyzer provides a schedule to the analyzer in the programmed sequence. Analyzer executes the schedules and sends the photometric results to the connected computer where they are processed, stored and then reported.

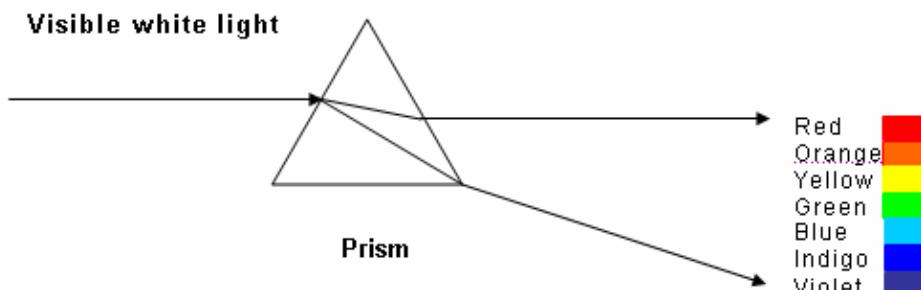
The robotics consists of Sample and Reagent arm (SRPT), Stirrer unit, Cuvette Rinsing Unit, Sample tray, Reagent tray and Reaction tray.

Barcode identification system is provided for both, reagents and samples.

#### 2.1.1. Operating Principle

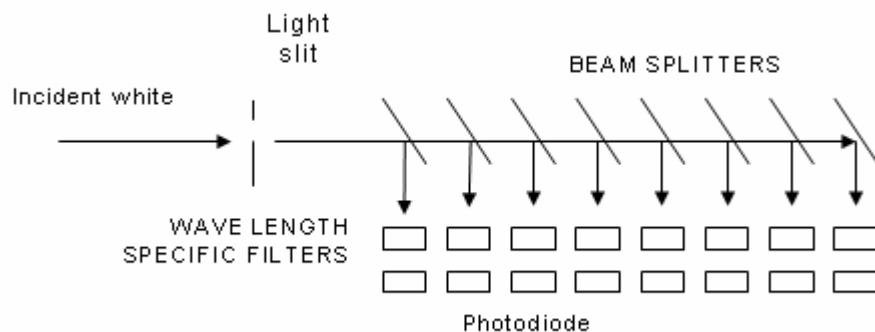
The analyzer is an automated clinical biochemistry analyzer based on the principle of photometry, it measures light transmittance at various wavelengths

White light as we see it, is actually composed of several colors. This becomes evident, when we pass a beam of white light through a prism. If the light emerging from the prism on the opposite side were allowed to fall on a screen, we would see a wide spectrum of colors, beginning with red on the top and ending with violet at the bottom. The colors visible in between are in the order of indigo, blue, green, yellow and orange.



Incident or white light contains the entire spectrum, objects that appear colored, absorb light at a particular wavelength and reflect others, thus giving different colors. That color is a function of its wavelength.

Light having a wavelength of less than 400 nm is termed Ultraviolet, whereas light having a wavelength greater than 800 nm is described as Infrared, both ultraviolet and infrared lights are invisible to the human eyes. Light corresponding to wavelengths between 400 nm and 800 nm is visible to the human eye and is termed as Visible light.



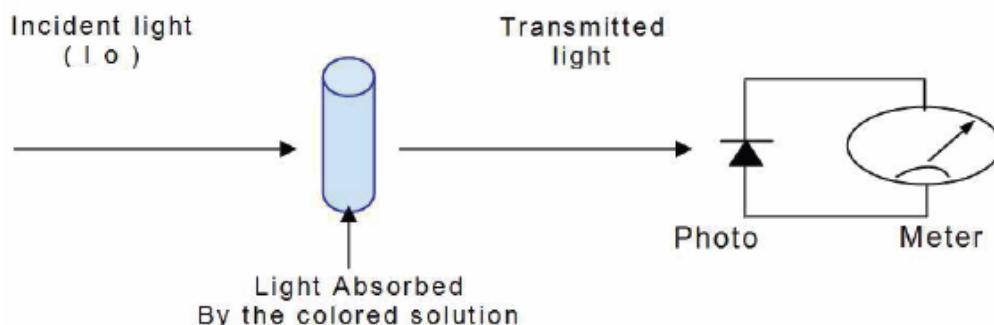
## 2.1.2. Principles of Absorption Photometry

### Beer's Law

If light is allowed to pass through a colored solution, the solution will absorb some light while the rest of it will be transmitted. The amount of light absorbed is proportional to the nature, concentration and color of the solution.

### Lambert's Law

The light absorbed by the colored solution is directly proportional to the light path of the color solution (diameter of the cuvette): that is if the cuvette diameter is doubled, the light absorbed will be doubled.



Since the total incident light = light absorbed + light transmitted, it follows that:

$$\text{Absorbed light} \propto \frac{1}{\text{Transmitted light}}$$

Therefore as the absorbed light (Absorbance) increases, the transmitted light will decrease.

As we increase the concentration of the colored solution, the light absorbed increases, and we find that the transmittance varies inversely and logarithmically with concentration.

$$\text{Absorbance (Absorbed light)} = \log \left[ \frac{1}{\text{Transmittance}} \right]$$

$$\text{Absorbance (Absorbed light)} = \log \left[ \frac{100}{100} * \frac{1}{\text{Transmittance}} \right]$$

$$\text{Absorbance (Absorbed light)} = \log \left[ \frac{100}{\% \text{ Transmittance}} \right]$$

$$\text{Absorbance (Absorbed light)} = \log 100 - \log \% \text{ Transmittance}$$

$\text{Absorbance (Absorbed light)} = 2 - \log_{10} \% \text{ Transmittance}$
---

Using the above formula, the following absorbance are obtained for different percentage of transmittance.

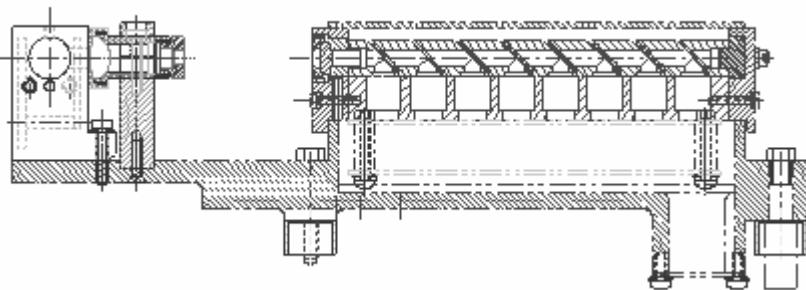
Percentage Transmittance	Absorbance
100	0.000
50	0.301
25	0.602
12.5	0.903

The study of the correlation between the concentration of a colored liquid the intensity of its color and the amount of light absorbed by the colored solution is termed as Colorimetry.

#### Useful Information:

Percent	Absorbance	Absolute Error	Per Cent Relative Error
10	1.000		
11	0.959	0.041	4.1
45	0.347		
46	0.337	0.001	2.9
90	0.046		
91	0.041	0.005	10.9
95	0.022		
96	0.018	0.004	8.2

The relative error is minimal at an absorbance of 0.434 (36.8 %T). Consequently, methods should be designed such that readings fall near the center of the scale, preferably within an absorbance of approximately 0.1 and 0.7 (20 and 80%T).



**Photometer System**

### 2.1.3. Sequence of Operation

The instrument works on the principle of light photometry combined with the best mechanics for sampling. The sample under test is sampled into the cuvette, which is then read at defined time intervals to find out optical densities.

The reaction is read at defined time interval of 18 seconds to obtain their optical densities.

The entire operation can be divided into the following sequence:

1. Getting ready for operation
2. Cuvette rinsing (cleaning)
3. Reagent 1 + Sample addition
4. Stirrer Mixing for R1 + Sample mixture
5. Reading and then reporting
6. Reagent 2 Addition (optional)
7. Stirrer Mixing after R2 addition (optional)
8. Reading and then reporting
9. Removal/emptying of biohazard reaction waste from the cuvette.

## 2.1.4. Measurement Operation Table

The analyzer records absorbance for a cuvette every 18 seconds over a span of 10 minutes 48 seconds. These readings are used for result calculation. The measurement points are referred to as M1Start, M1End, M2Start and M2End. Refer section 7.2.1 *Test Details*, point number **Assay Points**.

Time (Minutes)	Cycle Number	Analyzer Action
0.00	0	Dry the cuvette, Add Reagent 1 + Sample
0.18	1	Stir 1 + Measure reaction mixture absorbance
0.36	2	Measure reaction absorbance
0.54	3	Measure reaction absorbance
1.12	4	Measure reaction absorbance
1.30	5	Measure reaction absorbance
1.48	6	Measure reaction absorbance
2.06	7	Measure reaction absorbance
2.24	8	Measure reaction absorbance
2.42	9	Measure reaction absorbance
3.00	10	Measure reaction absorbance
3.18	11	Measure reaction absorbance
3.36	12	Measure reaction absorbance
3.54	13	Measure reaction absorbance
4.12	14	Measure reaction absorbance
4.30	15	Measure reaction absorbance
4.48	16	Measure reaction absorbance
5.06	17	Add Reagent 2 + Stir 2 + Measure reaction absorbance
5.24	18	Measure reaction absorbance
5.42	19	Measure reaction absorbance
6.00	20	Measure reaction absorbance
6.18	21	Measure reaction absorbance
6.36	22	Measure reaction absorbance
6.54	23	Measure reaction absorbance
7.12	24	Measure reaction absorbance
7.30	25	Measure reaction absorbance
7.48	26	Measure reaction absorbance
8.06	27	Measure reaction absorbance
8.24	28	Measure reaction absorbance
8.42	29	Measure reaction absorbance
9.00	30	Measure reaction absorbance
9.18	31	Measure reaction absorbance
9.36	32	Measure reaction absorbance
9.54	33	Measure reaction absorbance
10.12	34	Measure reaction absorbance

10.30	35	Measure reaction absorbance
<b>10.48</b>	<b>36</b>	<b>Measure reaction absorbance + Final result reporting</b>
11.06	37	Empty cuvette contents + Add detergent
11.24	38	Empty cuvette contents + Add DI Water
11.42	39	Empty cuvette contents + Add DI Water
12.00	40	Empty cuvette contents + Add DI Water
12.18	41	Empty cuvette contents + Add DI Water
12.36	42	Empty cuvette contents + Add DI Water
12.54	43	Measure cuvette blank absorbance
13.12	44	Empty cuvette contents
13.30	45	Drying the cuvette

## 2.2. Technical Specification

### 2.2.1. General Specifications

Item	Description
Throughput	200 tests per hour for a cycle time of 18 seconds (400 tests per hour with ISE).
System type	Discrete, open, automated, random access, patient prioritized, 1/2 Reagent system.
Sample	Serum, Urine, CSF, Plasma, Whole Blood, Others.
Measurement principle	Turbidimetric Immunoassay, Colorimetry (Rate/End Point), Ion Selective Electrodes (optional).
Applicable analytes	<b>Photometric assays:</b> Enzyme, lipid, protein, sugar, nitrides, inorganic substances, complements and others. <b>Turbidimetric assays:</b> IgG, IgA, IgM, C3, C4, RF, CRP, ASO, Transferrin and others. <b>ISE Potentiometric Assays:</b> Na, K, Cl, Li
Test method	Absolute measurement, Relative measurement, ISE (optional).
On board Reagent Positions	50 test items maximum, 54 test items with ISE.
Programmable parameters	Any number of photometric tests Any number of calculation items
Assay modes	1-Point, 2-Point, Rate-A, and Rate-B.
Sample volume	2-70 µl (adjustable in 0.1 µl step).
Reaction volume	180 µl to 550 µl.
Reaction temperature	37 °C. Temperature stability: ± 0.2 °C.
Reaction time	Depends on the designated cycle time and number of reagents used For 1 step assay (using R1) <ul style="list-style-type: none"> <li>▪ 648 seconds (10 minutes 48 seconds) for a cycle time of 18 seconds</li> </ul>

	For 2 step assay (using R1 and R2) <ul style="list-style-type: none"> <li>▪ 1st reaction 306 seconds (5 minutes 6 seconds) + 2nd reaction 324 seconds (5 minutes 24 seconds) for a cycle time of 18 seconds</li> </ul>
Test selection	Setting of tests one by one or with profile key for each sample. Group order entry is possible. Setting from host computer via interface (optional).
Maintenance	<b>Programmable maintenance actions:</b> Cuvette Rinse, Water Save, Auto Wash, Probe Wash, Prime Wash, ISE maintenance and Calibration
Barcode identification	Sample barcode formats - NW7, Code 39, Code 128, ITF, 2 of 5 standard, UPC A. Reagent barcode ID (ITF). During batch run, barcode scan for reagent is performed.
Water supply unit	Water consumption: Less than or equal to 7.5 liters/hour. Manufactures and supplies: Type 2 quality (by NCCLS standards) ion exchange water (optional).
System Warm-up Time	5 minutes system warm-up time.
Safety mechanism	Vertical obstruction detection, Capacitance based liquid level sensing.
Noise level	Less than 65 dB with cover closed.

## 2.2.2. Installation Conditions

Item	Description
Power source/consumption	AC 220 V ± 10%, 50 ± 1 Hz or AC 110 V ± 10%, 60 ± 1 Hz. Power consumption: 600 VA (excluding PC/Printer/Monitor).
Fuses	5A for 220V and 10A for 110V input supplies
Drainage	Used sample (concentrated waste solution) and washed sample (diluted waste) are to be drained separately.
Ambient temperature	15 – 30 °C. Variation during operation: Less than ± 2 °C per hour.
Relative humidity	40 – 80% free from water dew formation.
Dimensions	810 mm (W) * 700 mm (D) * 600mm (H).
Weight	Approximately 120 kg.

## 2.2.3. Sampling Unit

Item	Description
Sample container	Blood collection tube 10 ml (16 x 100 mm), 7 ml (14.5 x 84 mm), 5 ml (13 x 75 mm). Adaptors will be provided for 5 and 7 ml tubes. 2 ml Sample Cup, 500 µl Standard Cup
Sample placement	<ul style="list-style-type: none"> <li>• Sample tray</li> </ul>

	<ul style="list-style-type: none"> <li>▪ Outer Most Track: 15 positions for placing barcode tubes.</li> <li>▪ Middle Track: 15 positions for placing barcode tubes.</li> <li>▪ Innermost Track: 9 positions for placing Sample cup and Standard cup without barcode.</li> </ul>
STAT samples	<p>Place anywhere on the Sample Tray.</p> <p>STAT samples are measured preferentially.</p> <p>Interrupt permitted even during analysis.</p>
Sampling	<p>Pipetting system with plunger, driven by stepper motor.</p> <p>Sample volume: 2-70 µl (adjustable in 0.1 µl step).</p>
Pipetting mode	<p>Discharges set volume of sample into cuvette or the ISE module (optional).</p>
Sampling probe	<p>Micro-pipette with level sensor.</p> <p>Washing solution.</p> <p>Outside: Preheated DI water.</p> <p>Inside: Preheated DI water.</p> <p>Equipped with vertical obstruction detection facility to prevent probe crash.</p>
Sample dilution	<p>Dilution ratio: 2 to 150 times.</p> <p>A cuvette is used as dilution vessel.</p> <p>Set amount of diluent and sample is dispensed into a cuvette by probe.</p> <p>Dilution possible for repeat run.</p> <p>Direct reduced/increased volume runs are also possible.</p>
Repeat run	<p>Execution by repeat run list or auto execution.</p> <p>Auto execution according to abnormal marking and/or range over.</p> <p>Reduced/increased volume repeat run also possible.</p>
Sample identification	<p>Sample bar-code format - NW7, Code 39, Code 128 (A,B,C), ITF, 2 of 5 standard, UPC A and 3-18 digits (depending on the length of the barcode)</p> <p>Position ID for non barcoded samples</p>
Dead Volume	<p>≤ 450 µl for 10ml Sample Tubes.</p> <p>≤ 350 µl for 5ml /7ml Sample Tubes.</p> <p>≤ 100 µl for 2ml Sample Cup.</p> <p>≤ 100 µl for STD Cup.</p>

## 2.2.4. Reagent Unit

Item	Description
Type	Turn table type reagent tray.
Reagent tray	Common reagent tray for reagent 1 and reagent 2.
Reagent cooling temperature	8 ± 4 °C cooled with refrigeration unit.
Reagent bottles	25 positions for placing 50 ml bottles 25 positions for placing 20 ml bottles
Reagent dispensing	<p>Pipetting system with plunger, driven by stepping motor.</p> <ul style="list-style-type: none"> <li>▪ R1 dispensing in the 1st cycle</li> </ul>

	<ul style="list-style-type: none"> <li>▪ R2 dispensing in the 17th cycle</li> </ul>
Reagent volume	Reagent 1: 50 – 300 µl (adjustable in 1 µl step). Reagent 2: 0 or 10 – 200 µl (adjustable in 1 µl step).
Dead volume	≤ 2.0 ml for 50 ml Bottles. ≤ 1.5 ml for 20 ml Bottles. ≤ 0.5 ml for 5ml Tube Adapters.
Reagent identification	Sample bar-code format - ITF. Reagent bar-code ID (18 digit barcode readability).
Residual volume information	Calculated by countdown system as well as measured by capacitance type level sensor and displayed on screen.
Reagent positions	Total 50 positions for accommodating reagent 1 and reagent 2.
Reagent protection	Reagent cover to protect from evaporation, dust, and direct light.
Carry over actions	Provision for extra Reagent Wash, Detergent Wash, System Wash and Cuvette Skipping given for Carry-Over Pairs.

## 2.2.5. Reaction Unit

Item	Description
Type	Turn table.
Reaction tray	Rotating tray. Number of reaction cuvettes: 45. Temperature control: Turn table direct heating by foil heaters.
Reaction temperature	37 ± 0.2 °C
Cuvettes	Reusable. Number of reaction cuvettes: 45. Dimensions: 5 x 4.9 mm. Optical path length: 5 mm (factor to be fed for 10 mm). Material: Hard glass made of Quartz. Volume: 700 µl. Reaction liquid volume: 550 µl maximum, 180 µl minimum.
Reaction liquid mixing	Type: Immersion mixing by rotating mixers. Single mixer (3 variable mixing speeds). Mixing steps. <ul style="list-style-type: none"> <li>▪ The 1<sup>st</sup> step: Right after Reagent 1 and sample dispensing into the respective cuvette</li> <li>▪ The 2<sup>nd</sup> step: After Reagent 2 dispensing in the cuvette containing Reagent 1 + sample</li> </ul>
Cuvette washing	Type: By the automatic washing system. The reaction waste is aspirated out, then cuvette is washed by washing solution and repeatedly by DI water, finally residual liquid is removed. Number of washing operation steps: 7 steps. <ul style="list-style-type: none"> <li>▪ Reaction waste removal: 1 step</li> <li>▪ Washing: 5 steps</li> <li>▪ Residual liquid removal: 2 steps</li> </ul> Number of washing solution application.

	<ul style="list-style-type: none"> <li>▪ Detergent solution: 1</li> <li>▪ Ion exchange water: 5</li> </ul> <p>Washing solution container.</p> <ul style="list-style-type: none"> <li>▪ Detergent: 10 liters Capacity</li> </ul> <p>Reaction waste is collected into two waste cans (concentrated waste and diluted waste) by pumps.</p> <p>In built cuvette overflow protection.</p>
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## 2.2.6. Optical Absorption Measurement Unit

Item	Description
Type	Multiple Wavelengths, Static Filter.
Photometric system	Multi-wavelength direct measurement of light after penetration into reaction cuvette (transmitted light).
Wavelength	8 Wavelengths: 340 nm, 405 nm, 505 nm, 546 nm, 578 nm, 600nm, 660 nm and 700 nm.
Wavelength per chemistry	One or two wavelength.
Measurement interval	Total 36 points. Every 18 seconds for 18 second cycle time.
OD range	OD 0 – 2.5. Light path calculated as 10 mm.
Resolution	0.0001 OD
Light source	Pre-aligned Halogen lamp (12V/20W).
Detector	Silicon photo-diodes.
Cell blank correction	Corrected by water blank measured after cuvette washing.
Minimum reaction liquid volume	180 µl.

## 2.2.7. Data Processing Unit

Item	Description
Calibration curve	K-Factor, Linear (one point, multipoint, and point-to-point), Cubic Spline, Exponential, 4P Calibration Logit-log, 5P Calibration Logit-log, Polynomial.  Multipoint curves up to 10 points.  One point correction (using Blank) to multi-point calibration line is provided.  Auto-dilution for non linear curves.
Quality control	Within day as well as day-to-day X and X-R control diagram.  Mean, SD, %CV, R are calculated for the each chemistry.  QC graph based on west gard QC rules
Repeat run	Execution by repeat run list or auto execution.  Auto execution according to abnormal marking or range over.  Increased/decreased volume repeat run also possible.
Monitor function	Reaction curve, Calibration curve, Status of sample operation and Reagent level in bottles can be viewed graphically.

Calculation between items	Correlation correction factor ( $Y = aX + b$ ). Calculation by the formula defined by user. <ul style="list-style-type: none"> <li>▪ No Limit for Programming Calculation Items.</li> <li>▪ Each calculation item can include up to 5 chemistries.</li> </ul> Recalculation of results possible. Test profile can be defined.
Report/list format	Report generation: Patient wise, Test wise, Date wise, Location wise, Abnormal result wise, Doctor name wise, Batch wise. Lists: Abnormal values list, Pending run list, Repeat run list.
Backup	Partial backup of selective data such as Consumables, Patient, Patient with Results, Test Parameters, Calibration, Error Log, System parameters Is possible in the Text, XML, XLS and CSV formats. Full Backup.
Special treatment	Reagent blank correction.
Data check	Reference range check by age, gender, sample type. Panic limit check. Reagent absorption check. Technical limits check. Reaction linearity check. Reaction mixture absorbance checks. Antigen excess/prozone check (by reaction curve analysis method).
Alarms and notices	Types of alarms: Erroneous operation, mechanical malfunction of analyzer, data processor hardware error, erroneous test results. Alarm level: Notice, temporary halt of analysis, suspension of analysis, system stop. Prompts on display alarms.
Diagnostic checks	Mechanical movements and functional performance can be checked through diagnostic menu.
Password	Different user ID with password to login into the application. Access Control for Menu options can be defined by Administrator.

## 2.2.8. Ion Selective Electrode (ISE) Unit (optional)

Item	Description
Type of measurement	Ion selective electrode. Direct measurement for Serum samples. Urine sample diluted with urine diluent (on board, on Reagent Tray).
Sample types	Serum, Urine (urine diluted 10 times on board for first determination)..
Test items	Na, K, Cl, Li
Measurement cycle	Serum: 30 seconds/sample. Urine: 40 seconds/sample.

## 2.2.9. Computer Specifications

A minimum specification for the system is shown in the table below. However, you are recommended to use the most powerful system available to you.

Item	Description
User interface hardware	<p><b>Processor:</b> Pentium IV, 2.8 Ghz or above.</p> <p><b>Operating System:</b> Windows XP Service Pack 2/3 or Windows 7 Professional English Edition (32-bit).</p> <p><b>RAM:</b> 1 GB or above for Windows XP and 2 GB or above for Windows 7.</p> <p><b>Hard Disk:</b> 80 GB or above.</p> <p><b>Monitor:</b> 17 inch / 19 inch Color Monitor supporting 1024 * 768 resolution.</p> <p><b>External Drives:</b> CD-ROM drive.</p> <p><b>Printer:</b> DeskJet, LaserJet.</p>
System interface	Analyzer – PC: USB bi-directional USB connectivity through USB



**NOTE: The specifications are subject to change without prior notice.**

## 2.3. Technical Features of the System

### 2.3.1. Technical Features

- On board Biohazard and regular waste management.
- 1 Teflon coated mixer (stirrers) with 3 different mixing speeds
- 2 Reagent capability.
- 45 position permanent hard glass cuvettes.
- 50 positions on reagent tray. 25 positions for 20 ml Reagent bottles and 25 positions for 50 ml Reagent bottles
- On board reagent cooling
- 30 positions on sample tray to accommodate 5 ml, 7 ml and 10 ml tubes
- 9 positions to accommodate 2 ml cups and Standard cups on sample tray
- Throughput of up to 200 photometric tests per hour for a cycle time of 18 seconds (400 test/hour with ISE)
- Barcode identification for Sample tubes and Reagent Bottles
- Low DI water requirement.
- Bi-directional host computer interface capability

## 2.3.2. Other Features of the Analyzer

- **Sample Tray - Flexibility and Convenience**

The sample tray has positions to accommodate up to 30 samples (1 to 30).

Also, nine positions are for placing Blanks, Standards, Controls, and Calibrators (1 to 19).

Position from 1 to 30 can accommodate tube sizes of 5, 7, 10 ml tubes or 2 ml cups (using adaptor). Positions from 1 to 19 can only accommodate 2 ml cups or 500 $\mu$ l Standard cups.

Tubes can be barcoded or non barcoded. Cups can not be barcoded.

Patient Samples or Emergency Samples, Calibrators, Blank, Controls, and Standards can be placed anywhere on the sample tray.

- **Reagent Tray - Offers a wide choice of on-board bottles**

The reagent tray can accommodate 50 reagent bottles. All reagents are refrigerated to ensure extended stability. The wide choice of on board reagents eliminates the need for sample splitting and cuts down the turnaround time of reporting.

- **Economy - Quick returns without compromise**

The analyzer uses permanent hard glass cuvettes, thereby eliminating recurring costs of disposable cuvettes. Low reagents requirement per test, maximizes the number of tests per sample tray .

- **Barcode Identification System**

The bar-coded reagents and sample identification system provides sample identification faster and accurate, minimizing operator's programming time.

- **Optical System - Ensures reliability of results**

The analyzer uses narrow bandwidth wavelength specific filters to ensure high degree of photometric accuracy. The user can select from 8 available filters, from 340 nm - 700 nm to cover the entire clinical chemistry application range. The long life halogen light source and the wavelength specific photodiode complete the photometric system of the analyzer.

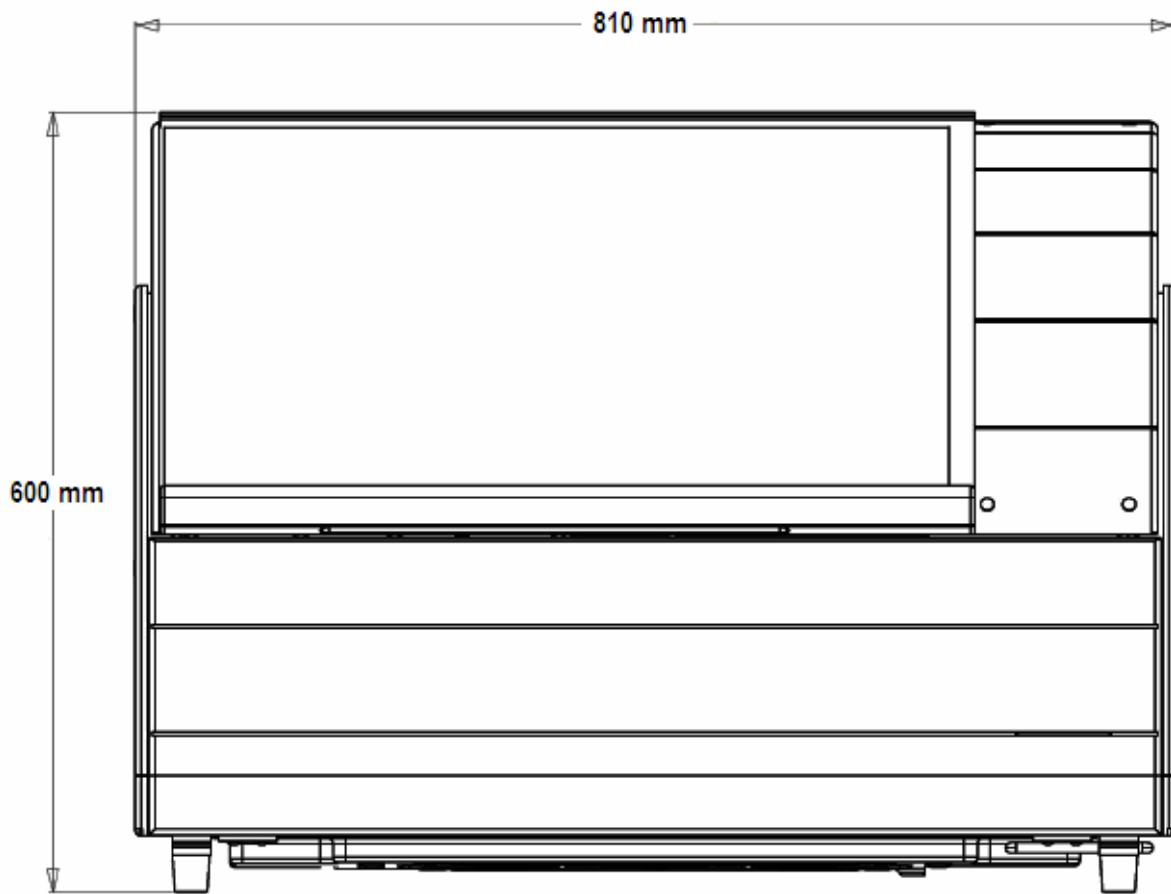
- **The main features of analyzer**

- Unique soft start and stop of all mechanical assemblies, ensures smooth operation and adds reliability.
- Software routines provide the user with all functions to run the analyzer.
- User-friendly graphic interface and easy to learn system operations.
- The probe's vertical obstruction detection (VOD) system, detects obstructions, thereby protecting the probe from potential damage.
- Capacitive level sensing ensures accurate level detection.

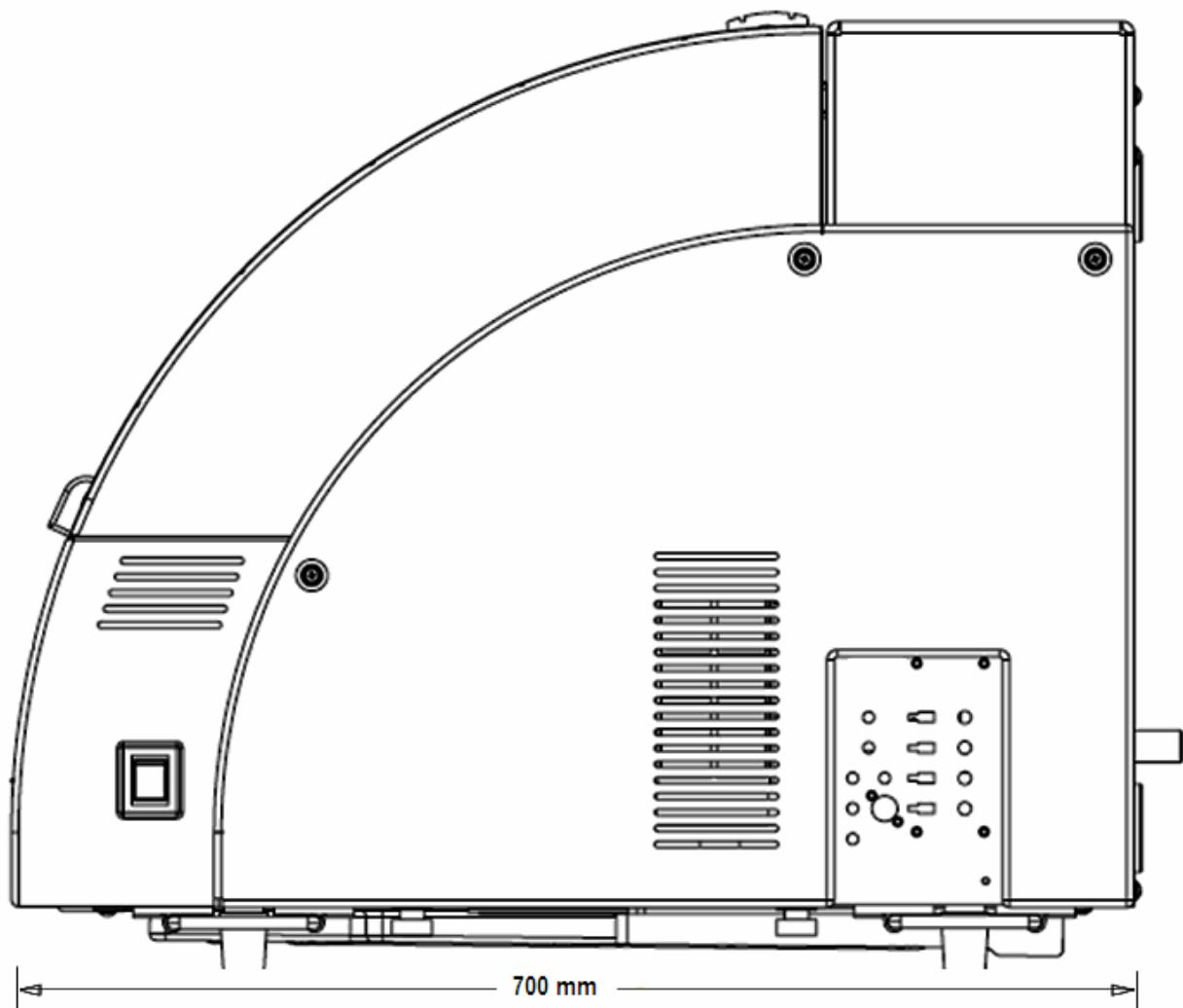
- Bi-directional host computer interface capability
- **Instrument analytical features.**
  - Barcode identification system for Samples tubes and Reagent bottles
  - 50 position reagent tray with built-in cooling.
  - Primary tube sampling with bar code identification.
  - Capability to run 1 or 2 reagent chemistries.
- **Instrument performance features.**
  - Throughput of 200 tests per hour for a cycle time of 18 seconds.
  - Throughput of 400 tests per hour for routine biochemistry tests with ISE.
  - Automatic maintenance procedures on start of the day.
  - 45 permanent hard glass cuvettes.
  - Sample tray accommodates sample tubes of 5, 7 or 10 ml and 2 ml sample cups.
  - Low reagent requirement per test.
  - 8 individual band pass filters.

## 2.4. Equipment Overview

### 2.4.1. Front View



## 2.4.2. Right Side View



## 3. Pre-installation

### 3.1. Installation Conditions

Read the instructions carefully before using the analyzer for the first time. You must be trained before you may perform the procedures described in this document.

Only qualified trained personnel should use the analyzer.

1. When the analyzer is installed, the following precautions should be taken:
  - a. Keep the analyzer out of the rain and any other water splash.
  - b. Avoid areas that are adversely affected by atmospheric pressure, temperature, humidity, ventilation, sunlight, dust, air containing salt or sulfur, etc.
  - c. Pay attention to inclination, vibration, shock (including shock during transportation), etc.
  - d. Use level indicator for ensuring the machine is leveled properly.
  - e. Do not install the analyzer at the place adjacent to the storage room of chemicals or the place where any gas is likely to be generated.
  - f. Pay attention to frequency, voltage and permissible current (or power consumption).
  - g. Connect the analyzer to the operational computer using accompanying USB cable supplied with the analyzer.



**Caution: When other cable is used, this may cause the analyzer to suffer from disturbing noise, exert an adverse effect on its surroundings or get incorrect measurement results.**

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2. Before operating the analyzer, you must follow the necessary instructions:
  - a. Check the power supply frequency, voltage and current capacity (power consumption).
  - b. Ensure that the analyzer is correctly and well grounded.
  - c. Ensure that all the necessary electrical cables are correctly connected.
    - ◆ Power cord between Mains and Analyzer
    - ◆ USB cable between Analyzer and Computer
    - ◆ Float sensor cables with CANs
  - d. Check that the contact conditions of switches and indicators are appropriate and that the analyzer is ready to be activated correctly.

Extreme care must be taken not to result in misdiagnosis or pose any danger to the analyzer or human body when the analyzer in conjunction with other equipment.

- e. Wipe the probe tips of SRPT several times with cloth or by rubbing alcohol before the analyzer is used. At this time, do not forget to put medical rubber gloves. Pay attention to prevent bare skins of hands or arms from being touched by or pricked with the probe tip.
3. The caution should always be exercised when replacing the halogen lamp.
  - a. Replace the halogen lamp by a new one after a lapse of 30 minutes after the analyzer is turned off, to avoid the danger of burns. Keep hands away from the glass part of the new halogen lamp. Make sure that there is no crack or breakage in the glass part.
4. The following cautions should be exercised during the operation of analyzer:
  - a. Pay attention not to exceed the time and volume necessary for diagnosis.
  - b. Keep monitoring the behavior of the whole system in order to detect any malfunction.
  - c. Take immediate corrective measures including shutdown of operation when any malfunction is detected in the analyzer.
  - d. Avoid possibilities of any direct access by the patients.
5. The following cautions should be exercised after the use of the analyzer:
  - a. Turn off the power after every operation so that control is restored to its previous state as directed.
  - b. Do not remove the line cord plugs from receptacles by pulling the cords so that no undue stress is developed in the cords.
  - c. Wipe the probe tips of SRPT several times with cloth or by rubbing alcohol before the analyzer is used. At this time, do not forget to put medical rubber gloves. Pay attention to prevent bare skins of hands or arms from coming in contact or being pricked by the probe tip.
  - d. Pay attention to the storage area.
    - i) Keep the analyzer out of the rain and any other water splash.
    - ii) Avoid areas that are adversely affected by atmospheric pressure, temperature, humidity, ventilation, sunlight, dust and air containing salt, sulfur, etc.
    - iii) Pay attention to inclination, vibration, shock (including shock during transportation), etc.
    - iv) Avoid areas adjacent to the storage room of chemicals or areas that are likely to generate gasses. Avoid areas that are likely to be subject to inclination, vibration and shock.

- e. Organize and store parts and cords associated with the analyzer after they have been cleaned.
  - f. Keep the analyzer clean not to cause any inconvenience to the next use.
6. In the event of trouble, do not fiddle with the analyzer. You must contact the authorized service personnel for troubleshooting.
  7. Maintenance and checks.
    - a. It is important for the analyzer and its associated parts to be periodically checked. For example:
      - ◆ Arm probes
      - ◆ Cuvette rinsing unit (laundry)
      - ◆ Stirrers
      - ◆ Syringe
- Refer section *8.2 Replacement Schedule for Spares and Consumables* as directed in the operator manual.
- b. Ensure that the analyzer operates normally and correctly, when it is reused after being kept unused for some time.
    - ◆ Perform Daily, Weekly, Monthly and Annually maintenance procedures as directed in the operator manual. Refer section *8.1 Maintenance Intervals* for more details.
  8. The following cautions should be taken when using and handling the reagents:
    - a. After unpacking the reagents, be sure not to allow dust, dirt or bacteria to come in touch with the reagents.
    - b. Do not use reagents that are out of expiration date.
    - c. Handle a reagent gently to avoid formation of bubbles.
    - d. Take care not to spill the reagent. If it spills, wipe it off immediately using a wet cloth.
    - e. Follow other instructions described in the package insert on each reagent.
    - f. If a reagent happens to enter your eye, wash it off immediately using plenty of water, and take medical treatment at once.
    - g. If you swallow it inadvertently, call for a doctor immediately and drink plenty of water.



**Warning: Some reagents are strong acids or alkalis. Exercise great care so that your hands and clothing do not come into contact with reagents. If your hands or clothing comes into contact with either reagent, immediately wash them off with soap and water. If a reagent comes into contact with your eye(s), immediately rinse with water for at least 15 minutes.**

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9. Prohibit any alteration and/or modification to the analyzer without permission by manufacturer.
10. The following precautions should be taken for preventing infection due to sample handling:



**Warning: Do not touch the samples, mixtures & waste liquids with bare hands. Be sure to wear gloves to protect you from infection. In case any samples come in contact with your skin, thoroughly rinse the area that came in contact with the sample & consult a physician. Immediately wipe off any contaminants from the system.**

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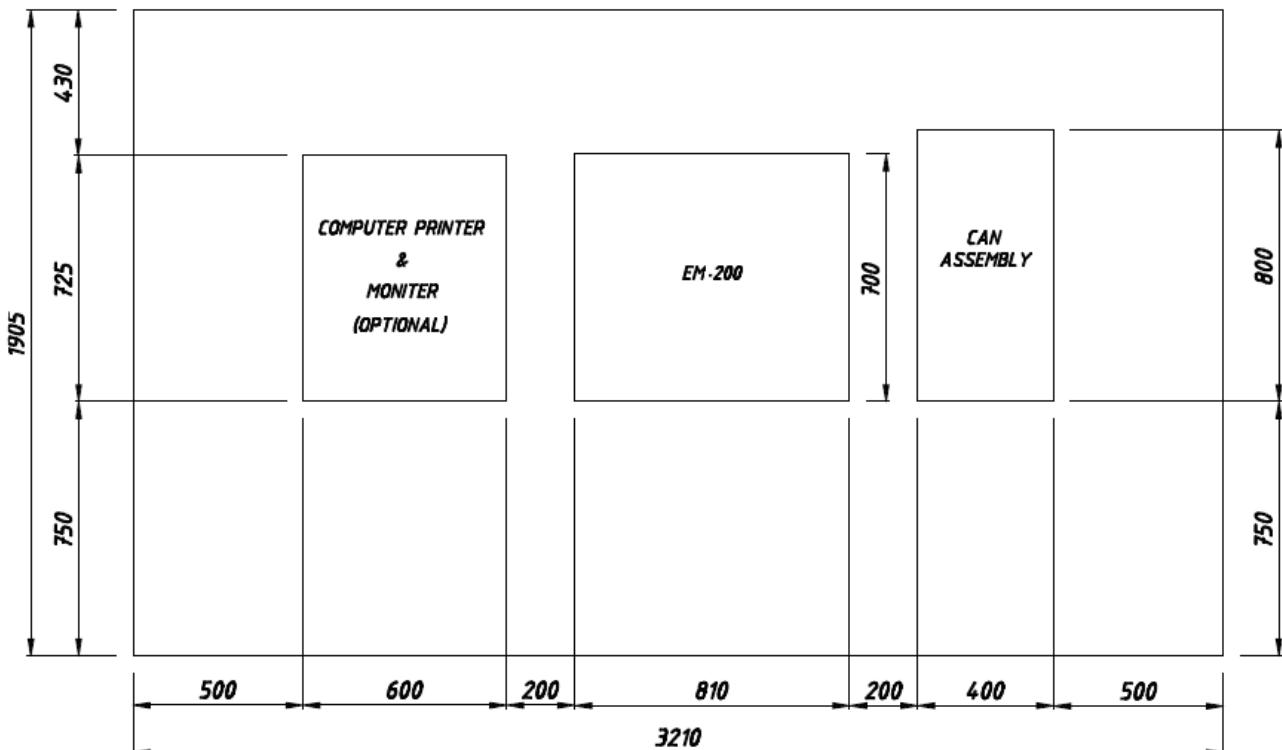
11. The following precautions should be taken for disposing the bio-hazardous waste:



**Warning: Treat the drain water as infectious waste. Collect the drain water in reserve can & allow it to be disposed of by expert distributors.**

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## 3.2. Floor Requirements



### 3.3. Electrical Requirement



**Warning: Improper grounding to analyzer bypasses the important safety features and may result in permanent damage to the analyzer that may void the warranty. It is absolutely necessary to ensure proper grounding**

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#### 3.3.1. Voltage and Frequency

Single-phase continuous stabilized AC 220 volts ± 10%, 50/60Hz or AC 110 volts ± 10%, 50/60Hz supply.

The analyzer comes equipped with a three-pin power cord. The type of cord and plug depends on the source voltage for the system.

#### 3.3.2. Grounding

Perfect grounding must be provided at the power source with all applicable local requirements. Only grounded three pin power plug should be used

#### 3.3.3. Plug Points

Four 5Amp sockets must be available near the analyzer.(Four sockets are required, one each for the analyzer, computer, monitor and printer).

It is recommended that two extra sockets be provided near the analyzer, for use by a measuring equipment or engineering tool if required while servicing (Example Oscilloscope, Soldering iron etc).

Heavy-duty electrical devices like Air conditioners, refrigerators, ovens etc. should not be operated on the same electrical lines as the analyzer.



**NOTE: Improper grounding to the analyzer bypasses important safety features and may result in an electrical hazard.**

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**NOTE: The 3 pin power cord plugs shipped with the analyzer, computer, printer and monitor may not be compatible with the local electrical sockets of some countries, you have to get these procured from the local market prior to the installation.**

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### 3.4. Site Requirement

The proper location is an important consideration; a poor location can lead to malfunction of the analyzer.

Please follow the following environmental and electrical suggestions to ensure the accuracy and precision of the analyzer.



**NOTE: This will also ensure a high level of operator and technical service personal's working comfort and safety.**

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### 3.4.1. Environmental Requirements

#### 3.4.1.1. Proper Room Temperature

Measure the room temperature at different corners of the Laboratory. The recommended temperature is 22 to 28°C with 40 to 80% humidity.



**NOTE: Room temperature should not vary more than 2°C per hour.**

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#### 3.4.1.2. Proper Ventilation

Make sure that there is at least 0.25 meters of un-used space around the instrument on all three sides, to enable proper ventilation. Please do not put any stationery or any other item by which operating the analyzer becomes difficult.

Please make shure that there is no direct air flow of air-conditioner on analyzer.

#### 3.4.1.3. Dust Free Environment

Verify and ensure a dust free environment for analyzer, this is a small but very important consideration when installing the analyzer.

### 3.4.2. External Interferences

Heavy-duty electrical devices like Air conditioners, refrigerators, ovens, centrifuges etc. should not be operated on the same electrical lines as that of the Analyzer or in the close vicinity of the analyzer.

The room should be free of vibrations resulting from heavy-duty devices like Centrifuges and Compressors etc.

The room should be free from strong magnetic fields caused by other medical equipment, like CT Scans, MRI etc. Mobile phones should not be operated close to the Analyzer.

### 3.4.3. Verifying Proper Room Lighting

There should be sufficient room lighting, the lighting should be even, and there should be no shadow areas, this problem can be eliminated by the use of multiple light source from diagonally opposite directions.

This will enable effcient operator use, and will give a clear visable access to the internal components of the analyzer during operation and technical servicing.

## 4. Installing Analyzer

### 4.1. Basic Operational Information

#### Receiving Instructions

The analyzer is thoroughly tested before shipment and is packed carefully to prevent damage during shipping and handling.

Please follow these guidelines on receipt of the analyzer:

- Ensure that the arrows on the sides of the packages are pointing up. If the arrows do not point up, make a remark about this on the invoice copy.
- Visually inspect the outside of the package for rips, dents, or possible shipping damage. Document any sign of damage on the bill of lading, regardless of how insignificant it may appear. This is to protect your interests.
- Notify your service representative that the analyzer system and its components have arrived. Wait for your local service representative to unpack the system and open the packages.
- Follow the unpacking and storage instructions provided on the outside of the package. Special requirements such as refrigeration are clearly marked on the outside of the cartons and will be included in the unpacking instructions and pack inserts.

#### Warranty Information

All analyzers are warranted against defective materials or workmanship for a period of one year commencing from the date of the shipment of the analyzer.

This warranty does not cover any defect, malfunction, or damage due to:

- Accident, neglect or willful mistreatment of the product.
- Failure to operate, service or maintain the product in accordance with the applicable Operator Manual and Service Manual.
- Use of reagents or chemicals of corrosive nature, though the unit is an open system allowing the use of any commercial reagents from any manufacturer that are meant for such an automated clinical chemistry analyzer.

## 4.2. Unpacking the Analyzer



**Caution:** Unpack the analyzer carefully; otherwise you may damage the accurately adjusted optical and electronic assemblies.

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The analyzer is packed carefully to prevent any shipping damage. Upon arrival, inspect the packing according to the list and notify the carrier of any apparent damage. Follow the steps to install the analyzer:

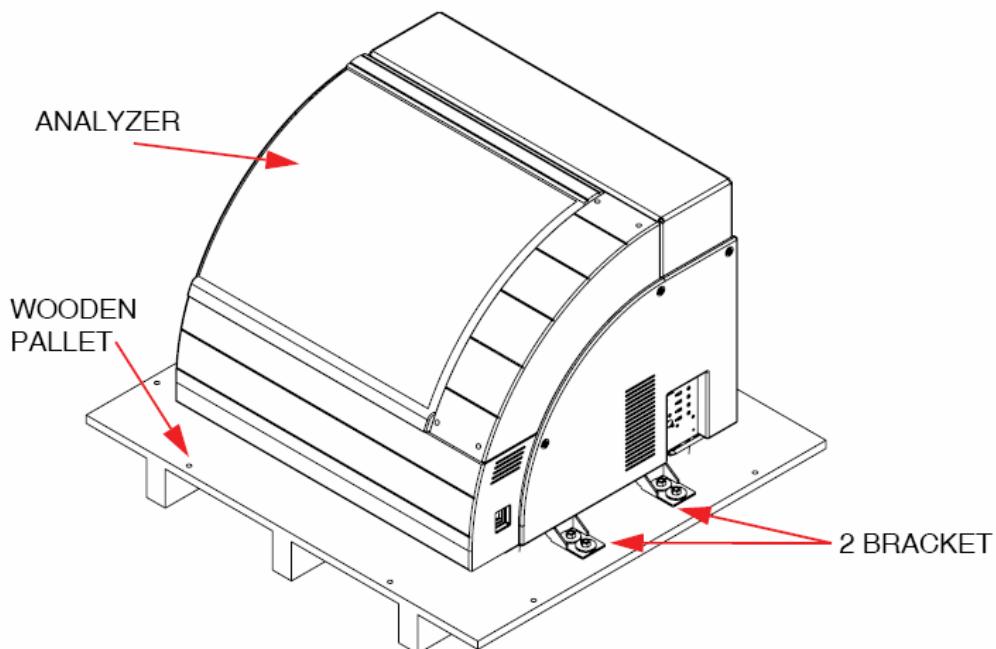
1. Remove the front panel of the wooden box by loosening the bolts. The front panel on the wooden box is marked.
  2. Remove the top and side panels of the wooden box as a whole section by loosening the bolts from the back panel side.
  3. Remove the four "Z" brackets, which are holding the analyzer on the pallet.
- 



**Caution:** The "Z" bracket and the footrest may support the entire weight of the instrument. Cautiously open the bolts of the "Z" bracket to prevent any personal injury.

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4. Lift the analyzer from the pallet & place at installation space. (Refer section *3.2 Floor Requirements*).
5. Gently slide the Probe upwards, making sure you do not damage the probe, once you have reached the top most position, rotate it and position it over the trough.
6. Gently slide the Stirrer arm upwards, making sure you do not damage the paddles, once you have reached the top most position, rotate it and position it over the trough. Remove the protective material.
7. Gently slide the CRU arm upwards to the top most position, making sure you do not damage the probes, and remove the protective material and clean debris.
8. Remove the buffers that are present in the RGT & ASP areas, as well around the CRU Stirrer and Probe.



**Caution: The instrument is shipped, mounted on "Z" brackets; the "Z" bracket and the four legs may support the entire weight of the instrument.**

**Open the bolts of the "Z" bracket to prevent any personal injury.**

**It is important to have leveling done of the place where analyzer is going to be installed before placing the analyzer.**

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## 4.3. Inspection and Accessories Checklist

The analyzer is fully inspected before leaving the factory and carefully packed to withstand shocks in transit.

On receiving the analyzer, check the package externally; make sure that there is no external visible damage to the shipping container. If there is damage please make a note of it, if possible photograph it and inform the designated service personnel. Verify with the invoice, if all the boxes have arrived.



**NOTE: The accessories supplied with the analyzer are subject to change without prior notice.**

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The shipment generally contains the following packages:

1. Analyzer wooden box.
2. Accessories Cardboard box. (mounted on pallet)
3. Other accessories boxes (optional) could include.
  - a. Printer
  - b. Computer etc.

<b>SR.NO.</b>	<b>ITEM CODE</b>	<b>DESCRIPTION</b>	<b>QTY.</b>
1	---	Operator Manual	1 No.
2	---	Software CD	1 No.
3 *	105412	20 liter Can Assy for D I Water assy.	1 No.
4 *	105419	20 liter Can Assy for Waste assy.	1 No.
5 *	105365	10 liter Can Assy for Bio-hazardous Waste assy.	1 No.
6 *	105415	10 liter Can Assy for cleaning solution assy.	1 No.
7	105403	Reagent Tray Assy.	1 No.
8 *	104764	Reagent Tray Cover Assy.	1 No.
9 *	104664	Standard Sample Tray (1-30) Assy.	1 No.
10	107051	RGT Bottle Locating Plate	1 No.
<b>Tool-kit—Containing</b>			
11	101494	Plastic Tool Box	1 No.
12	101688	Screw Driver (imp) +Ve No.-1-CR-V –carbon tip	1 No.
13	101687	Screw Driver (imp) +Ve No.-2-CR-V –carbon tip	1 No.
14	101689	Screw Driver (-) NO.3	1 No.
15	101675	Nut Driver (M3)	1 No.
16	101676	Nut Driver (M4)	1 No.
17	101495	Box Spanner 10 / 11	1 No.
18	101692	ALLEN DRIVER (M3) 2.5 MM T TYPE-9" LONG	1 No.
19	101693	ALLEN DRIVER (M4) 3.0 MM T TYPE-9" LONG	1 No.
20	101694	ALLEN DRIVER (M5) 4.0 MM T TYPE-9" LONG	1 No.
21	111604	HEX BALL ALLEN KEY SET CONSISTING OF 1.5mm, 2mm, 2.5mm, 3 mm, 4mm, 5mm, 6mm ALLEN KEYS WITH PLASTIC HOLDER & BLISTER PACKING	1 Set.
22	101514	Nose plier	1 No.
23	101515	Flat Spanner 10 / 11	1 No.
24	101524	Flat Spanner 14 / 15	1NO.
25	100323	Forcep – 6 inches	1 No.
26	100295	Trimmer (3x75).	1 No.
27	101516	Bunch spanner set (1 to 8 no.)	1 No.
28	101678	6" Adjustable Spanner	1 No.
29	100294	Tube cutter	1 No.
30	100679	Calibration Plate	1 No.
31	201209	GAUGE FOR PROBE CALIBRATION	1 No.
32	100263	CUVETTE (4C:0609)	3 Nos.
<b>Shipper Box Containing</b>			
33	101421	USB JUMPER CABLE USBC-AM-BM-B-B-S-2	1 No.
34	100342	TYPE B PLUG - PS204 V1625 SJT AWG 16 X 3 2 MTR. LENGTH	1 No.
35	105067	Sample tube with bar code labels.	10 Nos.
36	100634	Test Tube Adapter for moulded sample holding plate	30 Nos.

## Operator Manual

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37	108159	Assy. of waste Can tube & can cap	1 No.
38	108162	Assy of Bio-hazard Can tube & can cap	1 No.
39	108160	Assy. of D.I.Water Can tube & can cap	1 No.
40	108161	Assy of Cleaning solution can tube & can cap	1 No.
41	106653	LEVEL SENSOR ASSY FOR 20LTR DI WATER CAN	1 No.
42	106654	LEVEL SENSOR ASSY FOR 10LTR CLEANING SOLN CAN	1 No.
43	106655	LEVEL SENSOR ASSY FOR 10LTR BIOHAZARDOUS CAN	1 No.
44	106656	LEVEL SENSOR ASSY FOR 20LTR WASTE CAN	1 No.
45	182581	REAGENT BOTTLE (20ML) WITH CAP	25 No.
46	182584	REAGENT BOTTLE (50ML) WITH CAP	25 No.
47	---	Reagent Bottles (20 ml.) With Caps and Bar code labels	2 Nos.
48	---	Reagent Bottles (50 ml.) With Caps and Bar code labels	2 Nos.
49	100592	5 ml. Reagent bottle Adapter (new)	50 Nos.
50	102090	Outer Holder for 5ml Reagent Adaptor	5 Nos.
51	100660	PVC Support For 20ml Reagent Bottle	25 Nos.
52	100536	Rubber Cup For Sample Tray	10 Nos.
53	105140	Screw Cap For Philips Head CSK Screw	11 Nos.
54	110318	CABLE TIE SIZE 2.5 MM X 100 MM KP138	25 Nos.
55	180510	SUPPORT FOR CRICK	10 Nos.
56	102932	Sample Cups (Pack of 150 nos.)	2 Packs.
<b>P. M. Kit (new) II ---</b>			
57	102851	Cuvette Drier	2 Nos.
58	105474	Laundry Aspiration tubing set (2 probe construction )	2 Set
59	105475	Laundry Dispensing tubing set (2 probe construction)	1 Set
60	182220	Photometer Lamp Assembly	4 Nos.
61	104604	Set of Fuses	1 Set
62	107613	10 micron filter (125mm length)	4 Nos
63	107580	BD SPINAL NEEDLE (25 GA 3.5IN,0.50x90mm, item 405257)	1 No.
64	101677	Probe Cleaner	1 No.
65	106265	Washer For CRU Knob	1 No.
<b>Accessories for ISE Unit</b>			
66	200004	Reference Electrode For ISE	1 No.
67	200001	Na Electrode For ISE	1 No.
68	200002	K Electrode For ISE	1 No.
69	200003	Cl Electrode For ISE	1 No.
70	100316	Li Electrode For ISE	1 No.
71	105542	Cleaning Solution	1 No.
72	100315	Reagent Pack	1 No.
<b>Optional Items</b>			
73	---	Computer with mains cord	1 No.

74	---	Keyboard	1 No.
75	---	Mouse	1 No.
76	---	Flat screen monitor with cord	1 No.
77	181219	Printer with cord & cable	1 No.
78	---	Reagent pack location pad	1 No.
79	111169	Computer Trolley	1 No.
<b>Miscellaneous</b>			
80	---	FQC Report	1 No.
81	---	Unit Installation Instruction Sheet	1 No.
82	---	Hydraulic diagram sheet	1 No.
83	----	Instructions for assembling computer trolley.	1 No.
84	102683	ERBA XL WASH Kit	1 No.

## 4.4. Installing the Components of the Analyzer



**NOTE:** To avoid a shock hazard; ground the Analyzer, Computer, Printer and Monitor using a 3 pin grounded electric outlet. Do not use an adapter, as it could cause a loose contact and improper grounding.



**NOTE:** Confirm that all cuvettes have been fitted properly into their respective slots on the reaction tray and none of them are jutting out.

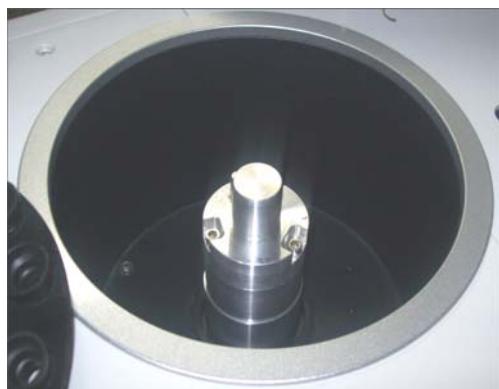


**NOTE:** When removing or placing the cuvettes into their slots make sure that you grip them by their sides and top end, never let the fingers or any sharp objects coming in contact with the optical area of the cuvettes.

### 4.4.1. Installing the Sample Tray and the Reagent Tray

1. Unpack the Sample tray from the accessories box and hold the sample tray with your right hand.
2. Gently place the sample tray into the Sample tray container.

Make sure that the index pin on the Sample Transport, slides into the index hole provided on the sample tray.



**Step 1**



**Step 2**



**Step 3**

3. Unpack the Reagent tray from the accessories box and hold the Reagent tray with your right hand.
4. Gently place the Reagent tray into the reagent tray well.

Make sure that the index pin on the Reagent transport slides into the index hole provided on the Reagent tray.



**Step 1**



**Step 2**

5. Place the respective tray lid over the Reagent Tray and Sample Tray.

## 4.4.2. Installing DI Water, Cleaning, Bio-hazardous and Waste Cans

1. Unpack the Float Sensors for the 4 Cans and place them on one side.
2. From the accessory box remove the 20 liters DI Water Can, 20 liters Waste Can, 10 liters Bio-hazardous Waste Can and the 10 liters Cleaning solution Can, and put them on the floor.
3. Unpack Float Sensors cables and connect one end to respective connector (located on the right panel of the analyzer) and connect other end to the respective Cans (Longer float sensors with blue sleeves for DI Water, green sleeves for Cleaning solution, red sleeves for Bio-hazardous Waste, and yellow sleeves for Waste).
4. Fill the DI Water Can with 20 liters of fresh DI water and unpack the tubing's from the accessory box. Install filter in DI water Can.
5. Take two separate tubes and connect one end to the Blue ringed outlet marked **DI-WATER** and White ringed outlet marked **DI-WATER LAMP** provided on the analyzer. Connect other ends to the SS (stainless steel) nozzle and White ringed nozzle on 20 liter DI Water Can.



**NOTE: Make sure that the tube connected to Blue ring on the analyzer should be connected to SS nozzle on the DI water Can and the tube connected to White ring should be connected to White ringed nozzle (for lamp cooling).**

6. Now, fill 5 liters of DI water into the cleaning solution to prepare working cleaning solution: Add 50 ml of neutral cleaning solution to 5 liter of DI water to prepare a 2% solution.
7. Now take another tube and connect one end to the Green ringed outlet marked **CLEANING** and other end to green ringed nozzle on 10 liter Cleaning solution Can.
8. Take two separate tubes and connect one end to the Red ringed outlet marked **WASTE-3** and **BIO-HZ**. Connect other ends to the red ringed nozzle on 10 liter Bio-hazardous Can.
9. Take one more tube and connect one end to the Yellow ringed outlet marked **WASTE-2** and connect its other end to the yellow ringed nozzle on 20 liter Waste Can.
10. Now connect the large diameter silicon tube to the analyzer outlet marked **THROUGH WASTE** and connect the other end of the tubing into the 20 liter Waste Can.

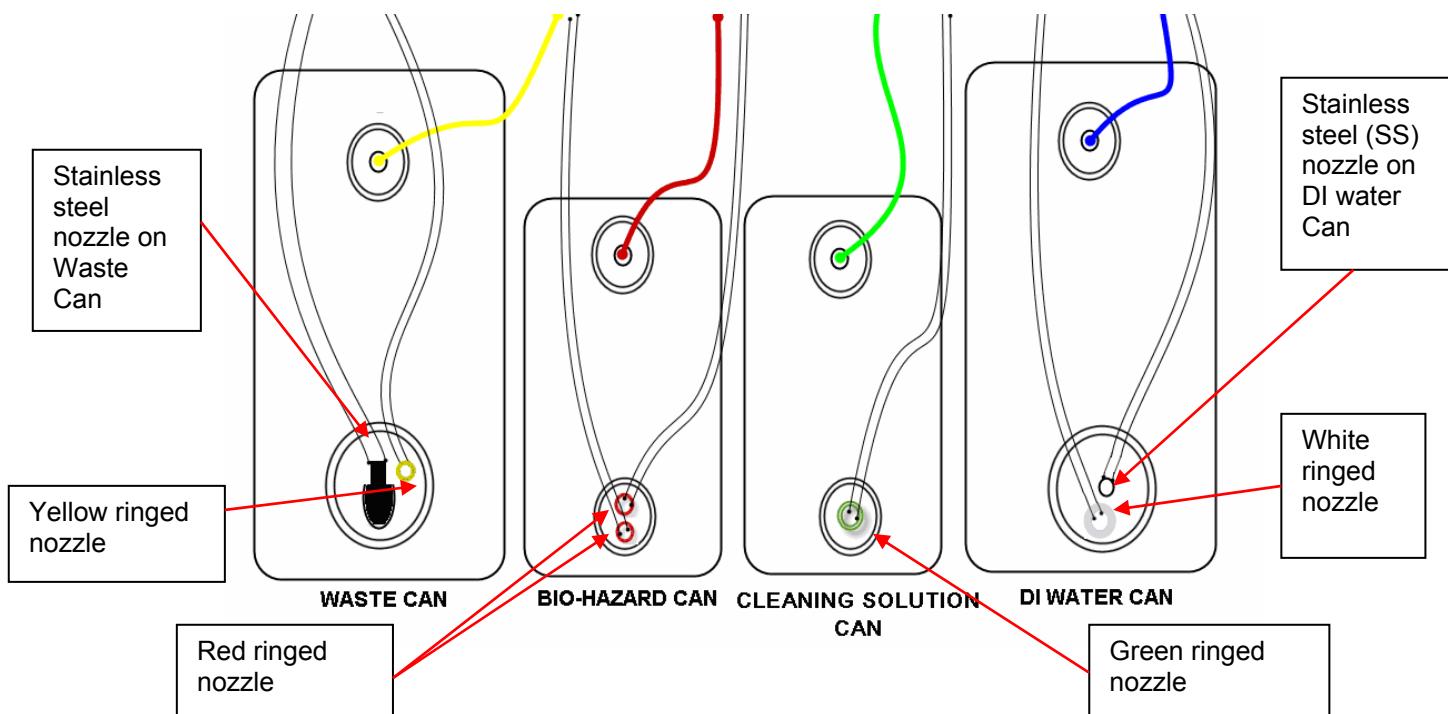
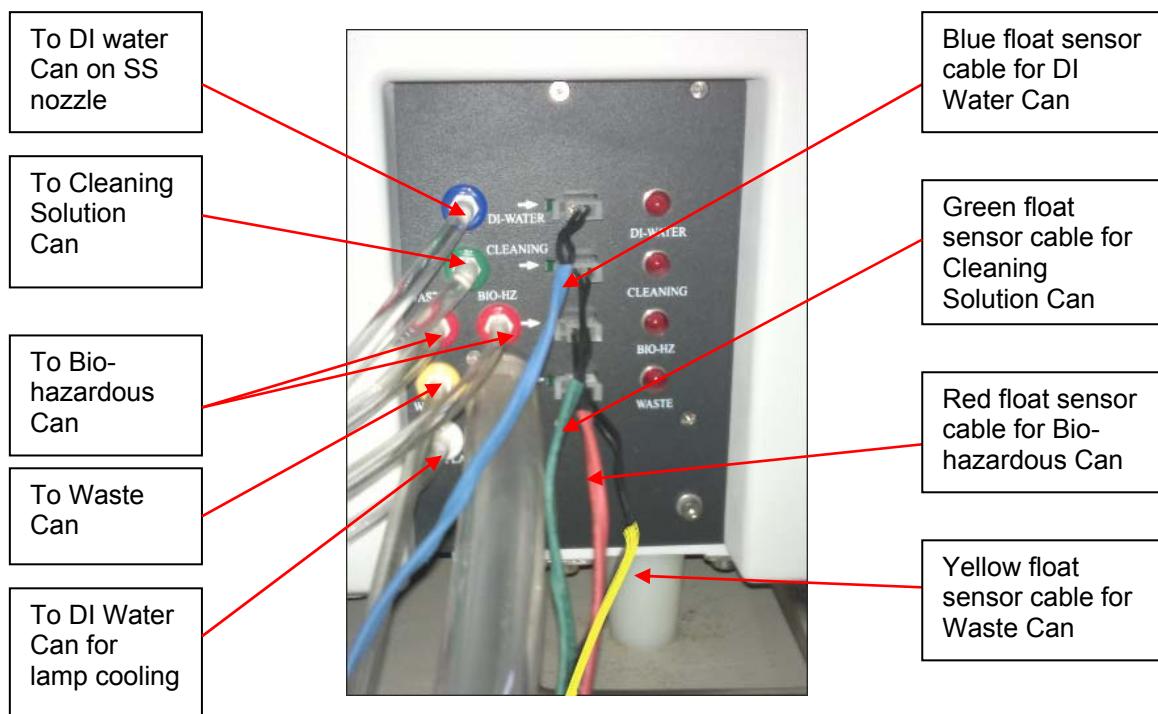


**NOTE: Take care that all the above-mentioned tubes reach their respective containers without any sharp bends or obstructions.**



**NOTE: The waste consists of a natural drain. Make sure that the large silicon waste tube from the analyzer to the Waste can is slant and in downwards direction without any bends.**

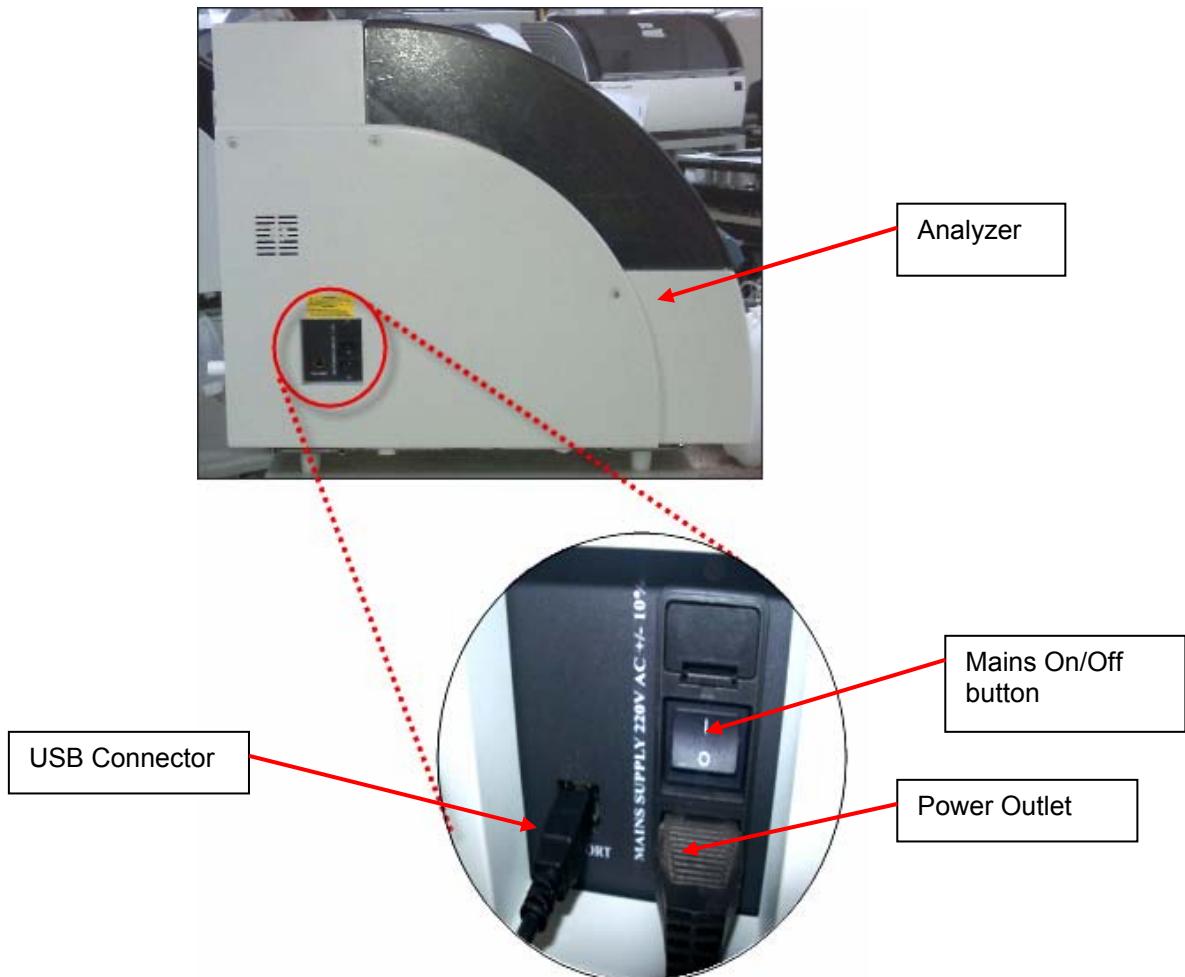
**Failing to take the above precaution may cause a back flow of waste solution, out of the manifold air release tube on waste manifold. Or could result in noisy operation, big gargling sounds being created by the waste lines.**



#### 4.4.3. Connecting communication cable between Computer and Analyzer

Follow these instruction to connect the analyzer from the computer:

1. Unpack the USB cable from the accessories box, and connect its one end to the USB port of the computer and other end to the USB connector located on the left side of the instrument, as shown in figure below.



2. Connect one end of the power cord to the analyzer's power outlet and other end to the main power supply as shown in figure above.



**NOTE: Make sure that the On/Off power button should be in OFF condition before turning on the main power supply**

3. The instrument is connected with the computer and ready to power on.

#### 4.4.4. Printer Installation (DeskJet or Laser)

Check for following points before using Application Software to generate printouts:

1. Install appropriate printer driver on the analyzer PC.
2. Connect the printer to the analyzer PC.
3. Feed the paper to the printer and switch it 'ON'.
4. There should be no paper jam or any other obstruction in the printer.
5. Print a test page from the analyzer computer to confirm correct printing.

#### 4.5. Equipment Startup Procedure

Perform the following verification before starting the equipment:

- Make sure that tube connections with Bio-hazardous waste Can, Cleaning Can, DI Water Can and Waste Can are properly done.
- Make sure that tray lids are properly placed on Sample Tray, RCT and Reagent Tray.

Once the verification is done, the instrument can be connected to power supply.

After performing the above checks, follow the procedure for starting the equipment:



**NOTE: Before starting the main supply, make sure that the Main ON/OFF switch and secondary switch provided on the left and right side of the analyzer should be in OFF condition.**

1. Plug in the one end of the power cord to the main supply.
2. Turn on the main power switch.



**NOTE: The 3 pin power cord plugs shipped with the analyzer, computer, printer and monitor may not be compatible with the local electrical sockets of some countries, you have to get these procured from the local market prior to the installation.**

3. Turn on the switch that is provided on the back side of the instrument.



**NOTE: When this button is pressed, the ISE unit will be started, if installed on the instrument.**

Verify and confirm that all ISE electrodes have been properly installed; their walls are flush against each other with the rubber "O" rings in place if analyzer is equipped with ISE.

Verify and confirm that the reagent cooling fan has started rotating, also touch and physically verify the cooling of the reagent tray, also verify from the sound, that the ISE pumps have started priming.

4. Turn on the instrument switch provided on the right side.

This initializes the system, and all assemblies will come to home position.

5. Now the instrument is powered-ON, and ready.
6. Power on the PC.

Refer section 6.1.3.3 *Power-on of personal computer (PC)* for more details.

## 4.6. Software Installation Procedure

This section guides you through the installation and up-gradation procedure of MultiXL software.

You must read the installation instructions carefully before installing the software.

### 4.6.1. Overview

The MultiXL software is the application software for the automated clinical chemistry analyzer.

This software is multilingual and supports even Asian languages like Chinese, Japanese, and Thai etc.

### 4.6.2. Pre-requisite

#### 4.6.2.1. System Configuration

<b>Processor</b>	Pentium IV, 2.8Ghz or above
<b>Operating system</b>	Microsoft Windows XP Service pack 2 or 3 or Windows 7 Professional English Edition (32-bit)
<b>Hard disk</b>	80 GB or above
<b>RAM</b>	Minimum 1 GB RAM for Windows XP Service pack 2/3 or Minimum 2 GB RAM for Windows 7
<b>Monitor</b>	17 inch / 19 inch color monitor with 1024 * 768 resolution
<b>Printer</b>	Laser/ DeskJet

#### 4.6.2.2. PC Settings Required for Windows XP

- Remove all memory resident software including anti-virus software from the Analyzer PC.
- Remove firewall, automatic update, other security software and / or settings from the Analyzer PC.
- Do not run any other application on the Analyzer PC during batch run on Analyzer.

- Disable Screen-savers and Power Management on Analyzer PC before starting the Application Software.
- Ensure that a default printer (Laser Jet / DeskJet) is configured and connected to Analyzer PC. Set appropriate printer should be set as default printer.
- Delete the “**Microsoft Office Document Image Writer**” and “**Microsoft XPS Document Writer**” from the system. Following is the procedure.

Go to **Start > Settings > Control Panel > Printers and Faxes**. Select the “**Microsoft Office Document Image Writer**” and delete.

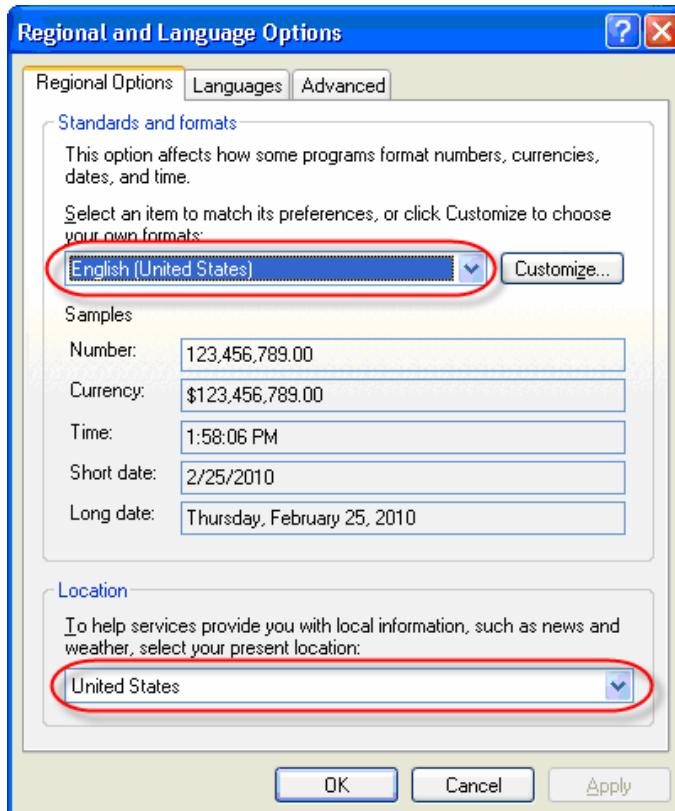
Similarly, delete “**Microsoft XPS Document Writer**”.

- Windows Login User requires Administrative privileges to Install and Run the Application.

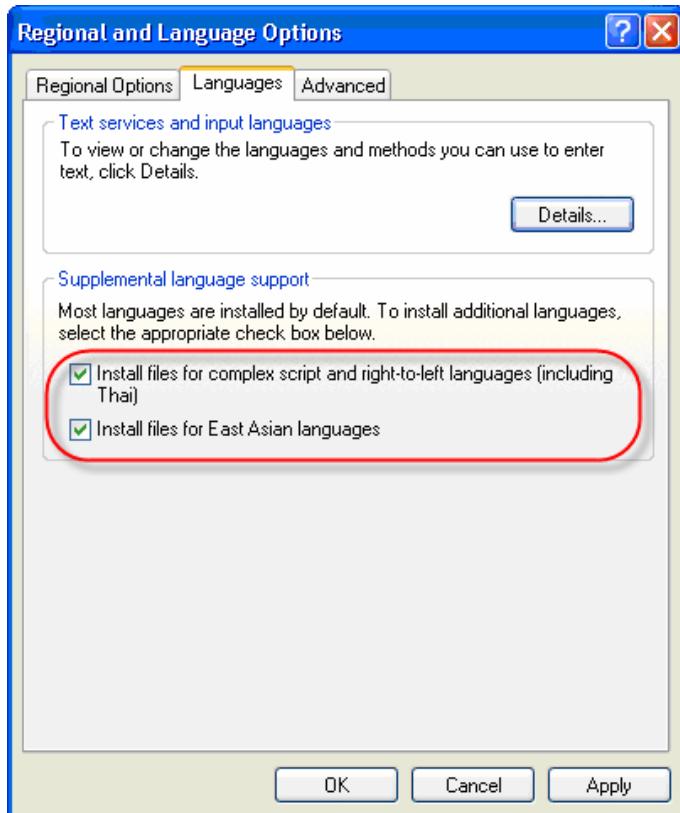
#### 4.6.2.3. Regional and Language Settings for Windows XP

Use the following procedure for setting the regional and language options:

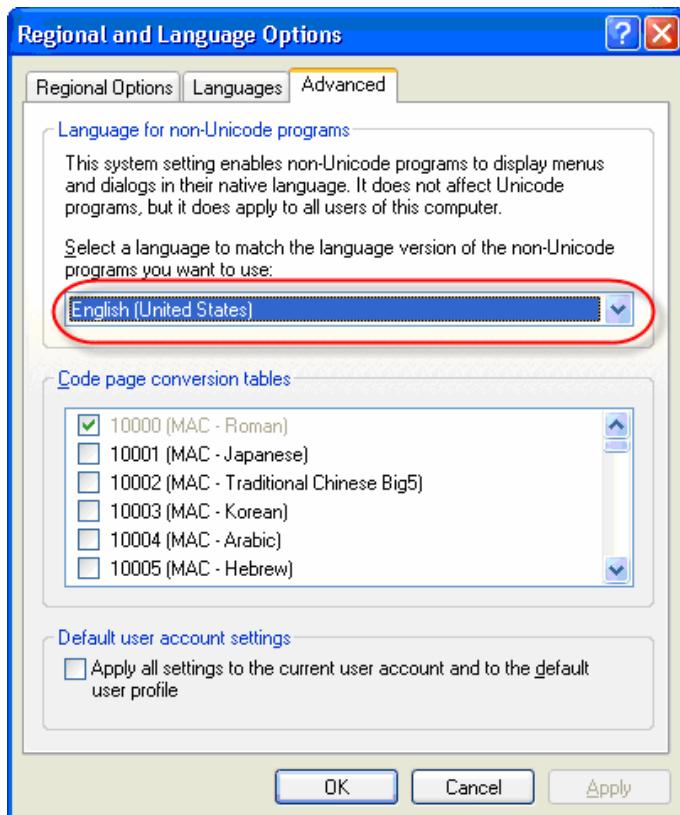
1. Select **Regional Options** tab, and define the following settings. See figure below:



2. Select **Languages** tab, and define the following settings. See figure below:



3. Select the **Advanced** tab, and define the following settings.



#### 4.6.2.4. PC Settings Required for Windows 7

- Remove all memory resident software including anti-virus software from the Analyzer PC if installed. Use the following procedure:

Click **Start** button, and click **Control Panel**. Now, under the **Category** view, go to **Programs > Programs and Features**. Select the desired anti-virus software from the list, and click **Uninstall**.

- Remove firewall, automatic update, other security software and from the Analyzer PC.

Click **Start** button, and click **Control Panel**. Now, under the **Category** view, go to **System and Security > Windows Firewall**, and click on the link **Turn off Windows Firewall on or off**. Now select the option **Turn off Windows Firewall (not recommended)**, and then click **OK** button.

To turn off automatic updates, under **Control Panel**, go to **System and Security > Windows Update**, click on the link **Change settings**, and select the **Never check for updates (not recommended)** from the drop down list, and click **OK**.

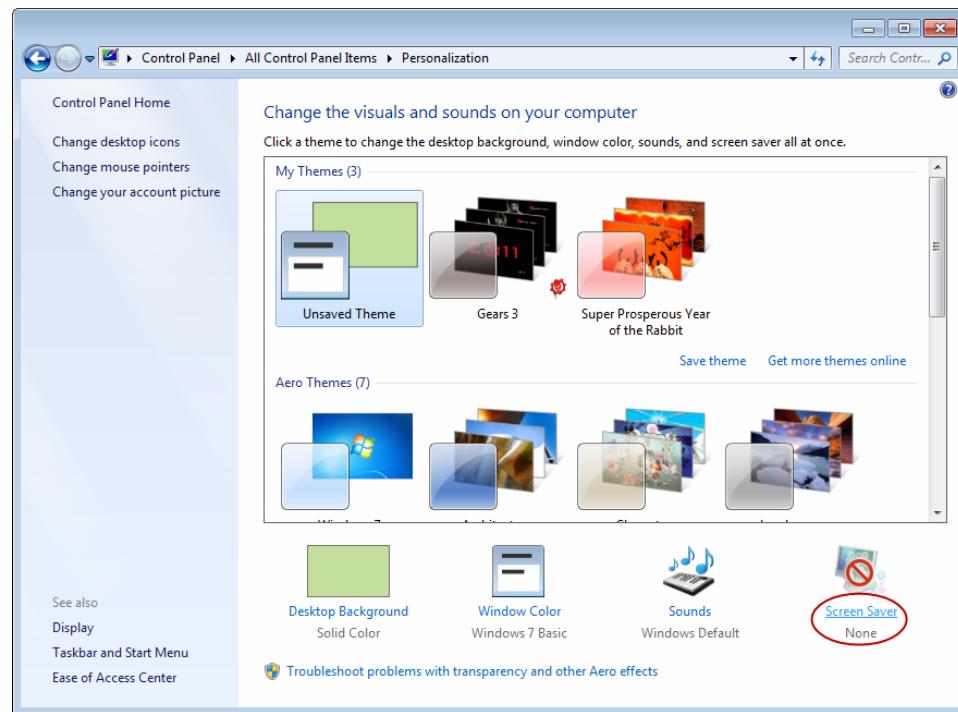
- Do not run any other application on the Analyzer PC during batch run on Analyzer.
- Ensure that a default printer (Laser Jet / DeskJet) is configured and connected to Analyzer PC. Set appropriate printer as default printer.
- Delete the “**Microsoft Office Document Image Writer**” and “**Microsoft XPS Document Writer**” from the system.

Click **Start** button, and click **Control Panel**. Now, under the **Category** view, go to **Hardware and Sound > Devices and Printers**. Right click on the **Microsoft Office Document Image Writer**, and choose **Remove Device** to delete. Similarly, delete “**Microsoft XPS Document Writer**”.

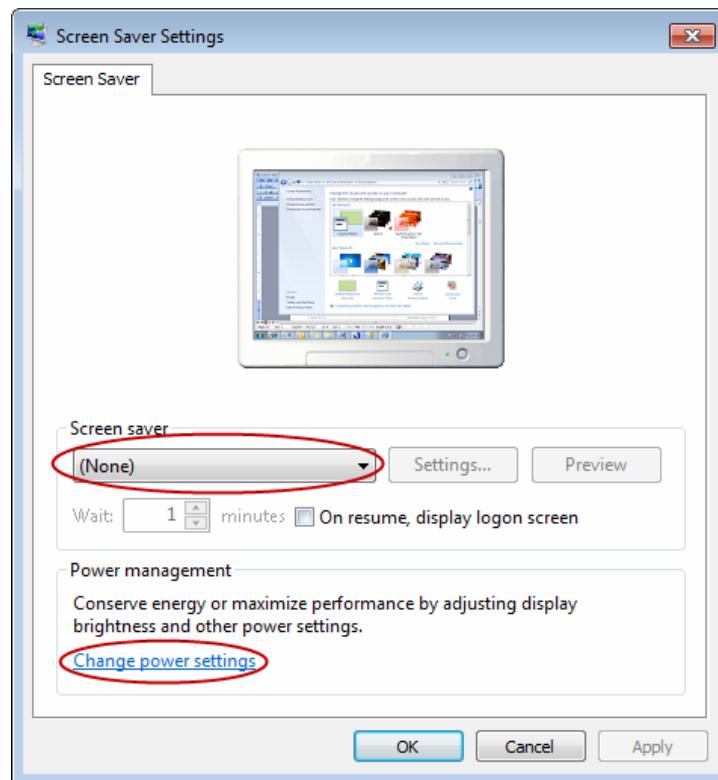
- Windows Login User requires Administrative privileges to Install and Run the Application.
- Disable Screen-savers and Power Management on Analyzer PC before starting the Application Software.

Use the following procedure for disabling the screen saver and power management:

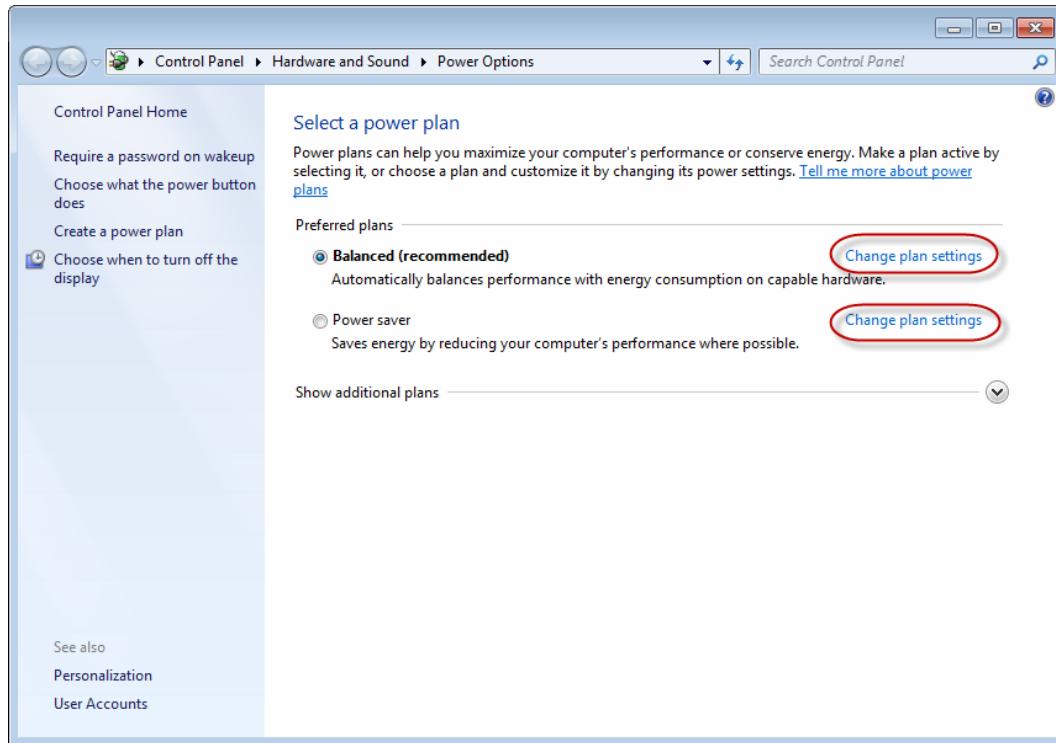
- a. Open Screen Saver Settings by clicking the **Start** button, clicking **Control Panel**, clicking **Appearance and Personalization** under **Category** view, clicking **Personalization**, and then clicking **Screen Saver**.



- b. To turn off all screen savers, under **Screen Saver**, select **(None)** from the drop-down list, and then click **OK**.

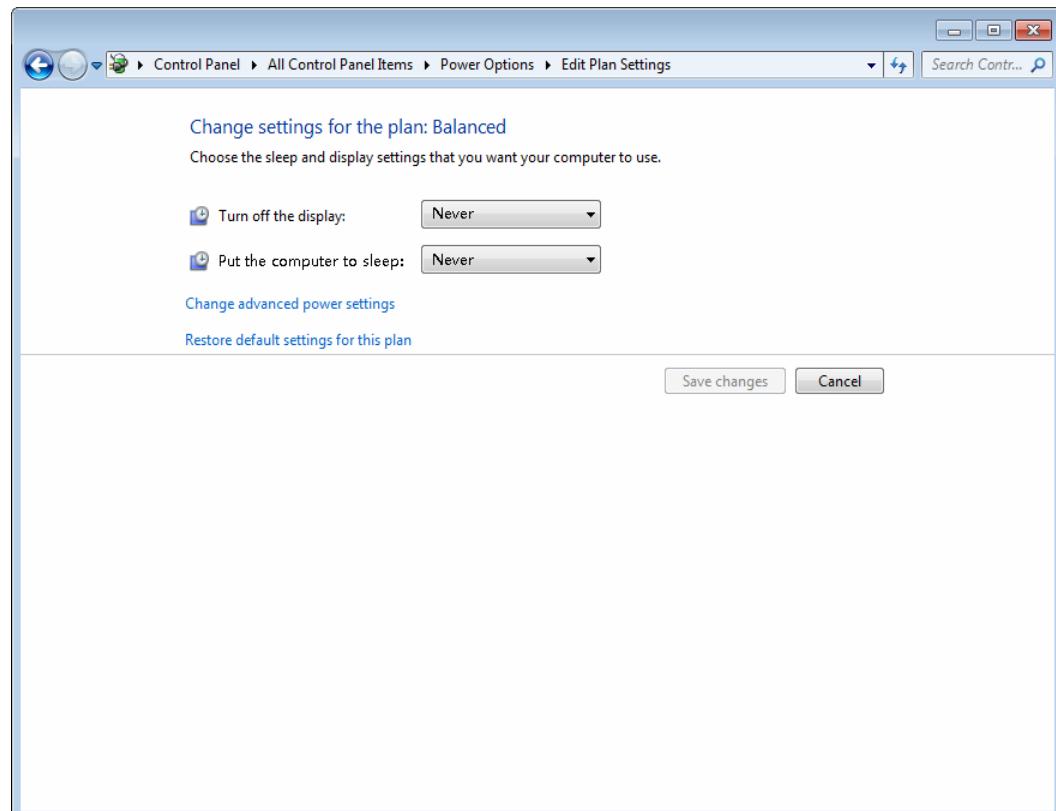


- c. Now click on the link **Change power settings**. The following screen will be displayed.



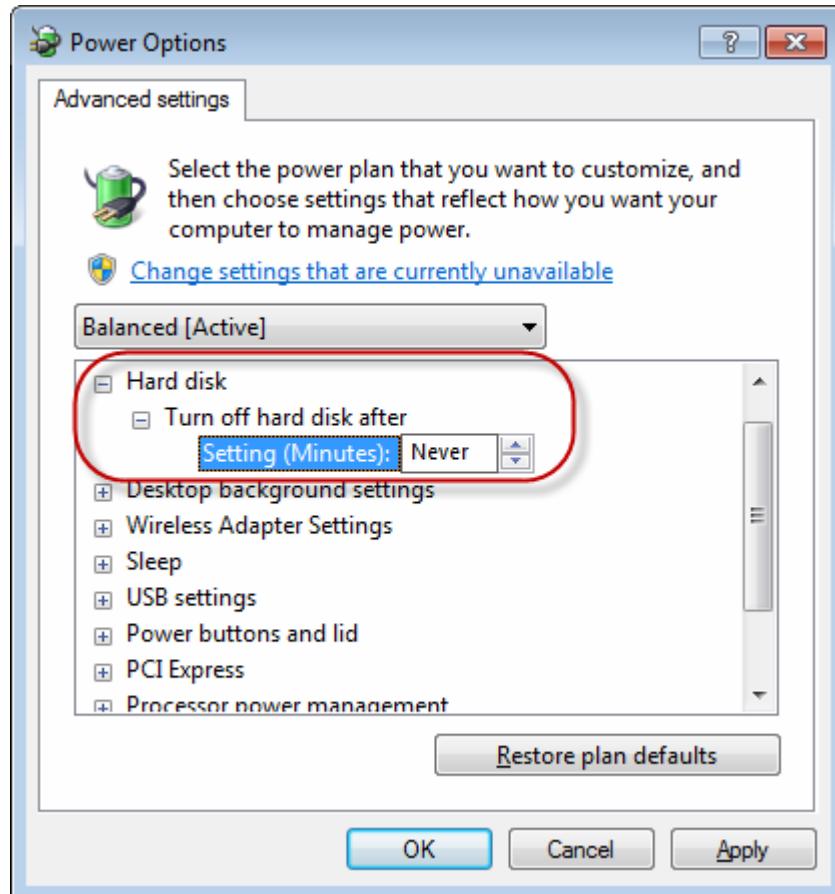
d. Click on Balanced **Change plan settings**.

- ◆ Set **Turn off the display** to **Never**
- ◆ Set **Put the computer to sleep** to **Never**



e. Click on **Change advanced power settings**.

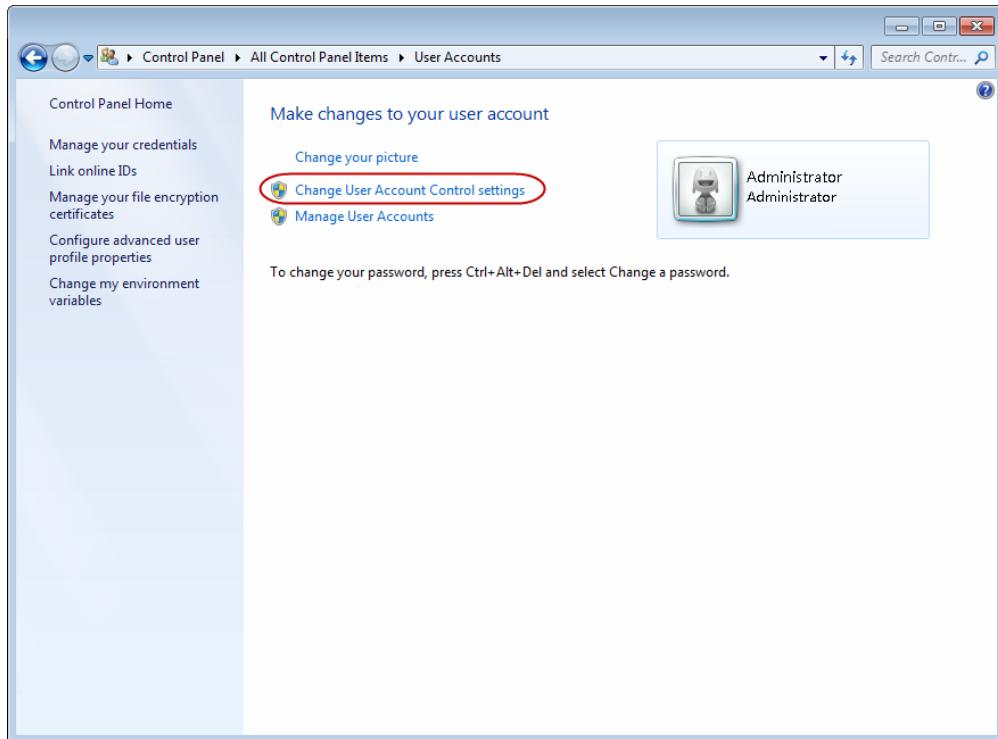
### Set Turn off hard disk after to Never



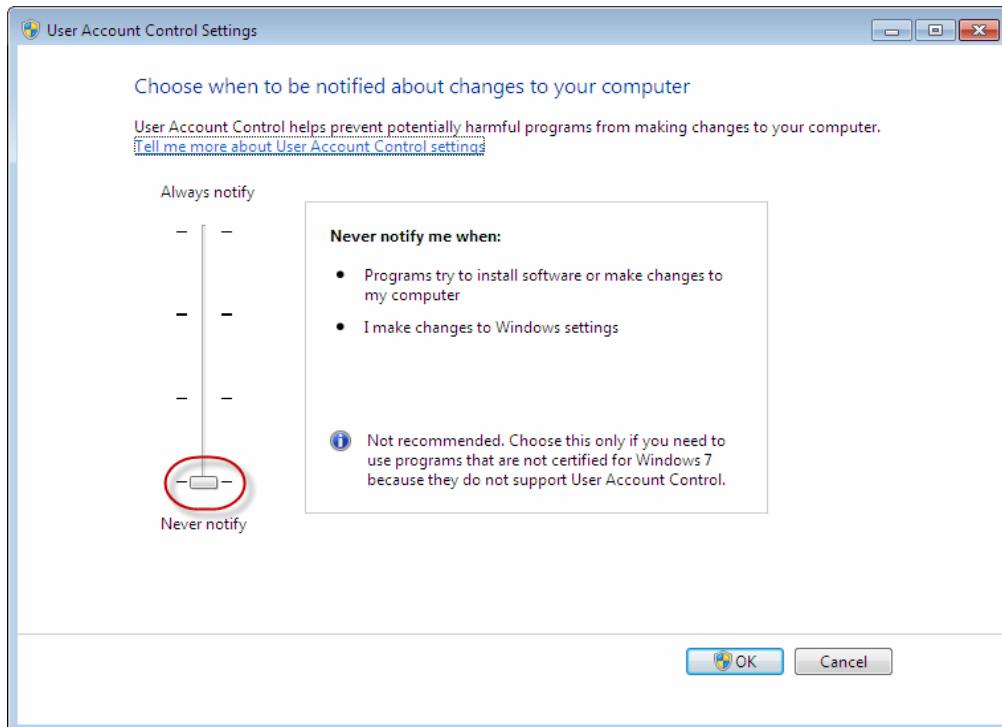
Similarly apply same settings to power saver option. Repeat the step c to e.

- **User account control settings**

- a. Open User Account Control Settings by clicking the **Start** button, and then clicking **Control Panel**. Under **Small** or **Large icons** view, click on **User Accounts** and then click **Change User Account Control settings**.



The following screen will be displayed:



b. Move Pointer to **Never Notify** and click **OK**.

You must re-start the analyzer PC to turn on the User Account Control.

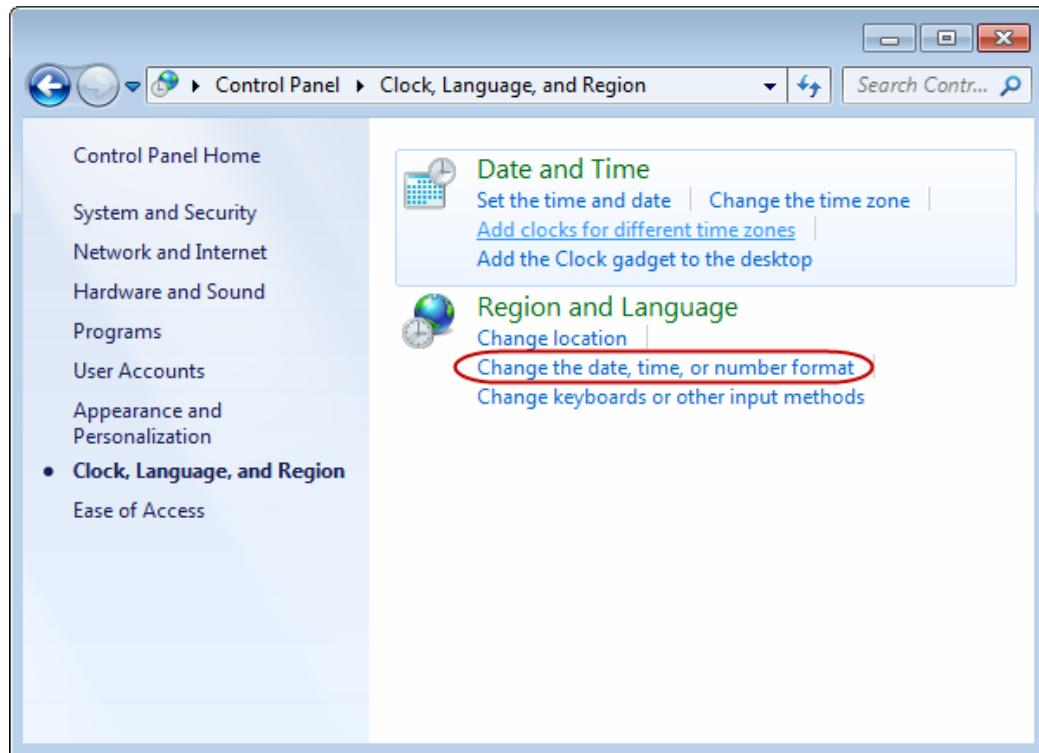
### 4.6.2.5. Regional and Language Settings for Windows 7

Use the following procedure for setting the regional and language options:

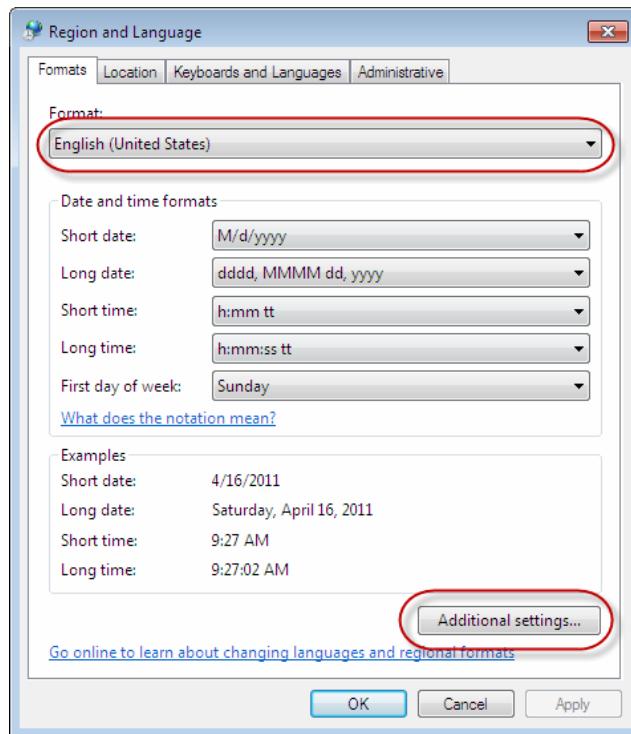
Ensure that the following regional and language settings are appropriate.

Note that these are critical settings for the communication with the analyzer.

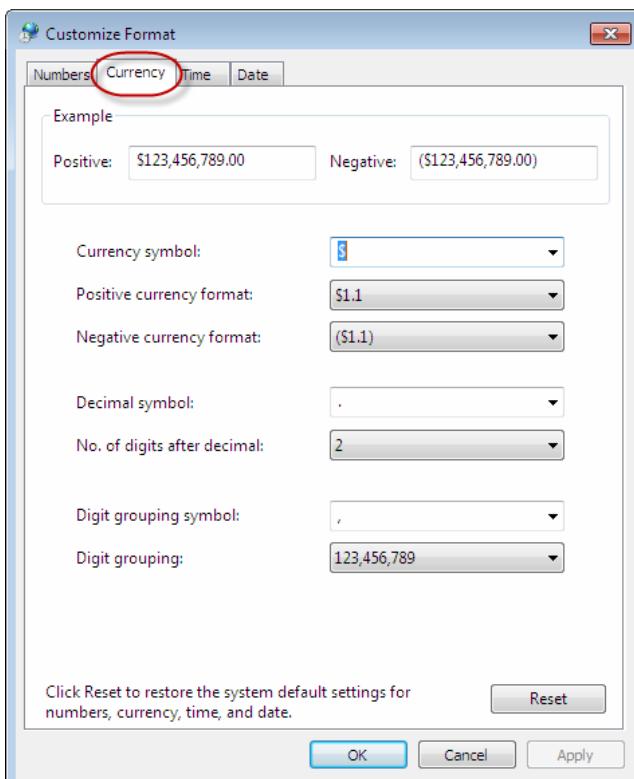
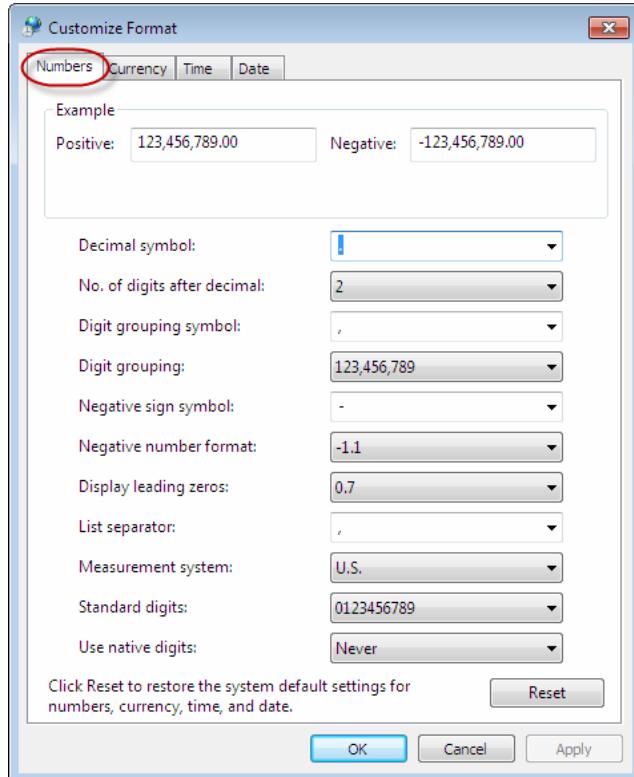
Go to **Settings > Control Panel > Clock, Regional and Language Options > Change the date, time and number format.**



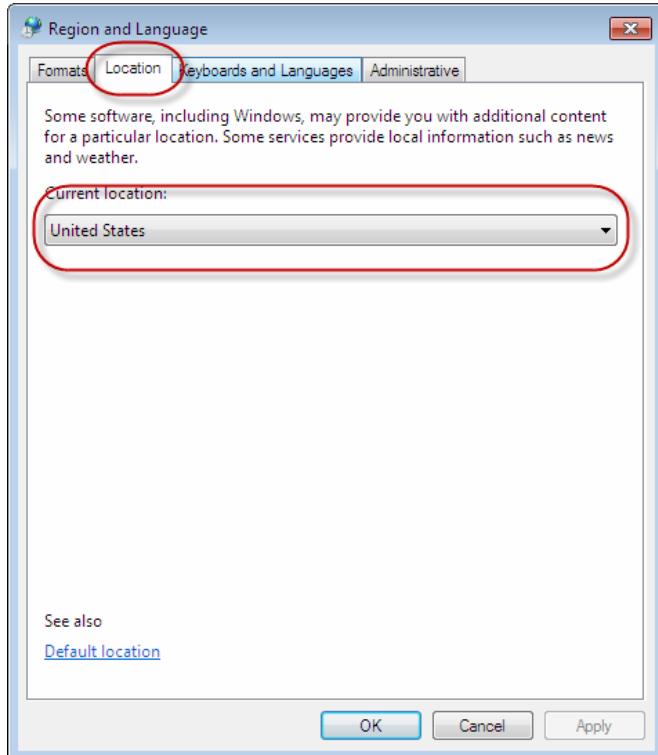
a. Following should be the settings for **Formats** tab:



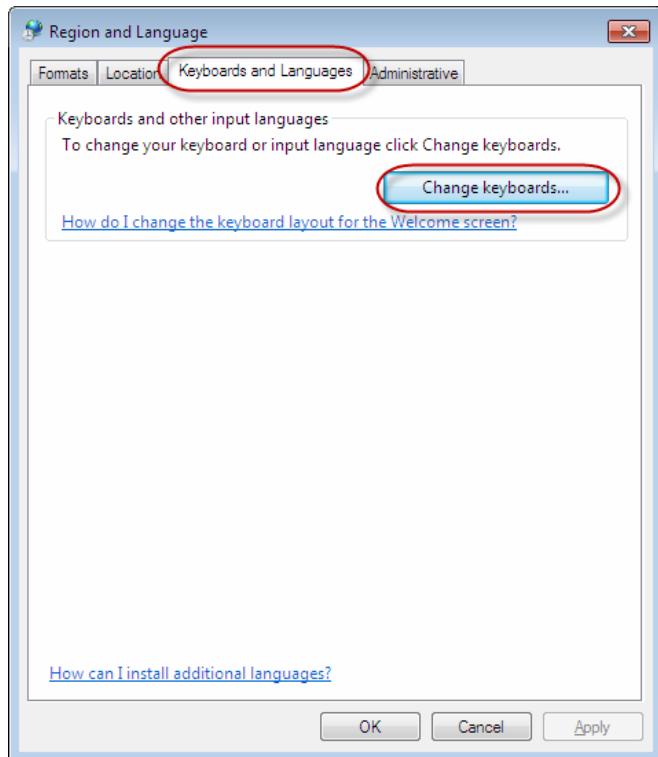
b. To set Number and Currency Click on **Additional settings**



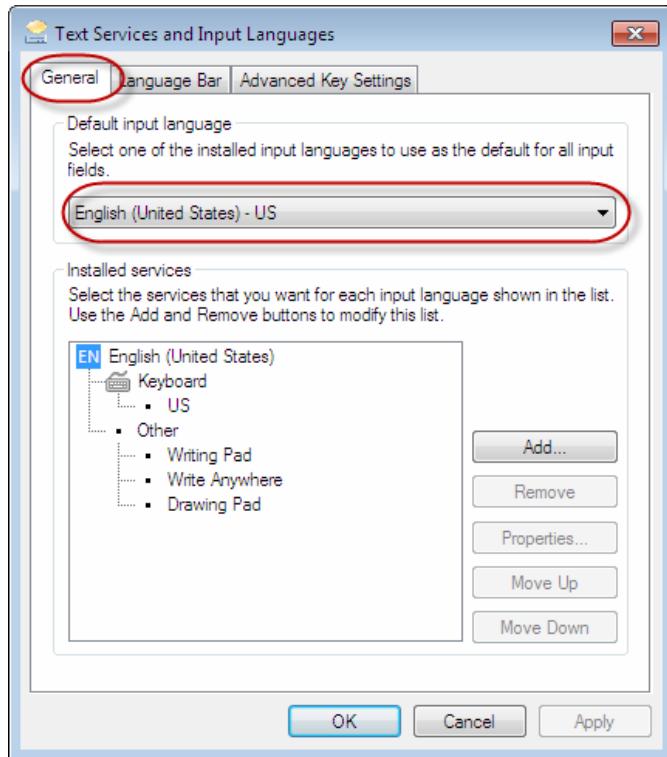
c. Following should be the **Location** tab:



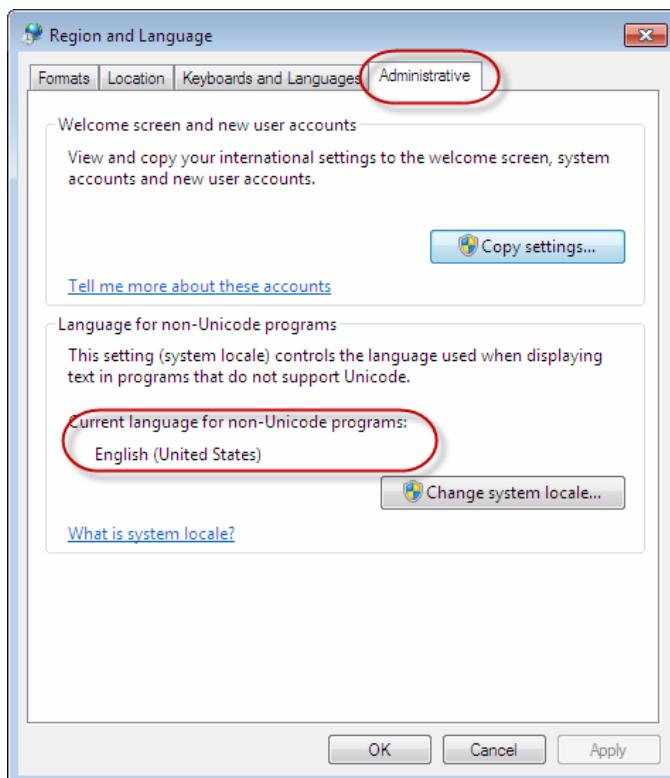
d. Following should be the **Language** tab.



e. Click on **Change Keyboards** following screen will display:



f. Following should be the settings for **Administrative** tab:



## 4.6.3. Installing MultiXL Software

Follow the instructions in this section in case you are installing the application software for the first time on the computer i.e. there is no previous installation of the software on that computer.

Refer to section *4.6.4 Upgrading MultiXL Software*, to upgrade software from existing version to the new higher version.

### 4.6.3.1. Installing MultiXL

Follow these instruction for installing the application:

1. Insert the Software Installation CD into the CD drive of the analyzer PC. On inserting the CD, the MultiXL Installation screen will be displayed.

**Or**

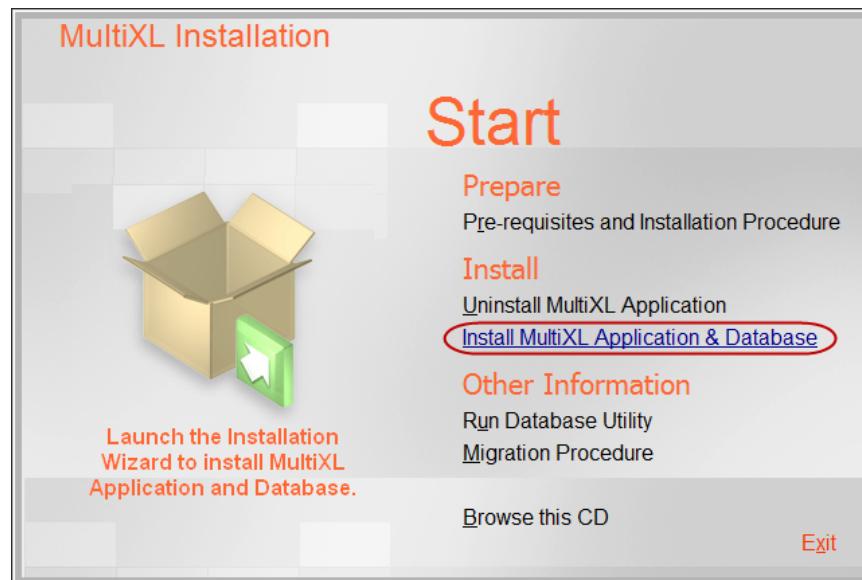
Go to **Windows Explorer**. Right-click on CD/DVD ROM-Drive. Click on **AutoPlay** option.



**Or**

Go to **Windows Explorer**. Right-click on CD/DVD ROM-Drive. Click on **Explore** and double-click on **Launcher.bat**.

The following screen will be displayed.

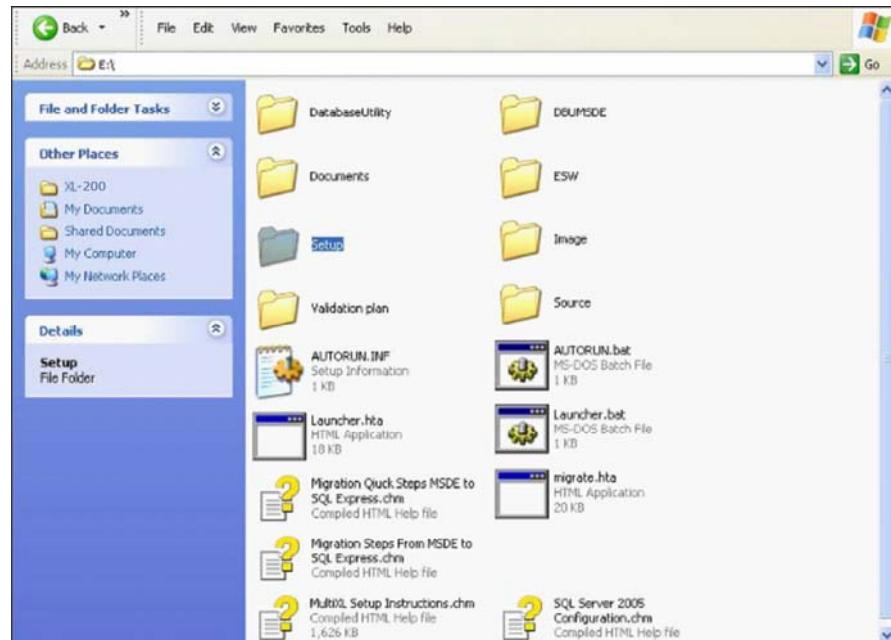


2. Click on **Install MultiXL Application & Database** link and follow the on-screen instructions.

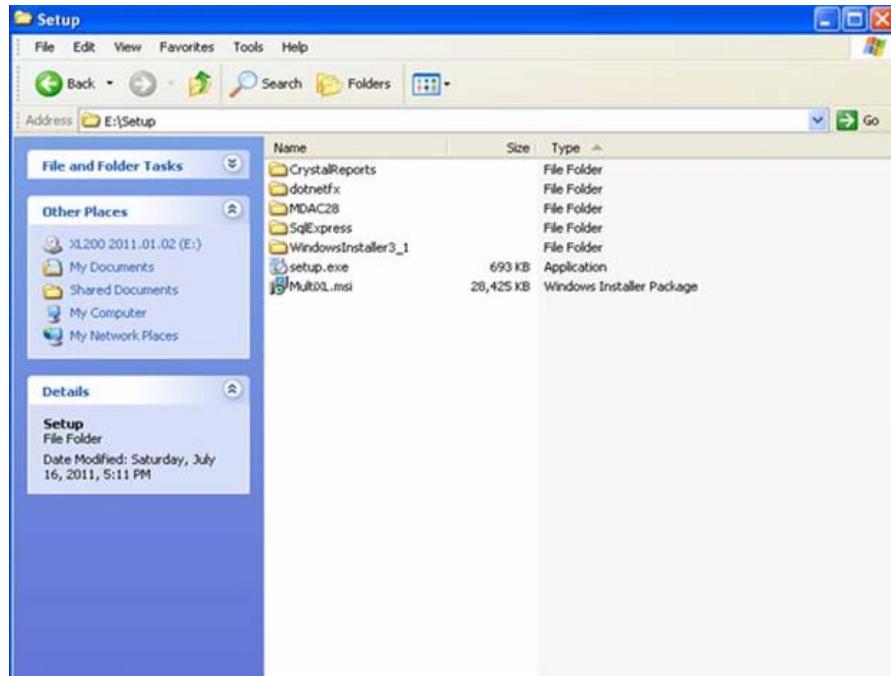
Or

Click on the **Browse this CD** link.

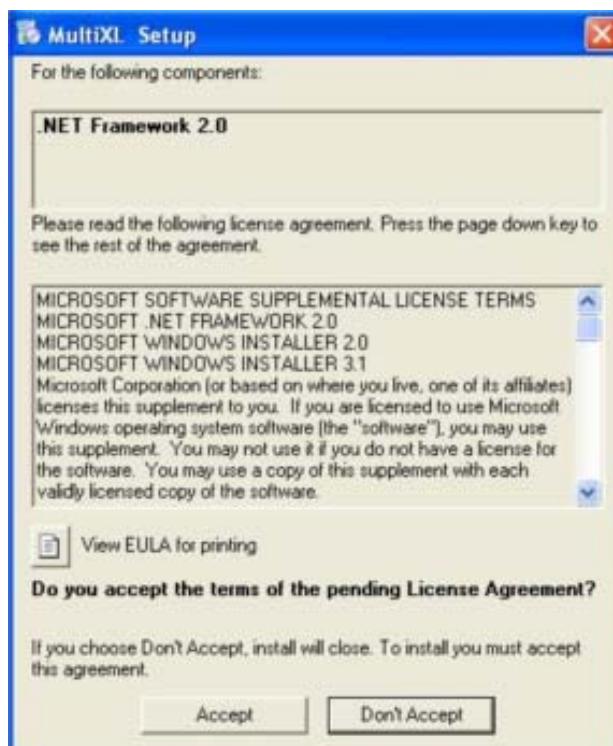
The software installation CD contains the folders and files as shown in the figure below:



3. Open **Setup** folder, and double-click on the **setup.exe**.



On clicking, the following screen will be displayed.



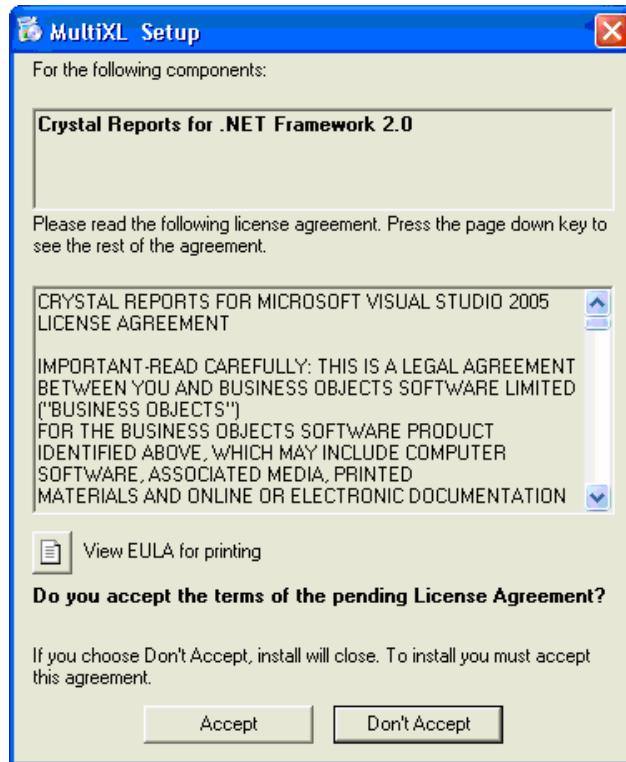
---

**NOTE: This screen will not be displayed if .NET framework 2 is already installed on your computer.**

---

4. Click **Accept** to continue.

On clicking, the following screen will be displayed.



---

**NOTE: This screen will not be displayed if Crystal Reports for .NET framework 2.0 is already installed on your computer.**

---

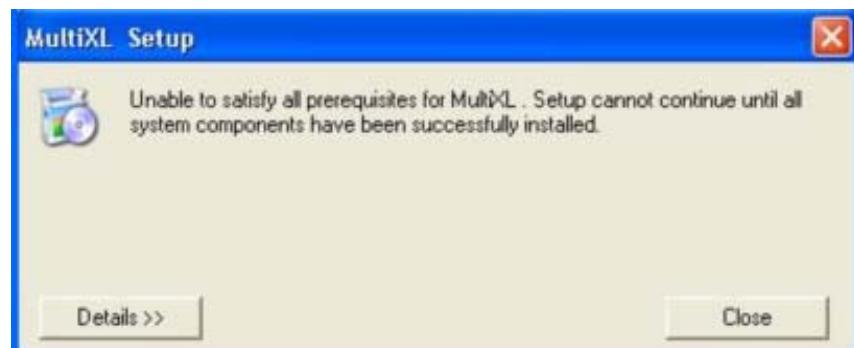
5. Click **Accept** to continue.

On clicking, the following screen will be displayed.



**NOTE: This screen will not be displayed if SQL Server 2005 Express Edition is already installed on the analyzer computer.**

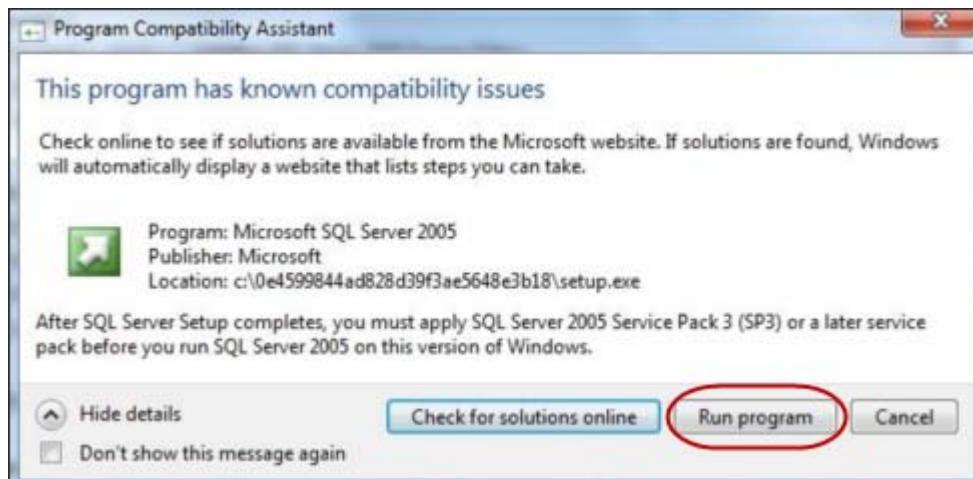
In case, Microsoft SQL Server Desktop Engine (MSDE) is already installed then the following screen will be displayed. The installer will not proceed with the MultiXL installation.



Click on **Close** and uninstall the Microsoft SQL Server Desktop Engine from **Control Panel > Add / Remove Program**. Then start the MultiXL installation again.

Please refer to Migration Guide for Database Engine, MSDE to SQL Server Express 2005 from the Installation CD, namely "Migration Steps from MSDE to SQL Express.chm".

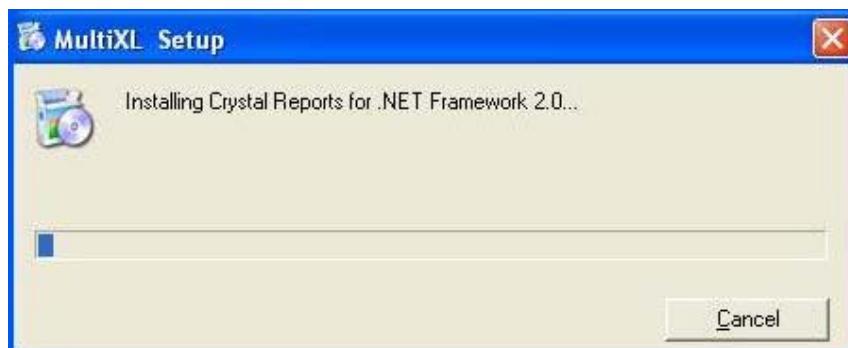
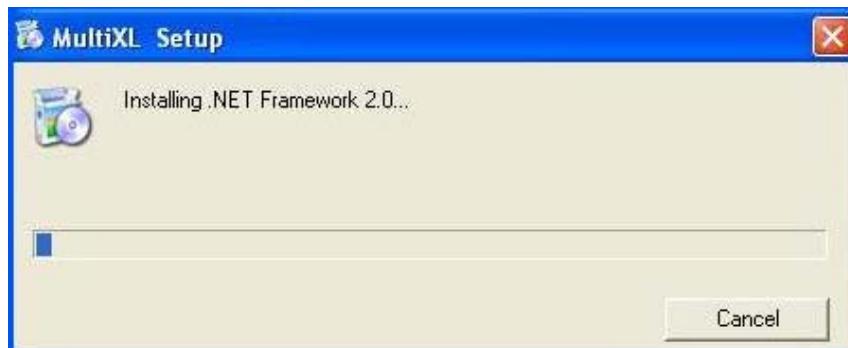
In case of Windows 7 operating system, following screen may appear while installing MultiXL Application. Please click on **Run Program** button to continue with MultiXL Installation.

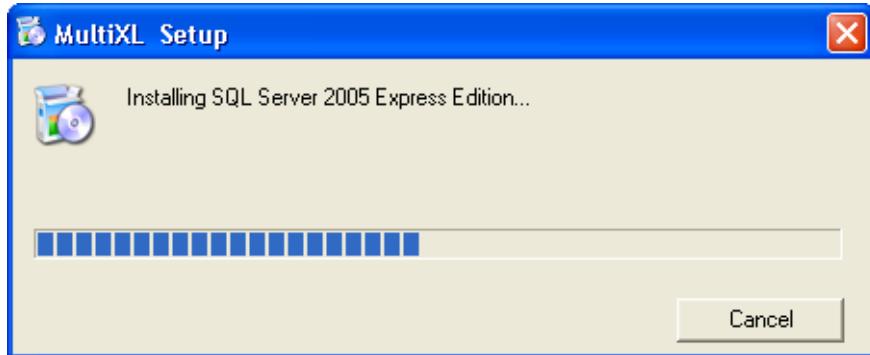


**NOTE: It is not necessary to apply SQL Server 2005 Service Pack 3 (SP3) or later Service Pack as shown in the above screenshot.**

---

On clicking, the following screens will be displayed in a sequence.



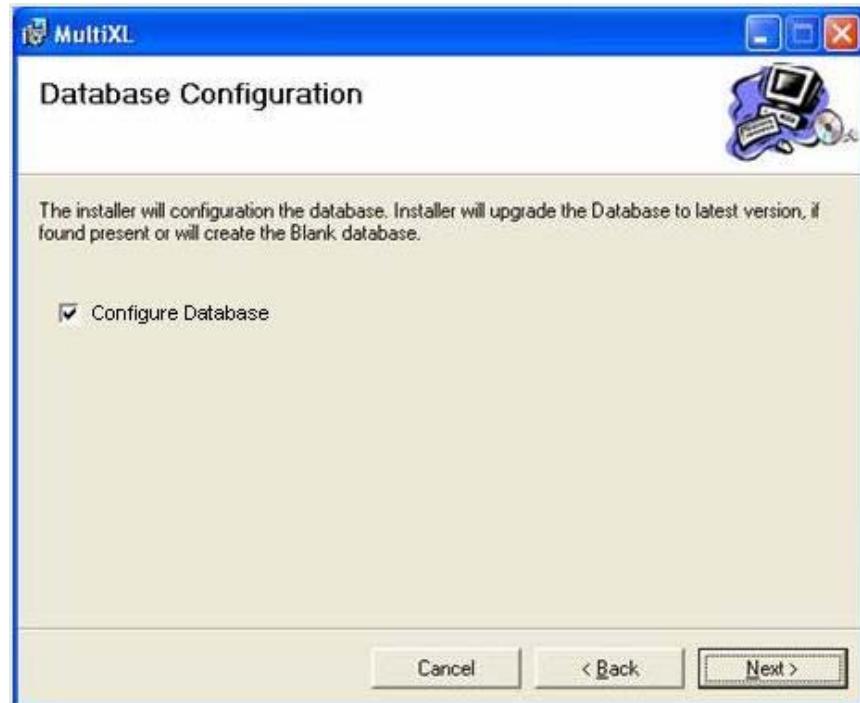


Wait until the setup wizard is visible on the screen as shown below.



**6. Click **Next**.**

On clicking, the following window will be displayed.



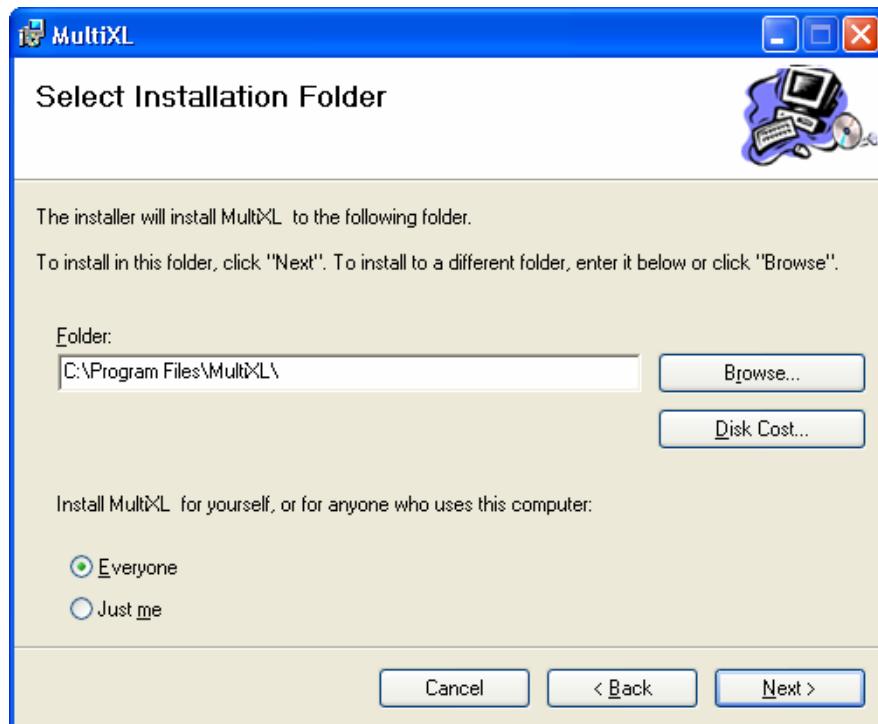
On keeping **Configure Database** checkbox checked (ticked), the installer will create or upgrade the database along with the installation of MultiXL.

(In case, the Database is found present then the existing database will be upgraded to the latest version. When the Database is not found then the installer will create a blank Database).

In case, **Configure Database** option is unchecked; the installer will not create/upgrade the database and you have to install it manually. Refer section [4.6.3.2.1 Installing Blank Database](#) for more details.

7. Click **Next**.

The following screen will be displayed.



The installer will install the software in the default location **C:\Program Files\MultiXL\**.



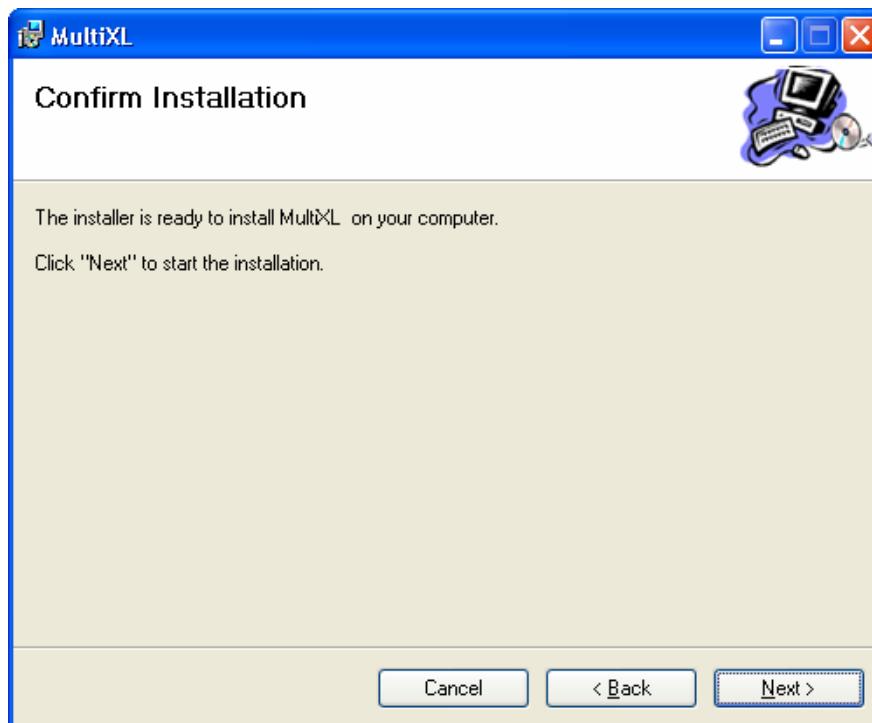
---

**NOTE: The installation in a location, different from the default one, is not recommendable.**

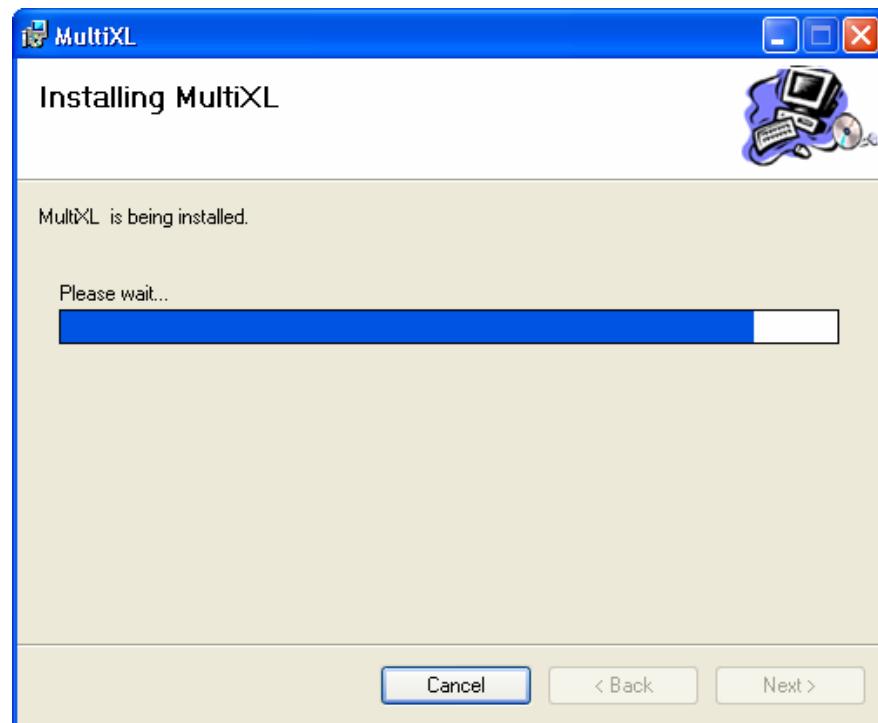
---

8. Ensure that “Everyone” is selected, and click **Next**.

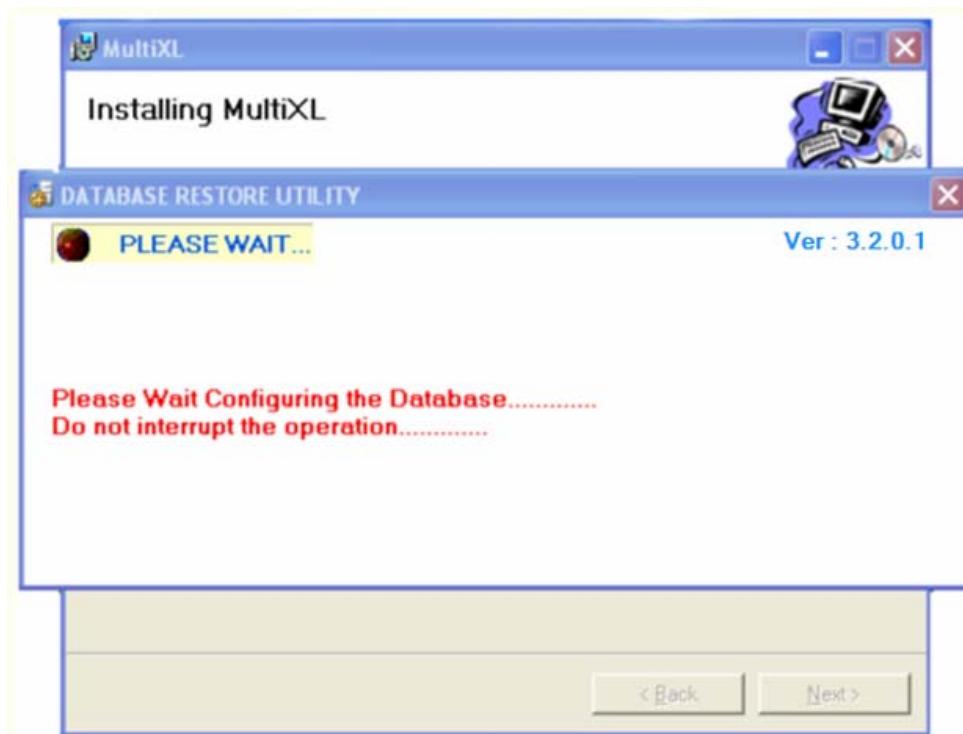
On clicking, the following window will be displayed. Click **Next** to confirm the installation.



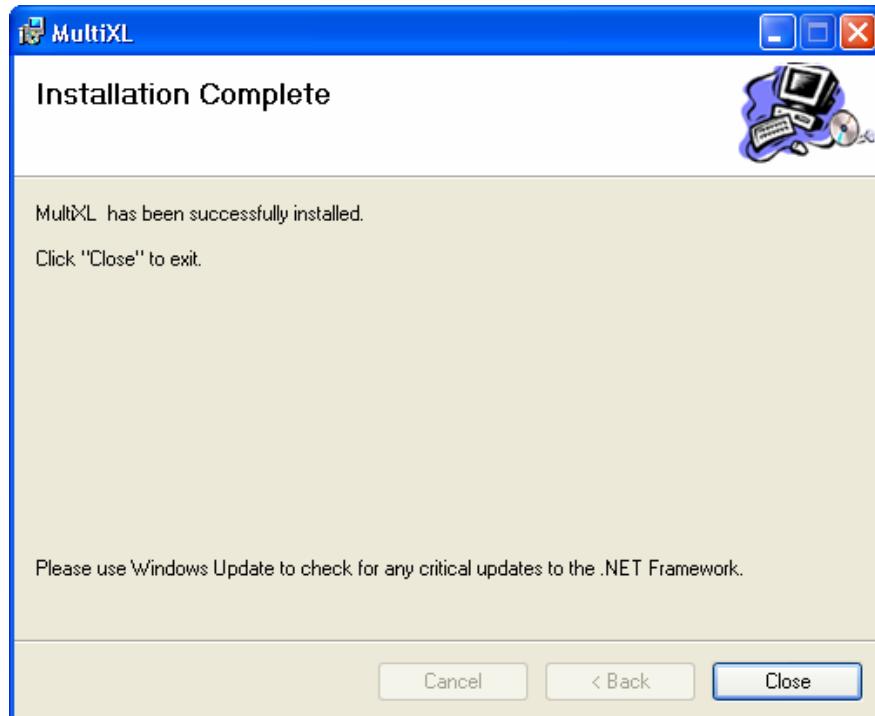
9. On clicking **Next**, the installation is started and the status will be displayed, as shown below.



The following screen will be displayed if the **Configure Database** option is selected.



Once the above operation is completed, the software icon will be created on the desktop and the **Installation Complete** screen will be displayed



10. Click on **Close** to close the screen and restart the computer.
11. Now double click on the icon from the desktop or choose **Start > All Programs > MultiXL** to start the application.



---

**NOTE: The Detect Regional Settings screen will be displayed and the application halts in case, if the language setting is other than English (United States).**

---



See section *4.6.2.3 Regional and Language Settings for Windows XP* in more details.

For Windows 7 operating system, refer section *4.6.2.5 Regional and Language Settings for Windows 7*.

#### 4.6.3.2. Installing Database

---



**Warning: The installation and restoring database should be performed by the trained person only.**

---

Database installation is required only if the **Configure Database** option was deselected (unchecked) during installation (Refer step 6 of section *Installing MultiXL*).

In case, Configure Database option is selected (ticked by default) during Software Installation then the Database will be created / upgraded automatically as part of installation. (Database, when already exists, will be upgraded to the latest version. When database is not found on PC, then the installer will create a blank database).

In case, the Configure Database option is not selected, then the database should be installed manually, as follows.

Refer to the folder Database Utility in the CD, which consists of DatabaseUtility.exe for installing (restoring) the Database file MultiXL.BKP.

See section 4.6.3.2.1 *Installing Blank Database* for more details.



---

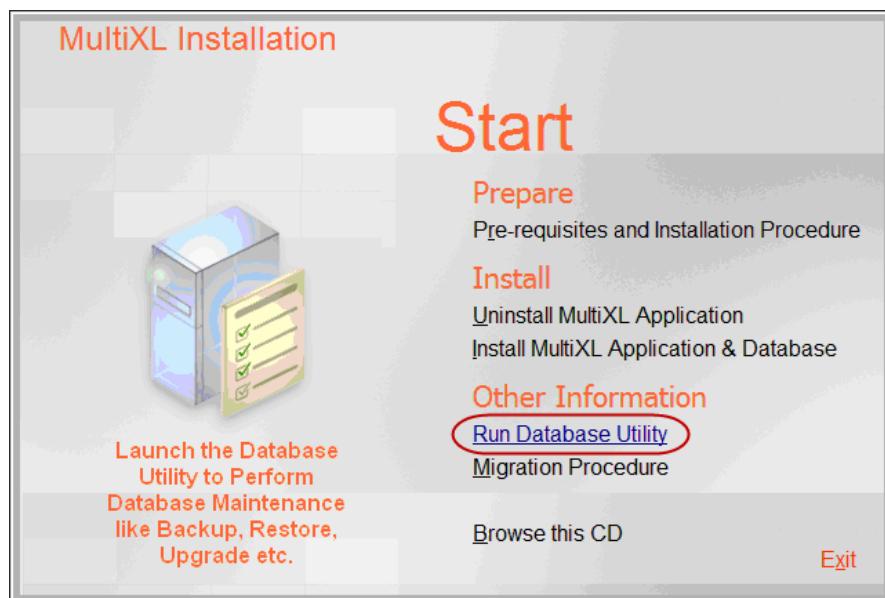
**NOTE: If you are getting “Operating System error 5 (Access denied)” while performing the above mention steps then refer SQL Server 2005 Configuration.chm file for SQL Server 2005 Settings.**

---

#### 4.6.3.2.1. Installing Blank Database

For installing the Blank Database from Software CD, use the following instructions:

1. Click on **Run Database Utility** from the MultiXL installation screen as shown below.

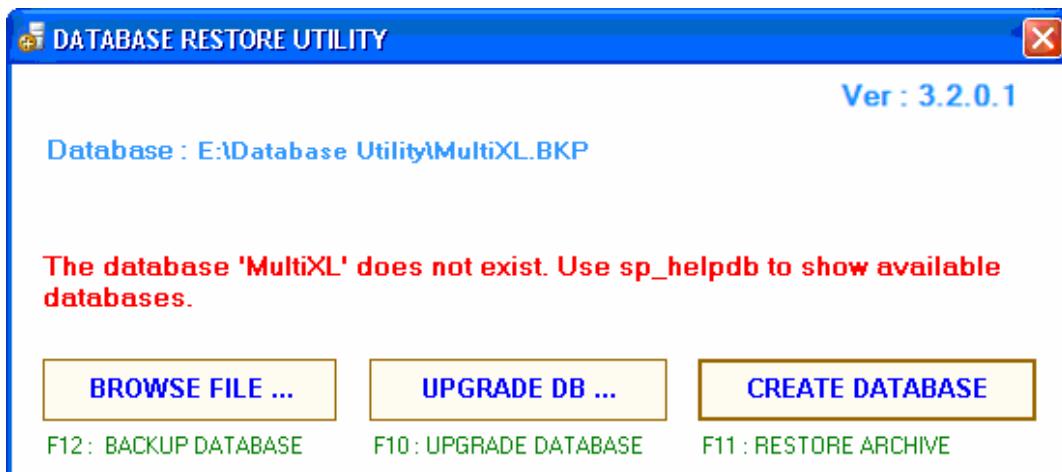


Or

Open the **Database Utility** folder from the software installation CD, and double-click **DatabaseUtility.exe**.

2. Click on **CHECK DATABASE**.

This command will check for the existing database on your computer. If no database is available, a message is displayed on the following screen.



3. Click on **CREATE DATABASE**.

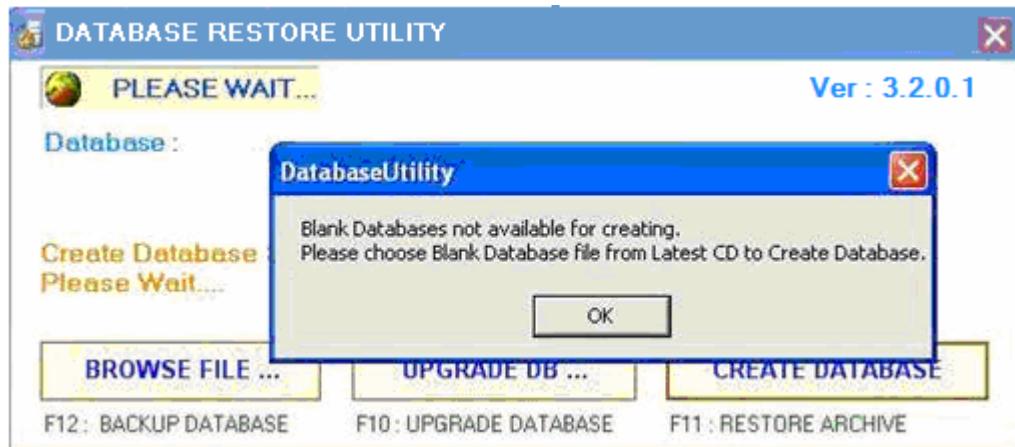
This will create the database from the location specified on the screen. This is the default location where the blank database is stored in software installation CD.

(To restore the backup of new database, you need to change the location using BROWSE FILE button. Refer section 4.6.5.2.2 Restoring Backup of New Database in more details).

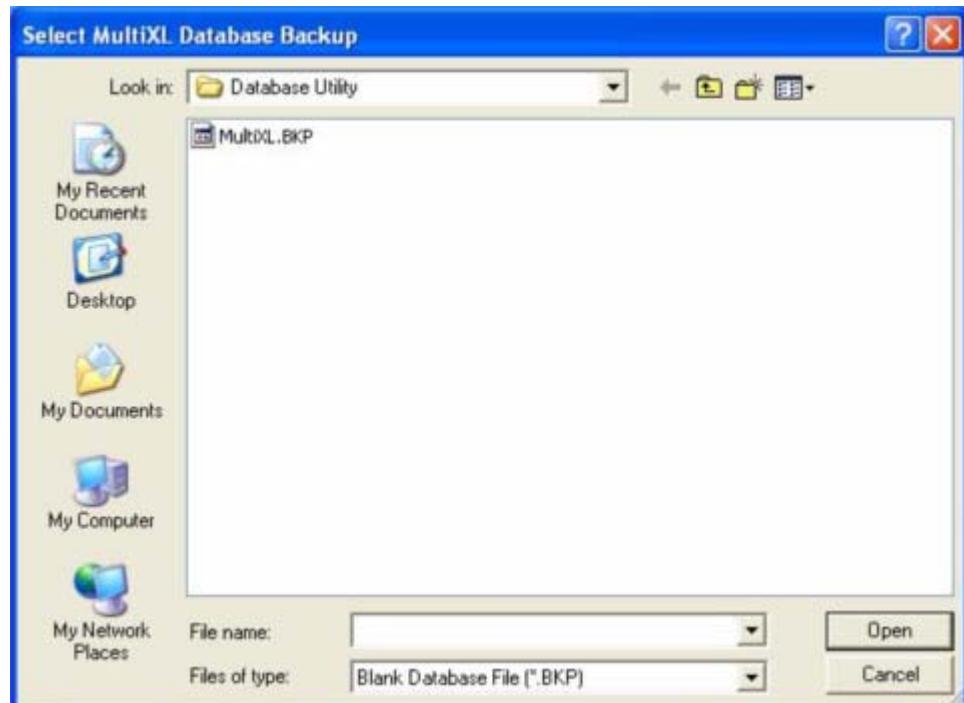
For example, in the above screen, the database location is E:\Database Utility\MultiXL BKP.



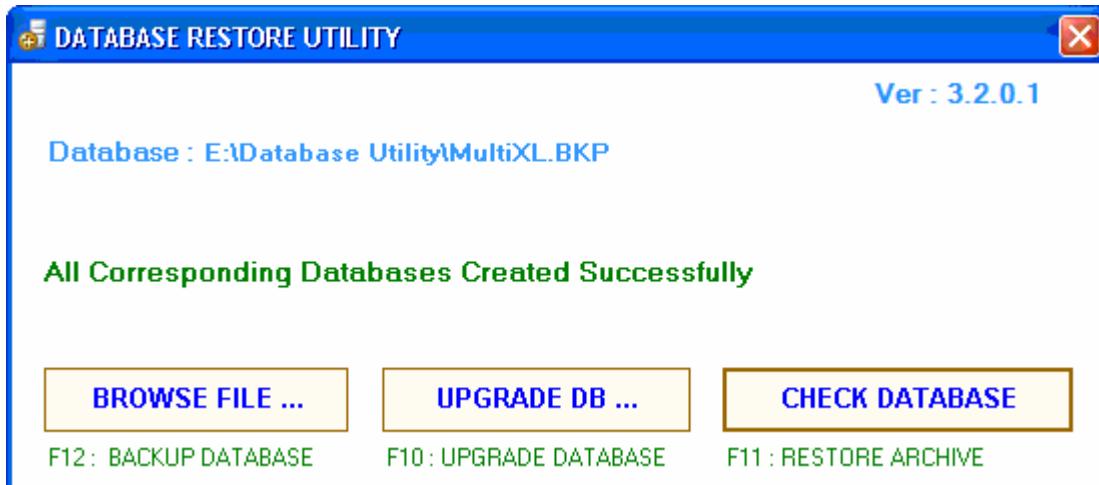
If Archive is not available then utility will ask for Blank Database location and the following window will be displayed.



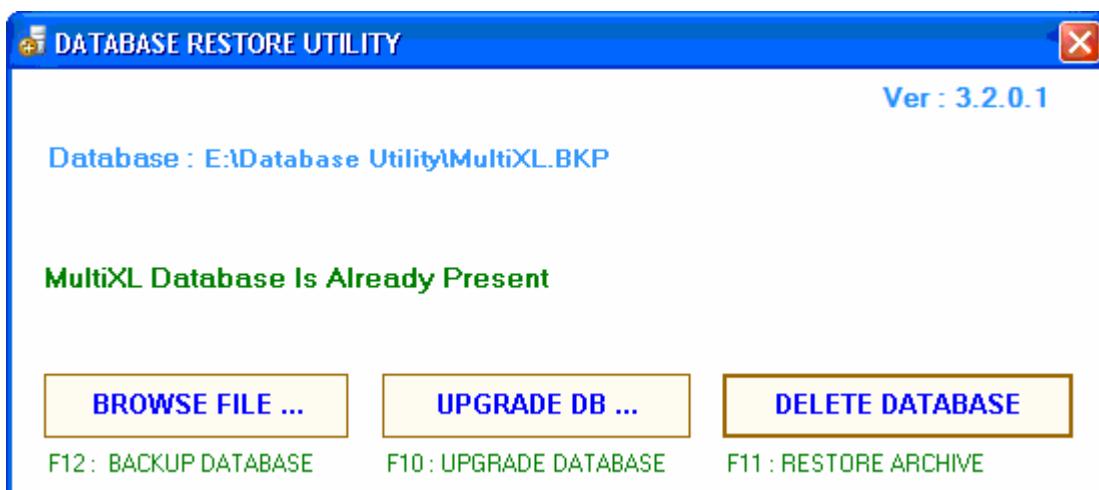
4. Now click **OK** and select the blank database file **MultiXL.BKP** from the software CD, and then click **Open**.



After some time, the database will be created successfully and the following screen will be displayed.



5. Once the database is created, click **CHECK DATABASE** to ensure the proper creation of the database. The following screen will be displayed.



6. The above screen indicates that the database is installed successfully. Click **Close** to exit from the utility screen.
7. Now you can access the MultiXL application. Refer section *4.6.6 Accessing MultiXL Software* for more details.

#### 4.6.4. Upgrading MultiXL Software

If the MultiXL software is already installed on the analyzer computer and you receive a newer version of software, then the following steps should be performed:

- Upgrade MultiXL Software
- Upgrade MultiXL Database



**Caution: Take a database backup, before proceeding with software upgrade.**

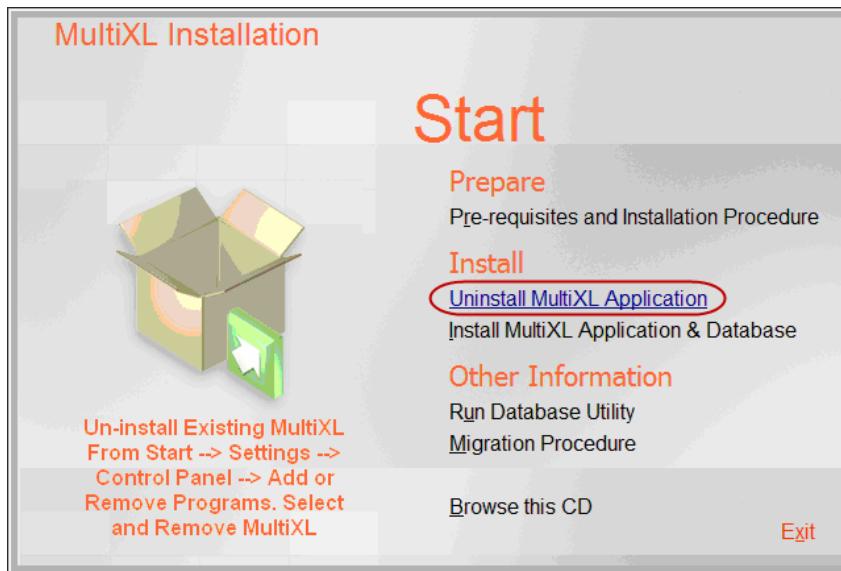
##### 4.6.4.1. Upgrade Software

You can upgrade the software version by un-installing the existing software version from the PC and installing the newer version from the CD as follows.

#### 4.6.4.1.1. Un-installing Software

To un-install the software, do one of the following:

1. Click on the **Uninstall MultiXL Application** from the MultiXL Installation screen as shown below.



Or

Go to **Start > Settings > Control Panel**. In the **Control Panel**, double click on **Add or Remove Programs**. This method is used only, if you are using Windows XP operating system.

For Windows 7 operating systems, click **Start** button on the desktop, under **Category** view, go to **Control Panel > Programs > Programs and Features**.

2. Select the **MultiXL** software, and then click **Remove**.

On clicking, the software will be removed from the computer.



---

**NOTE: To uninstall the MultiXL software you must be logged on as user “Administrator”.**

---

#### 4.6.4.1.2. Installing Software - New Version

Refer section *4.6.3.1 Installing MultiXL* for more details.

#### 4.6.4.2. Upgrade Database

Upgrade the database using the software CD of the newer version whenever you install the new software version.

Database can be upgraded to match the newer software version without deleting the database of the existing version.

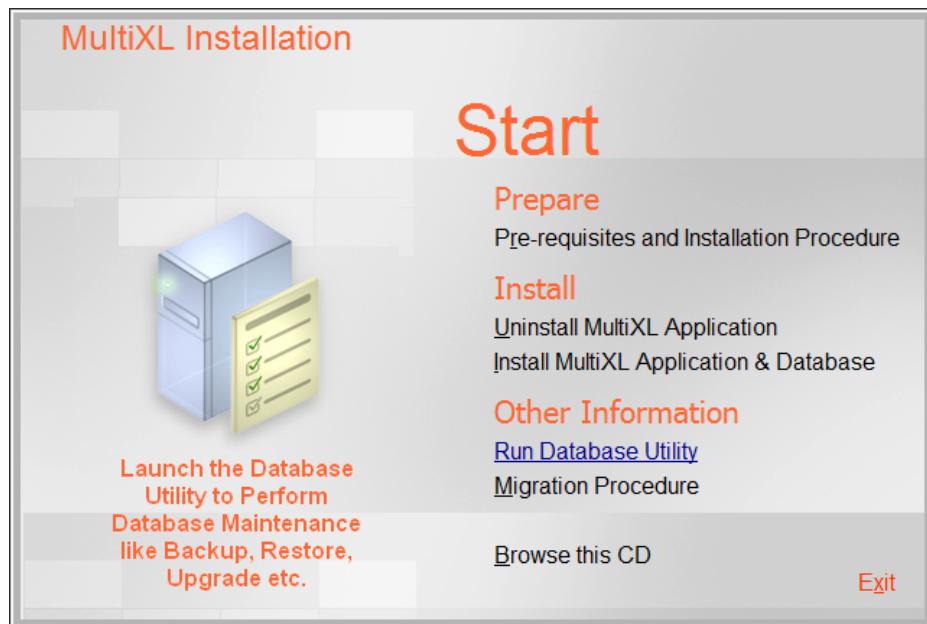


**NOTE: Ensure to take Database backup before upgrading the Database.**

#### 4.6.4.2.1. Upgrading Database

Follow these instructions for upgrading the database:

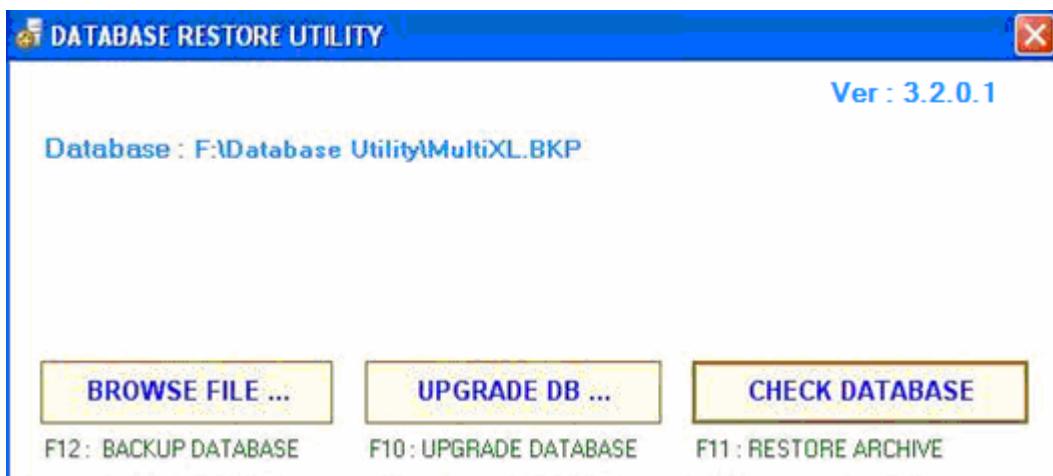
1. Click on the **Run Database Utility** link from MultiXL Installation screen as shown below.



Or

Open the **Database Utility** folder from the software installation CD. Double-click on **DatabaseUtility.exe**.

2. Click **UPGRADE DB**.

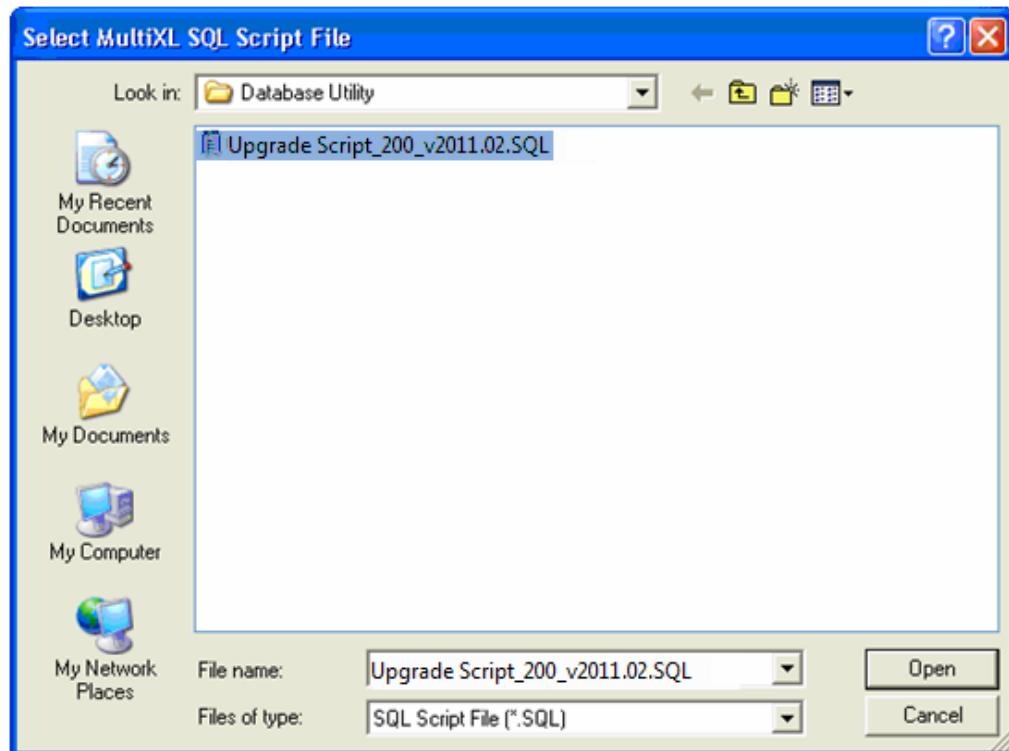


On clicking, the system prompt to select the upgrade script file, as shown in the following screen

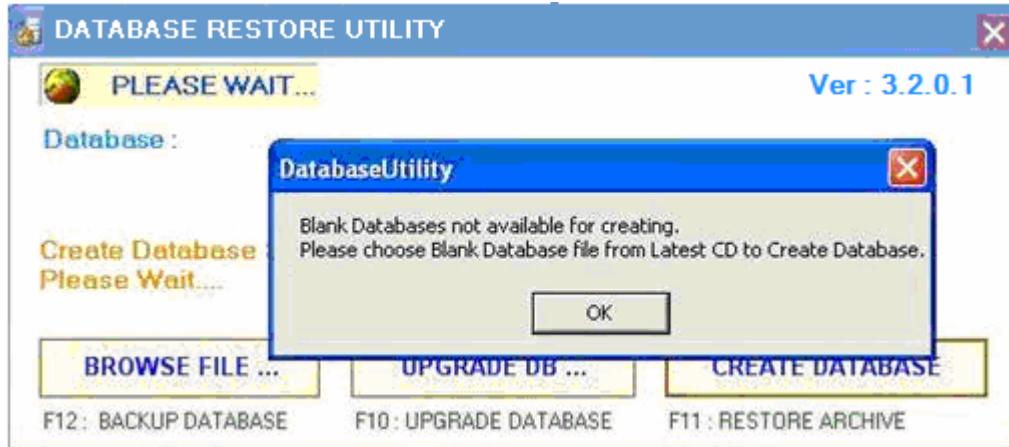
Select the upgrade script file from the software CD, and then click **Open**.



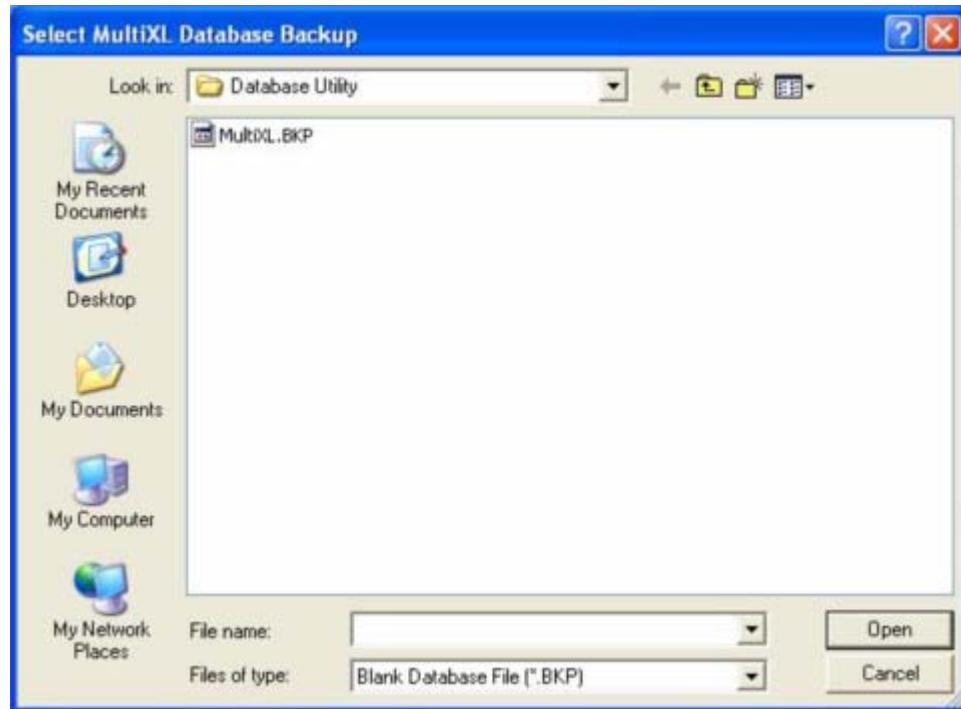
**NOTE: The upgrade script file is provided in the application software CD in the Database Utility folder.**



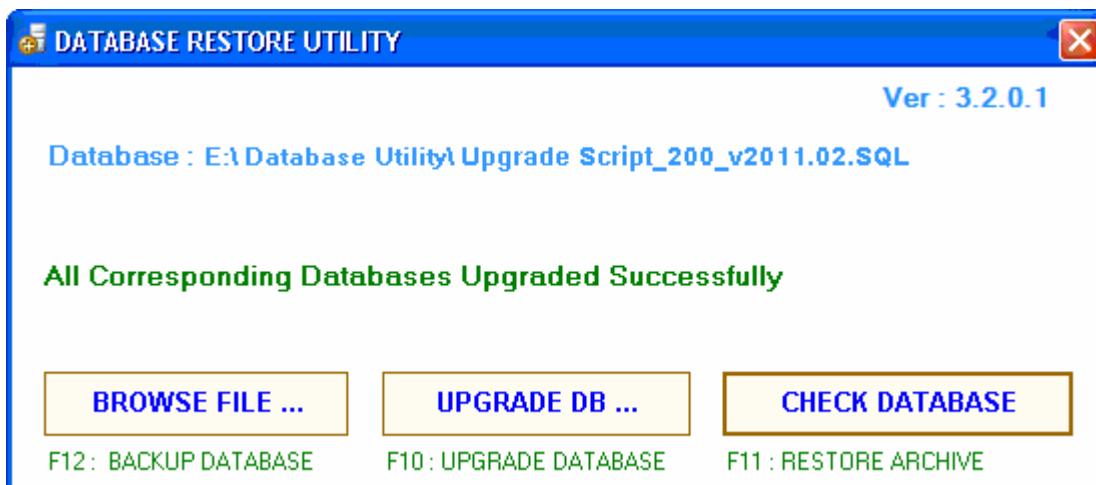
On clicking, the upgrade process starts. If archive Database is not available then the utility will prompt to select the path for Blank Database and the following screen will be displayed.



3. Click **OK** and select the blank database file **MultiXL.BKP** from the software CD, and then click **Open**.



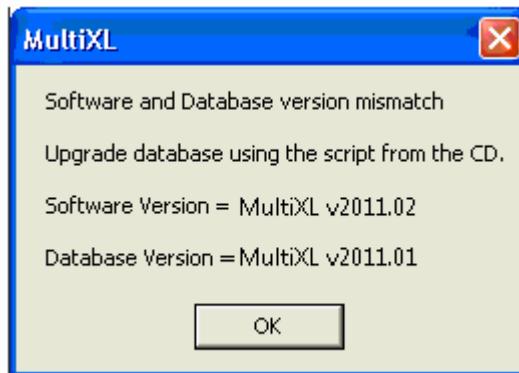
After some time, the database will be upgraded successfully and the following screen will be displayed.



4. Click to close the database utility screen.
5. Now you can access the MultiXL application. Refer section 4.6.6 Accessing MultiXL software for more details.



**NOTE: After installing the new software version, if the database is not upgraded using the upgrade script file provided in the Software CD then the following screen will be displayed on starting the application software. This screen indicates the software and database version mismatch.**



---

In case, the software and database version mismatch screen is displayed; upgrade the database using the script file, provided in the software CD. Refer section software CD. Refer section *4.6.4.2.1 Upgrading Database* for more details.

## 4.6.5. Database Utility Options

The Database Utility can be used to take the Database Backup or change the Database.

### 4.6.5.1. Database Backup

Follow these instructions for taking the backup of database:

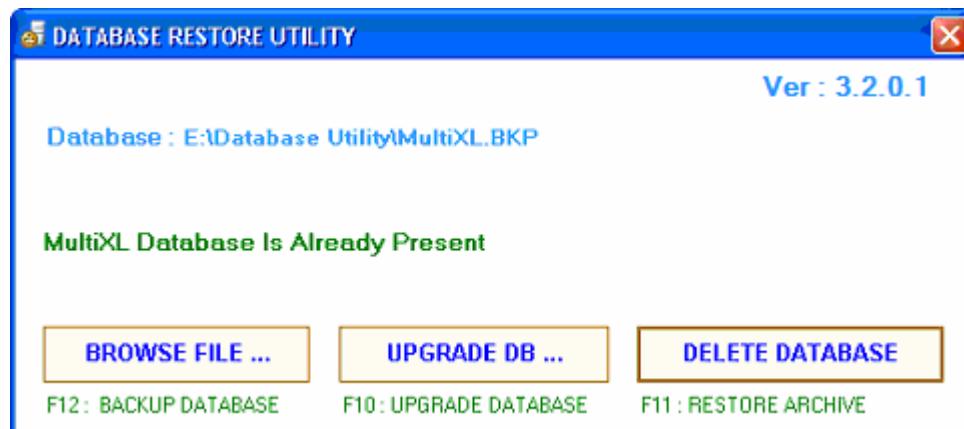
1. Click on **Run Database Utility** from the MultiXL Installation screen.

**Or**

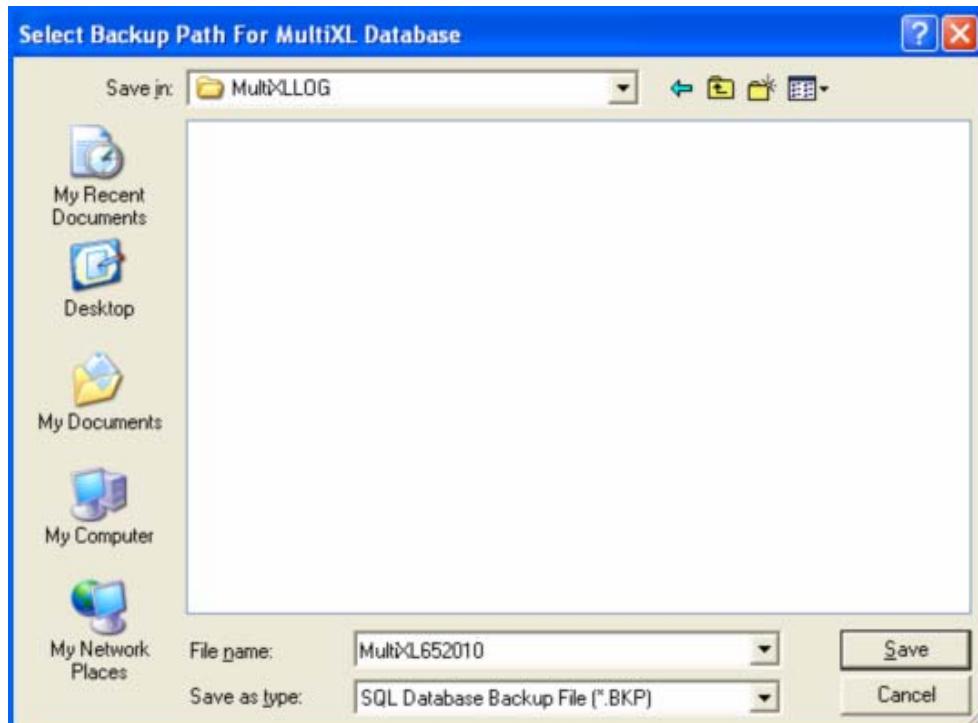
Open **Database Utility** folder from the software installation CD, and double-click **DatabaseUtility.exe**.

2. Click on **CHECK DATABASE**.

The following screen will be displayed.



3. Press **F12** key. The following screen will be displayed.



4. Choose the path to store the backup, and then click **Save**.

On clicking, the following screen will be displayed to confirm the successful completion of backup database.



If archive database is present then backup will be stored with “ARH” extension with the same default file name.

For example: In this case archive backup will be stored on the same path with default file name “MultiXL652010.ARH”. The default file name contains “MultiXL” (the application name), followed by date, month and year.

#### 4.6.5.2. Change Database

In case, if you wish to change the database, you must delete the existing database and then restore the backup of another database using database utility,



**NOTE: It is recommended to change the database with proper guidance of expert service engineer. Improper installation may impact the calibration of the analyzer, in addition to loss of data such as QC data and chemistry calibration.**



**NOTE: Before installation, you should take the backup of the database before deleting or changing the database.**

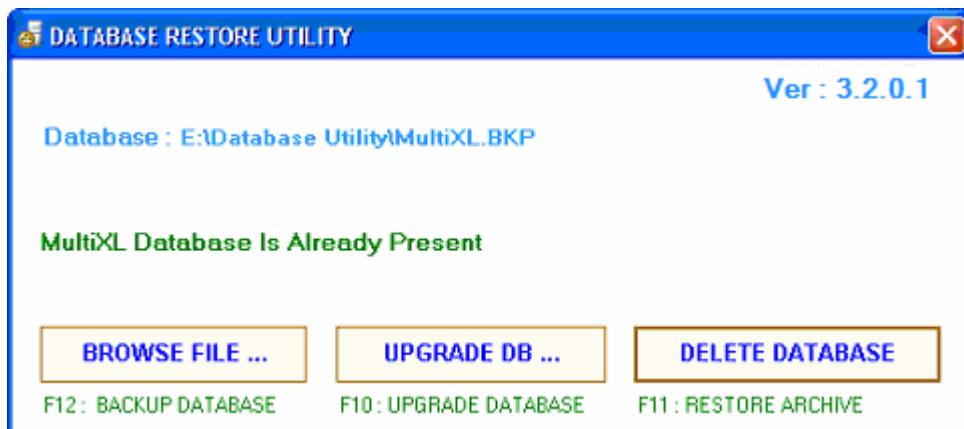
Database can be changed in two parts:

1. Delete (existing) Database.
2. Restore Backup of another Database.

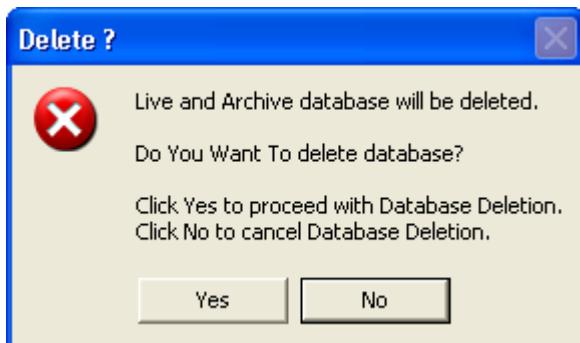
##### 4.6.5.2.1. Deleting existing database

Follow these instructions for deleting the database:

1. Click on the **Run Database Utility** from the MultiXL Installation screen.  
**Or**  
Open the **Database Utility** folder from the software installation CD, and double-click **DatabaseUtility.exe**.
2. Click on **CHECK DATABASE** to check whether the database is present.

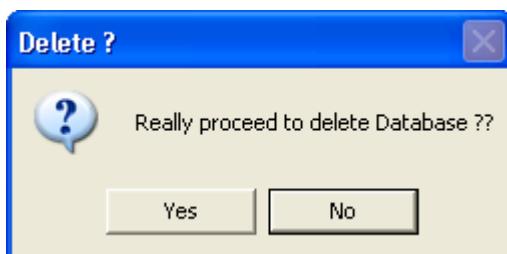


3. Click on **DELETE DATABASE** to delete the existing database. The following screen will be displayed.



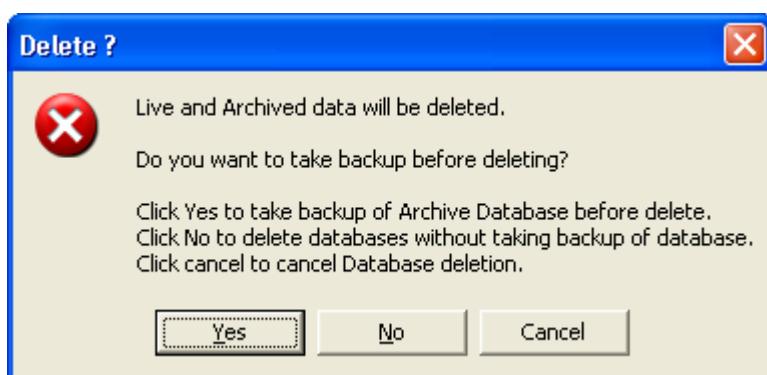
4. Click on **Yes** to continue with database deletion.

On clicking, the warning message will be displayed to re-confirm the deletion.



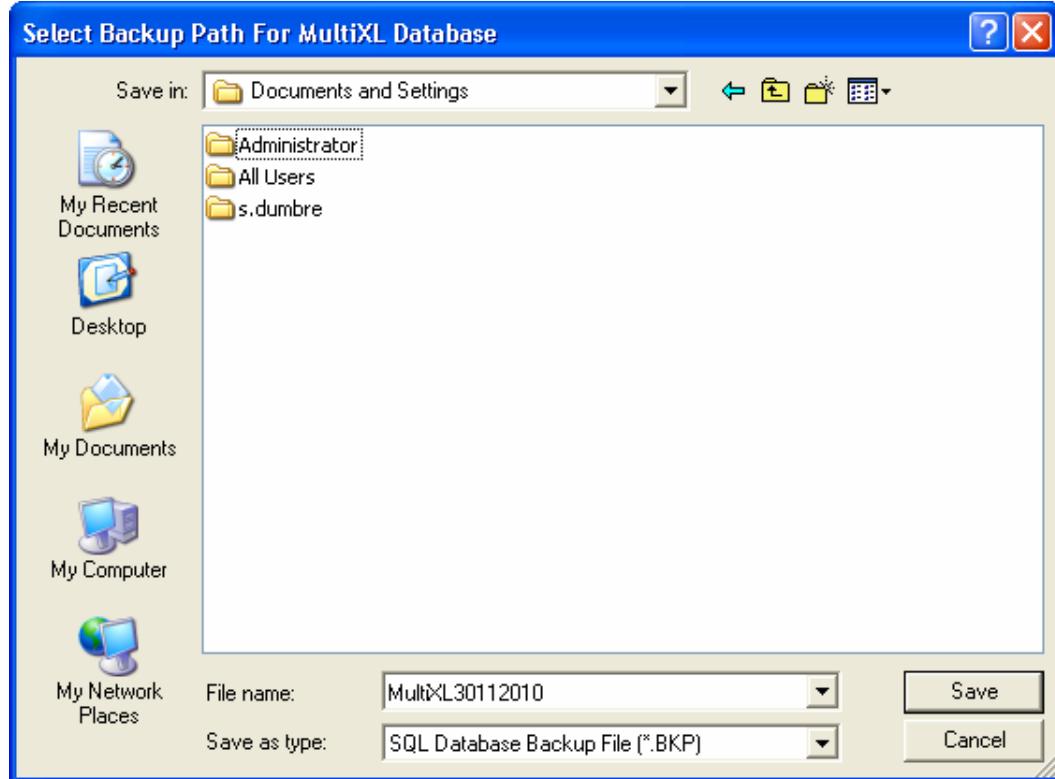
5. Click **Yes** to continue

On clicking, a message will be displayed to take the database backup before deletion.



6. Click **Yes** to take the backup.

The following window will be displayed. Select the appropriate location for saving the backup database.



**NOTE: On clicking No, the Live and Archive data will be deleted without taking the database backup.**

**Best Practice: Backup database before deleting the same.**

7. Click **Save** to save the database.

The following screen will be displayed after successful deletion of the database.



#### 4.6.5.2.2. Restoring backup of new database

1. Click on **Run Database Utility** from the MultiXL Installation screen.

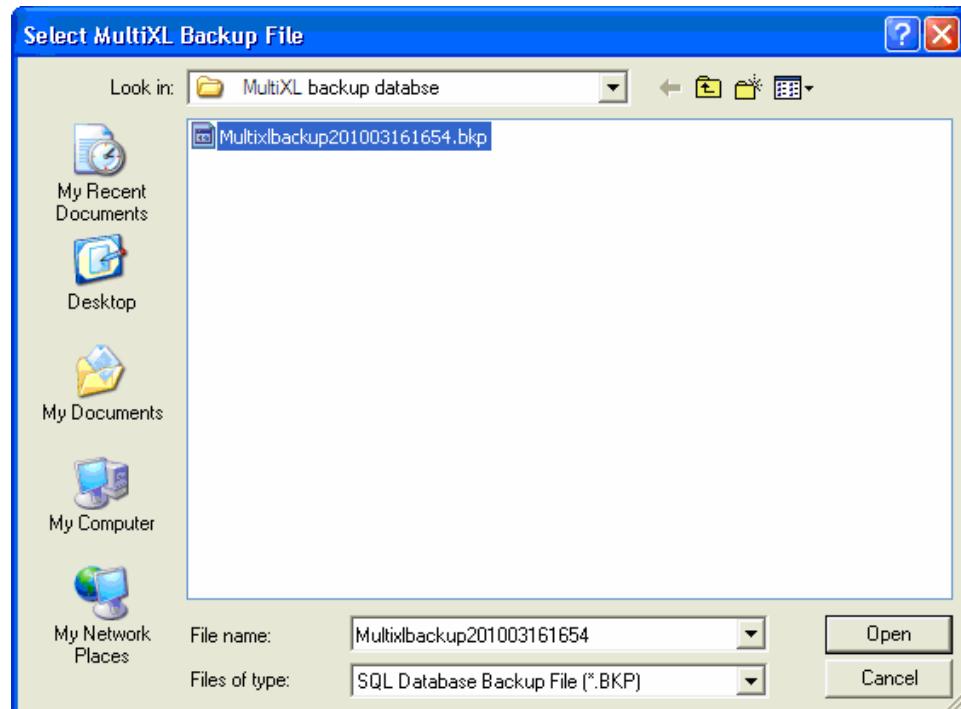
Or

Open **Database Utility** folder from the software installation CD. Double-click **DatabaseUtility.exe**.

2. Click on **CHECK DATABASE**.

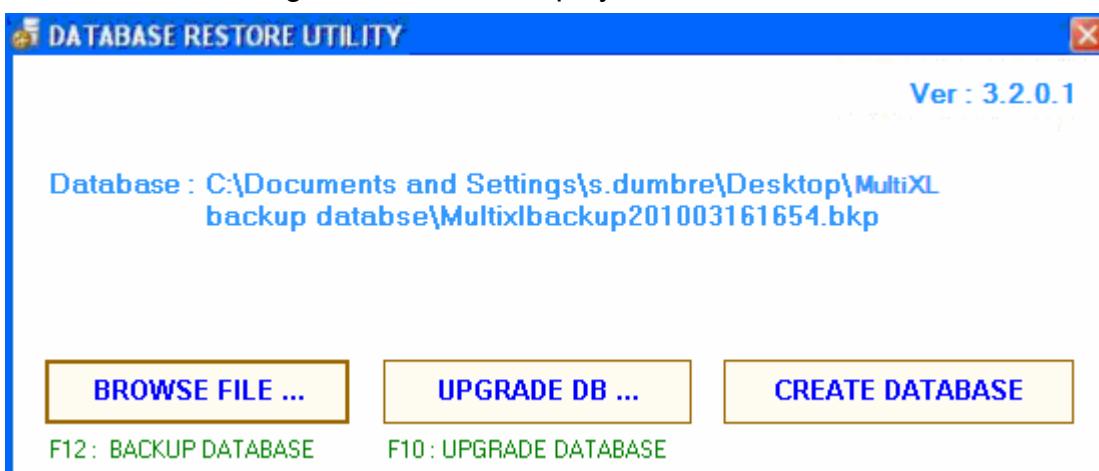
3. Now, click on the **BROWSE FILE**.

Select the location where the backup database file is saved.



4. Select the database file and then click **Open**.

The following screen will be displayed.

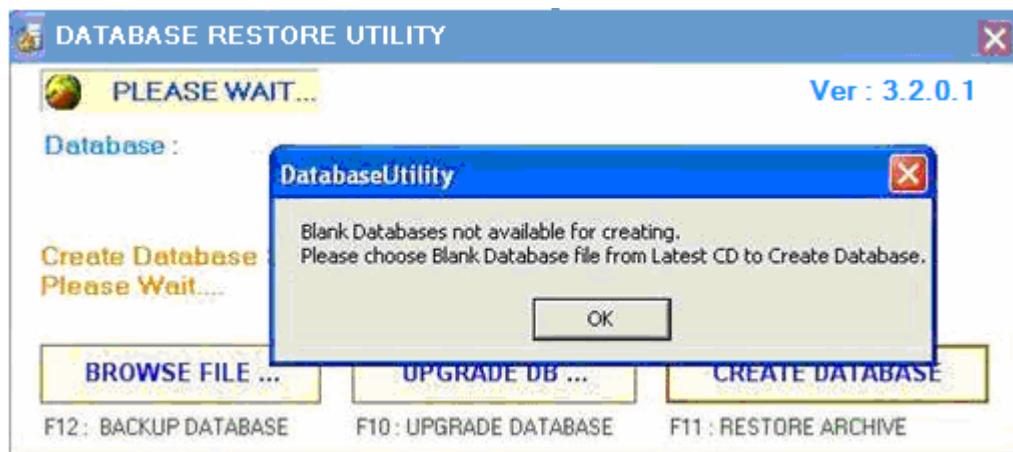


5. Click on **CREATE DATABASE**.

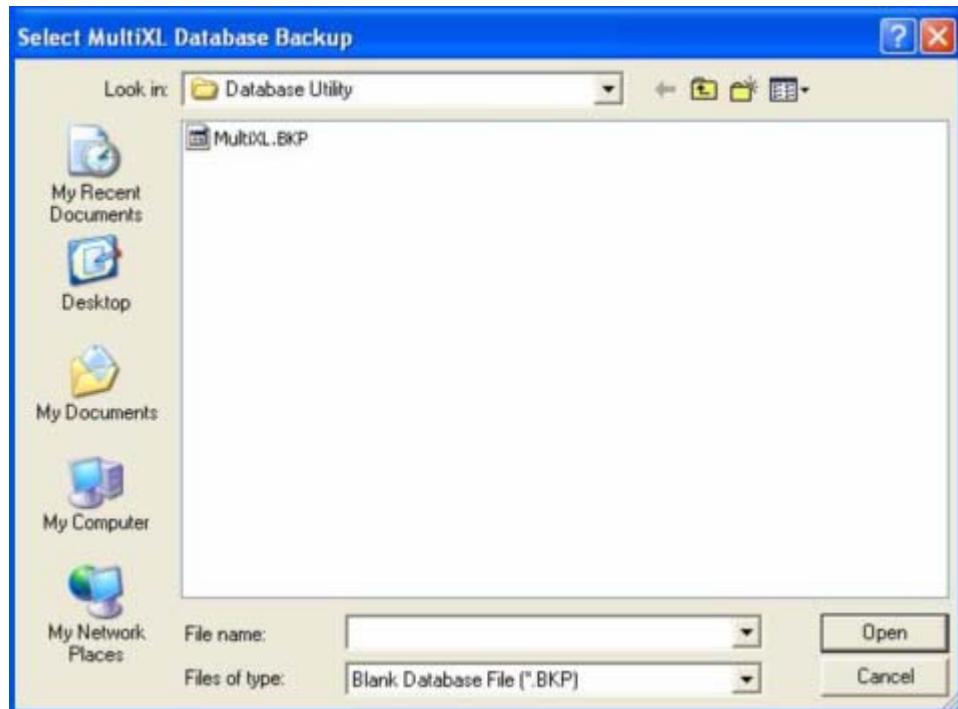
On clicking, the database will be created and the following screen would be displayed.



**NOTE: If the Archive is not available then utility will ask for blank database location.**

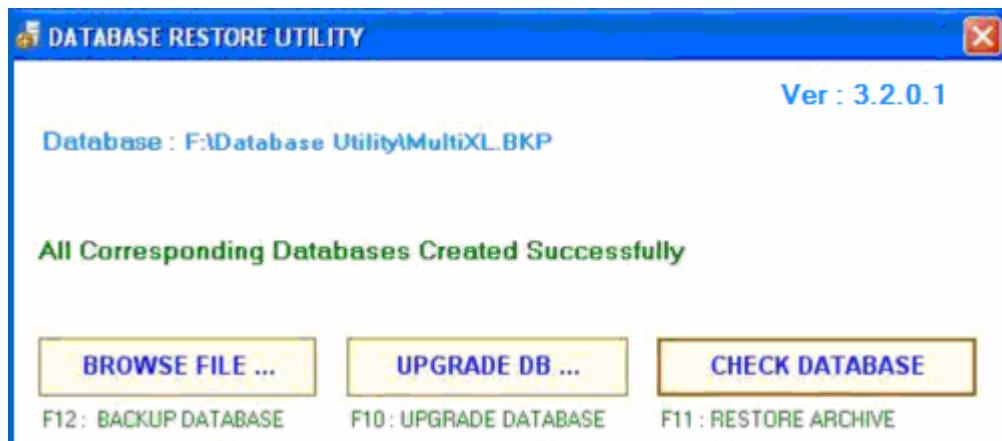


6. Click **OK** and select the blank database file **MultiXL.BKP** from the application CD.



7. Click **Open**.

The following screen will be displayed after successful creation of database.



8. Click on **CHECK DATABASE** to ensure proper creation of the database.
9. Click **X** to close the database utility screen.
10. Now you can access the MultiXL application. Refer section *4.6.6 Accessing MultiXL Software* for more details.

#### 4.6.5.2.3. Restoring Archive Database

Follow these instructions to restore the archived database:

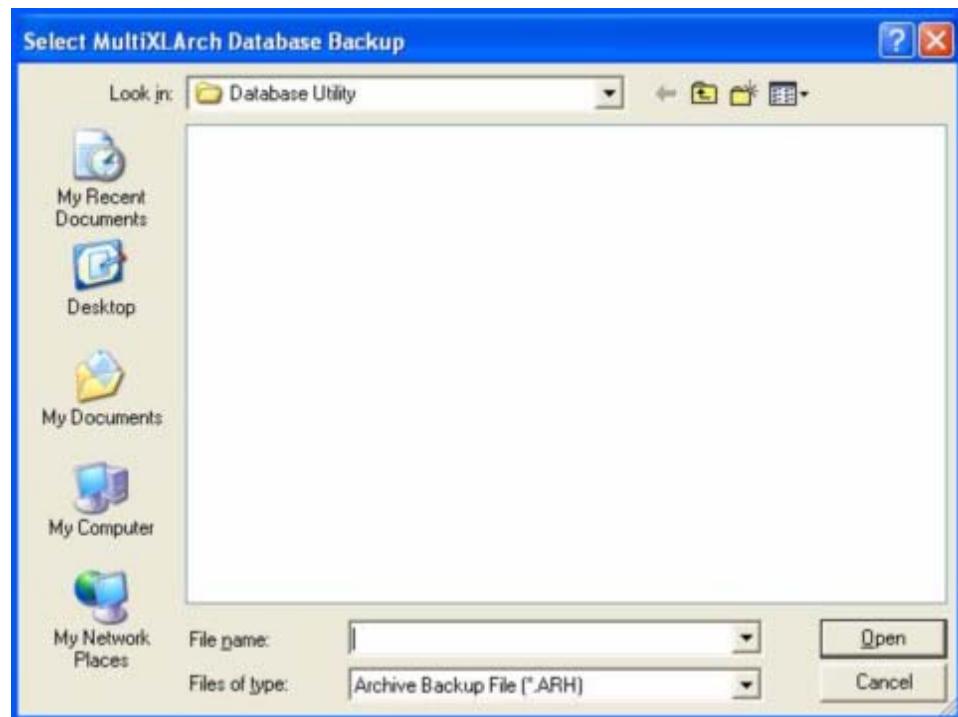
1. Click on the **Run Database Utility** from the MultiXL Installation screen.

**Or**

Open the **Database Utility** folder from the software installation CD. Double-click **DatabaseUtility.exe**.

2. Press **F11** key from the keyboard.

The following window will be displayed. Select the appropriate location where the archive database is saved and then click **Open**.



3. After restoring the archive database successfully, the following screen will be displayed.



## 4.6.6. Accessing MultiXL Software



**NOTE: MultiXL screens are best viewed with 1024 \* 768 resolution.**

**On starting MultiXL, the monitor resolution, if different, will change automatically to 1024\*768 pixels.**

**On closing MultiXL, the previous resolution will be restored.**

Once MultiXL software is installed successfully; next time on PC startup, MultiXL software will be launched automatically.

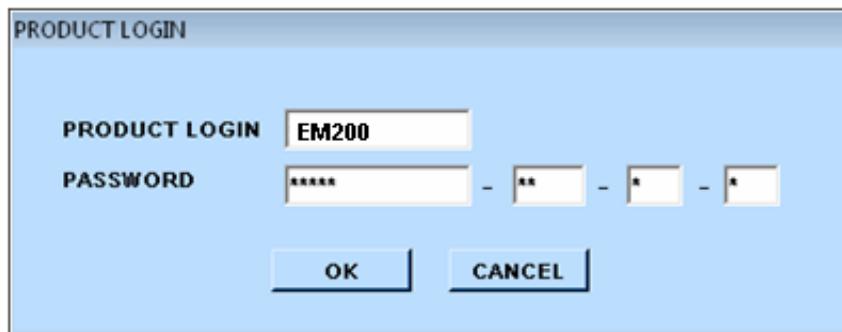
To access the software do one of the following:

- Turn on the analyzer PC. MultiXL application will start automatically
- Double click on the **MultiXL** icon created on your desktop.
- Go to **Start > Programs > MultiXL**.

When starting MultiXL first time, the product login screen as shown below will be displayed.

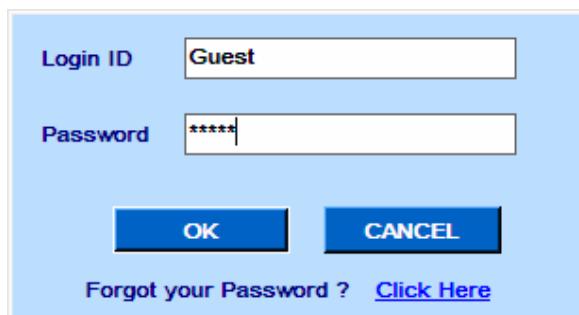
The product login and password is written on the application software CD.

Enter the appropriate details in the **PRODUCT LOGIN** and **PASSWORD** text box, and click **OK**.



User login screen as shown below will be displayed.

This screen will be displayed every time, on starting MultiXL.



Enter the following details, and then click **OK**. You may use this Login details for the first time and create the other login IDs with appropriate user access rights. See section 7.4.5 *User Rights* for more details.

**Login ID** : Guest or guest.

**Password** : Guest (Case – sensitive)

The main screen will be opened.

Patient Entry(F2)

Test Parameter(F3)

Profiles / Calc(F4)

QC/Calibration(F5)

Consumables(F6)

Status Monitor(F7)

Search(F8)

Reports(F9)

Master

Utility(F11)

Service Check

Maintenance(F12)

Settings

Shut Down

Sample ID : 1 Emergency Barcoded \* Group 1 Position 0

Sample Type : SERUM Container Type : TUBE (10 ml)

Sample Vol Type : Normal Collection Date : 20-Apr-2011

Area : Reg. Date : 20-Apr-2011

Ref. Doctor : Analyst :

Sample Remark :

Patient Name : Category : Default

Age : 0 Year(s) Patient ID :

Height (m) : Weight (kg) : Urine vol (ml/24 hrs) :

Address : Tel. No. :

Patient Remark :

Clear Schedule Work List

Mask Test(s) Copy Test(s)

A Scheduled / Pending A Masked A Not Selected A Run Performed Calib Expired

Profiles << >>

Calculated Items << CEC >>

Tests << Na K Cl Li LDH GPT GPTHL GOT GOTL ALP >>

GGT AMY CKN CKMB PHO BID BIT UREA CRE GLU

TRIG CHO HDLC LDL UA CLO CAA ALB PRO CO2

MG MPR

Indication : Enter Patient Name / To view Patient Details, click button on the right side.

◀ ▶ PRINT SAVE CLEAR EDIT DELETE

## 4.6.7. Password Recovery Procedure

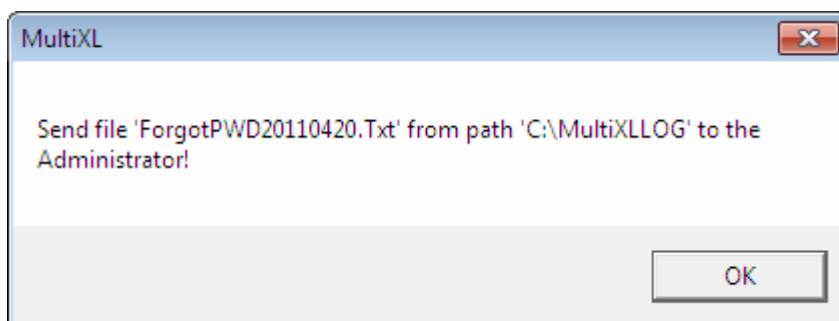
This section describes the procedure to recover the password for the user login Guest, in case you lose or forget the password. However, the password for other user logins can be reset by the administrator for their login from the **Settings > User Rights** screen. See section **7.4.5 User Rights** for more details.

Follow this procedure for recovering login password for Guest:

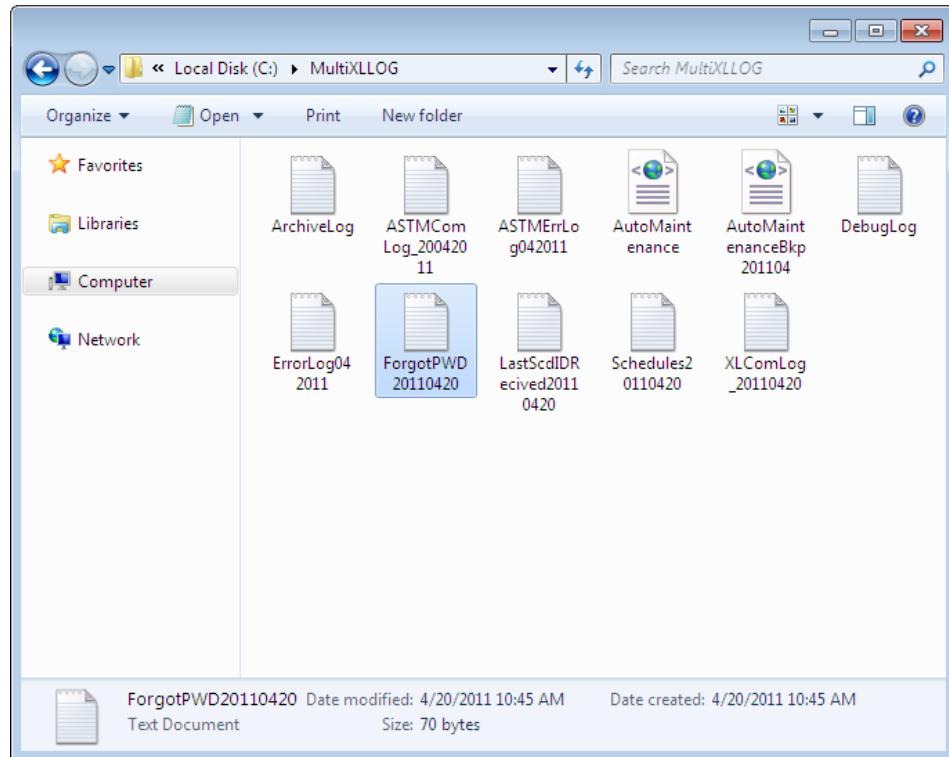
1. In the login screen, enter Guest in the **Login ID** textbox and click on the link “**Click Here**” as shown in figure below.



2. On clicking the link, a text file with the password details is created at the location **C:\MultiXLLOG**. The file name and the path will be displayed as follows.



3. Go to folder C:\MultiXLLOG, and send the generated text file, for example '**'ForgotPWD20110420.Txt'** to the service engineer. See figure as shown below.



4. Click **OK** to close.

## 4.7. Main Menu Software Layout



The Main Menu consists of following screens:

**Patient Entry** – This option is used to define patient demographics and schedule tests, Calculation items, and Test profiles.

**Test Parameters** – This option is used to define Test details, set Auto-rerun for a single or multiple test, set Online Calibration to trace reagent bottle change, Cuvette Wash, Download & Upload test, and initialize test

**Profiles/Calc** – This screen is used for defining new Profiles or Calculation Items

**QC/Calibrations** – This option is used to schedule calibration (Blanks, Standards, and Calibrators) and Controls. This option is also used to view the calibration curves for a particular test, the QC Data and Twin Plot graph.

**Consumables** – This option is used to define consumables such as Blanks, Reagents, Standards, Calibrators, Controls, Diluents/Serum diluent, Wash Solution, SI reagent, and Urine ISE diluent.

**Status Monitor** – This option is used to perform calibration/patient batch run, view liquid level of reagents for different Tests and perform Sample & Reagent Barcode scans. It is also used to view online reaction curve and the progress of the batch run.

**Search** – This screen is used for searching Patient Results, Calibration / Control Results, Patients, Consumables or Test Details.

**Reports** – This option is used to view Patient Reports, Statistical data using Test Statistics screen, the test results on Result Reprint screen, calibration of a test over a period of time on Calibration Trace screen, Calibration Monitor screen with current calibration, errors reported (during sample run, service, maintenance, and auto-startup) in Error Log screen, Reaction curves, Reagent consumption and ISE calibration details.

**Master** – This option is used to define miscellaneous parameters like Area (location of collecting samples), Laboratory, Doctor, Analyst, Manufacturer, Reference range, Unit, Calculation formula and Instrument (for offline result entry) details.

**Utility** – This option is used to define Reagent Positions and Backup Data, to enter and print Offline Results and recalculate the results obtained from analyzer.

**Service Check** – Only the authorized Service Personnel should use this option.

**Maintenance** – This option is used to perform various maintenance operations on analyzer, dead volume calibration for sample and reagent, ISE maintenance activities. The automatic maintenance on startup and shut-down of analyzer can be initiated from this screen.

**Settings** – This option is used to define system parameters, carryover pairs, test sequence, rerun flags, to assign user rights. This option is also used to establish the communication between the analyzer PC and host computer (LIS) using Host Settings screen.

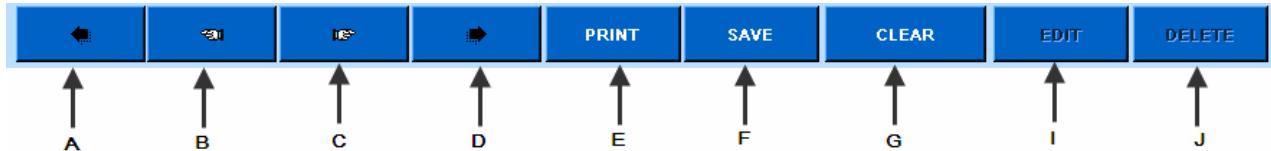
**Archive** – This option is used to archive patient results and view the Archived data at a later date. This option will be visible only after the patient data exceeds the defined threshold limits for the first time, requiring to archive the data. Refer section 7.8 *MultiXL – Archive Database* for details.

**Shut Down** – This option is used to turn off the application software with / without maintenance of analyzer.

The menus can also be accessed using the keyboard shortcut keys shown in brackets.

The selected menu option will be displayed in yellow color.

Following screenshot shows list of Common buttons used:



**A** – Moves to First Record.

**B** – Moves to Previous Record.

**C** – Moves to Next Record.

**D** – Moves to Last Record.

**E** – Prints the Screen Details in Report Format.

**F** – Saves a new Entry or Modified Entry.

**G** – Clears the data on the current screen.

**H** – Edits/Modifies the data on the current screen.

**I** – Deletes the Record.

Following is a three dotted button available on most of the screens. This button is to be clicked either to select or enter data for that text box.



For example: In the screenshot below, button is placed near a box with caption 'Area'. If this button is clicked, small window opens up for selecting a particular area.



Following is an indication bar available on most of the screens. This provides help or warning messages to the user.



**NOTE:** The sign \* near any of the fields on the software screens indicate that the field is mandatory. The sign \*\* near any of the column in the master option indicate that row is a default row and can't be deleted by the user.

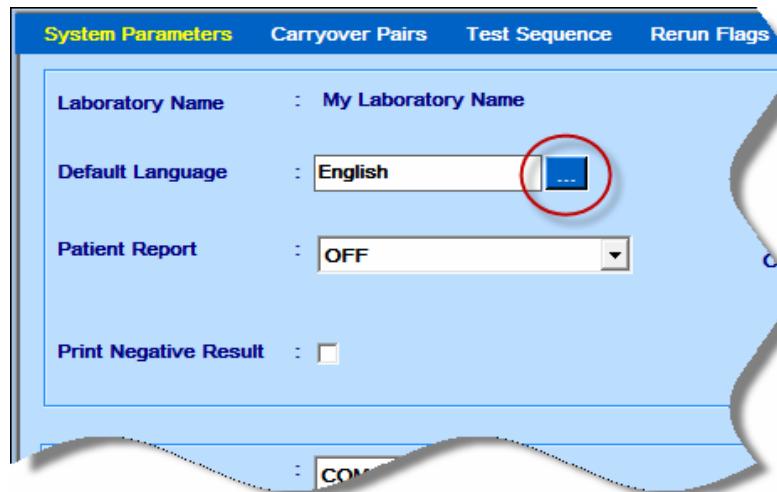
---

## 4.8. Display Language Settings

The display language can be changed according to your choice from the available list of languages. MultiXL application uses this language in dialog boxes, menus, captions, header in the screen, and other items in the user interface.

To change the language, do the following:

1. Click on the **Settings** from the main menu.
2. Now go to **System Parameters** screen, and click on the three dotted button available on the **Default Language** text box.



On clicking, the **Change Language** dialog box will be displayed.

3. Select the desired language from the **Set Language** drop down list.



4. Click **OK**.

The captions on the screen will appear in the selected language.

Alternatively, language can also be changed using **F10** key from the keyboard.

## 5. Analyzer Overview

This chapter provides the user with necessary background on the analyzer for its use. This section contains the description of each unit constituting the system.

### 5.1. Identification of the Main Components

The analyzer consist of the following main components:

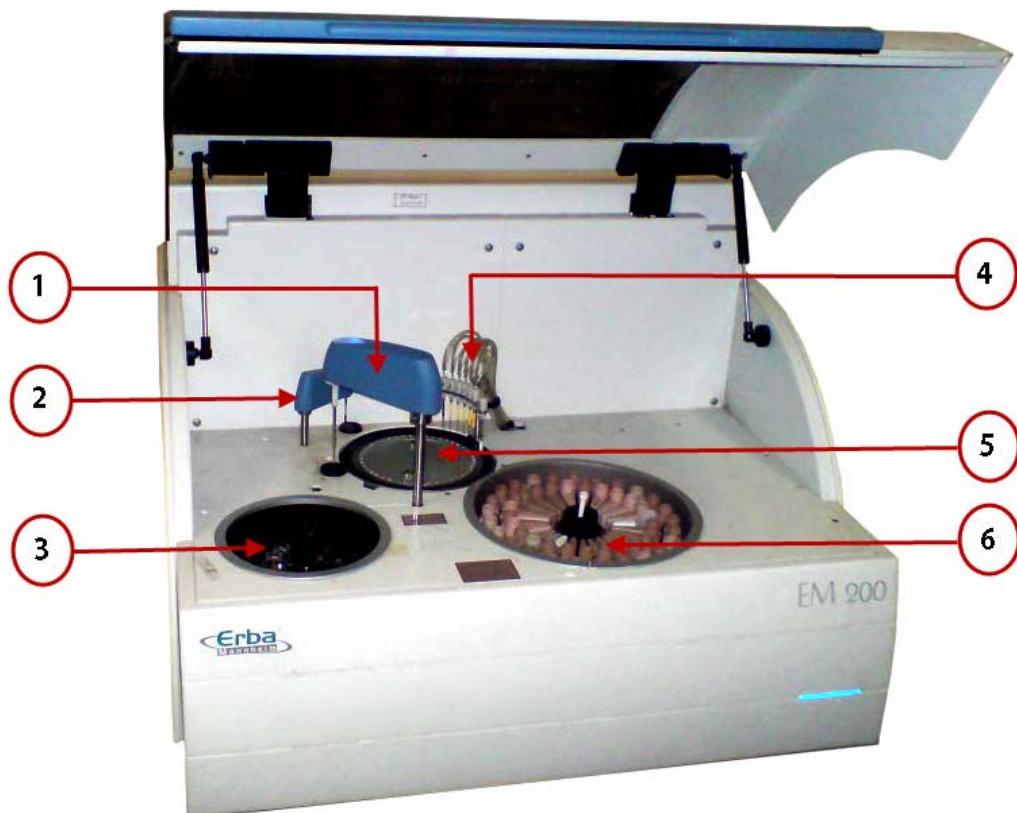


Figure 5-1. Analyzer

1      Sample and Reagent Pipette Unit (SRPT)

2      Stirrer

3      Auto Sampler Unit

4      Cuvette Rinsing Unit (CRU)

5      Reaction Cuvette Tray (RCT)

6      Reagent Tray (RGD)



Figure 5-2. ISE Reagent Pack (optional)



Figure 5-3. Power supply connectors (on the left hand side)

## 5.2. Functionality of Each Unit

### 5.2.1. Auto Sampler Unit (ASP)

The auto sampler unit (ASP) consists of a removable turntable with sample tube adaptor and rotating mechanism with a bar code reader for identifying samples.

The ASP tray can accommodate:

- 30 barcoded sample tubes of 5, 7, and 10 ml
- 9 non-barcoded cups of 2 ml

The sample is aspirated by the Sample & Reagent Pipette Unit (SRPT) and dispensed into cuvettes of the Reaction Tray Unit (RCT).

The ASP tray of the analyzer consists of three rows:

- Outer
- Middle
- Inner

The outer and middle row has total 30 positions that are used for placing Patient's or Emergency samples. Sample tubes as well as 2 ml cups could be placed in these two rows.

The inner row has 9 positions for placing Blank, Control, Standards and Calibrators. Patients and Emergency samples can also be placed in these locations in 2 ml cups, if required. Only 2 ml Sample cups or 500  $\mu$ l STD cups can be placed in the positions marked as I1 to I9.



Figure 5-4. Auto sampler unit (ASP)



Figure 5-5. ASP tray

## 5.2.2. Sample and Reagent Pipette Unit

The Sample & Reagent Pipette Unit (SRPT) consists of a probe (nozzle), up-and-down movement mechanism, rotating mechanism, liquid level sensor and nozzle down limit sensor. The SRPT is connected to the syringe pump for sample aspiration via PTFE tube. The sample or reagent on the ASP unit or RGT tray is aspirated by the pipette and then dispensed into the cuvettes (reaction cells) in the RCT unit. Probe has smooth finish surface from outside is passivated and polished from inside to minimize any sample carry over. When an optional ISE unit is fitted and the ISE measurement is performed, the SRPT aspirates sample for ISE measurement and dispenses it into the sample port of the ISE unit.



Figure 5-6. SRPT unit

### 5.2.2.1. Liquid Level Sensor (LLS)

When the tip of the nozzle reaches and touches the sample surface, the electrostatic capacitance of the metallic nozzle varies. The variation of the capacitance is detected and consequently the level of sample is detected.

### 5.2.2.2. Probe Down Limit Sensor

When the tip of probe hits the bottom during any of the downwards movement due to the obstruction, the lower limit sensor detects that the tip of probe hits the bottom and stops its downward movement (Vertical obstruction detection or VOD).

### 5.2.2.3. SRPT Washing Station

The wash station for the sample & reagent probe consists of a two position used as "Drain Position" (for internal cleaning of the probe) and as "Trough Position" (for external cleaning of the probe). After the sample & reagent probe has dispensed sample & reagent 1 or reagent 2 into the cuvette, the arm moves to the drain station where the chase volume is dispensed & then moves to trough position where it is cleaned internally as well as externally using a jet of DI Water at approx 40° C & 0.8 -1.2 bar pressure.

### 5.2.3. Sample Barcode Reader

The barcode reader reads barcode of the label affixed on the outer surface of the sample tube. When the reader does not read the barcode even if the bar code label exists, the appropriate error message is indicated.

The readable bar codes are as follows:

<b>Symbol</b>	<b>Valid character and symbol</b>
NW-7	Numerals (0 – 9), symbols (-, \$, /, +)
Code39	Numerals (0 – 9), alphabetical characters, symbols (-, space, \$, /, +, %)
ITF	Numerals only (0 – 9)
UPC	Numerals only (0 – 9)
Code128: Set A, Set B, Set C	All ASCII code characters [numerals (0 – 9), alphabetical characters (uppercase/lowercase), symbols, control characters]

Resolution of the barcode label should be 0.25 mm. Length of the barcode should be 42 mm and width should be 10 mm.

Number of digits should be between 3 to 18 but the combination of digit and type should be within the specified length of the barcode label.

### 5.2.4. Reagent Tray (RGT)

The Reagent Unit (RGT) consists of reagent bottle tray, barcode reader, cooler, sensor and rotating mechanism.

The reagent tray of the RGT can accommodates 50 Reagent bottles with big and small type of containers.

The reagent tray rotates and the required reagent bottle is moved to the position where the reagent is aspirated. At this position, the reagent is aspirated by the SRPT unit and then dispensed into cuvettes in the RCT unit.



Figure 5-7. Reagent tray unit



Figure 5-8. Reagent tray with reagent bottles

#### 5.2.4.1. Type of Reagent Bottles

The reagent bottles are available in two types. The type of usable reagent bottles are shown below:

1. Big, (50 ml)
2. Small (20 ml for outer bottle).

The reagent bottles provided with the analyzer is shown below.



Figure 5-9. Reagent bottles

All bottles are screw capped to prevent evaporation of reagents while not in use. Total 50 bottles can be placed (25 numbers of 50 ml and 25 numbers of 20 ml). Bar-code reader reads the bar-coded labels on the reagent containers for identification.

## 5.2.5. Reagent Bar Code Reader

The barcode reader reads barcode of the label affixed on the outer surface of the reagent bottle. When the reader does not read the barcode even if the bar code label exists, the appropriate error message is indicated. The barcode reader used is Laser type reader. Resolution of the barcode label should be 0.25 mm. The readable bar codes are as follows:

Symbol	Valid character and symbol
NW-7	Numerals (0 – 9), symbols (-, \$, /, +)
Code39	Numerals (0 – 9), alphabetical characters, symbols (-, space, \$, /, +, %)
ITF	Numerals only (0 – 9)
UPC	Numerals only (0 – 9)
Code128: Set A, Set B, Set C	All ASCII code characters [numerals (0 – 9), alphabetical characters (uppercase/lowercase), symbols, control characters]

## 5.2.6. RGT Cooling Unit

Even if the analyzer is turned off (by analyzer's ON/OFF switch located on the right side of the analyzer), the temperature inside the RGT unit is kept within the specified limits by the Peltier element which is controlled by temperature controller.

## 5.2.7. Reaction Tray (RCT)

The reaction tray (RCT) consists of the cuvette ring set and rotating mechanism. RCT is provided with 45 hard glass cuvettes (5mm \* 5mm) on its outer circumference and the temperature inside is maintained at 37°C (+/- 0.2°C) constantly. The cuvettes are moved at 10-second step and a series of process including dispensation, stirring, photometric measurement and washing will be performed.

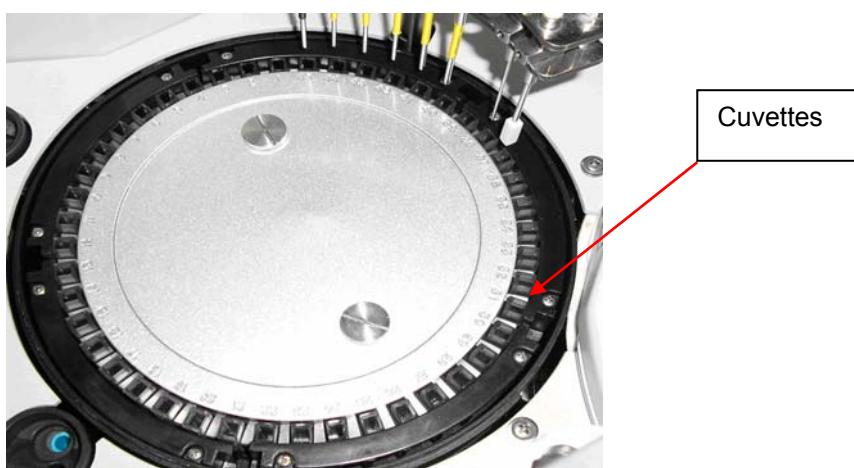


Figure 5-10. Reaction tray

## 5.2.8. Pipette Pump Assembly

There is one syringe pump of 500 µl capacity, common for both reagents as well as sample. The syringe pump of the analyzer is a modular type by which it aspirates & dispenses volumes between 2 µl to 300 µl. Sample volumes can be increased in steps of 0.1µl. The syringe is located behind the front plate of the analyzer and is connected to the probe via appropriate tubing.

The analyzer may have any one of the syringe type as shown below:



Figure 5-11. Sample and reagent syringe assembly

## 5.2.9. Mixing Stirrer Unit

The mixing stirrer unit (STIRRER) consists of the up-and-down mechanism and the paddle rotating mechanism.

The sample and the primary reagent dispensed into the cuvettes are stirred by rotating the paddle at predefined requested speed of high, low or medium. The paddle is washed in the STIRRER trough with system water at 37 ° C – 41 ° C and pressure of 0.8-1.2 bar.

The secondary reagent dispensed into the cuvettes is stirred by rotating the paddle at predefined speed of high, low or medium. The paddle is again washed in the STIRRER trough with system water at 37 ° C – 41 ° C and pressure of 0.8-1.2 bar.



Figure 5-12. Stirrer unit

### 5.2.10. Cuvette Rinsing Unit (CRU)

The Cuvette Rinsing Unit (CRU) serves the purpose of washing the inner surface of the cuvettes in which the measurement of specimen have been completed and allow them to be reused. The CRU consists of 8 probes, probes 1 to 6 are in pairs (one for dispensing and the other one for aspirating), followed by a single probe for final aspiration and the last probe attached with a drier serves the purpose of drying the cuvettes. The cuvette washing via the CRU takes place in 8 stages as described below:

Probe 1 – Aspirates the bio hazardous waste and dispenses cleaning solution.

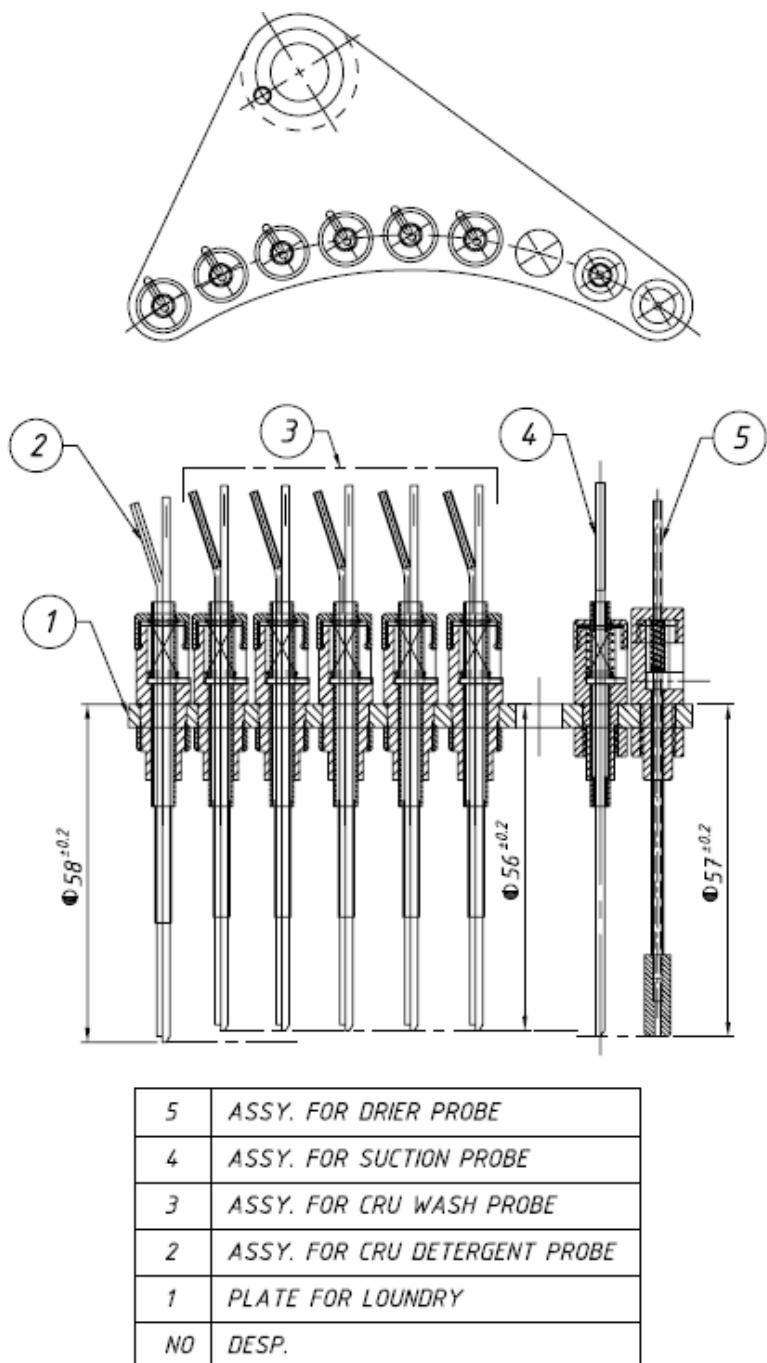
Probe 2 to 6 – Aspirates the cuvette contents, and dispenses DI water.

Probe 7 – Aspirates the cuvette content.

Probe 8 – Dries the reaction cuvette.



Figure 5-13. Cuvette rinsing unit



## 5.2.11. Photometer Unit

The photometer unit consists of the optical measurement system having narrow bandwidth, wavelength specific filters with light source. The absorbance inside the cuvette is measured by using a photometer. Measurement is performed with any combinations of 2 wavelengths selected among the following 8 wavelengths:

**340 nm, 405 nm, 505 nm, 546 nm, 578 nm, 600nm, 660 nm, and 700 nm**

The photometer consists of an illuminant (halogen lamp), lenses, optical filter and photoreceptor (photodiode). The light passing through the cuvette (reaction

mixture) is splitted by beam splitter, which in turn passes through wavelength specific filter on to diode. This eliminates several optical interferences and greatly improves the efficiency of the photometer.

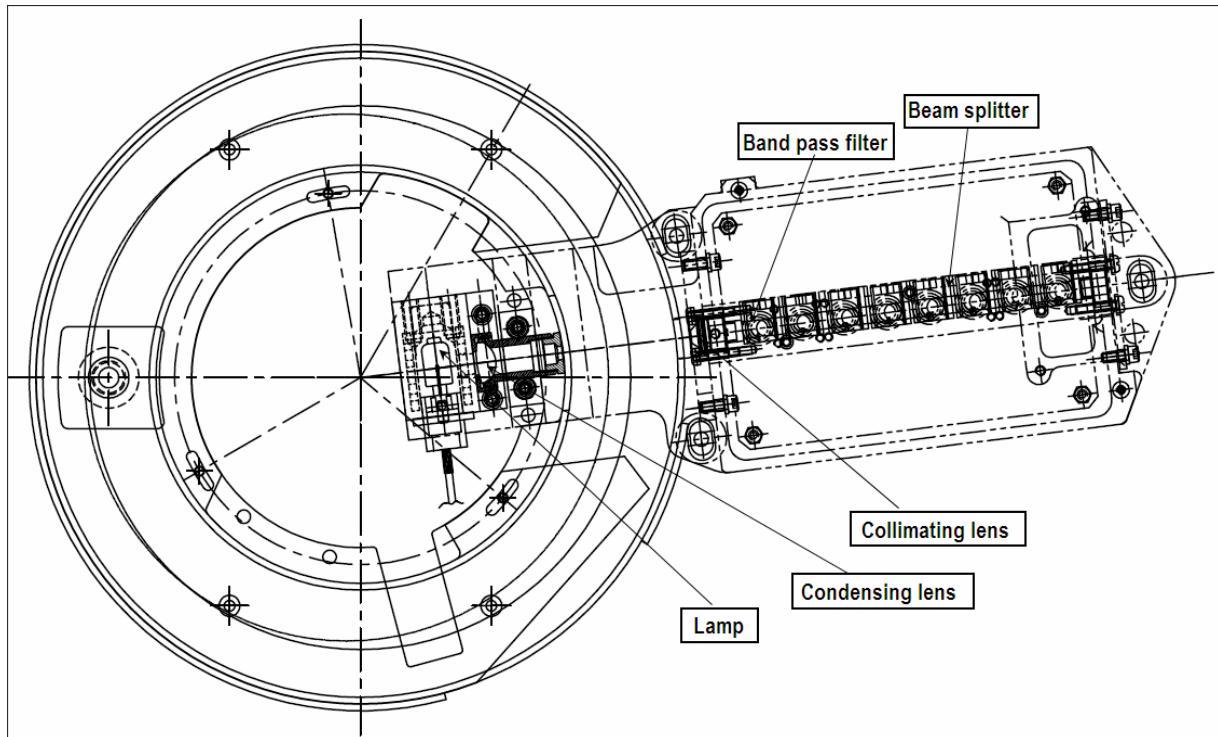


Figure 5-14. Photometer unit

### 5.2.12. Liquid Level Sensing for Cans (Float Sensors)

The Liquid Level Sensor are placed inside the respective Cans of DI water, Cleaning solution, Bio-hazardous waste & normal waste Can. Accordingly, for DI water & cleaning solution, the float based level sensors will sense the low level of DI water or cleaning solution & respective LED will lit on the instrument with the beep sound.

Similarly, full levels are detected for both the waste can & respective LEDs are lit accordingly with beep sound. All the LEDS are placed just near to the tube connection for the same cans.

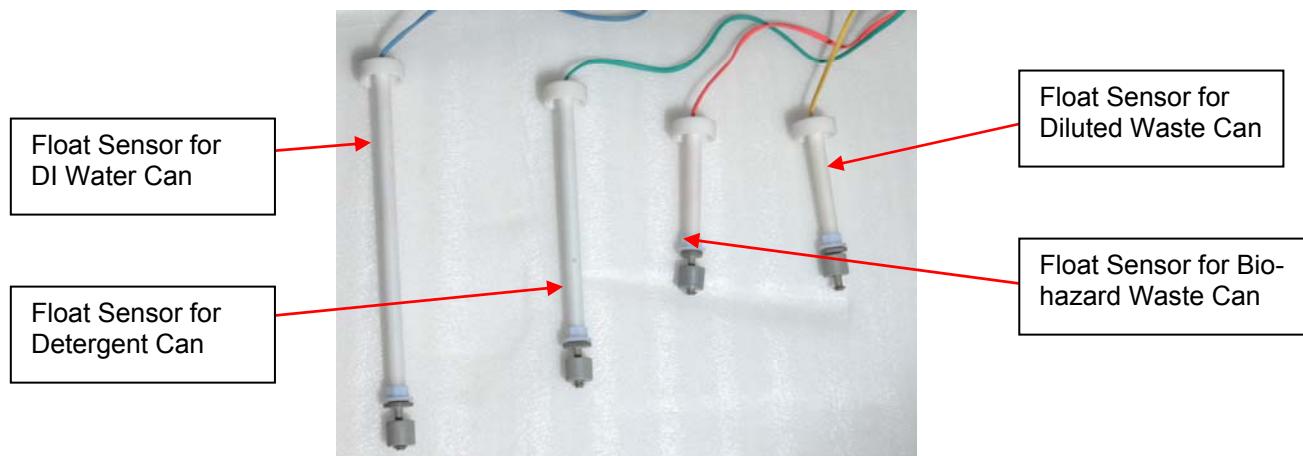


Figure 5-15. Liquid level sensors

### 5.2.13. Ion Selective Electrode Unit (ISE) 4-Channel

The ISE module measures the concentration of Li<sup>+</sup>, Na<sup>+</sup>, K<sup>+</sup>, and Cl<sup>-</sup> in serum, plasma and diluted urine. This unit is located inside the analyzer on the left hand side. This unit is optionally supplied with the analyzer.

The ISE unit consists of ISE module, ion electrodes, supply and drain pump.



ISE module	This module unit is fitted electrodes (Na, K, Cl, Reference and Spacer) and controls pumps, measurement of concentration by electrodes and rinsing movement. Communication to the analyzer is carried out through RS232C.
Ion electrode	This unit consists of Na, K, Cl, Li reference and spacer electrodes. The reagent pack for Calibrant-A and Calibrant-B is placed on the top panel. Dedicated wash solution are placed in the ASP unit and wash solution is supplied by the SPT in the same way as for the sample.
Supply pump	These pumps perform the infusing of Calibrant-A and Calibrant-B into ISE module.
Drain pump	This pump performs the transferring of liquid in ISE module.

The following solutions are requested for the ISE unit:

### 5.2.13.1. Calibrant-A

Calibrant-A is used at the time of one-point calibration.

The one-point calibration is carried out at the same time when the Calibrant-A is dispensed to wash electrodes every time the sample measurement is performed. 95 $\mu$ l of Calibrant-A and 36 $\mu$ l of Calibrant-B is automatically dispensed into the ISE unit at every 30 minutes to prevent the electrode from drying during standby cycle.

Reagent pack containing Calibrant-A solution is placed on the front panel of the analyzer.

### 5.2.13.2. Calibrant-B

Calibrant-B is used at the time of two-point calibration.

The two-point calibration should be carried out at the beginning of the day and at least once every 8 hours or after completion of 50 samples.

Reagent pack containing Calibrant-B solution is placed on the front panel of the analyzer.

### 5.2.13.3. Cleaning Solution

To avoid deposition of protein on the electrodes, the cleaning solution needs to be dispensed into the unit.

The removal of protein build-up on the electrodes and fluid path is accomplished by the use of cleaning solution. Cleaning solution is placed in a cup on the analyzer sample tray, which is aspirated by the sample probe, and deposited into the sample entry port.

This function should be carried out twice a day, once in the beginning of the day before the calibration and at the end of day. When more than 50 samples of measurement are carried out, washing must be carried out.

### 5.2.13.4. Diluent

The diluent is used to dilute urine to one-tenth in concentration. It is contained in a reagent bottle that is placed on the reagent tray. The necessary volume for diluting one sample is 200  $\mu$ l. The dilution is carried out using a cuvette in the CRU unit and therefore one cycle of chemistry analysis is allocated to this processing.

#### Sampling volume at each measurement

In the case of analytic measurement	Sample Volume for Serum 70 $\mu$ l Sample Volume for Urine 140 $\mu$ l (after dilution)
In the case of full calibration	Calibrant-A: 180 $\mu$ l, Calibrant-B: 180 $\mu$ l
In the case of 1-point calibration (Serum cycle)	Calibrant-A: 180 $\mu$ l
In the case of 1-point calibration (Urine cycle)	Calibrant-B: 230 $\mu$ l Calibrant-A: 100 $\mu$ l

## 6. Routine Check Procedure

### 6.1. Checks Prior to Work and Power-on

#### 6.1.1. Checks Prior to Work

##### 6.1.1.1. System Water Can and Waste Can

**Make sure that:**

- The system water Can is filled with pure DI water and the pH of the water is maintained at 7.0.
- Bio-waste Can should be emptied.

##### 6.1.1.2. Cleaning Can

**Make sure that:**

- The cleaning solution Can is filled with wash solution.

##### 6.1.1.3. ISE Unit (optional)

Ensure that the following checks are performed before ISE measurement:

1. Before performing measurement with the ISE unit, confirm that Electrode unit (Na, K, Cl, Li and Reference electrodes) whose term of validity is not expired is installed.
2. The Reagent Pack is filled with sufficient Calibrant-A and Calibrant-B solution.
3. Cleaning was carried out at the end of the last ISE measurement.
4. The Calibrant-A is flowing from the side of sample port by executing of ISE purge.
5. In the following cases, ISE purge should be carried out 5 times or more:
  - At the first measurement of ISE.
  - At the time of exchanging the ISE Reagent pack.



**NOTE: The analyzer should be kept ON because 95 µl of Calibrant-A and 36 µl of Calibrant-B is automatically dispensed into the ISE unit every 30 minutes to prevent the electrodes from drying; even under the sleep condition.**

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Just after turning on the analyzer, 3-4 times of ISE purge should be carried out. All electrodes should be fitted to the ISE module, otherwise the liquid of Calibrant-A solution will flow into the inside of the analyzer, which may cause serious problem.

## 6.1.2. Preparation of External Tank Solutions

The external tanks of the system DI water, detergent, bio-hazardous waste and diluted waste are to be placed near the right-hand side or rear side of the analyzer and to be connected to the analyzer with the corresponding tubes which includes float sensors.

Just before measurement, the external tanks of the system DI water and cleaning solution are filled with the corresponding liquid, and the tanks of the bio-hazardous waste and diluted waste have to be empty.

- De-ionized Water – 20 liters (NCCLS Type II or better)
- Detergent solution – 10 liters (should be filled with sufficient cleaning solution)
- Bio-hazard (Concentrated) Waste – 10 liters (should be emptied)
- Diluted Waste – 20 liters (should be emptied)

The DI water should have a resistivity of more than 1 Mega Ohm-cm (or conductivity less than 1 $\mu$ S/cm). Also the pH of the DI Water should be maintained to 5.0 to 7.0.

### 6.1.2.1. Preparation of Detergent Solution

1. Fill the detergent solution can (given with the Accessories List) with 10 liter of DI water.
2. Pour the 100 ml concentrated solution into the can to prepare a 1% detergent solution.
3. Mix it well before use.

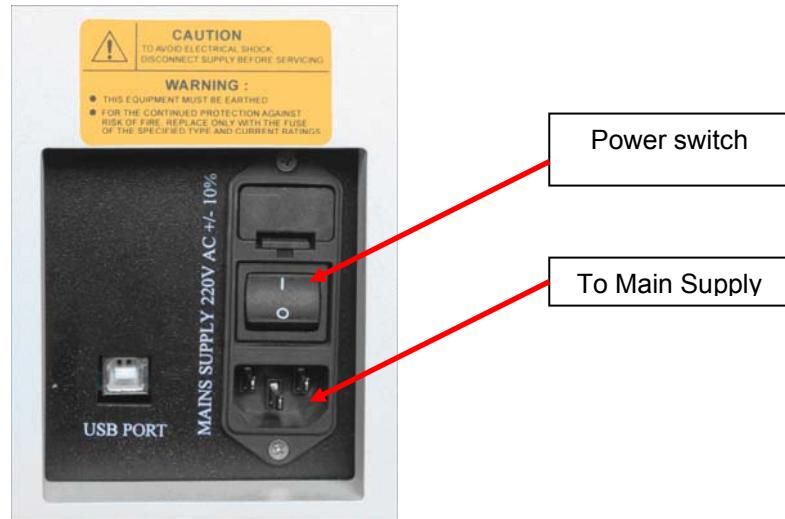
## 6.1.3. Power On

### 6.1.3.1. Primary power-on of main unit

If the main unit is attached with the ISE unit, all electrodes and Reagent pack (with sufficient Calibrant-A and Calibrant-B solution) should be fitted properly to the ISE unit in advance before turning on the main switch.

The power switch is located on the left panel of the main unit.

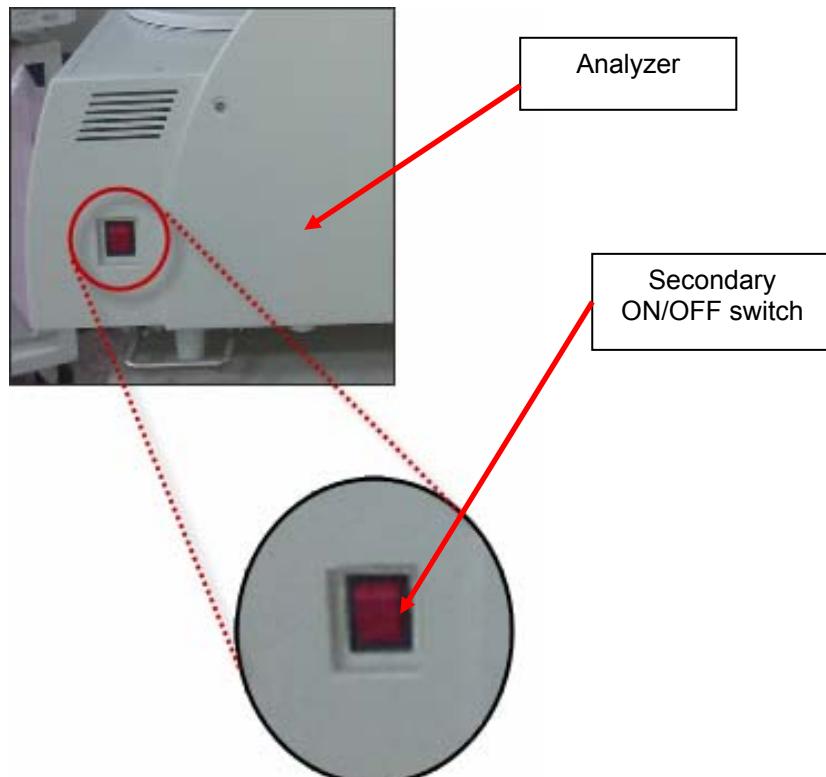
This is the main switch of the analyzer and supplies power to the analyzer switch as well as the Reagent cooling system and the ISE unit, if installed (ensure that the electrodes are fitted, the ISE reagent pack is connected and the ISE power connector is connected).



### 6.1.3.2. Secondary power-on of main unit

This is the secondary switch, which supplies power to the rest of the analyzer and is located at the right side of the analyzer.

In case the malfunction occurred is fatal and the instrument is not able to come to its stable state then the user needs to switch OFF the switch provided on the instrument. This will turn OFF the instrument and will not allow further hazard. The user can turn ON the instrument again so as to restart the functionality.



### 6.1.3.3. Power-on of personal computer (PC)

1. Power on the PC that is connected to the analyzer main unit.
2. The MultiXL application will be automatically started on PC startup. See section 4.6.6 Accessing MultiXL Software for more details.
3. If the analyzer is already ON, the system goes through a series of automatic service maintenance actions. Typically, these actions are performed before the work day begins, so that the instrument is ready to use when you start work. No user action is required in this process.

See section 8.4.3.6 Auto Maintenance for more details.

The maintenance actions can be performed any time through Maintenance screen.



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**NOTE:** : The main switch of the analyzer supplies power to the Analyzer as well as the Reagent cooling system and the ISE unit, if ISE unit is installed on the instrument make sure that the all electrodes and the ISE reagent are fitted properly.

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## 6.2. Preparation and Placement of Reagents

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**NOTE:** Necessary reagents, diluents and wash solutions for analysis are placed on the reagent tray.

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### 6.2.1. Consumable Definition for Reagents

**Consumables** screen is used to define the Reagents and Reagents lot.

#### 6.2.1.1. Open Consumable Screen

1. Click on **Consumables** from main menu.

The following screen will be displayed:

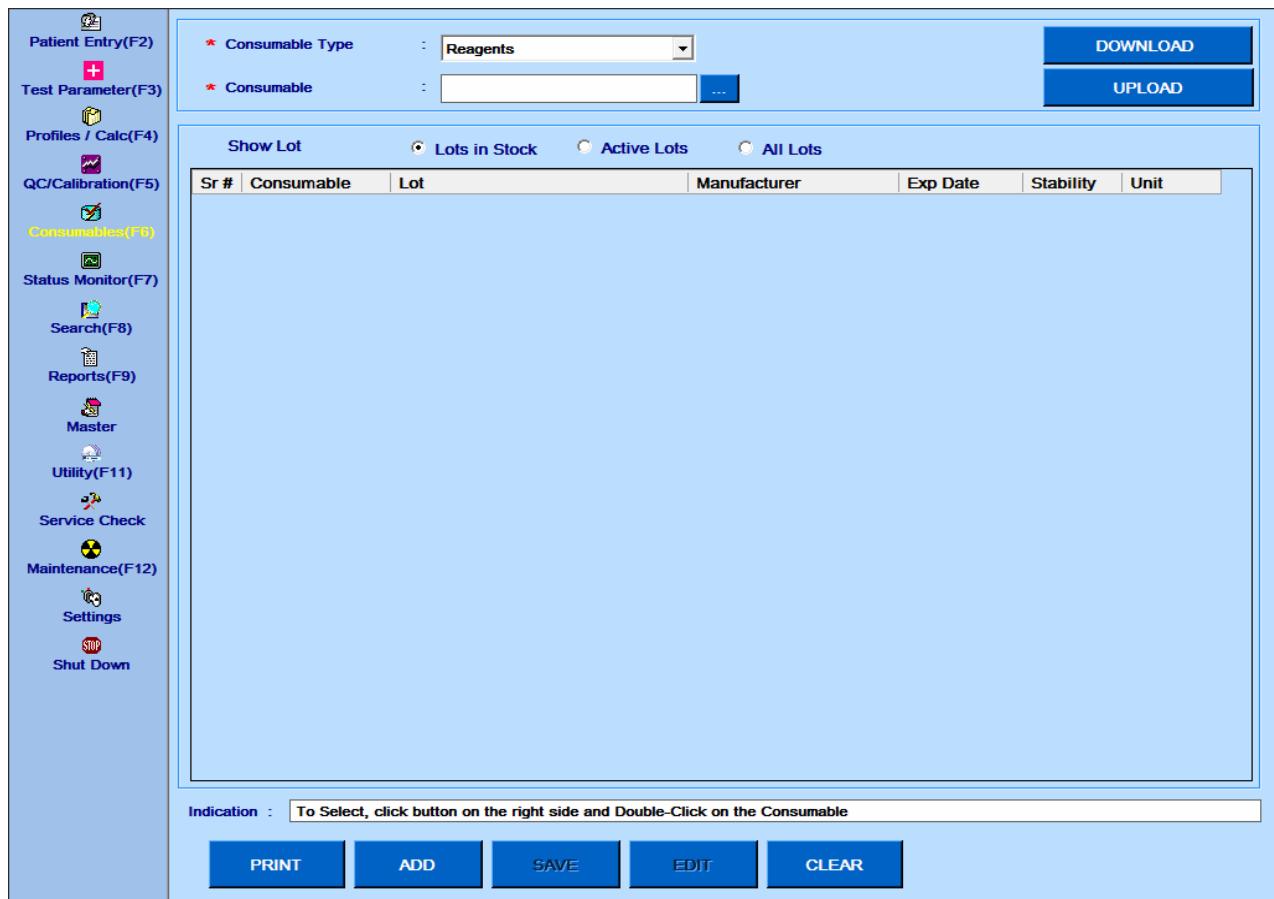


Figure 6-1. Consumable Screen

2. The following are the description for the button on the screen.

<b>ADD</b>	This button is used to Add a lot.
<b>SAVE</b>	This button is used to Save a lot
<b>EDIT</b>	This button is used to Edit a lot
<b>CLEAR</b>	This button is used to Clear the newly added lot details.
<b>PRINT</b>	This button is used to Print the details present on the screen
<b>DOWNLOAD</b>	This button is used to download the Blank, Calibrators, Standards, and Control lot details. See section 6.4.1 <i>Downloading Consumables</i> for more details.
<b>UPLOAD</b>	This button is used to upload the Blank, Calibrators, Standards, and Control lot details. See section 6.4.2 <i>Uploading Consumables</i> for more details.

### 6.2.1.2. Add a new Reagent

1. In the **Consumable** screen, select the **Consumable Type** to Reagents.
2. Now click on the button next to the **Consumable** box.

On clicking, the following screen will be displayed.

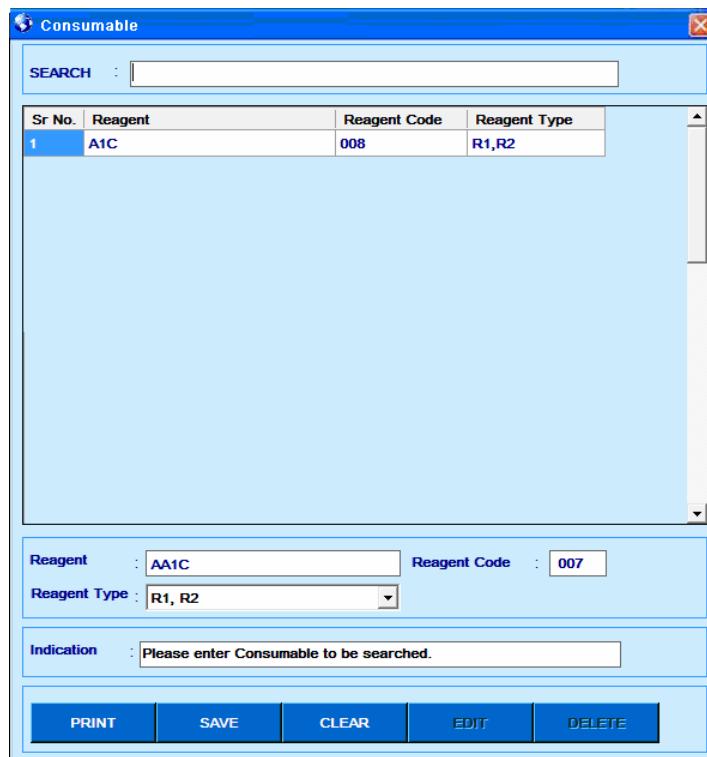


Figure 6-2. Consumables - Reagent Addition

3. Enter the **Reagent** name, **Reagent Code**, and **Reagent Type**.
4. Click **SAVE** to save the details.
5. The following are the description of the parameters on the screen.

<b>Reagent</b>	Enter the name of the reagent.
<b>Reagent Code</b>	<p>Enter the 2 digit Test Code. This is the 4<sup>th</sup> and 5<sup>th</sup> digit on the Reagent Barcode Label on the bottle. It is used to identify the Reagent after barcode scan.</p> <p>It is used for entering the 2-digit test code, which would be used for updating the reagent position after reagent barcode scan. This 2-digit test code is available on the Reagent Bottle barcode label.</p> <p>Reagent code should be a unique number.</p>
<b>Reagent Type</b>	Select whether the reagent is single reagent or dual reagent. The available options are: <ul style="list-style-type: none"> <li>▪ R1</li> <li>▪ R1, R2</li> </ul>

6. The following are the description of the buttons on the screen.

<b>PRINT</b>	This button is used to print the list of reagents.
<b>SAVE</b>	This button is used to save the reagent details.
<b>EDIT</b>	This button is used to edit the details of the selected reagent.
<b>CLEAR</b>	This button is used to cancel add / edit mode.

<b>DELETE</b>	This button is used to delete the reagent (till not used either in batch run or Test Parameters).
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7. On saving the details, the reagent will be added in the list of reagents as shown in the following figure.

The screenshot shows a Windows application window titled "Consumable". At the top, there is a search bar labeled "SEARCH :". Below it is a table with four columns: "Sr No.", "Reagent", "Reagent Code", and "Reagent Type". Two rows of data are visible: Row 1 contains "A1C" in the Reagent column, "008" in the Reagent Code column, and "R1,R2" in the Reagent Type column. Row 2 contains "AA1C" in the Reagent column, "007" in the Reagent Code column, and "R1,R2" in the Reagent Type column. A red oval highlights the second row (AA1C). Below the table, there are input fields for "Reagent" and "Reagent Code", a dropdown menu for "Reagent Type" (set to "R1, R2"), and an "Indication" field with the placeholder "Please enter Consumable to be searched.". At the bottom, there is a horizontal toolbar with five buttons: "PRINT", "SAVE", "CLEAR", "EDIT", and "DELETE".

Figure 6-3. Consumables – List of Reagents

#### 6.2.1.3. Add a Reagent Lot

1. Double click on the Reagent name, to select from the list of reagents. See *Figure 6-3 Consumables – List of Reagents*.

The selected Reagent will be displayed in the *Figure 6-1 Consumable Screen*.

# Operator Manual

The screenshot shows the 'Consumables' screen of the Operator Manual software. On the left is a vertical menu bar with icons and labels for various functions: Patient Entry(F2), Test Parameter(F3), Profiles / Calc(F4), QC/Calibration(F5), Consumables(F6), Status Monitor(F7), Search(F8), Reports(F9), Master, Utility(F11), Service Check, Maintenance(F12), Settings, Archive, and Shut Down.

The main window has the following components:

- Top header: 'Consumable Type' dropdown set to 'Reagents', 'Consumable' input field containing 'AA1C', and 'DOWNLOAD' and 'UPLOAD' buttons.
- Filter section: 'Show Lot' dropdown with options 'Lots in Stock', 'Active Lots', and 'All Lots'. Below it is a table header row with columns: Sr #, Consumable, Lot, Manufacturer, Exp Date, Stability, and Unit.
- Message bar: 'Indication : Double click on Row to Edit Lot Details Or Click on ADD To Add New Lot'.
- Bottom navigation buttons: PRINT, ADD, SAVE, EDIT, and CLEAR.

2. Click on the **ADD** button.

On clicking, the following window will be displayed.

# Operator Manual

The screenshot shows the 'Consumables' entry screen. The left sidebar lists various functional areas. The main area is titled 'Lot Details' and contains the following fields:

- \* Consumable Type : Reagents
- \* Consumable : AA1C
- \* Manufacturer : ERBA
- \* Lot No : 12345
- \* Expiry Date : 15-Oct-2011
- Onboard Stability : 2
- Unit : Days
- \* Reagent Type :  R1    R2

At the bottom, there is an indication message: 'Indication : Enter Stability for the Reagent-Lot '12345''. Below the message are five buttons: PRINT, ADD, SAVE, EDIT, and CLEAR.

3. Now enter the manufacturer name from the **Manufacturer** drop down list. See section 7.7.5 *Master – Manufacturer* for adding manufacturer name in the list.
4. Enter the lot number in the **Lot No** text box.
5. Enter the expiry date of the reagent in the **Expiry Date** list.
6. Enter the onboard stability and unit in **Onboard Stability** text box and **Unit** drop down list.
7. The **Reagent Type** checkboxes will be pre-selected. It is defined while entering the details for new reagent. See *Figure 6-2. Consumables - Reagent Addition*.
8. Once the above details are entered, click on **SAVE** to save these details.  
The reagent will be added and displayed on the grid.

The screenshot shows a software interface for managing consumables. On the left is a vertical menu bar with icons and labels for various functions: Patient Entry(F2), Test Parameter(F3), Profiles / Calc(F4), QC/Calibration(F5), Consumables(F6), Status Monitor(F7), Search(F8), Reports(F9), Master, Utility(F11), Service Check, Maintenance(F12), Settings, Archive, and Shut Down.

The main panel displays a form titled "Consumable Type" with dropdown menus for "Reagents" and "AA1C". It includes "DOWNLOAD" and "UPLOAD" buttons. Below this is a table header with columns: Sr #, Consumable, Lot, Manufacturer, Exp Date, Stability, and Unit. A single row is shown in the table body: Sr # 1, Consumable AA1C, Lot 12345, Manufacturer ERBA, Exp Date 15 Oct 2011, Stability 1, and Unit Days.

At the bottom of the main panel, there is an "Indication" message: "Double click on Row to Edit Lot Details Or Click on ADD To Add New Lot". Below this are five buttons: PRINT, ADD, SAVE, EDIT, and CLEAR.

## 6.2.1.4. Edit a Reagent Lot Details

1. To edit the reagent details, go to **Consumable** screen, select the **Consumable Type** as **Reagents** and click on the **---** button.

On clicking, the following screen will be displayed.

The screenshot shows a software window titled "Consumable". At the top is a search bar labeled "SEARCH :". Below it is a table with columns "Sr No.", "Reagent", "Reagent Code", and "Reagent Type". Two rows are listed: Row 1 has Reagent "A1C", Reagent Code "008", and Reagent Type "R1,R2"; Row 2 has Reagent "AA1C", Reagent Code "007", and Reagent Type "R1,R2". The "AA1C" row is selected, indicated by a blue border. Below the table is a form section with fields: "Reagent" (text box containing "AA1C"), "Reagent Code" (text box containing "007"), "Reagent Type" (dropdown menu showing "R1" as the selected item), and "Indication" (text box containing "Please enter Consumable to be searched."). At the bottom are five buttons: PRINT, SAVE, CLEAR, EDIT (highlighted in blue), and DELETE.

Figure 6-4. Consumable- Edit details

2. Double click on the desired reagent name from the list of reagents.
3. Click **EDIT** button.

On clicking, the following screen will be displayed for editing the details.

This screenshot shows the same "Consumable" window as Figure 6-4, but with the "AA1C" row selected (blue border). In the "Reagent Type" dropdown, "R1" is highlighted. The "Indication" text box now contains "R1, R2". The other fields and buttons are identical to Figure 6-4.

Figure 6-5. Consumable -Editing reagent type

4. Edit the appropriate details and click **SAVE**.

On clicking, the details will be saved.

5. Following table gives a brief explanation on the different parameters in the grid.

Parameters	Description
Manufacturer	Select the Reagent Manufacturer from the drop-down list. A Manufacturer from <b>Master &gt; Mfg</b> screen.
Stock Over	<p>Check this <b>Stock Over</b> box when the stock of the consumable lot is completely utilized.</p> <p>Lots marked as Stock Over will not appear in the Lot Selection List -</p> <ul style="list-style-type: none"> <li>▪ While defining Reagent Positions in the <b>Utility &gt; Reagent Position</b> screen</li> <li>▪ While scheduling Calibration and Controls from <b>QC/Calibration &gt; Schedule QC / Calibration</b> screen.</li> </ul> <p><b>Note:</b> In case, Stock Over is not ticked for a Lot; then the Lot will be excluded from the selection list after its expiry date.</p> <p>This checkbox is available only in Edit mode and not while adding a Lot.</p>
Lot No	Enter the lot number of the reagent.
Lot Status	Lot status as Active or Inactive is displayed based on the Expiry Date defined for the Lot. Expired Lot is displayed as Inactive.
Expiry Date	Select the expiry date of the Reagent lot.
On-board Stability	Enter the On-board shelf life of the reagent.
Unit	Select the On-board Stability unit, as appropriate. Options available are Hours and Days.
Reagent Type	Select whether R1 and/or R2 is received for the selected Lot number.  In case, lot numbers are different for R1 and R2, then define both the Lots for R1 and R2 appropriately.



**NOTE: Lot details can be edited directly by double-clicking on the required lot from the main Consumable Screen.**

### **6.2.2. Placement and Registration of Reagents**

### **6.2.2.1. For Barcode Reagent Bottles**

Reagent Barcode scan identifies the reagents and updates the positions of the Barcoded Reagent bottles placed on the reagent tray.

Steps to register barcoded reagent bottles are as follows.

1. Place the barcoded reagent bottles on the Reagent Tray.
  2. Go to **Status Monitor > BARCODE SCAN** screen.
  3. Click on **Reagent Barcode Scan** button.

Reagent tray will be scanned and Reagent Barcode information will be registered and displayed as shown below.

Patient Entry(F2)		SAMPLE TRAY		REAGENT TRAY		REACTION CURVE		BARCODE SCAN		PRE-RUN OPT																																																																																																																																																																																																																																																																																									
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Figure 6-6. Status monitor - Bar code scan screen

- Column **S.N.** represents the Position number in the Tray.
  - Column **Reagent Barcode** generally shows the barcode number read from bottle.

In some cases, instead of barcode number, following content may be displayed in this column.

- ◆ “Checksum Mismatch”: When the checksum digit does not match the calculated checksum of the bar-code digits.
- ◆ “Unknown-barcode”: When the digits read are not as per required format or less than 18 digits are read.
- ◆ “RGT Code Unknown”: When the Reagent Code is not found in the list of Reagents in **Consumables** screen.
- ◆ “-“: Reagent position is manually defined through **Utility > Reagent Position** screen.
- Reagent(s), their position, Lot number and Expiry date is registered in the system for the barcoded bottles.
- Reagent is identified from the Reagent code mentioned in the barcode pattern and matching this Reagent Code with the Reagent Code mentioned in the list of reagents in the Consumables screen.
- This updated information is available in the **Utility > Reagent Position** screen.
- Lot number is added in the list of Reagent Lots in **Consumables** screen.



**NOTE: Reagent Barcode Scan and Sample Barcode Scan options will not be available in case, the options Reagent Barcode and Sample Barcode, respectively, are de-selected (un-ticked) from the Settings > System Parameters screen.**

4. Alternatively, a batch run can be started with Reagent Barcode scan as a predecessor as follows.

Select (tick) Reagent Barcode Scan option from the Pre-run options (at the top right hand corner) in **Status Monitor > SAMPLE TRAY** screen. Click on start (batch) run button.

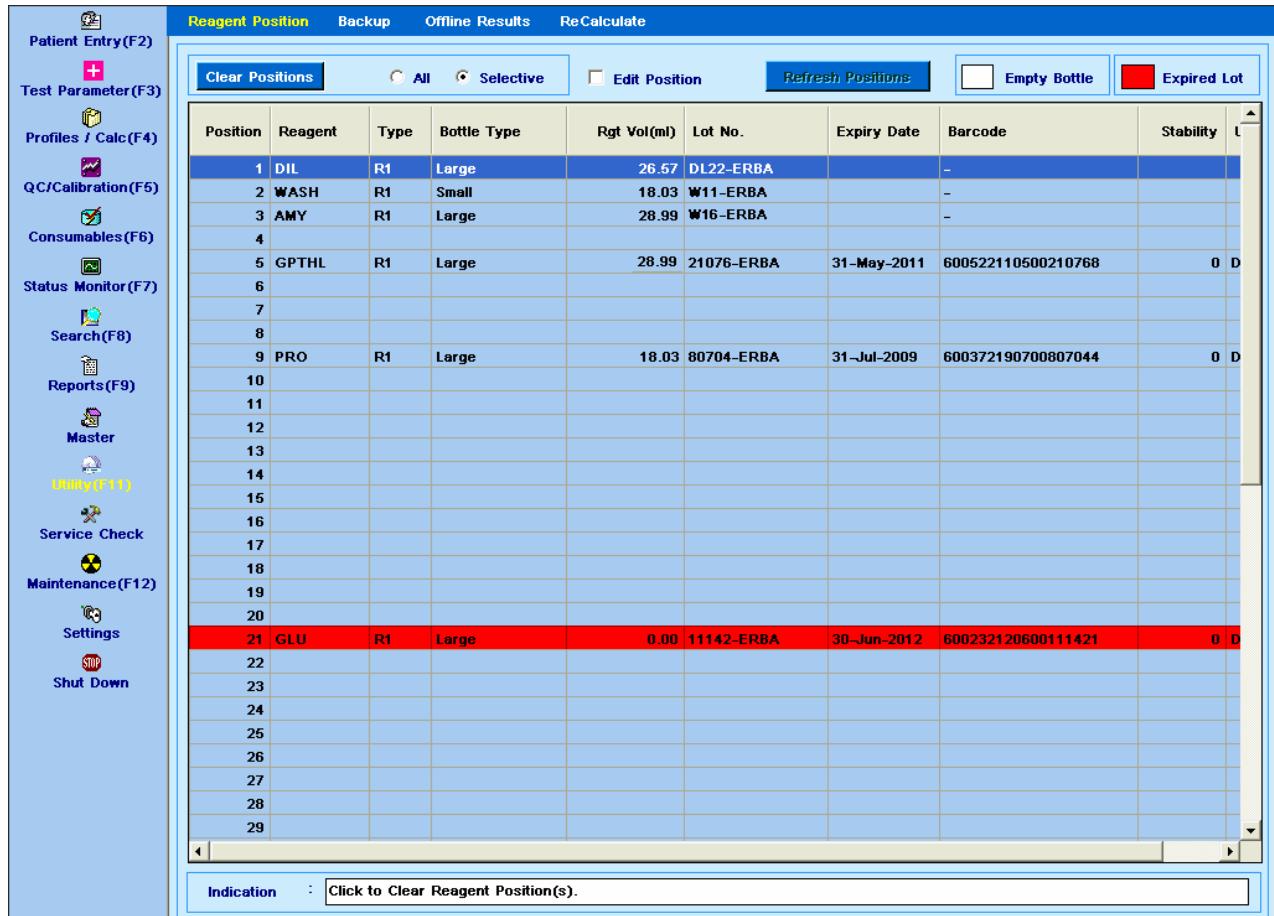
Reagent tray will be (barcode) scanned first and barcode information is updated automatically in the system (refer to point 3 above for details), before starting the batch run.

Batch run will start only if the reagent positions are available / known for all the test(s) scheduled in the selected group.

## 6.2.2.2. For Non Barcoded Reagent Bottles (Manual Definition of Reagent Positions)

Reagent positions for non-barcoded bottles are manually defined from the screen **Utility > Reagent Position** as follows:

1. Click on **Utility** from the main menu. The following screen will be displayed.



The screenshot shows a software interface titled 'Utility - Reagent position'. On the left is a vertical toolbar with icons and labels for various functions: Patient Entry (F2), Test Parameter (F3), Profiles / Calc (F4), QC/Calibration (F5), Consumables (F6), Status Monitor (F7), Search (F8), Reports (F9), Master, Utility (F11) (highlighted in yellow), Service Check, Maintenance (F12), Settings, and Shut Down. The main area has a header with tabs: 'Reagent Position' (selected), Backup, Offline Results, and ReCalculate. Below the header is a toolbar with buttons: 'Clear Positions' (radio buttons for All or Selective), 'Edit Position' (checkbox), 'Refresh Positions', and two checkboxes for 'Empty Bottle' and 'Expired Lot'. The main content is a table with columns: Position, Reagent, Type, Bottle Type, Rgt Vol(ml), Lot No., Expiry Date, Barcode, and Stability. The table contains 29 rows of data. Row 21, for 'GLU', is highlighted in red, indicating it is the current selected row. A message at the bottom says 'Indication : Click to Clear Reagent Position(s)'.

Reagent Position								
Clear Positions		<input type="radio"/> All <input checked="" type="radio"/> Selective		<input type="checkbox"/> Edit Position	Refresh Positions			<input type="checkbox"/> Empty Bottle <input checked="" type="checkbox"/> Expired Lot
Position	Reagent	Type	Bottle Type	Rgt Vol(ml)	Lot No.	Expiry Date	Barcode	Stability
1	DIL	R1	Large	26.57	DL22-ERBA		-	0 D
2	WASH	R1	Small	18.03	W11-ERBA		-	0 D
3	AMY	R1	Large	28.99	W16-ERBA		-	0 D
4								
5	GPTHL	R1	Large	28.99	21076-ERBA	31-May-2011	600522110500210768	0 D
6								
7								
8								
9	PRO	R1	Large	18.03	80704-ERBA	31-Jul-2009	600372190700807044	0 D
10								
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								
21	GLU	R1	Large	0.00	11142-ERBA	30-Jun-2012	600232120600111421	0 D
22								
23								
24								
25								
26								
27								
28								
29								

Figure 6-7. Utility - Reagent position screen

2. Options available on the screen are as follows:

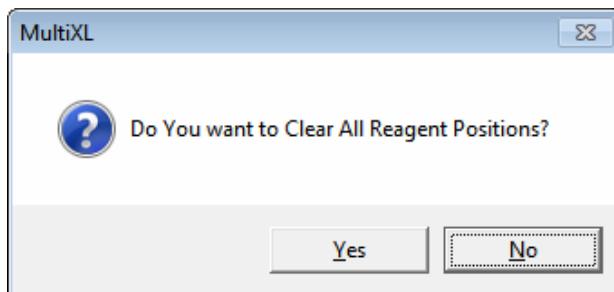
**Clear Position:** This option is used to clear the assigned reagent positions on the reagent tray. There are two sub-options available:

- ◆ All
- ◆ Selective

**Clear Positions - All:** This sub-option is used to clear all the position on the reagent tray. Use the following step:

- a. Select the **All** option.
- b. Click on **Clear Position** button.

Following message, asking for the confirmation, will be displayed.



- c. Click **Yes** to clear all the reagent positions.
- d. Click **No** to cancel clearing the positions.
- e. Click **Yes**.

This will clear all the reagent position.

**Clear Positions - Selective:** This sub-option is used to clear specific positions on the reagent tray, as selected. Use the following step:

- a. Select the **Selective** option.
- b. Click on **Clear Position** button.

The following screen, showing the occupied reagent positions, will be displayed.

Pos	Reagent	Type	Bottle Type
<input type="checkbox"/> 1	DIL	R1	Large
<input type="checkbox"/> 2	WASH	R1	Small
<input type="checkbox"/> 3	AMY	R1	Large
<input type="checkbox"/> 5	GPTHL	R1	Large
<input type="checkbox"/> 9	PRO	R1	Large
<input type="checkbox"/> 21	GLU	R1	Large

- c. Select (tick) the positions that are required to clear. Click on **All** (next to Select in the left-bottom of the screen) to select (tick) all the positions displayed in the above list. Click on **None** to de-select (un-tick) all the positions displayed in the above list.
- d. Click on **OK** button to clear only selected reagent positions and close the screen.

- e. Click on **CANCEL** button to close the screen without further clearing the reagent positions.

**Refresh Positions:** This option is used to notify the availability of reagent in the reagent bottle(s) at All or Selective positions on the reagent tray.

During run, while aspirating the reagent, when a reagent bottle is detected as empty bottle (no volume) then such reagent position is de-activated and not used for further aspiration of reagent.

Replace the Empty Reagent Bottle on the reagent tray with the filled Reagent Bottle. Then use this option as follows, to notify the reagent availability to the system. See section *6.7.3 Refresh Reagent Position during Run* for more details.

**Edit Position:** This option is used to add or alter the reagent definition at a specific position. (Refer to section *6.2.2.3 Procedure to Define Reagent Position Manually* for more details).

**Keys – Empty Bottle and Expired Lot:** These keys indicate the meaning of the white and red background color used for the rows of the positions grid displayed in the screen.

- **Empty Bottle:** When a row is highlighted with white background color, it indicates that the reagent volume at that position has become zero during run. See *Figure 6-7. Utility - Reagent position screen*.
- **Expired Lot:** An expired reagent lot on the reagent tray is highlighted with red background color. The expired reagent is not aspirated during run. However, volume scan will be performed for the position(s) having expired lot. See *Figure 6-7. Utility - Reagent position screen*.



**NOTE: Expiry date of reagent bottle is compared with batch run start date, to decide whether or not to aspirate the reagent during run.**

**Positions Grid:** This grid shows the reagents defined at each position of the Reagent Tray. The parameters in the grid are shown below.

Parameters	Description
<b>Position</b>	Reagent positions on Reagent Tray.
<b>Reagent</b>	Reagent name.
<b>Type</b>	Reagent type (R1/R2).
<b>Bottle Type</b>	Bottle type of the reagent (Large / Small / Tube).
<b>Rgt Vol (ml)</b>	Reagent volume scanned (ml).
<b>Lot No.</b>	Lot number of the selected reagent
<b>Expiry Date</b>	Expiry date of reagent as defined in consumables / read from barcode
<b>Barcode</b>	Barcode label read on Reagent Barcode Scan. “-”in this column indicates manual definition of reagents.
<b>Stability</b>	Onboard stability period as defined in consumables.
<b>Unit</b>	Unit of the stability period, hours/days as defined in Consumables.

### 6.2.2.3. Procedure to Define Reagent Position Manually

Define non-barcoded Reagent bottles on the Reagent tray as follows:

1. Click on **Utility** from the main menu.
2. Tick the **Edit Position** check box. The screen will change as follows:

The screenshot shows the 'Reagent Position' screen with the following details:

- Left Sidebar:** Contains icons and labels for various functions: Patient Entry (F2), Test Parameter (F3), Profiles / Calc (F4), QC/Calibration (F5), Consumables (F6), Status Monitor (F7), Search (F8), Reports (F9), Master, Utility (F11), Service Check, Maintenance (F12), Settings, and Shut Down.
- Top Bar:** Includes buttons for 'Reagent Position', 'Backup', 'Offline Results', and 'ReCalculate'. A checked checkbox labeled 'Edit Position' is present. To its right are two buttons: 'Empty Bottle' (white square) and 'Expired Lot' (red square).
- Table Grid:** A large table with columns: Position, Reagent, Type, Bottle Type, Rgt Vol(ml), Lot No., Expiry Date, Barcode, Stability, and Unit. Rows 1 through 21 contain data, while rows 22 through 27 are empty. Row 21 is highlighted in red, indicating it is being edited.
- Bottom Input Bar:** A row of dropdown menus and a button. The first dropdown is set to '16'. The subsequent dropdowns show 'ASL', 'R1', 'Tube', and '11142-ERBA'. To the right is a blue 'Save Position Detail' button.
- Message Bar:** A status message at the bottom stating 'Indication : Reagent Positions Updated successfully.'

Figure 6-8. Editing reagent details using reagent position screen

3. Select the required position to be defined, from the **Position** list or select the required position from the screen.
4. Select the reagents name from the **Reagent** list.
5. Select reagent type (R1/R2) from the **Reagent Type** list.
6. Select appropriate bottle type from the **Bottle Type** list.
7. Select the reagent available lot number from the **Lot No.** list (Optional).
8. Click on **Save Position Detail**.

Reagent details will be saved to the selected position and displayed in the positions grid on the screen.

Position	Reagent	Type	Bottle Type	Rgt Vol(ml)	Lot No.	Expiry Date	Barcode	Stability	Unit
1	DIL	R1	Large	26.57	DL22-ERBA		-		
2	WASH	R1	Small	18.03	W11-ERBA		-		
3	AMY	R1	Large	28.99			-		
4									
5	GPTH1	R1	Large	28.99	21076-ERBA	31-May-2011	600522110500210768	0	D
6									
7									
8									
9	PRO	R1	Large	18.03	80704-ERBA	31-Jul-2009	600372190700807044	0	D
10									
11									
12									
13									
14									
15									
16	ASL	R1	Tube	0.00			-		
17									
18									
19									
20									
21	GLU	R1	Large	0.00	11142-ERBA	30-Jun-2012	600232120600111421	0	D
22									
23									
24									
25									
26									
27									

Position    Reagent    Reagent Type    Bottle Type    Lot No.    Save Position Detail

Indication : Reagent Positions Updated successfully.



**NOTE: The Rgt Vol(ml) column will show 0.00 ml at the time of definition, and it will be updated after Reagent Volume Scan or at the first aspiration during run.**

## 6.2.3. Reagent Level Scan

### 6.2.3.1. Reagent Level Scan

The options under Reagent Level Scan are used for scanning the volume of the reagent present inside the reagent bottles before starting the run. It is available in the **Status monitor > PRE-RUN OPT**.

If the option is checked before the run, and when the run started, all the reagents positions will be scanned for reagent volume and the status will displayed on **REAGENT TRAY** screen and **Utility > Reagent Position** screen.

Two options are available for scanning:

- Selective
- All

**Selective:** This option is used for scanning the Reagent volume for only those reagents, which are defined and required by the samples in current batch. The Diluents & Wash solution positions are always scanned if defined.

**All:** This option is used to scan all the reagents available on the tray.



**NOTE: If both options are not selected then MultiXL will only scan volume at positions where Wash solutions, Serum Diluents and Urine ISE Diluents are defined.**

**After the volume scan, if the volume of wash solution and/or diluents in the reagent bottles is less than 10 ml, then the low volume message will be displayed in the error message grid of Status Monitor.**

**"ISE Urine Diluent Low (Less Than 10 ml)"**

**Click on Yes button to proceed with batch Run with ISE**

**Click on No button to proceed with batch Run without ISE**

**Click on Cancel button to stop the batch Run**

### 6.2.3.2. Volume Scan

To view this screen click on **Status Monitor > REAGENT TRAY** screen.

 Patient Entry(F2) Test Parameter(F3) Profiles / Calc(F4) QC/Calibration(F5) Consumables(F6) Status Monitor(F7) Search(F8) Reports(F9) Master Utility(F11) Service Check Maintenance(F12) Settings Shut Down	<table border="1"> <thead> <tr> <th colspan="2">SAMPLE TRAY</th> <th colspan="2">REAGENT TRAY</th> <th colspan="2">REACTION CURVE</th> <th colspan="2">BARCODE SCAN</th> <th colspan="2"></th> <th colspan="2"></th> </tr> </thead> <tbody> <tr> <td>01</td><td>ALB R1 # 222</td> <td>02</td><td>CAA R1 # 42</td> <td>03</td><td>ALP R2 # 967</td> <td>04</td><td>ALP R1 # 71</td> <td>05</td><td>BID R2 # 636</td> <td>06</td><td>BID R1 # 407</td> <td>07</td><td>BIT R2 # 903</td> <td>08</td><td>BIT R1 # 47</td> <td>09</td><td>CAA R1 # 269</td> <td>10</td><td>LDH R1 # 130</td> </tr> <tr> <td>11</td><td>CHO R1 # 103</td> <td>12</td><td>CKN R2 # 412</td> <td>13</td><td>CKN R1 # 231</td> <td>14</td><td>CRE R2 # 432</td> <td>15</td><td>CRE R1 # 232</td> <td></td><td></td> <td></td><td></td> <td></td><td></td> <td>20</td><td>GOT R2 # 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If you place the pointer over any of the bottle, it displays the Consumable Name, Bottle Type, available volume in ml, Reagent Name and the number of possible tests can be performed using # sign (only when run is not in progress).

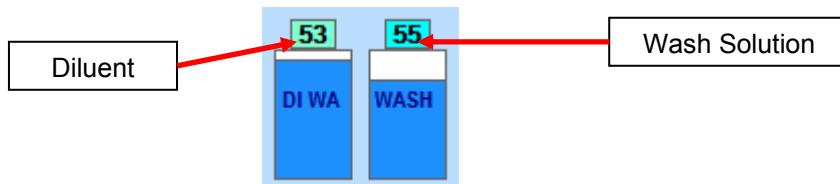
The following legends are used to depict the reagent bottle conditions:

- **NORMAL:** If the level in the reagent bottle is defined, then it is indicated with BLUE COLOUR.
- **LOW:** If the level in the reagent bottle is below 20% of the bottle capacity, then it is indicated with YELLOW COLOUR.
- **EMPTY:** If the reagent bottle is empty, then it is indicated with WHITE COLOUR.
- **VACANT:** If the reagent position is free (reagent not defined), then it is indicated with GRAY COLOUR.
- **REAGENT DEFINITION:** If reagent is assigned at a position on the reagent tray, then it is indicated with BROWN COLOUR.

Following legends are used to depict the reagent bottle cap:

- **DILUENT DEFINITION:** If diluent is assigned at a position on the reagent tray, then it is indicated with CYAN COLOUR (Bluish shade of green).
- **WASH SOLUTION DEFINITION:** If wash solution is assigned at a position on the reagent tray, then it is indicated with BLUE COLOUR.

For example: See the bottle cap color as shown in the following figure.



During run, the **Refresh Positions** button is enabled if any obstruction is detected (due to empty bottle or any other VOD error) and the reagent bottle is not defined at that reagent position. Click on the button, a screen with the reagent positions to be refreshed will be displayed, select the reagent positions and click on OK.



---

**NOTE: Reagent name can be assigned to a test from Test Parameters screen.**

---

## 6.3. Preparation and Placement of Blank, Standard, Calibrator, and Control

The Samples, Blanks, Standards, Calibrators and Controls are placed in 2 ml cups on the inner most row of standard tray position I1 to I9. The cups placed on these positions can not be barcoded.

The Blanks, Standards, Calibrators and Controls can also be placed on the outer and middle row on position 1 to 30 in 5 ml, 7 ml, and 10 ml sample tubes, if required. Tubes placed on these positions will be barcoded except 2 ml cups.

### 6.3.1. Preparation of Blank, Standard, Calibrator and Control

Preparation of Blank, Standard, Calibrator, and Control includes defining their name along with their respective lot numbers, reconstituted dates, concentration and on-board stability of the test are defined in the same screen.

To define the consumable, use **Consumables** screen from the main menu.

#### 6.3.1.1. Steps in Defining a Blank

1. From the **Consumables** screen, select **Consumable Type** as Blank.
2. Click on the dotted button next to **Consumable** name. This will open a new window "Consumable".
3. Enter new name in the **Blank** text box and select the tests associated with the blank, and then click on **SAVE**.



Figure 6-9. Consumables – Adding blank

- a. Once saved, the user can double click on the Blank name for which he wants to add Lot Details. This will close the window "Consumable" and

take him back to "Consumable" main screen. One can also leave the screen by clicking on "X" when one do not want to add Lot and go back to **Consumable** screen.

- Click **ADD** from the main screen, the following screen will be displayed.

Test	Concentration
AMY	0.000
CKN	0.000

Figure 6-10. Consumables - Adding blank details

- Select the **Manufacturer** name. Refer section 7.7.5 *Master – Manufacturer*.
- Enter appropriate **Lot No** and concentration for the selected blank.
- After entering the details, click on **SAVE** button.

On clicking, the blank will be saved and displayed on the Blank consumable screen.

### 6.3.1.2. Steps in Defining a Standard

- From the **Consumables** screen, select **Consumable Type** as Standard.
- Click on the dotted button next to **Consumable** name. This will open a new window "Consumable".
- Enter new name in the **Standard** text box and select the tests associated with the standard, and then click on **SAVE**.

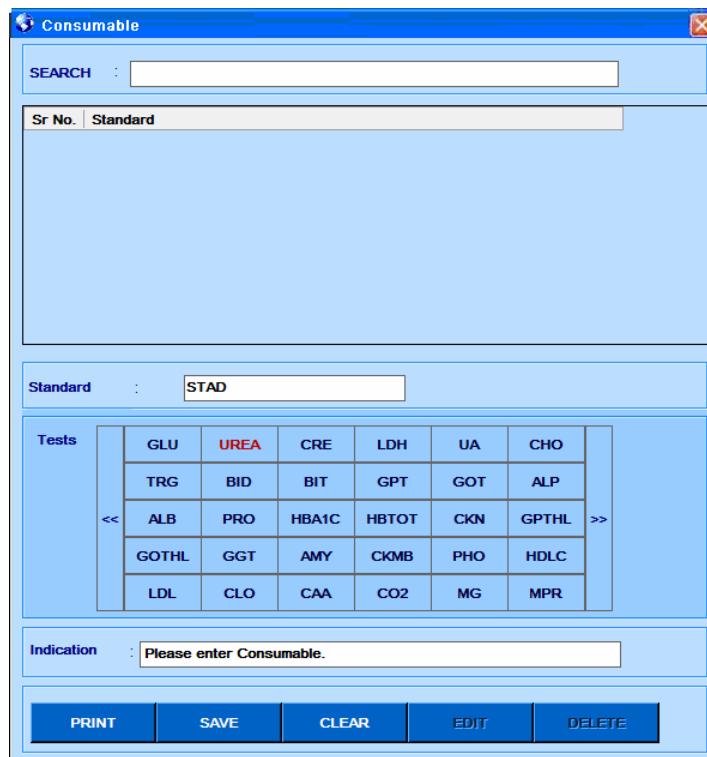


Figure 6-11. Consumable - Adding standard

Once saved, the user can double click on the Standard name for which he wants to add Lot Details. This will close the window "Consumable" and take him back to "Consumable" main screen. One can also leave the screen by clicking on "X" when one do not want to add Lot and go back to "Consumable" main screen

4. Click **ADD** from the main screen, the following screen will be displayed.

Patient Entry(F2)  
Test Parameter(F3)  
Profiles / Calc(F4)  
QC/Calibration(F5)  
Consumables(F6)  
Status Monitor(F7)  
Search(F8)  
Reports(F9)  
Master  
Utility(F11)  
Service Check  
Maintenance(F12)  
Settings  
Archive  
Shut Down

**\* Consumable Type** : Standards      **DOWNLOAD**  
**\* Consumable** : STAD      **UPLOAD**

Lot Details		
<b>* Manufacturer</b>	: ERBA	<input checked="" type="checkbox"/> Stock Over
<b>* Lot No</b>	: 123	<b>Lot Status</b> : Active
<b>* Expiry Date</b>	: 17-Oct-2011	
STANDARD TEST DETAILS		
<b>* Test</b>	: UREA	
<b>* Concentration</b>	: 12	

Indication : Enter Concentration for the Standard-Lot '123'

PRINT    ADD    SAVE    EDIT    CLEAR

Figure 6-12. Consumables - Adding standard details

5. Select the **Manufacturer** name. Refer section 7.7.5 *Master – Manufacturer*.
6. Enter appropriate **Lot No.**
7. Select the appropriate **Expiry Date**.
8. Enter the concentration for the selected standard.
9. After entering the details, click on **SAVE** button.

On clicking, the blank will be saved and displayed on the Standard consumable screen.

### 6.3.1.3. Steps in Defining a Calibrator

1. From the **Consumables** screen, select **Consumable Type** as Calibrator.
2. Click on the dotted button next to **Consumable** name. This will open a new window "Consumable".
3. Enter new name in the **Calibrator** text box and select the tests associated with the calibrator, and then click on **SAVE**.

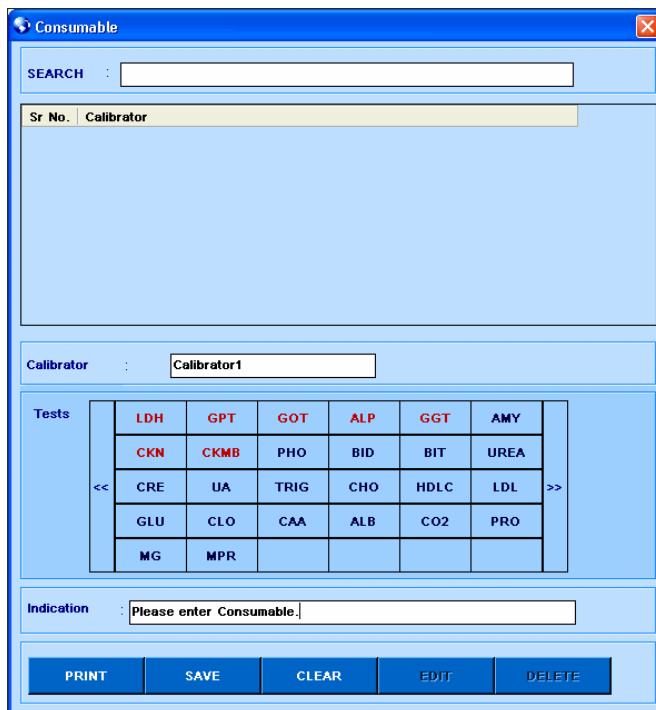


Figure 6-13. Consumable - Adding calibrator

Once saved, the user can double click on the Calibrator name for which he wants to add Lot Details. This will close the window "Consumable" and take him back to "Consumable" main screen. One can also leave the screen by clicking on "X" when one do not want to add Lot and go back to "Consumable" main screen

4. Click **ADD** from the main screen, the following screen will be displayed.

**Consumable Type**: Calibrators

**Consumable**: Calibrator1

**Manufacturer**: ERBA

**Lot No**: 1233

**Expiry Date**: 28-Jun-2011

**Stock Over**:

**Lot Status**: Active

Test	Concentration
GPT	0.000
LDH	0.000
GOT	0.000
ALP	0.000
GGT	0.000
CKN	0.000
CKMB	0.000

**Indication**: Enter Lot No For Calibrator1

**Buttons**: PRINT, ADD, SAVE, EDIT, CLEAR

Figure 6-14. Consumables - Adding standard details

5. Select the **Manufacturer** name. Refer section 7.7.5 *Master – Manufacturer*.
6. Enter appropriate **Lot No.**
7. Select the appropriate **Expiry Date**.
8. Enter the concentration for the selected calibrators.
9. After entering the details, click on **SAVE** button.

On clicking, the blank will be saved and displayed on the Calibrator consumable screen.

#### 6.3.1.4. Steps in Defining a Control

1. From the **Consumables** screen, select **Consumable Type** as Control.
2. Click on the dotted button next to **Consumable** name. This will open a new window "Consumable".
3. Enter new name in the **Control** text box, and select the **Level** from the available options (Low, Normal, High, Very High).
4. Select the tests associated with the control, and then click on **SAVE**.



Figure 6-15. Consumable - Adding control

Once saved, the user can double click on the Control name for which he wants to add Lot Details. This will close the window "Consumable" and take him back to "Consumable" main screen. One can also leave the screen by clicking on "X" when one do not want to add Lot and go back to "Consumable" main screen

5. Click **ADD** from the main screen, the following screen will be displayed.

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**Patient Entry(F2)**

**Test Parameter(F3)**

**Profiles / Calc(F4)**

**QC/Calibration(F5)**

**Consumables(F6)**

**Status Monitor(F7)**

**Search(F8)**

**Reports(F9)**

**Master**

**Utility(F11)**

**Service Check**

**Maintenance(F12)**

**Settings**

**Archive**

**Shut Down**

**\* Consumable Type** : Controls **Control Level** : Low **DOWNLOAD** **UPLOAD**

**\* Consumable** : CONT **Lot Details**

**\* Manufacturer** : ERBA **Stock Over**

**\* Lot No** : 123 **Lot Status** : Active

**\* Expiry Date** : 17-Oct-2011

**Acceptable Limit**  SD  CV

Test	Mean	SD
CHO	0.000	0.00
TRG	0.000	0.00

**Indication** : Enter Lot No For CONT

**PRINT** **ADD** **SAVE** **EDIT** **CLEAR**

Figure 6-16. Consumables - Adding standard details

6. Select the **Manufacturer** name. Refer section 7.7.5 *Master – Manufacturer*.
7. Enter appropriate **Lot No.**
8. Select the appropriate **Expiry Date**.
9. Enter the mean value for the selected tests in the **Mean** column.

CV will be automatically calculated, if the Mean and SD are entered for the test. Similarly, SD will be calculated if Mean and CV are entered.

For example: To calculate CV, select option **SD** and enter the mean and standard deviation value for the test in the **Mean** and **SD** column. On saving the Control, the CV will be calculated and displayed in the **CV** column.

Test	Mean	SD	CV
UREA	1.000	1.00	
ALP	2.000	2.00	
GGT	1.000	3.00	
AMY	1.000	4.00	

10. After entering the details, click on **SAVE** button.

On clicking, the control will be saved and displayed on the Control consumable screen.

### 6.3.2. Scheduling Blank, Standard, Calibrator and Control

The Blank, Standards, Calibrators, and Controls are scheduled using **QC/Calibrations > Schedule QC/Calibration** screen.

Pos	Tests	Mean/Conc	SampleID / Consumable	Lot No.	Sample Type	DilRatio	DilNo	StdVol(µl)	DilVol(µl)
I-1									
I-2									
I-3									
I-4									
I-5									
I-6									
I-7									
I-8									
I-9									
1									
2									
3									
4									
5									
6									
7									
8									
9									

#### 6.3.2.1. Scheduling Standard and Calibrators

Use the following procedure for scheduling:

1. Select the group number on which the calibration and QC run needs to be performed using **Group** dropdown list.
2. Select a desired position from the **Position** dropdown list. If the position is occupied, then the user can view it in the grid placed on the bottom side of the screen.
3. Select the appropriate container type from the **Container Type** drop down list.
4. Select the appropriate consumable from the **Consumable Type** drop down list.

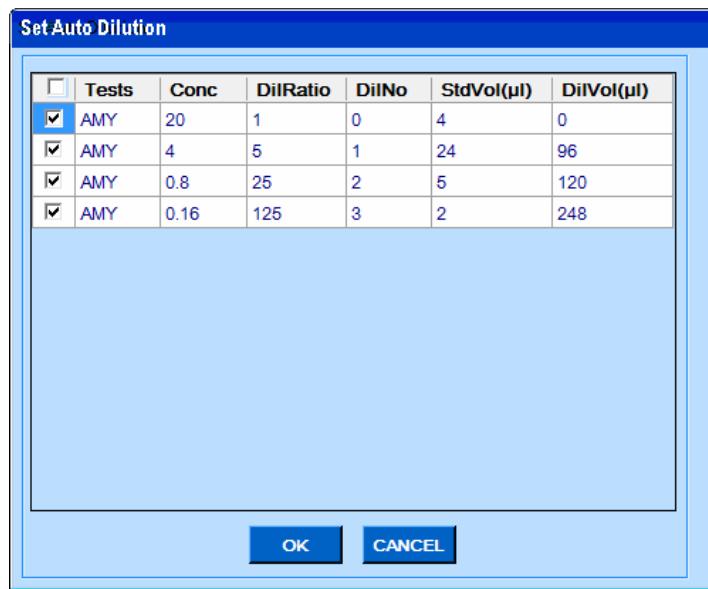
5. Select the appropriate consumable from the **Consumable** drop down list.
6. Select the **Lot No** of the consumable name.

If the selected **Consumable** is **Calibrators** or **Standards**, a grid will be displayed on right side of the screen where in option of auto dilution and dilution ratio can be selected.

Pos	Tests	Mean/Conc	SampleID / Consumable	Lot No.	Sample Type	DilRatio	DilNo	StdVol(µl)	DilVol(µl)
I-1									
I-2									
I-3									
I-4									
I-5									
I-6									
I-7									
I-8									
I-9									
1									
2									
3									
4									
5									
6									
7									
8									
9									

7. On selecting **AutoDil** and **DilRatio**, click **OK**.

Depending on the concentration and the dilution ratio of the test, the number of dilutions possible will be displayed in another grid as shown in the following figure.



Further dilution numbers can be selected using this grid.

#### 8. Click OK.

On clicking, the details will be added in the required position as shown in the following figure.

Pos	Tests	Mean/Conc	SampleID / Consumable	Lot No.	Sample Type	DilRatio	DilNo	StdVol(µl)	DilVol(µl)
I-1									
I-2									
I-3	AMY	20	STAD	ERBA-2356		1	0	4	0
	AMY	4				5	1	24	96
	AMY	0.8				25	2	5	120
	AMY	0.16				125	3	2	248
I-4									
I-5									
I-6									
I-7									
I-8									
I-9									
1									
2									
3									
4									
5									
6									



**NOTE: Auto-dilution is possible for non-linear curves.**  
**Auto-dilution is not possible for the curve types K-factor and Linear. The grey background color in the column AutoDil indicates that auto-dilution is not possible for the respective test.**

9. Once the Standards and Calibrators are defined, click on **SCHEDULE** button.

On clicking the SCHEDULE button, the Standards or Calibrators will be scheduled.



**NOTE: The MultiXL will prompt a message if the required Blank and Standards / Calibrators are not scheduled.**

While performing the Blank, Standards, Calibrators and Controls that are scheduled, the sample and reagent volumes defined (in **Test Parameter > Test Volume**) for Sample Type Serum is used. This is indicated by Serum in the column Sample Type.

To clear the schedule **CLEAR POSITIONS** button can be clicked. On clicking, following screen is displayed to either clear selected positions or all the positions.



**NOTE: Clear position button does not clear the sample positions. Only scheduled Blank, Standards, Calibrators and Controls will be cleared.**

Hence, either a particular position is selected or CLEAR ALL option is checked.

### 6.3.2.2. Scheduling Blank and Control

Use the following procedure for scheduling:

Following procedure is used for scheduling the controls.

1. Select the group number on which the calibration and QC run needs to be performed using **Group** dropdown list.
2. Select a desired position. If the position is occupied, then the user can view it in the grid placed on the bottom side of the screen.
3. Select the appropriate container type from the **Container Type** dropdown list.
4. Select the appropriate consumable from the **Consumable Type** dropdown list.
5. Select the appropriate consumable from the **Consumable** drop down list.
6. Select the **Lot No** of the consumable name.

If the selected **Consumable** is **Blank** or **Control**, then the grid on the right side of the screen displays the available tests for running QC.

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Schedule QC / Calibration   Calibration   QC Data   Twin Plot

Group	:	1	Tests <input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> GPTHL <input checked="" type="checkbox"/> GOT <input checked="" type="checkbox"/> GOTH
Position	:	I-4		
Container Type	:	CUP (2 ml)		
Consumable Type	:	Controls		
Consumable	:	Control 1		
Lot No.	:	ERBA-253		

OK   CANCEL

Pos	Tests	Mean/Conc	SampleID / Consumable	Lot No.	Sample Type	DilRatio	DilNo	StdVol(µl)	DilVol(µl)
I-1									
I-2									
I-3									
I-4									
I-5									
I-6									
I-7									
I-8									
I-9									
1									
2									
3									
4									
5									
6									
7									
8									
9									

SCHEDULE   CLEAR POSITIONS

Indication   Please select Lot No.

7. Select the tests that are required whose QC needs to be performed, and then click on the **OK**.

On clicking, the details will be added in the required positions as shown in the following figure.

Pos	Tests	Mean/Conc	SampleID / Consumable	Lot No.	Sample Type	DilRatio	DilNo	StdVol(µl)	DilVol(µl)
I-1									
I-2									
I-3									
I-4	GPTHL	23	Control 1	ERBA-253		8			
	GOT	20				16			
	GOTH	22				8			
I-5									
I-6									
I-7									
I-8									
I-9									
1									
2									
3									
4									
5									
6									
7									

**SCHEDULE**      **CLEAR POSITIONS**

Indication Click on Schedule to Save Schedules(s) .

- Once the Controls or Blank defined, click on **SCHEDULE**.

On clicking the SCHEDULE button, the Control or Blank will be scheduled.



**NOTE: The MultiXL will prompt a message if the required Blank and Standards/Calibrators are not scheduled.**

- To clear the schedule **CLEAR POSITIONS** button can be clicked.

## 6.4. Procedure for Upload and Download Consumables

The consumable details can be uploaded or downloaded using **UPLOAD** and **DOWNLOAD** button. These buttons are available in the **Consumable** screen.

The distributor will generate the files containing consumable details (like Calibrator and Control lot information along with concentration, target values etc) using **DOWNLOAD**.

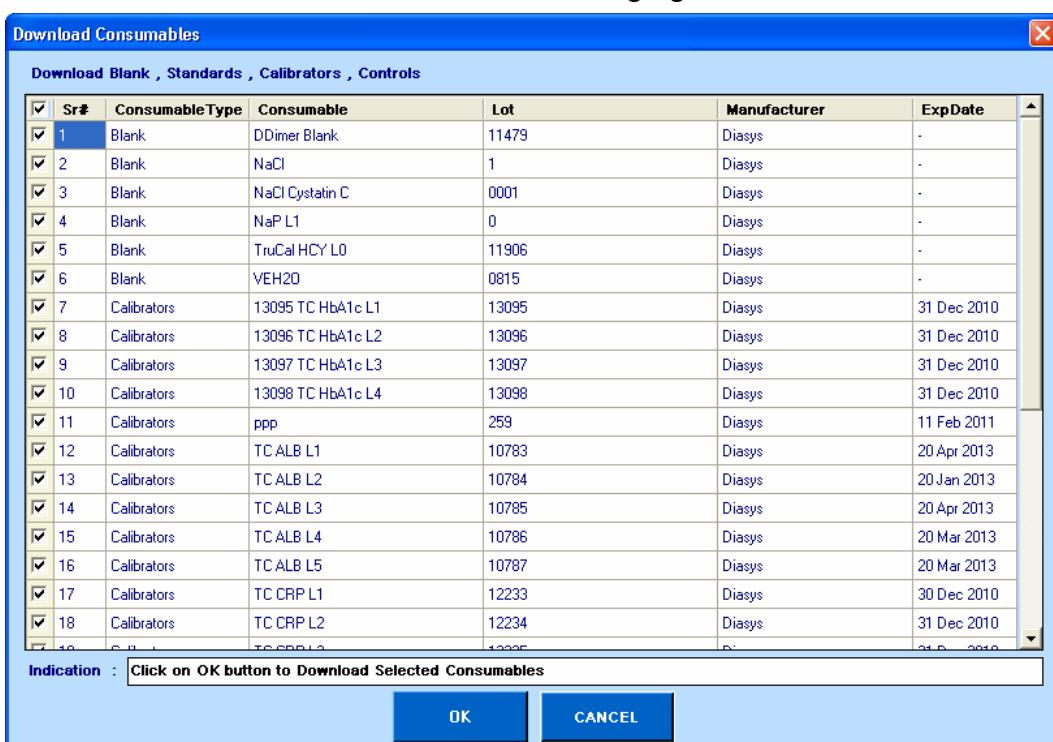
The distributor will send this generated file to the customers along with consumables. The customers will then upload the given consumable file using **UPLOAD**.

## 6.4.1. Downloading Consumables

Use the following steps to download the consumables:

1. Go to **Consumables** screen.
2. Define the appropriate consumables (Blank, Standards, Calibrator, Controls, and Reagent) with their respective lot details.  
Refer section *6.3.1 Preparation of Blank, Standard, Calibration, and Controls* for defining consumables for more details.
3. Click **DOWNLOAD**.

On clicking, the **Download Consumables** window will be displayed which contains the list of information about all the active (non-expired) lot(s) of consumables as shown in the following figure.



By default, all consumables will be selected for download. You can select the required consumables by un-checking the checkbox and then selecting it again as per your requirement.

**Download Consumables**

**Download Blank , Standards , Calibrators , Controls**

Sr#	ConsumableType	Consumable	Lot	Manufacturer	ExpDate
1	Blank	DDimer Blank	11479	Diasys	-
2	Blank	NaCl	1	Diasys	-
3	Blank	NaCl Cystatin C	0001	Diasys	-
4	Blank	NaP L1	0	Diasys	-
5	Blank	TruCal HCY L0	11906	Diasys	-
6	Blank	VEH2O	0815	Diasys	-
7	Calibrators	13095 TC HbA1c L1	13095	Diasys	31 Dec 2010
8	Calibrators	13096 TC HbA1c L2	13096	Diasys	31 Dec 2010
9	Calibrators	13097 TC HbA1c L3	13097	Diasys	31 Dec 2010
10	Calibrators	13098 TC HbA1c L4	13098	Diasys	31 Dec 2010
11	Calibrators	ppp	259	Diasys	11 Feb 2011
12	Calibrators	TC ALB L1	10783	Diasys	20 Apr 2013
13	Calibrators	TC ALB L2	10784	Diasys	20 Jan 2013
14	Calibrators	TC ALB L3	10785	Diasys	20 Apr 2013
15	Calibrators	TC ALB L4	10786	Diasys	20 Mar 2013
16	Calibrators	TC ALB L5	10787	Diasys	20 Mar 2013
17	Calibrators	TC CRP L1	12233	Diasys	30 Dec 2010
18	Calibrators	TC CRP L2	12234	Diasys	31 Dec 2010
19	Calibrators	TC CRP L3	12235	Diasys	31 Dec 2010

**Indication :** Click on OK button to Download Selected Consumables

**OK**      **CANCEL**



**NOTE: At least one consumable lot should be selected to download.**

- Once the required consumables are selected, click **OK**.

The will generate a XML file containing the consumable information with their respective lot details (only for active lot). This file is automatically saved in the appropriate location on your computer. The file name and the location will be displayed on the **Indication** text box as shown below:

**Calibrators**

10	Calibrators	13098 TC HbA1c L4	13098	Diasys	
11	Calibrators	ppp	259	Diasys	11 Feb 2011
12	Calibrators	TC ALB L1	10783	Diasys	20 Apr 2013
13	Calibrators	TC ALB L2	10784	Diasys	20 Jan 2013
14	Calibrators	TC ALB L3	10785	Diasys	20 Apr 2013
15	Calibrators	TC ALB L4	10786	Diasys	20 Mar 2013
16	Calibrators	TC ALB L5	10787	Diasys	20 Mar 2013
17	Calibrators	TC CRP L1	12233	Diasys	30 Dec 2010
18	Calibrators	TC CRP L2	12234	Diasys	31 Dec 2010
19	Calibrators	TC CRP L3	12235	Diasys	31 Dec 2010

**Indication :** Consumable(s) downloaded at C:\MultiXLLOG\DOWNLOAD CONSUMABLES\CONSUMABLES\_20101020.Xml

**OK**      **CANCEL**

## 6.4.2. Uploading Consumables

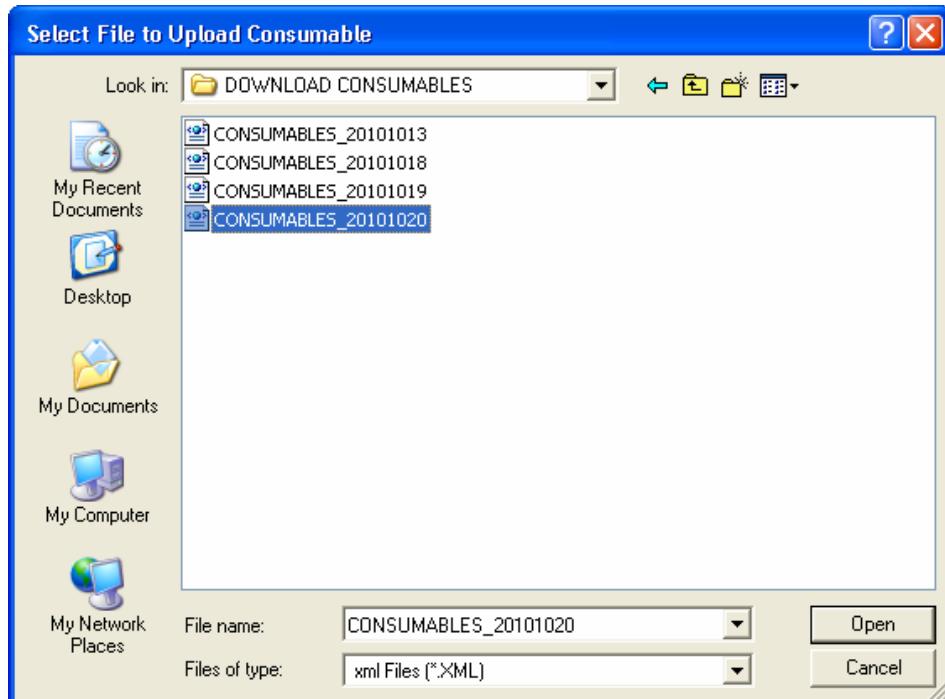


**NOTE: Before uploading the consumables, you should have access to the Consumable screen.**

Follow these instructions to upload the consumables:

1. Go to **Consumable** screen, and click **UPLOAD**.

On clicking, the following window will be displayed.



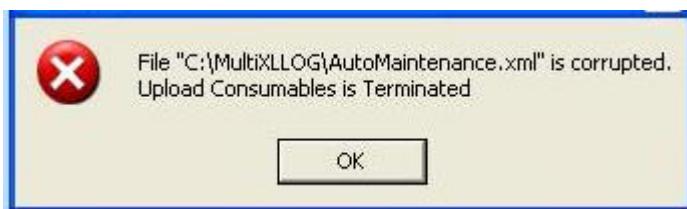
2. Now select the required consumable file from the appropriate location, and then click **Open**.

On clicking, the system will read and verify the data before uploading the file. The consumable information will be uploaded only if the lot number is not found. This means, if the system detects that the consumable lot with all or some test(s) already present in the database (uploaded earlier or defined manually), then it will skip those test(s) without comparing and changing its respective information (such as Expiry date and Target value(s)), and It will upload only those test(s) along with their respective details that are not available in the database.

In case, any error occurs during verification or upload, the error message will be displayed and data from the file will not get uploaded to database.

The following error message will be displayed during upload if:

- Incorrect xml file is selected (other than the one generated using Download option) for upload, then the following error message will be displayed and upload will not proceed.



- The XML file (generated using Download option and received) format is altered, then the following error message will be displayed “Error in Uploading Consumables” in the **Indication** text box, as a result the upload data will be terminated.



- On successful upload, a message “Consumables Uploaded Successfully” will be displayed.

#### 6.4.2.1. To Verify the Uploaded Consumables

Once the consumables are uploaded, you should verify each of the consumables lot.

From the **Consumable** screen, select the appropriate consumable (Blank, Standards, Calibrators or Controls) from the **Consumable Type** dropdown list, and verify the uploaded consumables.

## 6.5. Preparation and Placement of Sample

### 6.5.1. Sample Barcode Scan (Offline)

The **Sample Barcode Scan** button on the **Status Monitor > BARCODE SCAN** screen is used to scan the barcoded sample tubes placed on the sample tray.

During this process, all barcoded samples will be scanned for barcode. After scan is over the sample details (like Sample ID, Position, along with the Tests) will be updated and displayed in the following screens:

- Patient Entry
- Status Monitor > SAMPLE TRAY
- Status Monitor > BARCODE SCAN

During sample barcode scan, also the tests that are schedule on the LIS will be automatically downloaded and applied to the appropriate samples if the communication between analyzer and Host computer is ON.

Barcode scan of the samples will be performed prior to start of the run, if the option **Sample** is selected from the **PRE-RUN** options in **Status Monitor > SAMPLE TRAY**.



**NOTE: The Sample Barcode Scan button will be disabled if the option Sample Barcode is unchecked from the Settings > System Parameters screen.**

The screenshot shows the 'Barcode Scan' screen of the Status Monitor. On the left, a sidebar lists various menu options: Patient Entry(F2), Test Parameter(F3), Profiles / Calc(F4), QC/Calibration(F5), Consumables(F6), Status Monitor(F7), Search(F8), Reports(F9), Master, Utility(F11), Service Check, Maintenance(F12), Settings, and Shut Down. The main area features two tables: 'SAMPLE TRAY' and 'REAGENT TRAY'. Each table has columns for S.N. and Barcode type (Sample or Reagent). Below these are buttons for 'Sample Barcode Scan', 'Stop Scanning', and 'Reagent Barcode Scan'. A toolbar at the bottom includes 'Refresh Positions', 'Work List', 'ISE PACK', 'Add Reagent', 'Add Sample', and 'Calibration Required'. To the right, there's a 'PRE-RUN OPT' section with radio buttons for Auto Rerun (selected) and Disk Change, and checkboxes for Barcode Scan, Reagent, Sample, RGT Level Scan (with Selective and All options), and ISE Patient. There's also a 'De-Select All' button. A large table on the right lists positions from R1S to R36. At the bottom, there's a table for 'ERROR MESSAGE' and another for 'RESULT' with columns for SN, POS, TEST, RESULT, UNIT, and FLAG.

Figure 6-17. Status monitor - Barcode scan screen

## 6.5.2. Specifications of Barcode Label

Item	Description
Symbols	NW-7, Code39, ITF, UPC, Code128 (Set A, B, C)
Maximum Number of Digits	<p>The bar codes must be in conformity with one of the following bar modules and with bar code printing range.</p> <p>The maximum allowable number of digits varies depending on symbols.</p> <ul style="list-style-type: none"> <li>NW-7: 6 to 18 digits</li> <li>Code39: 6 to 18 digits</li> <li>ITF: 6 to 18 digits</li> <li>UPC: 6 to 18 digits</li> <li>Code128 (SetA) : 6 to 18 digits</li> <li>Code128 (SetB) : 6 to 18 digits</li> <li>Code128 (SetC) : 6 to 18 digits</li> </ul>
Bar module	Fine bar: 0.25 to 1.0 mm

	Bar length $\geq$ 15 mm
Barcode printing Range	Bar code printing area $\leq$ 46 mm
Printing	Black on white background (B633) Numeric coding information is printed beside bar code. Printing on thermal paper is not allowed in order to prevent bar code from time varying degradation.
Positioning of barcode label	The position is such that there is no obstacle between the barcode printing area and the bar code reader. Angle alignment deviation: within $\pm 1^\circ$

### 6.5.3. Patient Entry

The patient entry screen is used to enter the patient details. Details of patient like name, address, doctor referring patient, analyst, age, sex etc can be entered using this screen. Also, the routine tests, calculation items, profiles to be performed on the patient sample can be requested using this screen. These patient demographics are used to generate the patient report after analysis of the sample.

This screen is divided into 2 sections:

First section is used for defining the Sample ID and other information related to Sample definition.

Second section is used for Patient Demographics entry. One Patient can have more than one Sample ID.

To open this screen, clicking **Patient Entry** or F2 button. The following screen will be displayed:

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Figure 6-18. Patient entry screen

The following are the details of different parameters available on the screen:

**Sample ID:** It is used for assigning an alphanumeric identification number of up to 18 characters to each patient. It is mandatory textbox and cannot be skipped. If the Sample ID is already entered, then the user can view the Sample ID by clicking on the dotted button placed next to the Sample ID text box.

**Position:** In case the sample is not bar-coded, the user should specify the sample position in this text box. An assigned sample position cannot be used for some other sample. Any sample Positions on the sample tray can be entered. If there are more than maximum no of Sample Positions, then a different Group No. needs to be selected.

For bar-coded samples the sample position is automatically assigned as per the group number selected after the sample bar-code scan.

For emergency samples, any position that is vacant can be used for any group during Patient Run.

**Group:** It is used to assign group numbers for various samples processed during the day. If there are more than maximum sample positions, then the user needs to select Group No 2 and so on. The user can assign the Group Numbers from 1 to 99.

**Emergency:** Whether the given sample is an emergency sample or not is specified using this tick option. To designate a sample as an emergency sample, check this option and assign one of the free positions for the sample. Emergency samples are given priority over routine samples in a run.

**Barcoded:** The user can select whether to use sample bar-code facility or not. If the bar-code option is set to ON in the **Settings > System Parameters** screen, then the sample position fed by the user is ignored. The user has to select/deselect the checkbox for whether the sample for the particular patient is bar-coded or not. The barcoded option can be selected to only the outer two rings of sample positions.

**Sample Type:** Select the sample type from the drop down list. The default options available are: Serum, Urine, CSF, Plasma, Whole Blood and Other.

**Sample Volume Type:** Select the sample volume type using the drop down list. The available options are Normal, Increase and Decrease. If the sample has low concentration, then the user can select an increase volume. If the sample is high concentration sample, then the user can select decrease volume.

**Container Type:** Select the sample container type from the pull down option. There are various options available and one can select the Container Type by selecting the drop down list.

**Default container type can be set from Settings > System Parameters screen.**

**Collection Date:** This parameter is used to enter the date at which the sample was drawn.

**Registration Date:** This parameter is used to enter the date at which the patient was registered in the hospital.

**Area:** This is used to select the area (location) from where the sample is collected. One can select the desired area from the area list by clicking on the dotted button. On clicking the dotted button, area help screen containing the list of area is displayed. Select the desired area from the list by double clicking on the respective area name.

**Go to Master > Area screen to add a new area in the list or edit the existing name.**

**Ref Doctor:** This is used to select the name of the referral doctor. The list of doctors will be displayed on clicking the dotted button as shown in the following figure. You can select the doctor's name for the respective patient by double clicking on the particular doctor's name from the list. A doctor's name can be searched by entering the name in **Search** textbox.

If you want to add new doctor's name or edit the existing name, you can do it through **Master > Doctor** screen

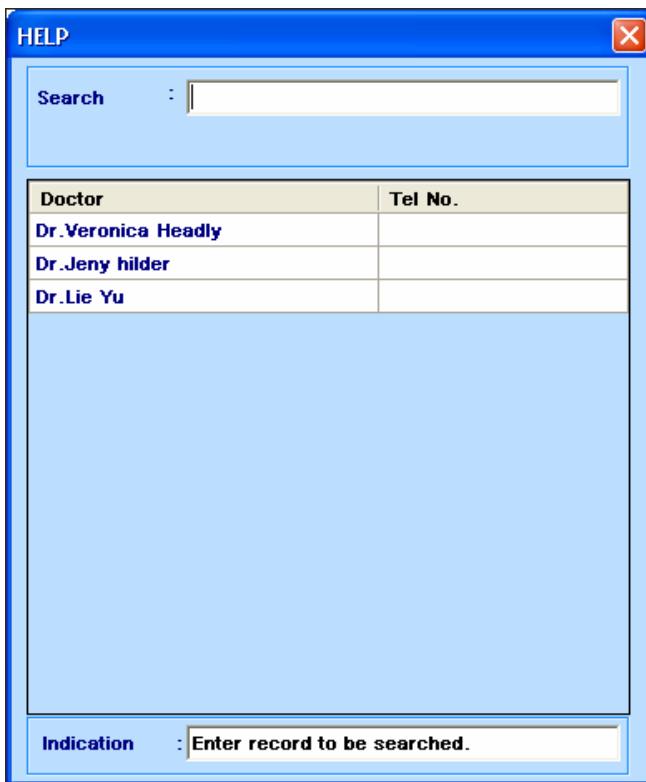


Figure 6-19. Doctor's detail screen

**Analyst:** This is used to select the name of the analyst. The list of analysts will be displayed on clicking the dotted button as shown in the following figure. You can select the analyst's name by double clicking on the particular name for the respective patient. The analyst's name from the list can also be searched by entering the name in Search textbox. If you want to add new analyst name or edit the existing name, you can do it through **Master > Analyst** screen.

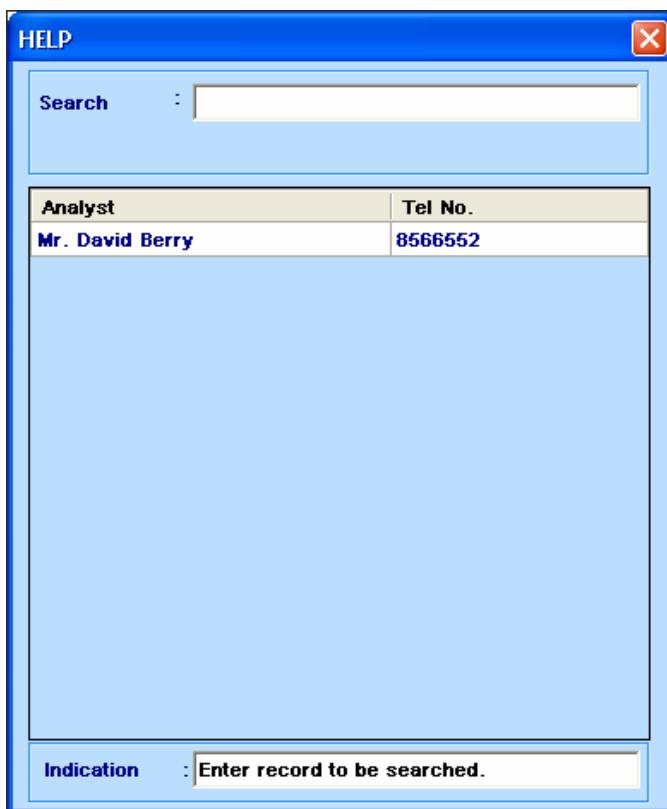


Figure 6-20. Analyst details screen

**Sample Remarks:** Remarks about sample can be fed here using up to 50 alphanumeric characters. Previously fed remarks can be selected by pull-down options. The remark is printed in the patient report.

**Patient Name:** Enter the patient name in the textbox using the keyboard. A maximum of 30 characters can be fed in this text box. Alternatively, patient can be selected using the dotted button placed next to the Patient Name. Also, if the user desires to use the same patient with different sample ID, then he/she can double click on the dotted button and select the patient name for a different Sample ID. Hence one Patient can have multiple Sample IDs.

**Category:** This dropdown list is used to identify the sex of the patient. Select as Male / Female / Child / Other. The default option is **Default**.



**NOTE: For a patient selecting the category is optional. But if the category is not selected then the default reference ranges will be applied. After the run is performed patient category can be updated and on recalculation of the results, reference ranges will be applied and hence the H / L flags will be attached.**

**Age:** Enter the numerical age of the patient (in three digits maximum). Choose age in Days/Months/Years using the pull down option. The patient age is used to issue H and L flag for the corresponding age range as mentioned in the Test Parameters (see section 7.2 *Test Parameters*). If age of a patient is not fed, default normal values are used to issue H and L flags.

**Patient ID:** Enter Patient identity number. For example, social security number or insurance number can be entered here for printing on Patient Report.

**Patient Address:** 50 alphanumeric characters are allowed in this textbox where one can enter the address of the patient.

**Patient Tel No:** This textbox is used to enter the contact number of the patient.

**Patient Remarks:** Remarks about patient can be fed here using up to 50 alphanumeric characters. Previously fed remarks can be selected by pull-down options. These remarks are printed in the patient report.

The following parameters are read only and can be entered through CEC screen only. See section 6.5.3.3 *To Schedule / Clear Schedule / Edit CEC for a Patient*

**Height:** It is used to enter the height of the patient (in meters).

**Weight:** It is used to enter the weight of the patient (in kilograms).

Body Mass Index (BMI) for the patient is calculated automatically that is used for Creatinine Clearance calculation. BMI is calculated by the following formula:

$$\text{BMI} = (\text{Weight})/(\text{Height})^2$$

**Urine Volume:** It is used to define the volume of urine collected from a patient in 24-hour duration. This is an optional parameter and is used in the calculation item of Creatinine Clearance. This textbox can be ignored if user does not want to use Creatinine Clearance calculation item.

If user wants to use Creatinine Clearance calculation item, entry in this textbox is necessary and the user should feed the urine volume (in ml) collected in 24 hours.

### 6.5.3.1. Defining Patient Sample

Use the following steps to define the barcoded sample:

1. Place the sample tube on the sample tray (at position 1 to 30).
2. Open **Patient Entry** screen, and enter the following necessary details:
  - a. Enter the **Sample ID**.
  - b. Select the **Barcoded** option (if sample tube is barcoded).

If it is not barcoded, then you need to:

- i) Uncheck the **Barcoded** option.
- ii) Enter the sample position number in the **Position** textbox.

For emergency samples, select **Emergency** option and follow the same steps given under **b**.

- c. Enter the group number in **Group** text box.
- d. Enter other details for the patient, as required:
  - ◆ **Sample Type**

- ◆ **Sample Vol Type**
- ◆ **Area**
- ◆ **Ref Doctor**
- ◆ **Sample Remark**
- ◆ **Container Type**
- ◆ **Collection Date**
- ◆ **Reg. Date**
- ◆ **Analyst**
- ◆ **Patient Name**
- ◆ **Age**
- ◆ **Category**
- ◆ **Patient ID**
- ◆ **Address (of Patient)**
- ◆ **Telephone**
- ◆ **Patient Remarks**
- ◆ Select the required tests from the **Tests** grid.

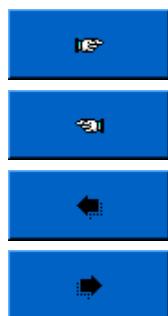
3. Click on **SAVE**.

This will save the programmed patient details and presents a new screen for programming the next patient where the sample ID and sample positions are automatically incremented if option **Barcode** is unchecked.

Use **EDIT** button, to edit or modify the already entered details.

#### 6.5.3.2. To Browse through Patient Records and Locate a Patient

You can browse through all the patient data by using the following buttons:



Click this button to view the next record.

Click this button to use the previous record.

Click this button to use the first record

Click this button to use the last record.

Alternatively, you can also click on the dotted button along side **Sample ID** to lookup for required sample Ids. On clicking, the following window will be displayed.

The screenshot shows a software window titled "MultiXL - Help". At the top, there are search fields for "Search By" (Sample ID and Reg.Date) and a "Show All Samples" button. Below is a table with columns: Group, Sample Pos, Sample ID, Collection Date, and Patient Name. The data is as follows:

Group	Sample Pos	Sample ID	Collection Date	Patient Name
1	0	1	16 Dec 2011	P JONES
1	1	2	16 Dec 2011	DAVID
1	2	3	16 Dec 2011	MIRANDA
1	3	4	16 Dec 2011	JOHNSON
1	4	5	16 Dec 2011	KELLY
1	5	6	16 Dec 2011	DUPAL
1	6	7	16 Dec 2011	SMITH
1	7	8	16 Dec 2011	HILDER
1	8	9	16 Dec 2011	LIE YU
1	9	10	16 Dec 2011	VERONICA
1	10	11	16 Dec 2011	MARY
1	11	12	16 Dec 2011	JONNY

At the bottom, there is an "Indication" field with the placeholder "Enter Sample ID to be searched."

You can search the specific records by entering **Sample ID** or **Reg.Date** text box.

#### 6.5.3.3. To Schedule / Clear Schedule / Edit CEC for a Patient

1. Click on CEC present in the calculation item list. Following is the screen displayed.

The screenshot shows a dialog box titled "CEC". It has fields for "Patient Name" (dropdown menu) and "Patient ID" (text input). Below are three radio buttons: "Schedule CEC" (selected), "Clear Schedule CEC", and "Edit". A "Show Sample ID" button is also present. The lower section contains input fields for "Sample ID-Serum / Plasma", "Sample ID-Urine", "Height (m)", "Weight (kg)", and "Urine Vol (ml/24 hrs)". At the bottom are "SAVE" and "CLOSE" buttons.

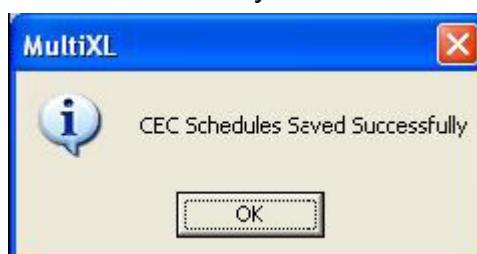
2. Select the Patient Name. If the patient name is selected then sample Id's will be displayed in the list for that patient only and if the patient name is not selected then the entire list of sample Id's will be displayed in the list irrespective of the patient name. (Patient Name selection is optional).
3. Patient ID is automatically displayed on selecting the patient name.
4. The options available to the user are Schedule CEC, Clear Schedule CEC, and Edit CEC Schedule.

- **Schedule CEC**

Follow this procedure to schedule CEC:

- a. Select **Schedule CEC** option.
- b. Click on **Show Sample ID** button to view and select the sample id from the list.
- c. Select the **Sample ID – Serum / Plasma** from the list of sample id with sample type as serum / plasma for the patient selected or all sample id's.
- d. Select the **Sample ID – Urine** from the list of sample id with sample type as urine for the patient selected or all sample id's.
- e. Enter the **Height** in meters.
- f. Enter the **Weight** in kg.
- g. Enter the **Urine Volume (ml/24 hrs)**.
- h. Click on **SAVE** button.

On clicking, the Height, Weight and Urine Volume will be updated for both the Sample ID and the message will be displayed indicating that CEC is scheduled successfully.



- **Clear CEC Schedule**

Follow this procedure to clear CEC schedule.

- a. Select Clear Schedule CEC option.
- b. Click on **Show Sample ID** button to view and select the sample id from the list.
- c. Select the **Sample ID – Serum / Plasma** from the list of sample id with sample type as serum / plasma for the patient selected or all sample id's.

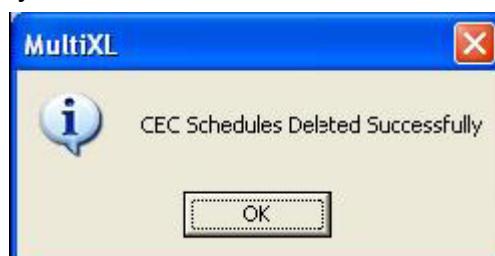
- d. **Sample ID – Urine** will automatically be displayed according to the Serum / Plasma Sample Id selection.
- e. **Height** will be displayed according to the Patient Name / Sample Id selection.
- f. **Weight** will be displayed according to the Patient Name / Sample Id selection.
- g. **Urine Volume (ml/24 hrs)** will be displayed according to the Patient Name / Sample Id selection.



Figure 6-21. Schedule CEC screen

- h. Click on **Delete** button

Message will be displayed indicating that CEC schedule is cleared successfully.



- **EDIT CEC Schedule**

Follow this procedure to clear edit CEC schedule:

- a. Select **Edit** option.
- b. Click on **Show Sample ID** button to view and select the sample id from the list.
- c. Select the **Sample ID – Serum / Plasma** from the list of sample id with sample type as serum / plasma for the patient selected or all sample id's.
- d. **Sample ID – Urine** will automatically be displayed according to the Serum / Plasma Sample Id selection.
- e. Height will be displayed according to the Patient Name / Sample Id selection. The height displayed can be changed.
- f. Weight will be displayed according to the Patient Name / Sample Id selection. The weight displayed can be changed.
- g. Urine Volume (ml/24 hrs) will be displayed according to the Patient Name / Sample Id selection. The Urine Volume displayed can be changed.
- h. Click on **SAVE** button.
- i. Message will be displayed indicating that CEC schedule is cleared successfully.

#### **6.5.3.4. Download Samples from LIS**

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**NOTE: This button is displayed on the Patient Entry screen only when the Host Connection checkbox is selected in Settings > System Parameters screen.**

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The **Download Sample** button is used to download the sample details (like patient name, age, gender, sample type, etc along with the tests) from the LIS for the barcoded or non barcoded samples, that are placed on analyzer's Sample Tray.

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**NOTE: The test details will be automatically downloaded by clicking Sample Barcode Scan button through Status Monitor > BARCODE SCAN or during batch before the run starts, if option Sample is selected from PRE-RUN options.**

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Before downloading the sample details from the LIS, make sure that you should have the following necessary pre-requisites:

- The option **Host Connection** in **Settings > System Settings** screen should be selected. The Host Setting screen is always enabled to view the settings.

Follow the procedure to download samples and schedules from the LIS without performing Sample Barcode Scan:

1. Place the barcoded or non barcoded sample on the analyzer's sample tray.
2. Go to **Patient Entry** screen, and define required details for the added samples. See section *6.5.3.1 Defining Patient Sample* for more details.
3. Click on **Download Sample** button.

It will display a window containing all registered sample IDs with checkbox option to select.

The screenshot shows a software window titled "MultiXL - Download Sample details from LIS". At the top, there are search fields for "Sample ID" and "Reg.Date" with a calendar icon. Below is a "Show All Samples" button. The main area is a table with columns: Group, Sample Pos, Sample ID, Collection Date, and Patient Name. Rows 1 through 11 are listed, with checkboxes in the first column. Rows 1, 2, 3, 4, and 5 have checkboxes checked. Row 6 has a blue border around its entire row. Rows 7 through 11 have checkboxes unchecked. At the bottom left is a "Download" button, and at the bottom center is a message: "Indication : Enter Sample ID to be searched."

	Group	Sample Pos	Sample ID	Collection Date	Patient Name
<input checked="" type="checkbox"/>	1	1	1	07 Mar 2011	
<input checked="" type="checkbox"/>	1	2	2	07 Mar 2011	
<input checked="" type="checkbox"/>	1	0	3	07 Mar 2011	
<input checked="" type="checkbox"/>	1	0	4	07 Mar 2011	
<input checked="" type="checkbox"/>	1	5	5	07 Mar 2011	
<input type="checkbox"/>	1	0	6	07 Mar 2011	
<input type="checkbox"/>	1	7	7	07 Mar 2011	
<input type="checkbox"/>	1	0	8	07 Mar 2011	
<input type="checkbox"/>	1	0	9	07 Mar 2011	
<input type="checkbox"/>	1	10	10	07 Mar 2011	
<input type="checkbox"/>	1	0	11	07 Mar 2011	

4. Now, select the required sample IDs for which the details to be downloaded from the LIS and click **Download**.

On clicking the button, the sample details will be downloaded from the LIS. The downloaded details are displayed in the **Patient Entry** screen.



**NOTE: If the communication between Host and LIS is not established then it should pop up message to check connection in Host Settings screen.**

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### 6.5.3.5. Mask Tests

Upon scheduling the tests, the user can click on the Mask Tests button to mask the tests temporarily which should not be run immediately but can be run in the middle of the run. The selected tests for the selected Sample ID will be masked. To mask the Test(s) for the (multiple) Samples. Tick the Mask Tests checkbox in the **Patient Entry > Work List** screen and select the required test(s). This feature is useful if the reagent for the tests are not available but would be made available during the middle of the run. In these cases, the user can mask the tests and keep them on hold. Once the reagents are available, then the user can unmask the selected tests from **Status Monitor > Work List** screen.

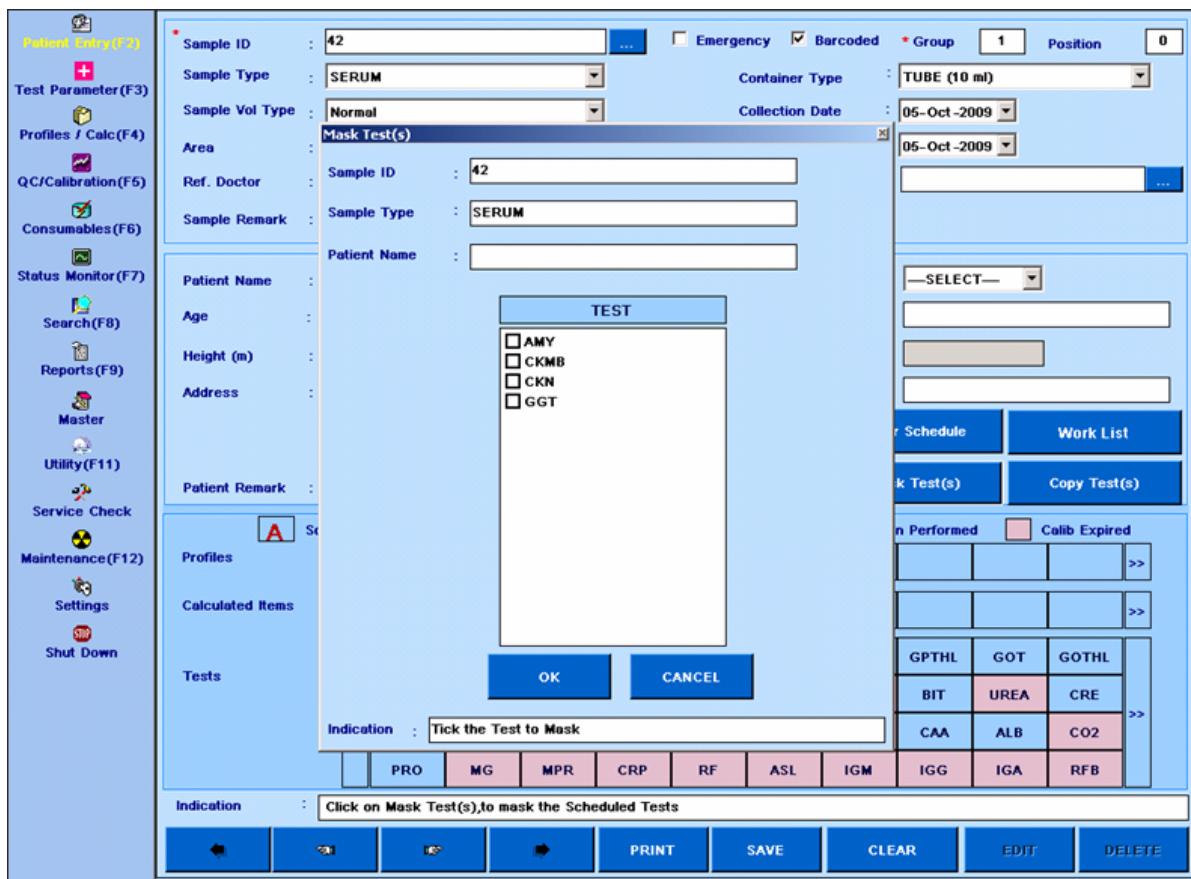


Figure 6-22. Mask test screen

### 6.5.3.6. Copy Tests

If the user wants to copy the same tests and calculation items across patients, then the user can use this option. Once the patient and sample details are entered and the tests/calculation items are scheduled, the user can click on the Copy Test(s) button. Upon clicking this button, you can enter the desired From and To sample positions. The entire range of sample positions would be assigned the same tests and calculation items. Also, the Sample ID with this feature would be incremented with the positions if the Generate Sample ID option is checked.

During run, when Copy test(s) option is used without generating Sample ID i.e. Generate Sample ID is un-checked; then the test will not be copied in case it is already in progress.

While copying test(s) from Serum Sample with ISE tests to Urine sample, Lithium test will be excluded. Lithium is not performed for Urine Samples.

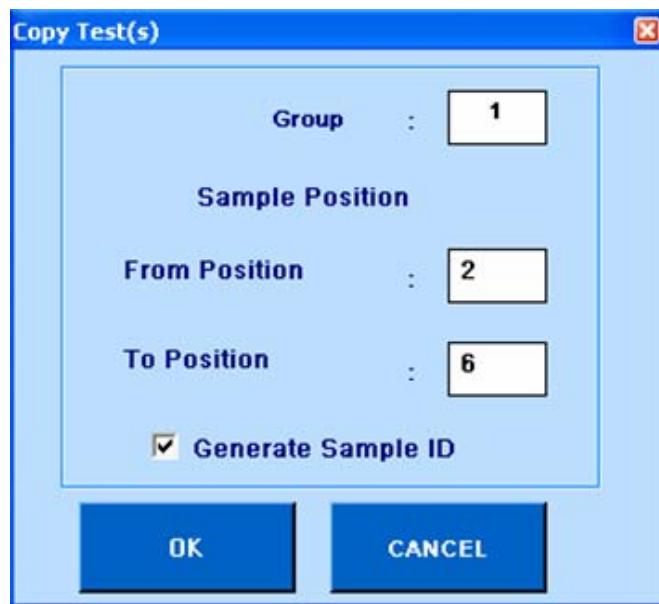


Figure 6-23. Copy test screen

### 6.5.3.7. Clear Schedule

Clicking on the **Clear Schedule** button on the **Patient Entry** screen presents the following sub-screen:

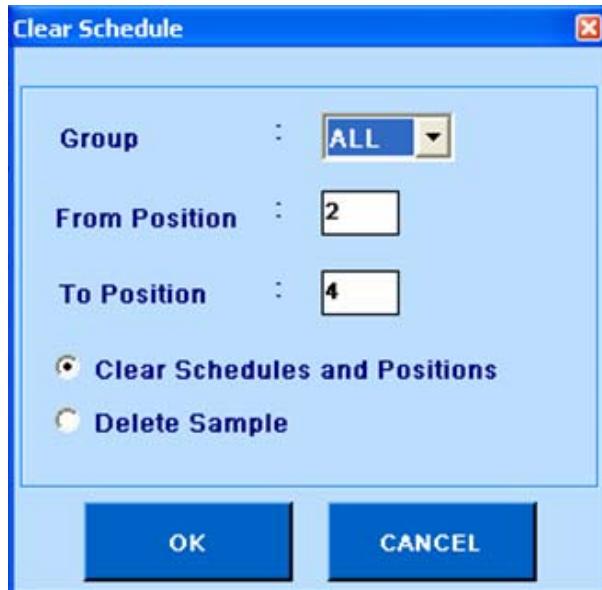


Figure 6-24. Clear schedule screen

This screen can be used to remove test requests from the WorkList. There are two options to achieve this, Clear Schedule and Positions or Delete Sample. Using these options, the user can either clear the entire patient schedule programmed along with the positions or delete the patients using the '**From Position**' and '**To Position**' option.

**Clear Schedules and Positions:** The program deletes the test requests scheduled for analysis and the positions for the selected positions on clicking **OK** button. The samples and patients are not deleted.

**Delete Sample:** The program deletes the samples for the selected positions along with demographics and the tests requests scheduled. After deleting the Samples, recalculation is not available.

### 6.5.3.8. Worklist

Click the WorkList button on the screen of **Patient Entry**. The display changes to the following screen:

The screenshot shows a software window titled "Worklist". At the top, there is a dropdown menu labeled "Group" with "02" selected, and buttons for "PRINT" and "CLOSE". Below this, there are four radio buttons: "All" (selected), "Patient", "Calibration", and "Control". To the right of these buttons is a checkbox labeled "Mask Test(s)" which is unchecked. Next to it is the text "Total No. of Test(s) : 12". The main area of the window is a table with the following columns: Group, Sample Pos, Sample ID, Sample Type, Sample Vol Type, Test, Replicates, Sample Volume, R1 Volume, R2 Volume, R1 Positions, and R2 Positions. There are four rows of data in the table:

Group	Sample Pos	Sample ID	Sample Type	Sample Vol Type	Test	Replicates	Sample Volume	R1 Volume	R2 Volume	R1 Positions	R2 Positions
2	2	80	SERUM	Normal	BID	1	25.0 µl	200 µl	50 µl		
2	2	80	SERUM	Normal	BIT	1	25.0 µl	200 µl	50 µl		
2	2	80	SERUM	Normal	CRE	5	2.0 µl	160 µl	40 µl		
2	3	81	URINE	Normal	CRE	5	2.0 µl	160 µl	40 µl		

Figure 6-25. Worklist screen

On this screen, a list of tests requested for a particular group number is shown. The WorkList for any group can be viewed by selecting either '**All**', '**Patients**', '**Calibrations**' or '**Controls**' option. On selecting 'Patients' option, only patient samples are displayed in the work list. On selecting 'Calibration', work list will display Blank, Standards and Calibrators programmed. On selecting 'Control', work list will display controls programmed in the respective group. The test from the worklist screen can be masked using **Mask Test(s)** option.

The work list includes the following details:

Parameters	Description
Group No.	It displays the Group number that has been selected
Sample Position	It displays the Sample position assigned. For bar-coded samples, the position is assigned after the sample barcode scan
Sample ID	It displays the Sample Id assigned to the patient.
Sample Type	It indicates whether the Sample type is Serum/ Urine/ CSF/ Whole Blood/ Other type.
Sample Vol Type	It indicates whether the sample volume is Normal/ Increase/ Decrease
Test	It displays the test name

Replicates	It displays the number of repetitions that a test will undergo during run
Sample Volume	It indicates the Sample volume programmed in test parameters for that particular test.
R1 Volume	It indicates the R1 volume programmed in test parameters for that particular test.
R2 Volume	It indicates the R2 volume programmed in test parameters for that particular test.
R1 Position	It displays the position of R1 for that particular test as defined in Utility-Rgt. Position.
R2 Position	It displays the position of R2 for that particular test as defined in Utility-Rgt. Position.

The WorkList includes the details of bar-coded samples too even though their positions may not be known.

Tick the Mask Tests option to mask one or more tests from the entire group.

## 6.6. Initiation of Measurement and Monitoring

### 6.6.1. Initiation of Measurement

1. The analyzer performs automatically sample measurement, computation and printout of measurement results and transfer of the measurement results to the host computer.
2. The lamp and the temperature in the analyzer are stabilized at least 5 minutes after switched ON; hence the user needs to wait for 5 minutes after switching on the instrument. For the same there is a warm-up bar on the Status Monitor.

### 6.6.2. Monitoring of Measurement

This section explains the procedure to start calibration process, measuring of control and patient sample concentration

Click on **Status Monitor > SAMPLE TRAY** screen. The following screen will be displayed.

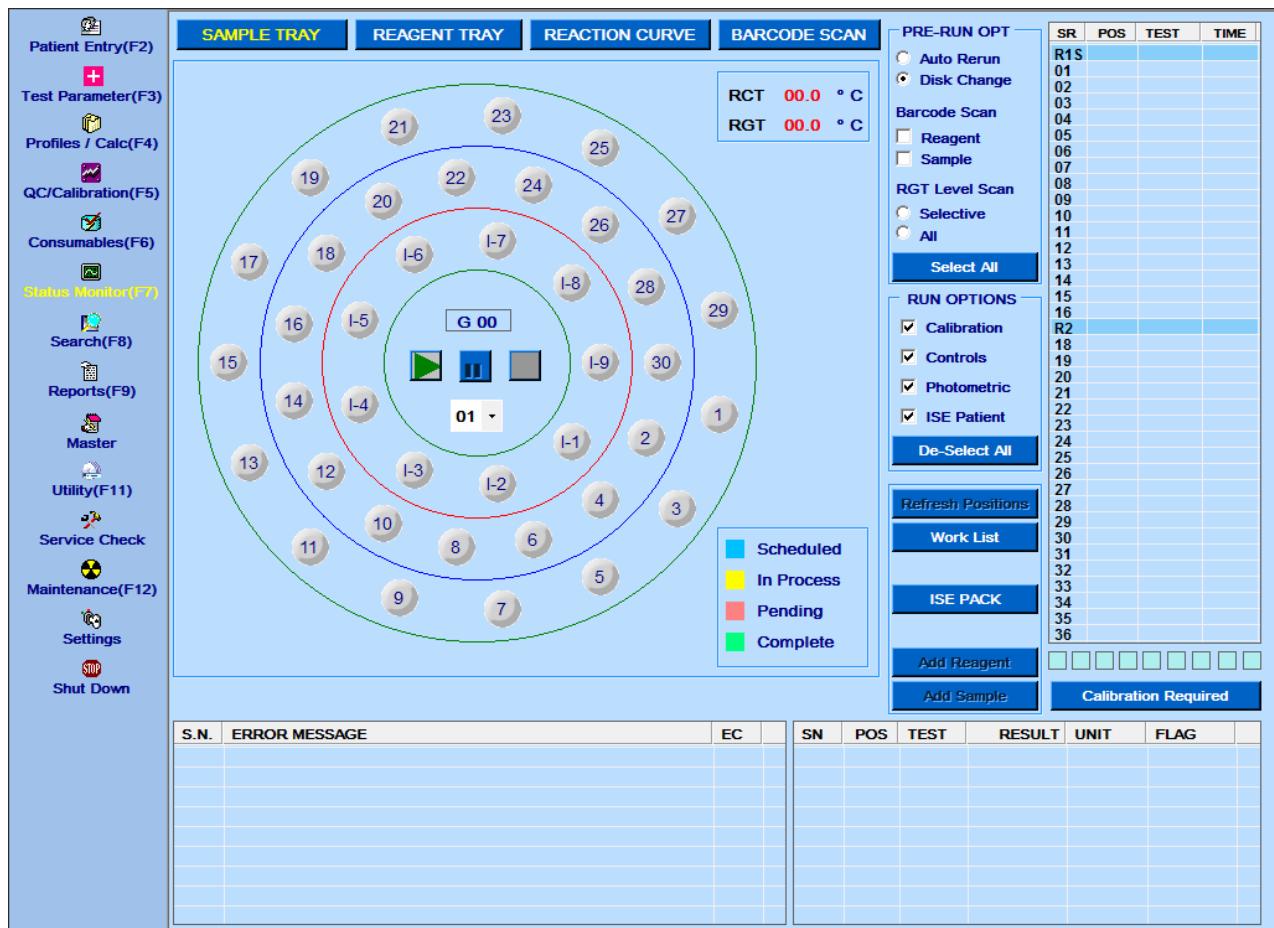


Figure 6-26. Status monitor - Sample tray screen

1. The legends shown on the Sample Tray are as follows:

**Scheduled:** When a sample position has scheduled test(s) then the circle with respective sample position is indicated with TURQUOISE COLOUR.

**In Process:** For a sample position, when sampling for test has been completed but the measurement is in progress and results are yet to be reported, then the circle is indicated with YELLOW COLOUR.

**Pending:** For a sample position, when one or more test(s) are pending due to Sample/Reagent/Diluent absent or occurrence of VOD error; then the circle is indicated with ROSE COLOUR. Pending test(s) on such sample positions can be re-scheduled either during run or at the start of the run.

**Completed:** When results of all the tests scheduled for a sample have been reported and no test results are pending, then the circle is indicated with GREEN COLOUR.

2. RUN OPTIONS available on screen for selection (before run) are as follows:

- Calibration
- Controls
- Photometric

- ISE Patient
3. All of the above option can be selected using **Select All** button and de-selected using **De-Select All** button. Depending on the selection, schedules will be performed during run.
- This means, a scheduled calibration will be performed in batch run only if the **Calibration** checkbox under RUN OPTIONS is ticked.
4. **PRE-RUN** options available on screen for selection are as follows. All activities under this option will be performed before the run starts.



**NOTE: On starting the batch run, the PRE-RUN options selected by the user are memorized. These memorized selections are made available as default selection for subsequent batches, which can further be changed before starting the next batch.**

- **Auto Rerun**

On checking this option, the patient samples after sample processing will be automatically re-sent for the sample run; in case the results are with specific flags. Only those tests will be sent for rerun for which the option **Auto Rerun** is selected in **Test Parameter > Test Details** screen.



**NOTE: Automatic Rerun of patient sample is performed if Auto Rerun is selected for:**

- a) **The Test in Test Parameter > Test Details screen.**
- b) **The Flag in Settings > Rerun Flags screen.**
- c) **The batch run from PRE-RUN options in Status Monitor.**

- **Disk Change**

This option is used if you want to change the current Sample Disk (or Sample tray, defined as Group in Patient Entry screen) with the new disk during the same batch run.

On completion of sampling from the current Sample disc in progress, the message will be displayed for loading the new sample disc, as follows.



Remove the current sample disc and load the new sample disc.

To proceed with the run:

- i) Select the newly installed disk by selecting the disk number from the **SELECT DISK NO.** drop-down list.
- ii) Use **SAMPLE BARCODE SCAN** option to scan the (newly installed) sample disk.
- iii) Click **LOADED** button to proceed with run.

▪ **Barcode Scan**

On checking this option, all samples and reagents that are placed on the Sample Tray and Reagent Tray will be scanned for barcode before starting the run. Two options are available:

◆ **Reagent**

On checking this option, the barcoded reagents (R1, R2) that are placed on Reagent Tray will be scanned for the barcode. After scan is over the reagent details (like Reagent name, lot number, expiry date, and reagent position number) will be updated and displayed in the following screens.

**Status Monitor > REAGENT TRAY**

**Status Monitor > BARCODE SCAN**

**Utility > Reagent Position**

◆ **Sample**

On checking this option, all samples that are placed on the Sample Tray will be scanned for the barcode. After scan is over, the sample details (Sample ID and Position) will be updated and displayed in the following screens:

**Status Monitor > SAMPLE TRAY**

**Status Monitor > BARCODE SCAN**

**Patient Entry**

When the Host communication (between analyzer PC and Host computer) is ON; on **completing** sample barcode scan, the tests that are schedule on the LIS will be automatically downloaded and applied to the appropriate samples.

The sample tray will be scanned during Sample Barcode scan and the Sample ID and Position number will be updated in the **Patient Entry** screen. The application will then query LIS for the details of these barcoded Sample ID. Patient demographic and the Test schedules are downloaded from LIS and can be viewed in **Patient Entry** screen. The tests scheduled for the samples will be performed on the analyzer and results will be sent back to LIS.

- **RGT Level Scan**

After the Reagent Barcode scan, the reagent bottles will be scanned for the available volume, when either Selective or All option under RGT Level Scan is selected. After the volume scan is over, the volume details will be updated and displayed in the **Status Monitor > REAGENT TRAY** screen and **Utility > Reagent Position** screen.

Refer section 6.2.3.1 *Reagent Level Scan* for more details.



**Caution: Make sure that the Reagent bottles should not be overfilled with the reagents. If the overfilled reagents bottles are detected during pre-run operation or reagent volume scan, the respective tests will be masked and added in the pending list.**

**However, during batch run, if reagent overfilled is detected, the run will proceed and the result will be NA with respective flag.**

---

5. To start the run (measurement), select the group no and click on Start arrow button.
6. On start of the batch run, firstly RCT temperature is checked and the status will be displayed on the screen. Secondly, Auto span is performed, if auto span operation fails, again run is stopped. Also if there are any errors occurred on initialization of the instrument then the run is halted.
7. Further, if insufficient volume details or incomplete test details are detected then the worklist will be displayed where the incomplete test details will be highlighted and the run is halted.
  - a. The worklist screen is displayed after all the pre-run options are performed. This screen can also be viewed by clicking on the Work List button present on the Status Monitor screen.

The worklist displays information about Sample Position, Sample ID with Container type, Sample Volume Required, Sample Type, Test, Sample Volume, R1 Volume Defined, R2 Volume Defined (optional), Number of Reagents, R1 Position Available, R1 Volume Available, R2 Position (optional) Available, R2 Volume Available (optional).

- b. The WorkList screen displays the schedule for the group selected (from the drop-down list below the buttons to Start and Stop run) in Status Monitor screen.
- c. Required test details such as Reagent Position, Sample Volume, Reagent Volume defined; when missing / incomplete are highlighted with red background.
- d. The reagent position for which reagent volume is 0 ml is highlighted with yellow background.
- e. Pending tests and masked tests are displayed in the grid at left bottom of the screen named as 'Pending and Masked Schedules'. To

reschedule the pending tests, the corresponding tests should be selected and clicked on **RE-SCHEDULE** button. Alternatively, the tests can be selected from the Test list, select Pending option and click on **RE-SCHEDULE** button.

Remove Reagent Bottle Caps. Use froth-free reagents.												
<input checked="" type="radio"/> Work List			<input type="radio"/> Volume Details			<input type="checkbox"/> Incomplete Test Details				<input type="checkbox"/> Reagent Volume Insufficient		
Sample Position	Sample ID	Sample Volume Reqd.	Sample Type	Test	Sample Volume	R1 Volume Defined	R2 Volume Defined	No. Of Reagents	R1 Position Available	R1 Volume Available	R2 Position Available	R2 Volume Available
1	1 [CUP (2 ml)]	20 $\mu$ l	SERUM	ALT	12.0 $\mu$ l	160 $\mu$ l	40 $\mu$ l	2	07	0.00 ml	07	0.00 ml
				AP	3.0 $\mu$ l	160 $\mu$ l	40 $\mu$ l	2		0.00 ml		0.00 ml
				ALB	2.0 $\mu$ l	180 $\mu$ l		1	03	0.00 ml		
				AMY	3.0 $\mu$ l	160 $\mu$ l	40 $\mu$ l	2		0.00 ml		0.00 ml
2	2 [CUP (2 ml)]	20 $\mu$ l	SERUM	ALT	12.0 $\mu$ l	160 $\mu$ l	40 $\mu$ l	2	07	0.00 ml	07	0.00 ml
				AP	3.0 $\mu$ l	160 $\mu$ l	40 $\mu$ l	2		0.00 ml		0.00 ml
				ALB	2.0 $\mu$ l	180 $\mu$ l		1	03	0.00 ml		
				AMY	3.0 $\mu$ l	160 $\mu$ l	40 $\mu$ l	2		0.00 ml		0.00 ml
3	3 [CUP (2 ml)]	20 $\mu$ l	SERUM	ALT	12.0 $\mu$ l	160 $\mu$ l	40 $\mu$ l	2	07	0.00 ml	07	0.00 ml
				AP	3.0 $\mu$ l	160 $\mu$ l	40 $\mu$ l	2		0.00 ml		0.00 ml
				ALB	2.0 $\mu$ l	180 $\mu$ l		1	03	0.00 ml		
				AMY	3.0 $\mu$ l	160 $\mu$ l	40 $\mu$ l	2		0.00 ml		0.00 ml
4	4 [CUP (2 ml)]	17 $\mu$ l	SERUM	ALT	12.0 $\mu$ l	160 $\mu$ l	40 $\mu$ l	2	07	0.00 ml	07	0.00 ml
				AP	3.0 $\mu$ l	160 $\mu$ l	40 $\mu$ l	2		0.00 ml		0.00 ml
				ALB	2.0 $\mu$ l	180 $\mu$ l		1	03	0.00 ml		
5	5 [CUP (2 ml)]	17 $\mu$ l	SERUM	ALT	12.0 $\mu$ l	160 $\mu$ l	40 $\mu$ l	2	07	0.00 ml	07	0.00 ml
				AP	3.0 $\mu$ l	160 $\mu$ l	40 $\mu$ l	2		0.00 ml		0.00 ml
				ALB	2.0 $\mu$ l	180 $\mu$ l		1	03	0.00 ml		

Pending And Masked Schedules ( Patients )												
Position	Sample ID	Sample Type	Test	Bulk Selection								
<input checked="" type="checkbox"/>	2	SERUM	LDH	<input type="checkbox"/> Test <input type="checkbox"/> Pending <input type="checkbox"/> Mask <input type="button" value="SELECT"/> <input type="button" value="RE SCHEDULE"/>								
<input type="button" value="PROCEED"/> <input type="button" value="CANCEL"/>												



**NOTE: If the tests are scheduled for the run and the Reagent for the tests are not defined or Reagent volume overfilled detected, in this case the test will be masked and displayed in the Pending and Masked Schedules (Patients) grid.**

- f. To view the volume details for checking no of tests possible with the available reagent volume, Volume Details option should be selected. Following screen is displayed on selecting the **Volume Details** option.

Test Schedule( Group : 1 )						
Remove Reagent Bottle Caps. Use froth-free reagents.						
<input type="radio"/> Work List		<input checked="" type="radio"/> Volume Details				
Test	RGT Type	RGT Position	RGT Volume Available	Sample Type	RGT Volume Defined	Possible Test(s)
ALB	R1	9	47 ml	SERUM	200 µl	230
	R1	32	0 ml	SERUM	200 µl	0
	R1	39	47 ml	SERUM	200 µl	233
ALB1	R1	9	47 ml	SERUM	200 µl	230
	R1	32	0 ml	SERUM	200 µl	0
	R1	39	47 ml	SERUM	200 µl	233
ALP	R1	27	25 ml	SERUM	160 µl	153
	R1	27	25 ml	URINE	160 µl	153
	R1	48	27 ml	SERUM	160 µl	164
	R1	48	27 ml	URINE	160 µl	164
	R2	28	20 ml	SERUM	40 µl	484
AMY	R2	28	20 ml	URINE	40 µl	484
	R1	4	21 ml	SERUM	200 µl	106
CAA	R1	5	42 ml	SERUM	200 µl	209
	R1	16	20 ml	SERUM	200 µl	100
GL1	R1	43	45 ml	SERUM	200 µl	223
	R1	10	21 ml	SERUM	200 µl	104
GLU	R1	37	48 ml	SERUM	200 µl	237
	R1	45	40 ml	SERUM	200 µl	197
GLU1	R1	45	40 ml	SERUM	200 µl	197
	R1	10	21 ml	SERUM	200 µl	104
GLU2	R1	37	48 ml	SERUM	200 µl	237
	R1	43	45 ml	SERUM	200 µl	223
GLU3	R1	45	40 ml	SERUM	200 µl	197
	R1	10	21 ml	SERUM	200 µl	104
GLU4	R1	37	48 ml	SERUM	200 µl	237
	R1	43	45 ml	SERUM	200 µl	223
GLU5	R1	45	40 ml	SERUM	200 µl	197
	R1	10	21 ml	SERUM	200 µl	104
GLU6	R1	37	48 ml	SERUM	200 µl	237
	R1	43	45 ml	SERUM	200 µl	223
GLU7	R1	45	40 ml	SERUM	200 µl	197
	R1	10	21 ml	SERUM	200 µl	104
GLU8	R1	37	48 ml	SERUM	200 µl	237
	R1	43	45 ml	SERUM	200 µl	223
GLU9	R1	45	40 ml	SERUM	200 µl	197
	R1	10	21 ml	SERUM	200 µl	104
GLU10	R1	37	48 ml	SERUM	200 µl	237
	R1	43	45 ml	SERUM	200 µl	223
GLU11	R1	45	40 ml	SERUM	200 µl	197
	R1	10	21 ml	SERUM	200 µl	104
GLU12	R1	37	48 ml	SERUM	200 µl	237
	R1	43	45 ml	SERUM	200 µl	223
GLU13	R1	45	40 ml	SERUM	200 µl	197

Note : Approximate number of possible test are shown.

**PROCEED**      **CANCEL**

Figure 6-27. Status monitor - Volume details

- Click on **PROCEED** button to start the run. Or else click on **CANCEL** to abort the run. However, clicking **CANCEL** during run will only close the screen.
- If the test details for all the tests are proper without any tests having background as red, when **PROCEED** button is clicked, the run will be started else run will not start.
- Indication of RCT and RGT Temperature.

Once the run starts RCT and RGT temperature are displayed. If the RCT / RGT temperature is within range specified in **Settings > System Parameters** screen, the temperature is displayed in GREEN color. When the temperature rises / falls out of the range, then it is displayed in RED color.

- Start time of the Run is displayed at top left corner of the screen.
- During run, Progress of the measurement is displayed at the right hand side of the screen.
- Results are displayed in the Result grid at the right bottom of the screen.
- Errors, if any, are displayed in Error grid at the left side bottom of the screen.

S.N.	ERROR MESSAGE	EC

SN	POS	TEST	RESULT	UNIT	FLAG

Figure 6-28. Result and error message grid

15. During run, schedule will be sent as follows:

- a. Blank, Standard, Calibrator, Control – Test-wise, according to test process sequence defined in Settings > Test Sequence option.
- b. Then Patient Samples will be performed as follows
  - i) Emergency patient samples will be performed at highest priority. All Emergency patient samples defined before starting the run will be performed in the order of Sample position number. Emergency samples defined during run will be performed on first-in-first-out basis.
  - ii) Then non-emergency Patient Samples will be performed in the order of Sample position number. However, samples defined during run will be performed on first-in-first-out basis.
- c. If control interval is defined, control schedules will be sent between patient samples according to the control interval defined in Test Parameters screen.

16. During run, the user can monitor the online reaction curve for a test through **Status Monitor > REACTION CURVE** screen.

17. In order to view the online reaction curve for a test, the user needs to double click on the test name in the Progress grid in the right-most corner of the screen. Upon double clicking the test name, the Reaction Curve (till “x” cycles) will be displayed. The pink arrow indicates the measurement points used for calculating the result.

18. When the run is completed, the final test result will be displayed on the result grid that is located on the right bottom corner of the screen.

19. To view the curve number for the particular test, double click on the result. On clicking, a small test details box will be displayed, which contains the information about the test result with curve number.

20. The final reaction curve will be generated and can be viewed in **Reports > Reaction Curve** screen.

21. During run, pending tests / mask tests can be re-scheduled by clicking on the **Work List** button in **Status Monitor** screen. On clicking button, the

**WorkList** screen is again displayed, using which the tests can be selected and then **RE-SCHEDULE** button can be clicked. (Pending / Mask tests can be scheduled only if the reagent and test details are available).

22. During the processing of ISE tests, ISE test is added in pending list when ISE module reports errors like “Air in Cal A/B, Time Out, and No Flow”.
23. During the processing of ISE tests, the ISE tests sampling will be stopped (for the current batch) on the 3 consecutive occurrence of error “Air in Cal A/B”.
24. Reagent defined on Multiple position

In case, there are multiple reagent positions defined for a reagent; during run reagent will be aspirated from the reagent (bottle) position having nearest expiry date. In case of multiple reagent bottles having same expiry date, the reagent will be aspirated in the order of position.

25. Addition of Non-barcoded Reagents during run

During run, non-barcode reagents can be added from Utility > Reagent Position screen on empty Reagent positions. See section 6.2.2.3 *Procedure to Define Reagent Position manually* for more details.

26. The ISE PACK button displayed on the Status Monitor will be visible only if the product is login with 4 Channel ISE.
27. On starting the run or during run, if the communication is lost between the PC and Analyzer, then the following error message “Analyzer not responding at COM” will be displayed in the error message grid .This message may be displayed in the Status Monitor, Service Check, and Maintenance screen.

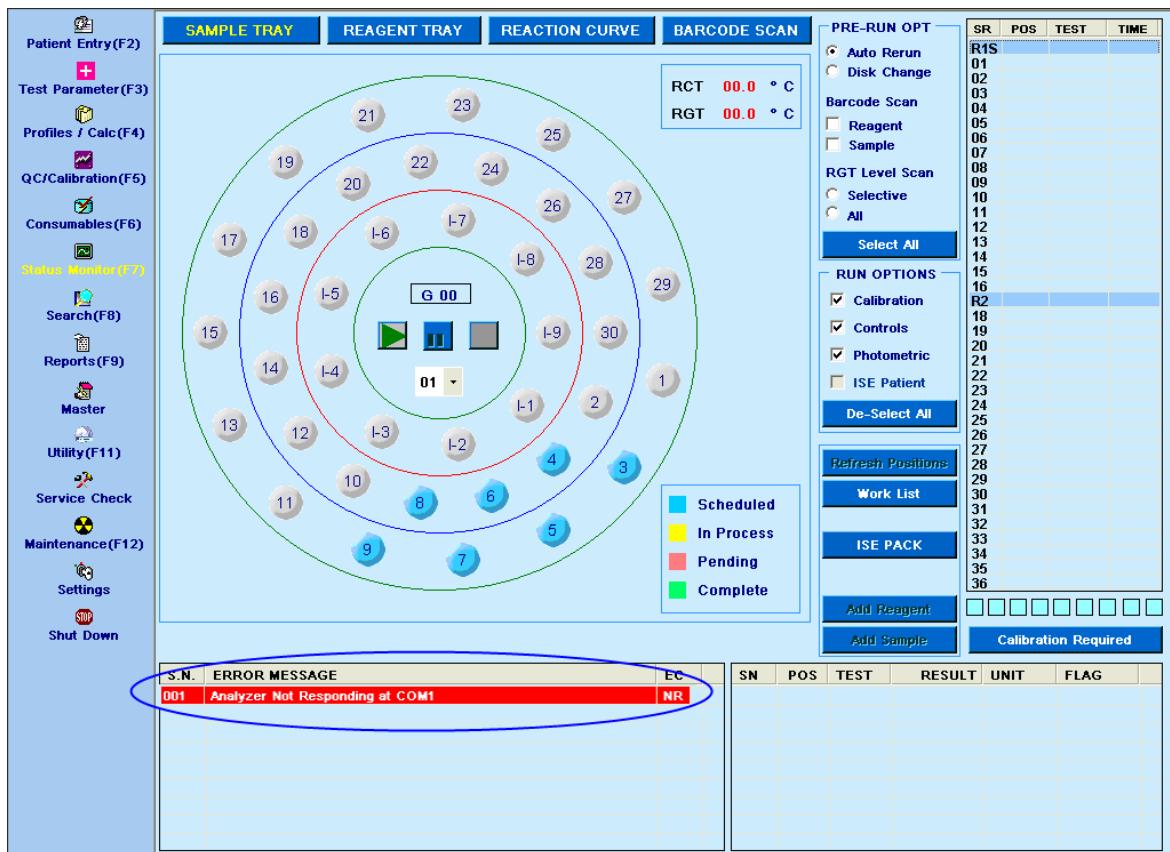


Figure 6-29. Analyzer com port error screen

In this case, check the cause of disconnection and change the required setting from the Settings > System Parameters. Then again start the run.

### 6.6.3. Interruption and Resumption of Measurement

1. The analyzer comes to rest when all the results are out.
2. During run, due to occurrence of some critical errors the run can be stopped in between or paused temporarily / permanently.
3. During run, it can be interrupted and resumed manually also through **Status Monitor > SAMPLE TRAY**.

- **Emergency STOP**

If you click on the Stop button, then the run stops immediately and the assemblies initialize.

- **Pause / Resume Sampling**

If you click on the Pause Sampling button, then the sampling is paused but the results of the processed samples are given out.

User can click on resume button to continue the sampling.

## 6.7. Addition of Sample and Reagent during run

### 6.7.1. Addition of Barcoded Sample during Run

If the user wants to add a new barcoded sample (Continuous Sample Loading), the following procedure should be used:

1. When the user wants to add new samples, Entries should be done in the **Patient Entry** screen keeping Barcode “ON” and not assigning any sample Position to the Patient. The user must use the same Group number as selected in the Run Monitor screen.
2. Click on the **Add Sample** button in **Status Monitor** screen.  
Message **Please Wait Sampling Is Being Paused** is displayed. Sampling will be paused after completing the current test in process.
3. When Message **Please Add Samples Now** appears, indicating that sampling is paused; place the sample tubes in the sample tray and click on **Sample Added**.
4. Once the user clicks on Sample Added, Sample Barcode scan starts with message displayed as **Please Wait Sample Barcode Scan In Process**. On completion of the Sample Barcode scan, each Sample ID, if not found in Patient Entry screen is added and the positions of new samples get updated in the **Patient Entry** screen.
5. Sampling resumes after updation.
6. The user can see the scanned data by clicking **Barcode Scan** button on the same screen.

### 6.7.2. Addition of Barcoded Reagent during Run

If the user wants to add a new barcoded reagent (Continuous Reagent Loading), the following procedure should be used:

1. The user clicks on the **Add Reagent** button.
2. After the button is clicked, the message “**Please Wait R1 Dispense Is In Process**”. Sampling will pause after the completion of Reagent 1 dispensing of the current test in process.
3. After the button is clicked, the message “**Please Wait R2 Dispense Is In Process**”. Sampling will pause after the completion of Reagent 2 dispensing. If no R2 is available, then this message is not displayed.
4. Once the message disappears, a message prompt appears “**Please Add Reagent Now**”. The user can then safely open the lid and place new reagent bottles.
5. Once the user is done with adding reagent, he can click on **Reagent Added**. Reagent barcode scan will starts with message displayed as “**Please Wait Reagent Barcode Scan In Process**”.

6. After the completion of Reagent barcode scan, the Reagent positions along with the barcode details of the new test are updated.
  7. The user can view the scanned reagent barcode data by clicking on the **Barcode Scan** button.
  8. The user can view the scanned reagent barcode data in **Utility > Reagent Positions** screen.

While scanning, earlier barcoded reagent positions are cleared when the reagent barcode is not found on the same.

### **6.7.3. Refresh Reagent Positions during run**

During run, if any of the reagents or diluents is absent then the position will be indicated as position with empty bottle and will not be used during run.

Hence, if the user wants to use that position, then using  button on the **Status Monitor > SAMPLE TRAY**, pause the sampling. Once the sampling is paused, open the Reagent cover and check for the message of Reagent Tray cover open. Put the new reagent bottle at reagent absent position and then close the Reagent Tray cover. Make sure that reagent cover open message has disappeared. Then click on **Refresh Positions** button either from **Utility > Reagent Position** or **Status Monitor > REAGENT TRAY** screen. On clicking “**Refresh Positions**” button, following screen is displayed.

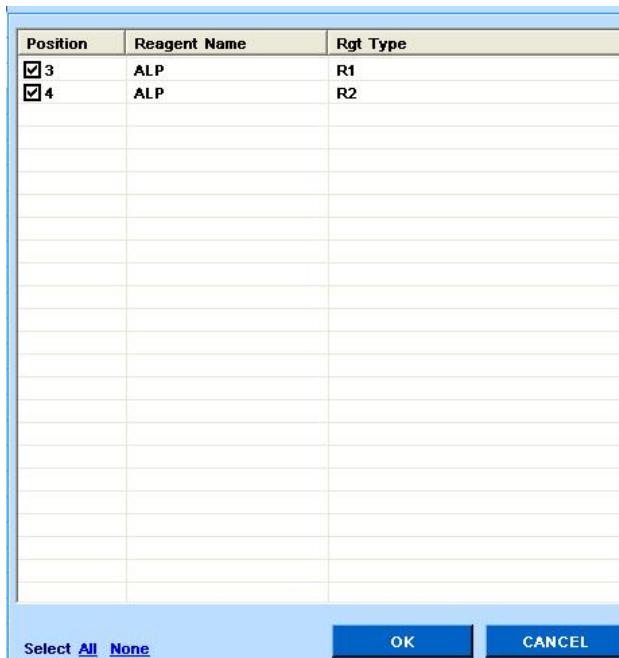


Figure 6-30. Refresh position screen

This screen would display only those reagent positions which had an empty bottle (no volume) at that position. If there are no empty bottles on the reagent tray then **Refresh Positions** button would be disabled.

In the above screen, select the position at which filled reagent bottle is placed and hence needs to be refreshed. Then, click on **OK** to refresh the position.

Click on **CANCEL** to close the screen.

## 6.8. Calculation of Results

### 6.8.1. Calibration Specific Results

#### 6.8.1.1. Calibration Table

The calibration table can be viewed in the **Calibration** screen. To open, click on **QC/Calibrations > Calibration** from the main.

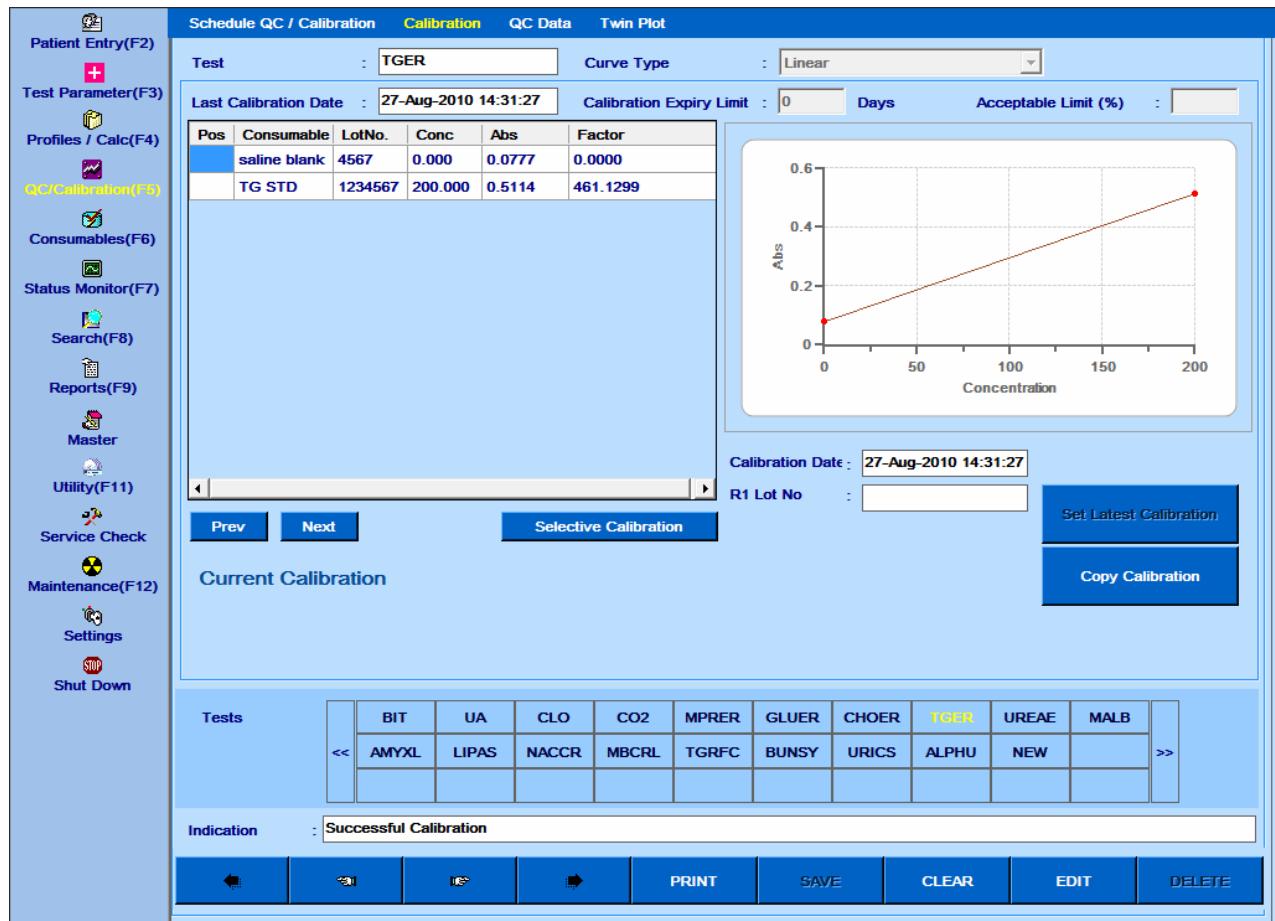


Figure 6-31. Calibration table screen

This screen allows to view calibration curve and to perform curve related operations. Lot Number and Concentration for that test are defined in the **Consumables** screen.

After the Calibration Run is completed, absorbance values obtained by the analyzer are updated in the Calibration screen along with the K-Factor. The date and time of calibration is also updated.

One of the last five calibration curves can also be selected for use in result calculations. Previous or next calibration can be viewed using or buttons. For using the calibration on the screen, click on **Set Latest Calibration** button.

In order to view the calibration details for a test in use, the user needs to select the test from the grid.

To print the calibration table along with the calibration graph, click on **PRINT** button.



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**NOTE: If any error occurred during calibration (like reagent absent or calibrator absent), the calibration data for which reagent, blank and calibrator was present is updated. However, Unsuccessful Calibration message will be displayed.**

---



**NOTE: Normally calibration requires 3 replicates of blank and 3 replicates of calibrator for successful calibration. The calibration will be successful; if there is at least one replicate of blank and one replicate of calibrator are processed successfully.**

---

**Following are the detailed explanation of the parameters on the screen:**

**Test:** It displays the selected test name.

**Last Calibration Date:** It displays the date on which the calibration in use (generally, the last calibration) was performed for that test.

**Curve Type:** It shows the curve type selected for the test in **Test Parameters > Test Details** screen.

**Calib Expiry Limit:** It allows the user to enter the Calibration Expiry Limit in days for that test. This limit is a decremented counter that commences after calibration for that test is done. The Test, for which the calibration is expired, is highlighted with Pink color in the **Patient Entry** screen.

**Acceptable Limit %:** Use this textbox to enter the acceptable limit allowable between 2 calibrations. The user can feed any value between 1% to 10% and is expressed in terms of percentage. The comparison is made on basis of the factor obtained. The new factor obtained is compared with the old one and based on the acceptance limit entered; the new calibration details are updated. If the value falls outside the acceptable limits, then the old calibration details are kept and the new details are updated with message Factor out of Range. This textbox is applicable only for Linear curve types.

**Calibration Date:** It displays the date on which the calibration, currently displayed on screen, for that test was performed. The display changes if previous calibration have been selected.

**K-Factor:** This parameter will be displayed only when the curve type for the test is selected as K-factor in **Test Parameter > Test Details**. It is used to enter the known factor for the required test. The value should be non-zero number between -99999.99 to 99999.99.

**R1/R2 Lot No:** It displays the Reagent Lot Number used for calibrating that test. If the test has only one reagent, then only R1 Lot No will be displayed.

**Following column are available in the table:**

**Pos:** It displays the Calibrator, Standard or Blank position; till the position is not utilized for scheduling any other sample.

**Consumable:** It displays the consumable name (Blank, Standard, or Calibrator) used for calibrating that test.

**Conc:** It displays the concentration of the blank or the calibrator used.

**Abs:** This column indicates the absorbance values that are automatically obtained by the analyzer after the calibration is carried out.

**Lot No.:** It displays the Lot Number of the consumable used for Calibration of that test.

**Factor:** It displays the Calibration Factor obtained for the selected test.

**Following buttons are available on the screen:**

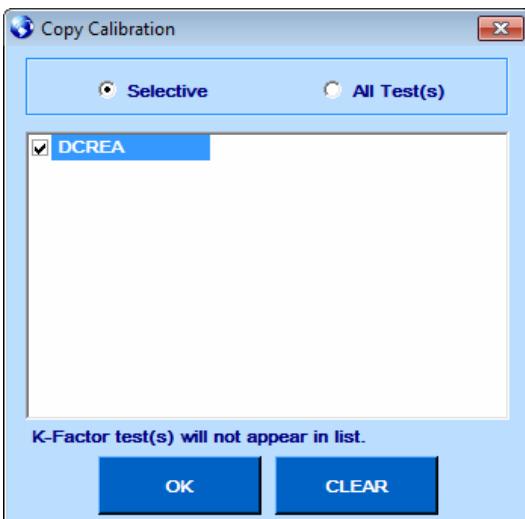
**Set Latest Calibration:** Use  or  buttons on the screen to view the previous or next calibration record, and then select any one calibration which should be used for patient result calculation. Click on **Set Latest Calibration** button to set the selected calibration and use the same for calculating results.

**Copy Calibration:** This button is used to manually copy calibration details across test(s) with same assay type and specific curve type (either both linear or both non-linear requiring same number of calibrators); sharing the same Reagents.

To copy, use the following procedure:

- a. Go to **Test Parameters > Test Details**.
- b. Select the required test from the available tests grid, and click **COPY TEST** button.
- c. Enter the name of the test and click **OK**.
- d. This will create a new test and displayed on the Tests grid.
- e. Now, go to **QC/Calibration > Calibration** screen, select the appropriate test to copy, and then click **COPY CALIBRATION** button.

On clicking, the following window will be displayed.



- f. Select the newly created test from the copy calibration window, and click **OK**.

This will copy the calibration details to the new test.




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**NOTE: For Automatic Copy Calibration, you must activate the Automatic Copy Calibration option from the Settings > System Parameters screen.**

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**Selective Calibration:** Selective calibration, also known as One point to Multipoint Calibration or Normalization of Calibration Curve is used when a user wants to use only a reagent blank for calibration. It is applicable for all curves except K-factor. The user can schedule and perform this type of calibration for individual chemistries.

On clicking this button, two options are available under Calibration Type for the selected test:

- **Full:** This option is the default selection through which you can schedules the entire calibration set again.
- **Selective:** This option is used to select blank available and then it uses the slope method to correct the other factors.

**To schedule Full calibration, use the following procedure:**

- a. Select the appropriate test.
- b. Click on **Selective Calibration** button.
- c. Select option **Full** from the **Calibration Type**.
- d. Select the required consumable from the grid, select position number from the **Position** drop down list, and then click **ADD TO LIST**.

On clicking, the position number will be added to the selected consumable and displayed in the grid.

- e. Similarly, by using the same procedure, add the required position number for all the other consumables in the list.
- f. Once all consumables are assigned, click on **SCHEDULE** button.

All consumables will be assigned and displayed under **QC/Calibration > Schedule QC/Calibration** screen.

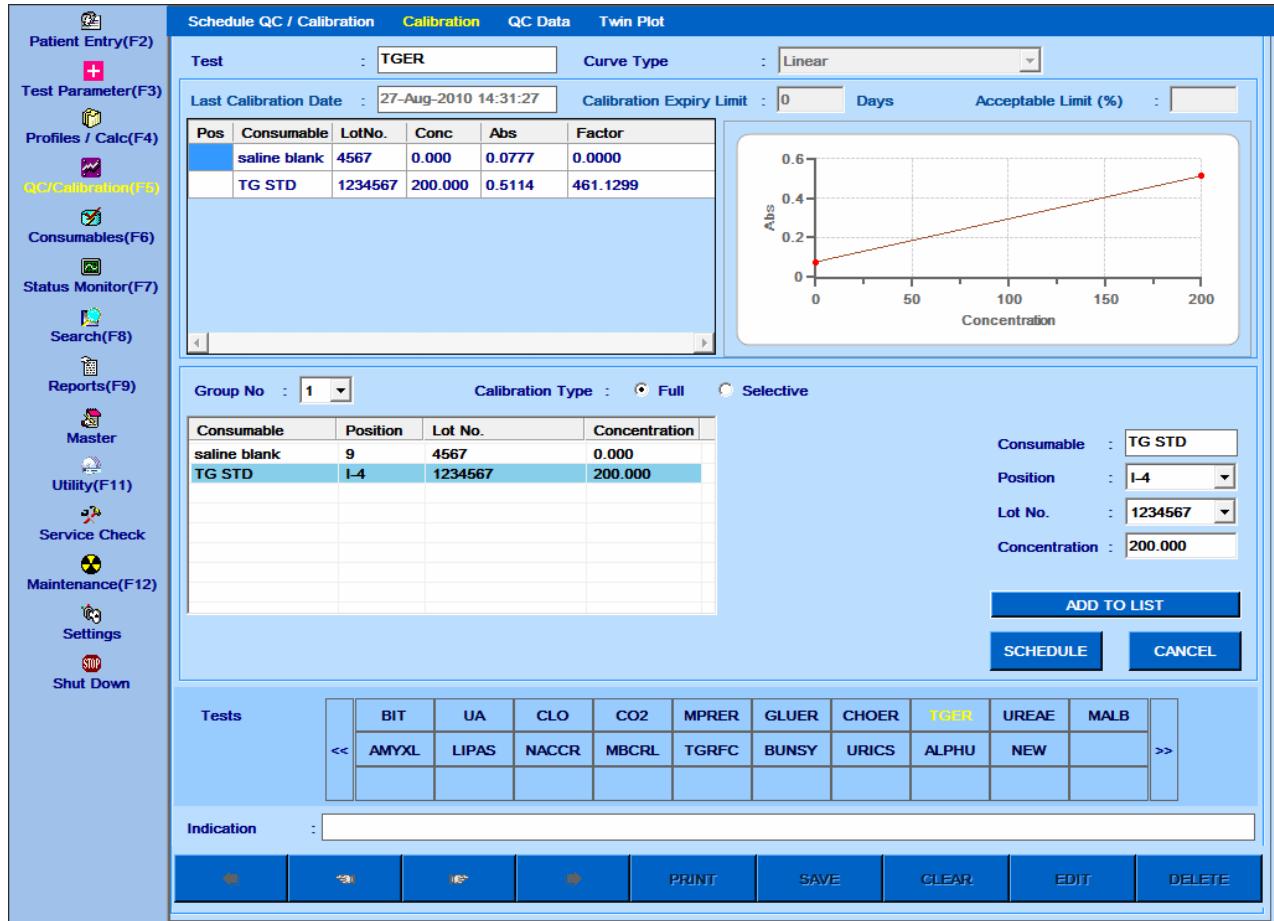


Figure 6-32. Selective Calibration - Full

#### To schedule Selective calibration, use the following procedure:

- a. Select the appropriate test.
- b. Click on **Selective Calibration** button.
- c. Select option **Selective** from the **Calibration Type**.
- d. Select the required consumable from the grid, and select the Test.
- e. Select the position number from the **Position** drop down list, and then click **ADD TO LIST**.
- f. Once the consumables are assigned, click on **SCHEDULE** button.

The consumable will be assigned and displayed under **QC/Calibration > Schedule QC/Calibration** screen.

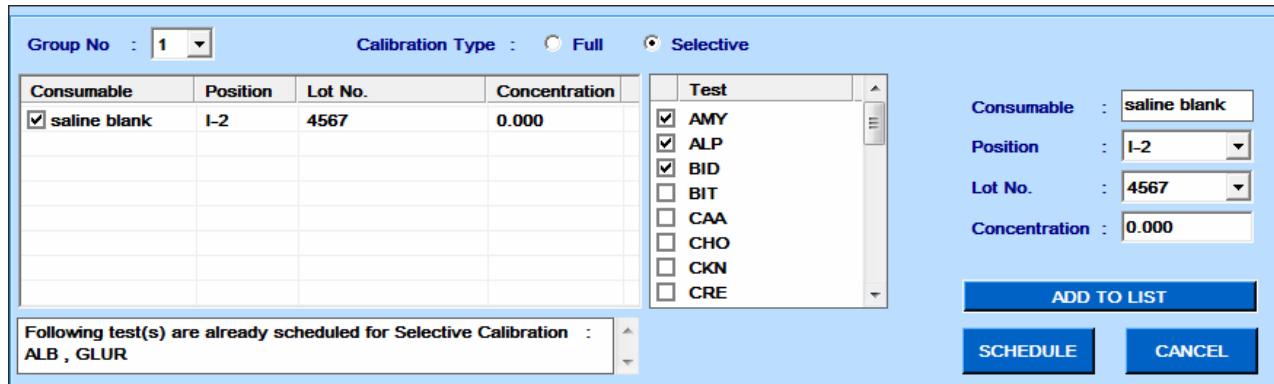


Figure 6-33. Calibration screen - Selective

**Consumable:** This text box consists of Blanks and Standards Concentrations. The user can select the Blank for which the calibration needs to be done. Accordingly, after the calibration, all the factors for other concentrations are updated using Slope Correction (Factor) method.



**NOTE: Selective Calibration is available for all Calibration Curves except K-factor only after calibration has been performed at least once.**

**Curve Type:** One of the following nine methods can be selected from **Test Parameters > Test Details** screen for calculation of the measurement results.

- Linear (For one standard or two standards)
- K-Factor (Use of K-Factor for Enzymes or substrates)
- Linear (MultiPoint) (Multi Standard)
- 5P Calibration Logit-Log (Multi Standard)
- 4P Calibration Logit-Log
- Exponential (Multi Standard)
- Point to Point
- Polynomial (Multi Standard)
- Cubic Spline (Multi Standard)

The calibration curve types are described in detail below:

### 1. Linear

Use this method when a linear response (between absorbance and concentration) is expected but a calibration is necessary. In this method a two-point calibration involving a blank and a standard is performed. Joining the sample absorbance to blank absorbance by a straight line creates the calibration curve. Additionally,

The concentration of the sample is calculated by using the following formula:

$$C_{sample} = \frac{C_{std} (A_{sample} - A_{Blank})}{A_{std} - A_{Blank}}$$

Where,  $C_{sample}$  = Concentration of the sample,

$C_{std}$  = Concentration of the standard,

$A_{std}$  = Absorbance of the standard,

$A_{Blank}$  = Absorbance of the blank,

and  $A_{sample}$  = Absorbance of the sample

If the Blank concentration is entered, then the following formula will be used in the calculation of Concentration of unknown sample:

$$C_{sample} = \left\{ \frac{(C_{std}) (A_{sample} - A_{Blank})}{A_{std} - A_{Blank}} \right\} + C_{Blank}$$

where  $C_{Blank}$  = Concentration of the Blank

Additionally, when a linear response (between absorbance and concentration) is expected but the 2 Standards are necessary for Calibration, then the same curve type can be used. In this method a two-point calibration involving 2 Standards is performed. Joining the 2nd standard absorbance to 1st standard absorbance by a straight line creates the calibration curve.

The concentration of the sample is calculated by using the following formula:

$$C_{sample} = \left\{ \frac{C_{std2} (A_{sample} - A_{std1})}{A_{std2} - A_{std1}} \right\} + C_{std1}$$

Where,  $C_{sample}$  = Concentration of the sample,

$C_{std2}$  = Concentration of the 2nd standard,

$C_{std1}$  = Concentration of 1st standard,

$A_{std2}$  = Absorbance of the 2nd standard,

$A_{std1}$  = Absorbance of the 1st standard,

and  $A_{sample}$  = Absorbance of the sample

## 2. K-Factor

Use this method when a linear response between absorbance and concentration is expected and you do not want to perform a calibration. The result can be obtained by feeding a theoretical factor. For example rate

assays are monitored by measuring the rate of change in absorbance per minute during the linear phase of the reaction (Abs/min).

The results of enzyme determinations are obtained by multiplying the change in absorbance with a factor. The factor for kinetic assay is calculated by the following formula:

$$\text{Factor} = \frac{TV \times 1000}{SV \times \text{Mol.Extn.Coeff} \times P}$$

Where, TV = Total Volume in  $\mu\text{l}$ ,

SV = Sample Volume in  $\mu\text{l}$ , and

P = Optical path length in cm.



**NOTE: The factor should be calculated for 5 mm path length and should be entered in the box near label K - Factor below the graph.**

The factor can also be fed for End-point test where Standards are not available.

It is possible to use a reagent blank for Absolute curve type. That is, a blank calibration can be performed for Absolute curve type. The sample concentration is calculated as follows:

$$C_{sample} = (A_{sample} - A_{blank}) * \text{Factor}$$

Where,  $C_{sample}$  = Concentration of the sample,

$A_{sample}$  = Absorbance for sample,

$A_{blank}$  = Absorbance for blank and

Factor = Theoretical factor

### 3. Linear (Multipoint)

Use this calibration curve type when linear response between absorbance and concentration is expected and you want to use multiple standards to generate the linear curve. For this method, 3 to 10 calibrators can be used (excluding blank). The linear calibration curve is obtained by fitting a straight line to the available standard concentrations and absorbance's using the least square linear regression method. If a set of points  $(x_1, y_1), (x_2, y_2), (x_3, y_3) \dots \dots (x_n, y_n)$  is available, the equation of a best-fit line fitted is given by

$$Y = a + b X$$

Where, the intercept  $a$  and slope  $b$  are obtained by least square linear regression method and are given by:

$$a = \bar{Y} - b \bar{X}$$

$$b = \frac{\left[ \frac{1}{n} \sum_{i=1}^n (X_i Y_i) \right] - \bar{X} \cdot \bar{Y}}{\left[ \frac{1}{n} \sum_{i=1}^n (X_i^2) \right] - \bar{X}^2}$$

Where, the intercept a and slope b are obtained by least square linear regression method and are given by:

The slope b is nothing but factor for a linear calibration curve type and therefore the concentration of the sample is calculated as follows

$$C_{\text{sample}} = (A_{\text{sample}} - A_{\text{blank}}) * b$$

Where,  $C_{\text{sample}}$  = concentration of the sample,

$A_{\text{sample}}$  = Absorbance of the sample,

$A_{\text{blank}}$  = Absorbance of the blank, and

b = Factor = measured slope of the concentration vs. absorbance curve (or measured factor) by least square linear regression method.

#### 4. 4P Calibration Logit-Log

The following equation is used to calculate:

$$\text{LOGIT4}(x) : y = R_0 + KC / (1 + \exp(-(a + b * \ln(x))))$$

where

y is the absorbance

x is the concentration

LOGIT4 has 4 parameters  $R_0$ ,  $KC$ ,  $a$ ,  $b$ ,

LOGIT4 is a reduction of LOGIT5 with  $c=0$

LOGIT4 has the advantage to be an invertible function, so concentration can be directly calculated from absorbance

#### 5. 5P Calibration Logit-Log

This calibration curve can be used for multipoint non-linear curve types. It is necessary to use at least three calibrators (excluding blank) for this calibration curve type. For this calibration curve type, the following equation is fitted using least square linear regression:

$$A = B + \frac{K}{1 + \exp(-a - b \log C - c \log C)}$$

Where, A = Absorbance of the standards,

B = Absorbance of the blank,

C = Concentration of the standards

K, a, and b are constants and are evaluated using least square linear regression method.

Once the constants a, b, and K are known, the concentration of the sample is obtained by feeding known absorbance in the above equation and finding the root by Newton-Raphson method.

## 6. Exponential

This is one of the most frequently used calibration curve type for multipoint calibration. It is necessary to have at least three calibrators (excluding blank) to use this calibration curve type. The model for non-linear exponential calibration curve approximation is given by the following equation:

$$A = B + K \exp \{a (\ln C) + b (\ln C)^2 + c (\ln C)^3\}$$

Where A = absorbance of standards,

B = absorbance of blank,

C = concentration of the standards,

K, a, b, and c = calibration curve constants

The above equation is fitted to the absorbance and concentration of calibrators and blanks and the constants K, a, b, and c are obtained using matrix solving methods. Once the constants are known, the concentration of the sample is obtained by feeding the sample absorbance in the above equation and finding the root by Newton-Raphson method.

## 7. Point to Point:

This calibration curve type can be used when one wants to approximate different segments of concentration vs. absorbance curve by a linear model. Therefore, this calibration curve is obtained by linear approximation of different standard concentration segments. It is necessary to have at least three calibrator concentrations and absorbance's available (excluding blank) for this calibration curve type.

The equation of a straight line passing through two points  $(x_1, y_1)$  and  $(x_2, y_2)$  is

$$\frac{(x - x_1)}{(y - y_1)} = \frac{(x_2 - x_1)}{(y_2 - y_1)}$$

If the absorbance of the sample  $A_{sample}$  lies between the absorbance of two standards  $A_m$  and  $A_n$ , such that  $A_m > A_{sample} > A_n$ , the following equation is used to calculate the concentration of the sample

$$C_{sample} = \frac{A_m - A_n}{C_m - C_n} x(A_{sample} - A_m) + C_m$$

Where,  $C_{sample}$  = Concentration of the sample

$C_m$  and  $C_n$  are the concentrations of the standards corresponding to the absorbance's  $A_m$  and  $A_n$  respectively.

## 8. Polynomial

This calibration curve is useful for multipoint calibration when one wants the estimation error to be zero at the concentrations where standards are defined. Therefore, the polynomial calibration curve obtained in this method passes through the available concentration-absorbance points precisely. It is necessary to have at least three calibrators (excluding blank) to use this calibration curve type.

If there are  $n$  points  $(x_1, y_1), (x_2, y_2) \dots (x_n, y_n)$ , then there is only one unique equation to define the curve that passes through all the  $n$  points. This is known as Lagrange's polynomial and is given by:

$$x = \sum_{i=1}^n x_i \prod_{j \neq i} \left( \frac{y - y_j}{y_i - y_j} \right)$$

In a similar fashion, Lagrange's polynomial is fitted to the standard absorbance and concentrations available and the following equation is used to calculate the sample concentration:

$$C_{sample} = \sum_{i=1}^n C_i \prod_{j \neq i} \left( \frac{A_{sample} - A_j}{A_i - A_j} \right)$$

Where  $C_{sample}$  = Concentration of the sample,

$A_{sample}$  = Absorbance of the sample,

$A_i$  = Absorbance of the  $i^{th}$  standards,

And  $C_i$  = Concentration of the  $i^{th}$  standards

## 9. Cubic Spline

This calibration curve can be used for multipoint non-linear curve types. It is necessary to use at least three calibrators (excluding blank) for this calibration curve. A mathematical description of Cubic Spline is beyond the scope of this manual. Suitable Mathematics textbooks can be referred to get more information on this type of curve fitting.

### 6.8.1.2. Calibration Trace

This screen is used for displaying the Calibration history for a test along with the graphical representation of calibration data over one month.

To open go to Reports > Calibration Trace screen.

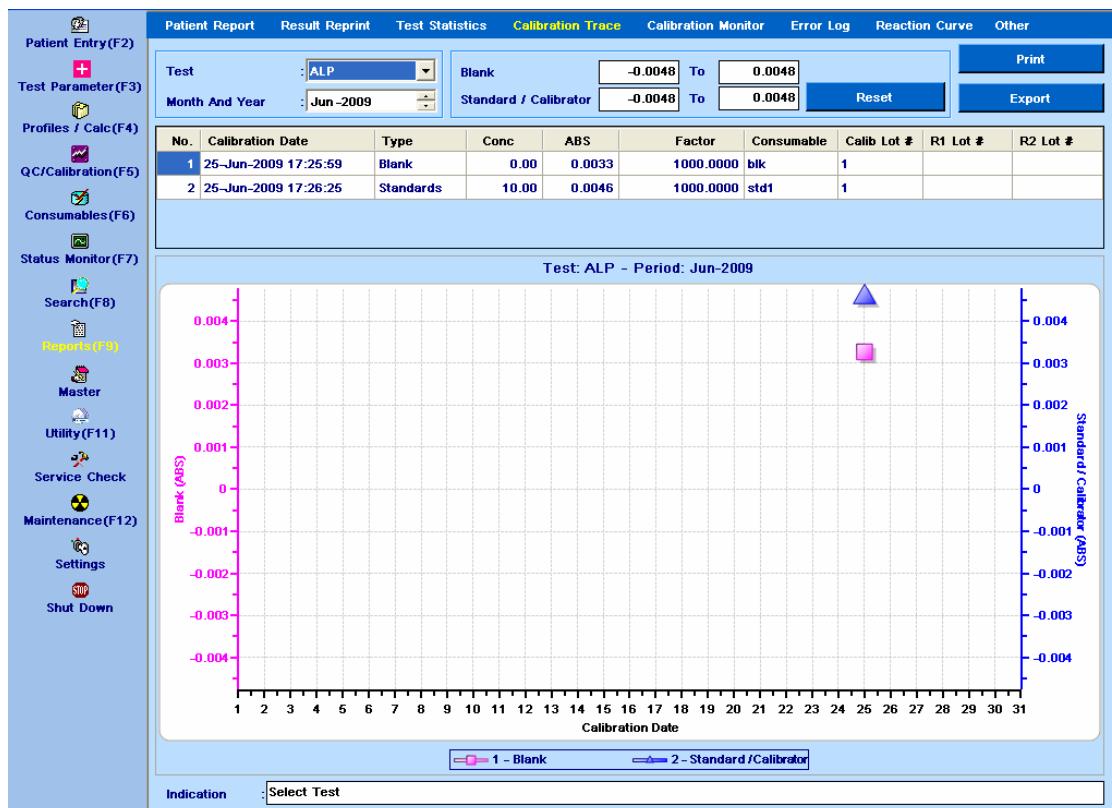


Figure 6-34. Calibration trace

**Following is the detailed explanation of the parameters present on the screen:**

**Test Name:** It is used for selecting the desired test whose calibration history needs to be viewed.

**Month and Year:** It is used for selecting the month and the year for the test whose calibration history needs to be viewed. Once the test and the month selection are done, the grid displays the different calibration dates and time along with the absorbance's for blanks and standards. Also, a graphical representation of the Blanks and Standards can be viewed.

**Blank:** It is used to change the range of blank absorbance.

**Standard/Calibrator:** It is used to change the range of Standard / Calibrator absorbance.

**Following is the explanation of the buttons present on the screen:**

**Reset:** It is used to reset the range for blank, standard and calibrator absorbance to range according to the minimum and maximum absorbance of the blanks, standards and calibrators.

**Export:** It is used to export the data and graph displayed on screen to an excel sheet.

**Print:** It is used to print the data and graph displayed on screen.

### 6.8.1.3. Calibration Monitor

If a user wants to view the latest calibration details of all the tests at the same time, to open, go to **Reports > Calibration Monitor** screen.

The following screen will be displayed as shown below:

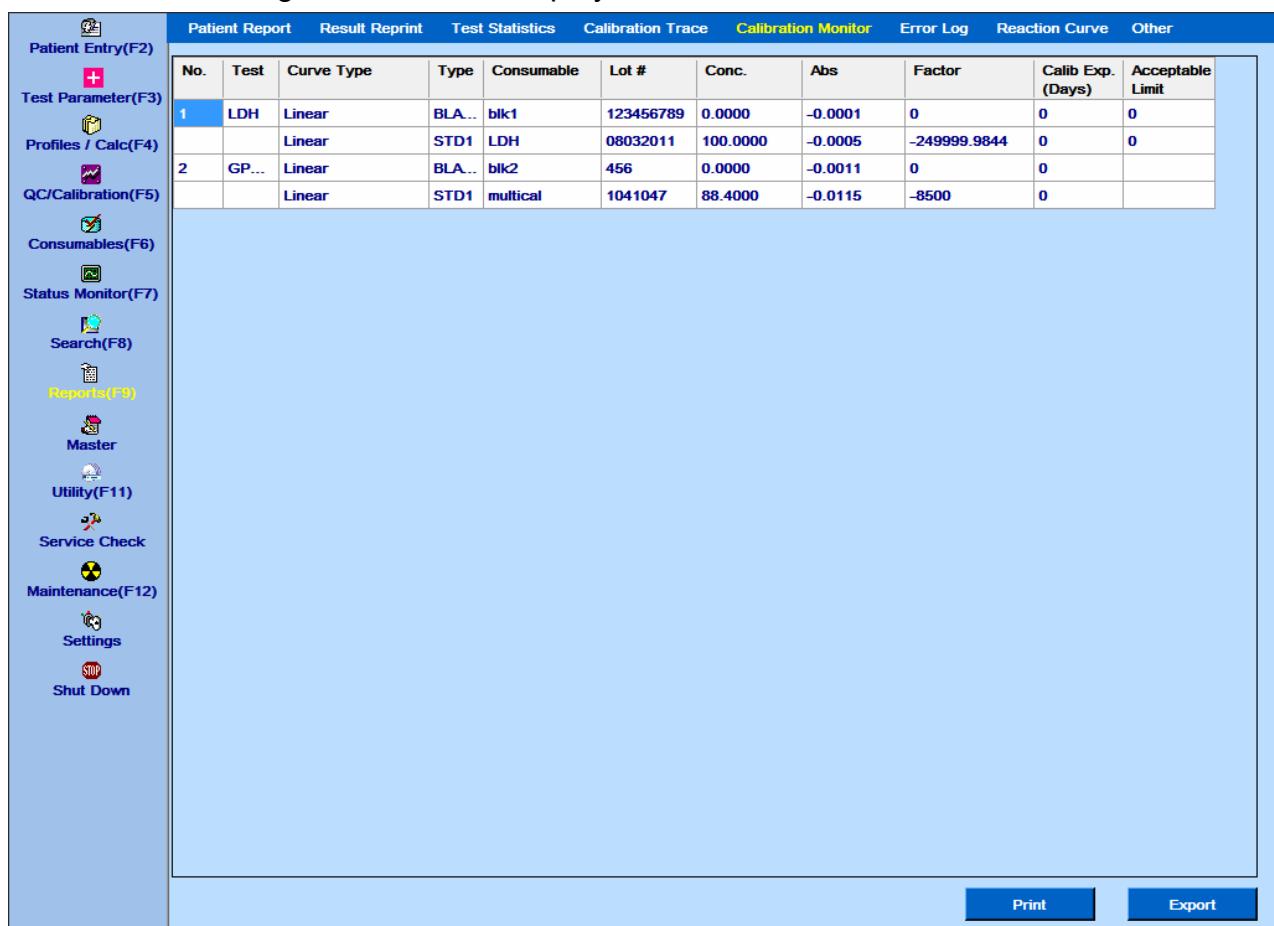


Figure 6-35. Calibration monitor screen

A description of different column available on **Reports > Calibration Monitor** is given in the table below.

Column	Description
Tests	Test name
Curve Type	Type of Curve assigned for that chemistry
Type	Either Blank or Standard S1,S2...etc

Consumable	Name of the consumable
Lot#	Lot no. of consumable used
Conc.	Concentration of the consumable
Abs.	Absorbance of the Blank/Standard
Factor	Factor value of the standards
Calib. Exp	Calibration Expiry Limit (in Days)
Acceptable	Acceptable Limit for New Factor

The user can export the Calibration data to desired location using the **Export** option.

The user can print the Calibration data using the **Print** option.

## 6.8.2. Control Specific Results

“Quality Control” is used for day-to-day monitoring of the performance of the analyzer.

It allows one to monitor the following:

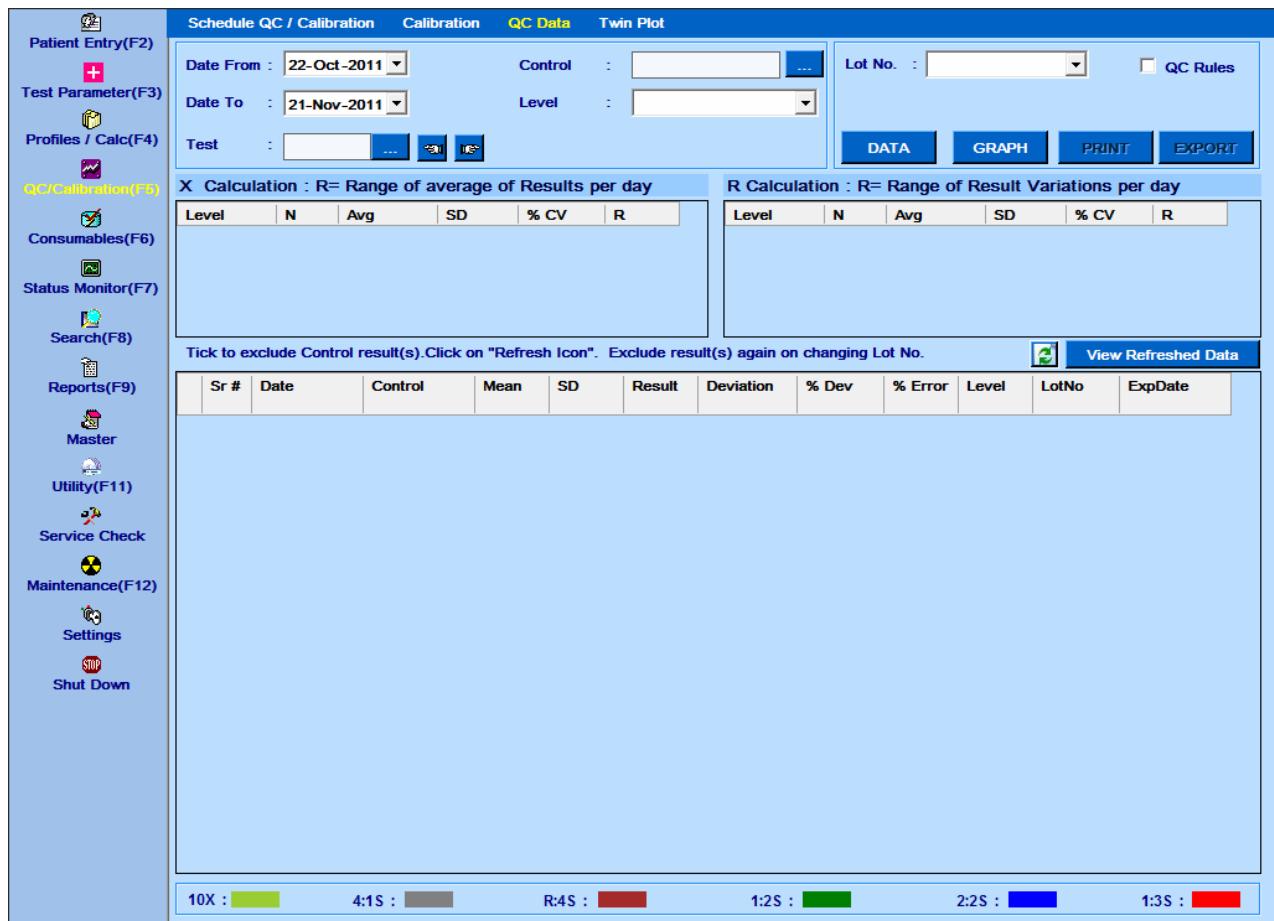
- Accuracy of the analysis (i.e. whether the values obtained are correct)
- Precision (i.e. the reproducibility – whether the same values are obtained when the sample is analyzed repeatedly)

### 6.8.2.1. QC Data

The QC Data is useful for viewing the QC Results in Graphical format. QC Rules implementation has been on QC Results on the QC Data and is marked with a symbol to indicate that which rule has been violated for that test.

The user should either rerun the controls again or recalibrate the test and run the controls.

To open the screen, go to **QC/Calibration > QC Data** screen. The following screen is displayed as shown below:



## Following are the steps to view the results and chart:

- Select **Date From** and **Date To**. The user can select the same date for viewing the daily QC or select a range for viewing the Monthly QC.
- To select the test, click on dotted button near the **Test** textbox, a small window will open up through which the test can be selected.
- Select the control level using dotted button near **Control** textbox and hence control name for which results and graph should be displayed. If the selected Date From and Date To are same, all the control results can be seen. But if the user has selected Date From and Date To different, then only one control results can be seen at a time.
- Lot number for a control can be selected from the **Lot No.** drop down list.
- Once the above selection is done, click on **DATA** button to view the results for the selection in the result grids.

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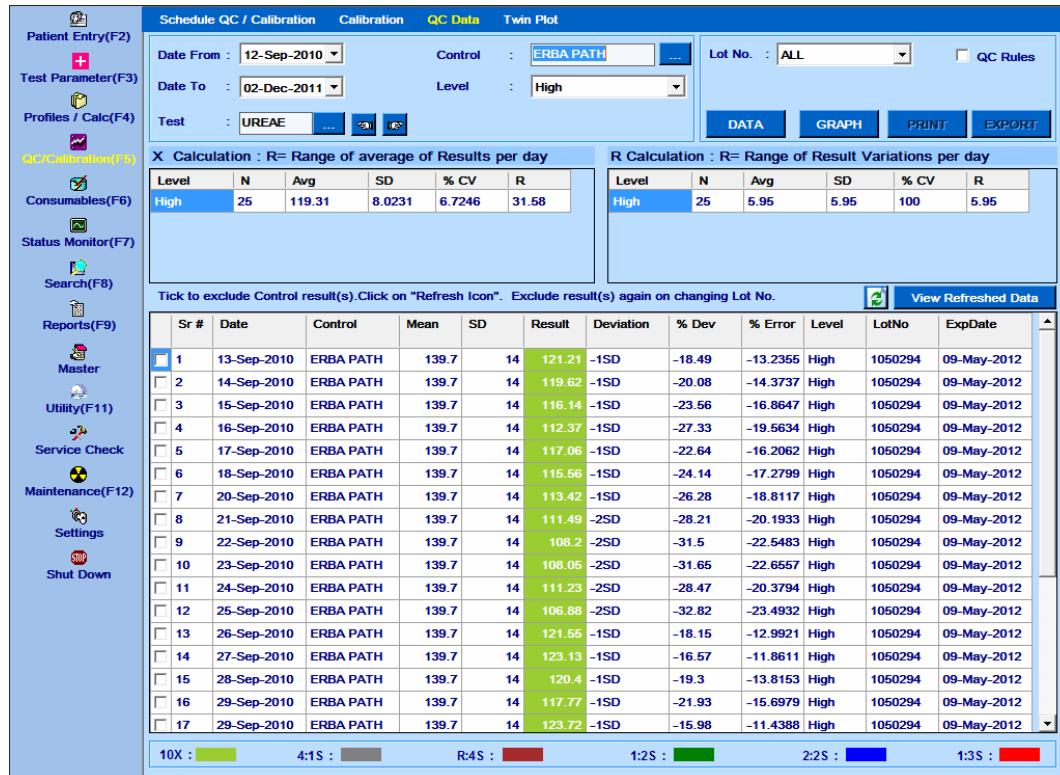


Figure 6-36. QC data screen – with different dates

- f. **Batch No.** will be displayed for selection, if the **Date From** and **Date To** are same.



Figure 6-37. QC data screen - with same data and batch number

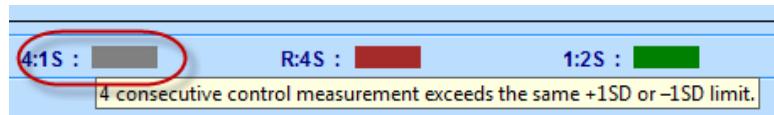
- g. If a single date is selected, then the X-bar Calculation grid signifies the following:

- ◆ **Level:** Displays the test control levels.
  - ◆ **N:** Number of replicates the control is run during that day.
  - ◆ **Avg:** Average of the test result values on that day.
  - ◆ **SD:** Standard Deviation for that day
  - ◆ **%CV:** Coefficient of Variation calculated from Mean and SD.
  - ◆ **R:** Difference between maximum and minimum result (if replicates are done)
- h. If the date range selected is from “x” period to “y” period, then the X-bar Calculation grid signifies the following:
- ◆ **Level:** Displays the test control levels.
  - ◆ **N:** Number of replicates the control is run during that day.
  - ◆ **Avg:** Average of the test result values over the period specified.
  - ◆ **SD:** Standard Deviation for specified period.
  - ◆ **%CV:** Coefficient of Variation calculated from Mean and SD.
  - ◆ **R:** Difference between maximum and minimum day's average (over specified period).
- i. If the date range selected is from “x” period to “y” period, then the R - Calculation grid signifies the following:
- ◆ **Level:** Displays the test control levels.
  - ◆ **N:** Number of replicates the control is run during that day.
  - ◆ **Avg:** Average of the test result values over the period specified.
  - ◆ **SD:** Standard Deviation of range for specified period.
  - ◆ **%CV:** Coefficient of Variation calculated from Mean and SD.
  - ◆ **R:** Difference between maximum and minimum day's range (over specified period).
- j. Click on **GRAPH** to view the graph for the selection.
- k. Select **QC Rules** option to highlight the plotted results, if any of the QC rules stated below is violated:

No.	QC Rules	Description
1	1:3S	A single control measurement exceeds +3SD or -3SD limit.
2	1:2S	A single control measurement exceeds +2SD or -2SD limit.
3	2:2S	2 consecutive control measurements exceed the same +2SD or -2SD limit.
4	R:4S	1 control measurement in a group exceeds the mean +2SD and other exceeds -2SD limit.
5	4:1S	4 consecutive control measurements exceed the same +1SD or -1SD limit.

		1SD limit.
6	10X	10 consecutive control measurement fall on one side of the mean.

The above six rules are given different colors to highlight the result or the point on the graph when the corresponding rule is violated. To see the QC rules, just place the pointer over any of the item, a pop message will be displayed with description.



The user needs to check the control result after the control run is completed and hence take corrective action whether to continue with patient samples or not. Or else perform calibration again and re-run the controls to check if the results are proper.

- I. User can click on **EXPORT** button to export the data to an excel sheet.
- m. User can click on **PRINT** button to print the data.

**Following are the buttons available on the screen:**

- : This button is used to exclude the selected QC results (tick to select).
- **View Refreshed Data**: This button is used to view the data after excluding the selected QC results.

### 6.8.3. Twin Plot

This feature of Quality Control helps the user to compare the trend in the values of the different level of Controls for any chemistry. It provides a running check on the linearity of instruments and integrity of calibration. For Twin Plot, two levels of Control samples with different lot numbers are required. Period and Test Name needs to be selected before viewing the Twin Plot.

If a user wants to view screen, go to **QC/Calibration > Twin Plot** screen. The following screen is displayed as shown below.

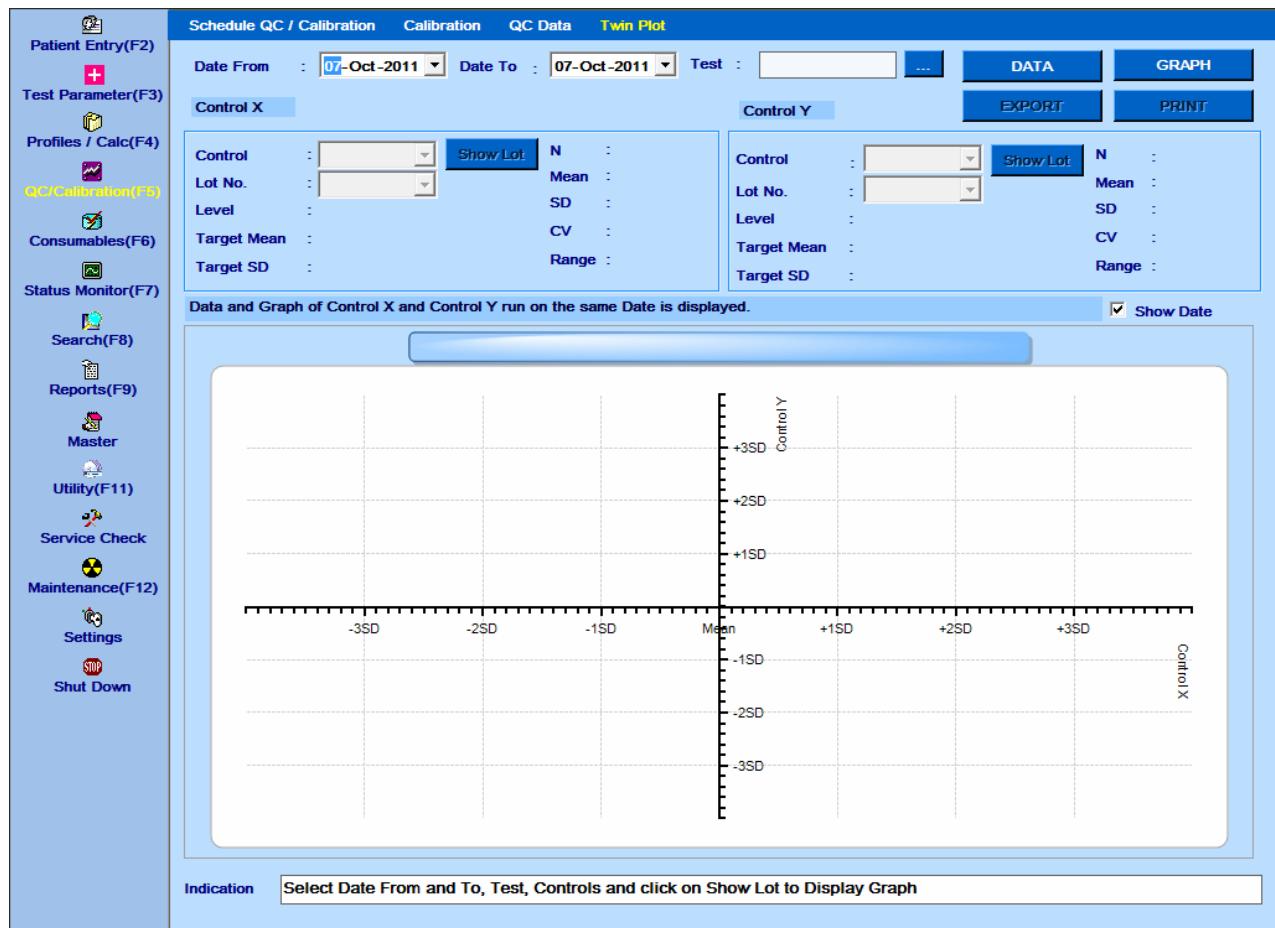


Figure 6-38 Twin plot screen

### Following are the steps to view the results and chart:

- Select **Date From** and **Date To**: The user can select the same date for viewing the daily graph or select a range for viewing the Monthly graph.
- To select Test, click on dotted button near the **Test** textbox, a small window will open up through which the test can be selected.
- Select **Control** for X and also for Y and then click on **Show Lot**.
- Select **Lot No.** for that Control X and also for Y from the list displayed.
- On selecting Lot no, the following data will be displayed:
  - Level** – Level of the control selected.
  - Target Mean** – Target Mean of the selected lot.
  - Target SD** – Target SD of the selected lot.
  - N** – No of Days is date range is selected or no of replicates if single date is selected.
  - Mean** – Mean of Daily averages if date range is selected Or Mean of all the replicates for the single date selected.

**SD** – Standard Deviation of Daily averages if date range is selected Or Standard Deviation of all the replicates for the single date selected.

**CV** - Coefficient of Variation calculated from Mean and SD.

**Range** - Range of Daily averages if date range is selected Or Range of all the replicates for the single date selected.

- Once the above selection is done, click on **DATA** button to view the results for both the controls selected.

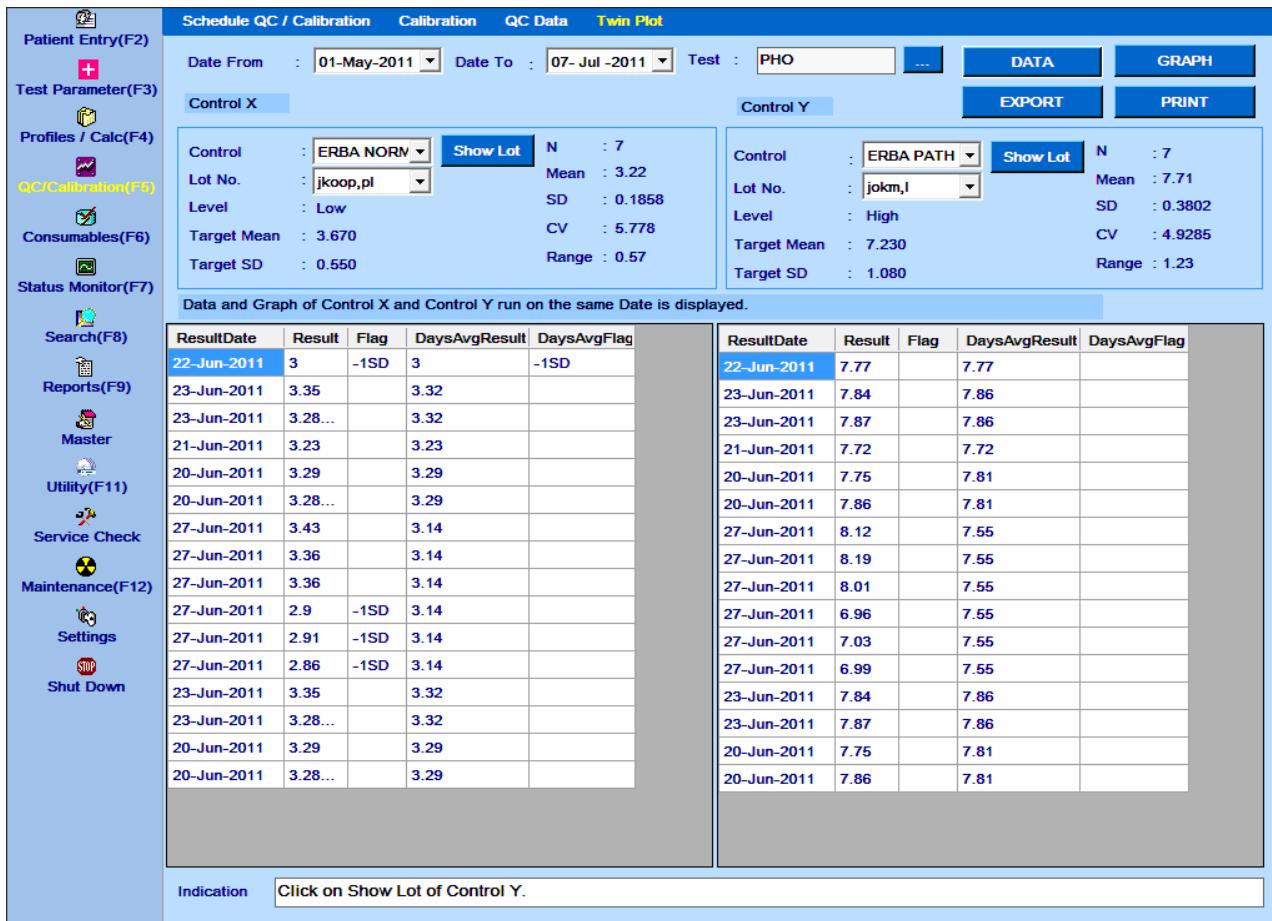


Figure 6-39. Twin plot – Data view

- Click on **GRAPH** to view the graph for both the controls selected. The daily averages for Control Y are plotted (on the Y-axis) against the daily averages for Control X (on the X-axis).

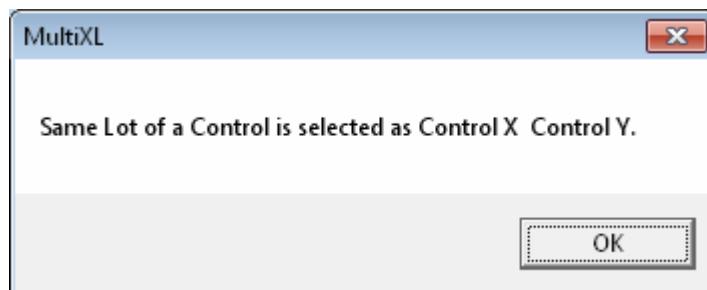


Figure 6-40. Twin plot - Graph view

- h. Uncheck the **Show Date** checkbox if you do not want to display the date on the marked points.
- i. User can click on **EXPORT** button to export the data to an excel sheet.
2. User can click on **PRINT** button to print the data and graph.



**NOTE: If same lot and same control is selected for control X and control Y then following message is displayed.**



## 6.8.4. Patient Specific Results

### 6.8.4.1. Patient Report

The **Patient Reports** screen is used for viewing and printing patient reports.

To open this screen, go to **Reports > Patient Reports** button. The following screen is displayed:

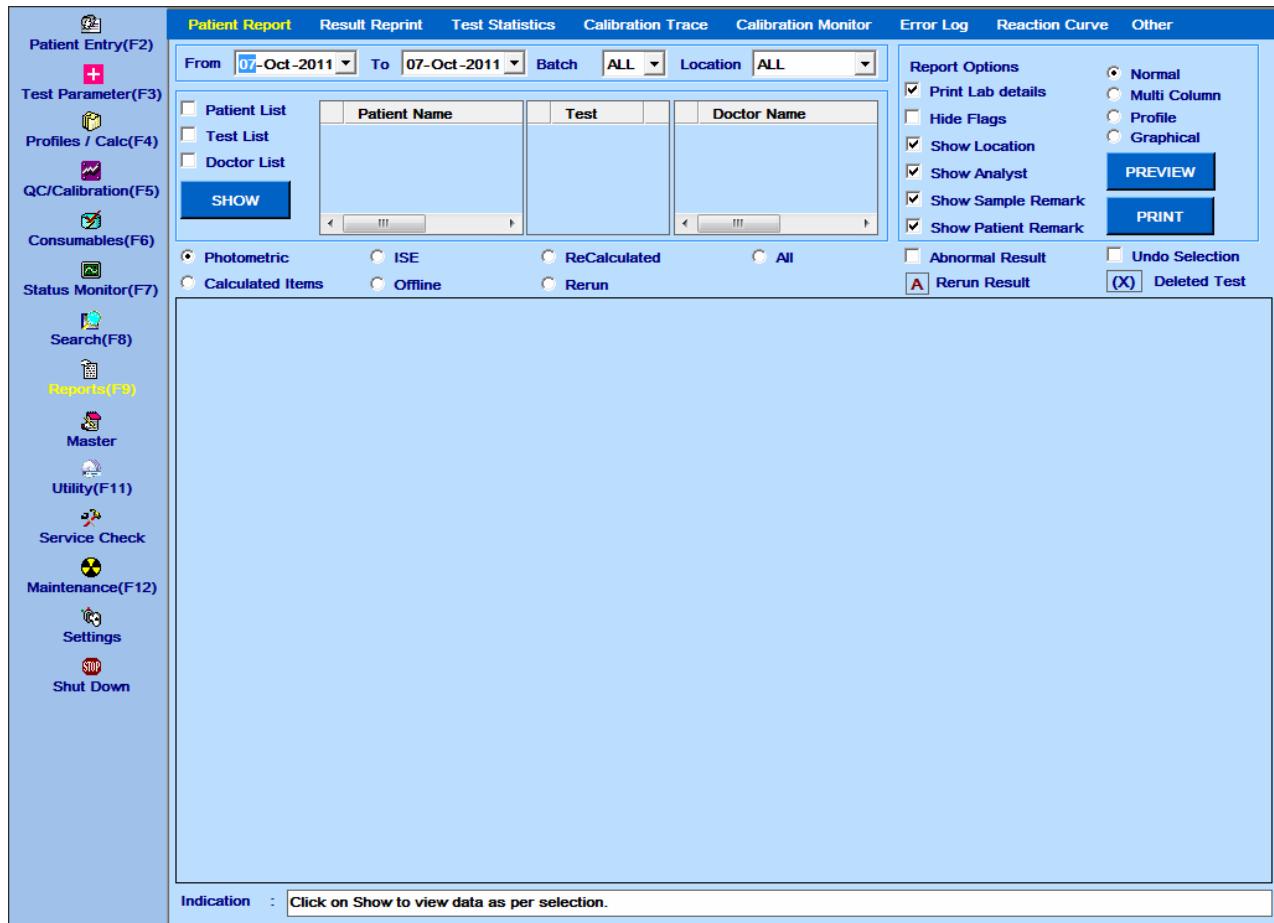


Figure 6-41. Patient reports screen

**To view the reports, use the following procedure:**

- Go to **Patient Reports** screen.
- Select the appropriate date range from the **From** and **To** drop-down list.
- Click **SHOW** button.

On clicking, the list of test results will be displayed in the grid.

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The screenshot shows the 'Patient Report' window. On the left is a vertical toolbar with icons for various functions: Patient Entry(F2), Test Parameter(F3), Profiles / Calc(F4), QC/Calibration(F5), Consumables(F6), Status Monitor(F7), Search(F8), Reports(F9), Master, Utility(F11), Service Check, Maintenance(F12), Settings, and Shut Down. The main area has tabs for 'Patient Report', 'Result Reprint', 'Test Statistics', 'Calibration Trace', 'Calibration Monitor', 'Error Log', 'Reaction Curve', and 'Other'. A date range from '11-Jul-2011' to '07-Oct-2011' is selected. The 'Location' dropdown is set to 'ALL'. Below this is a 'Report Options' section with checkboxes for 'Normal' (selected), 'Print Lab details', 'Hide Flags', 'Show Location', 'Show Analyst', 'Show Sample Remark', 'Show Patient Remark', 'Abnormal Result', 'Undo Selection', 'Rerun Result' (selected), and 'Deleted Test'. Buttons for 'PREVIEW' and 'PRINT' are also present. The central part of the screen displays a grid of patient results. The columns are: Result Date, Sample ID, Sample Type, Patient Name, Age, Category, Test, Result, Unit, Flag, and Normal Range. The grid contains numerous entries, mostly for 'SERUM' samples. An indication message at the bottom says 'Indication : Please select data to Print.'

Result Date	Sample ID	Sample Type	Patient Name	Age	Category	Test	Result	Unit	Flag	Normal Range
22-Jul-2011	01150070	SERUM			Default	GLU	370.4	mg/dl		70.0 – 110.0 mg/dl
15-Jul-2011	01200174	SERUM			Default	CHO	210	mg/dl		120 – 250 mg/dl
15-Jul-2011	01200174	SERUM			Default	TRG	124	mg/dl		--
15-Jul-2011	01200174	SERUM			Default	BID	0.23	mg/dl		0.00 – 0.20 mg/dl
15-Jul-2011	01200174	SERUM			Default	BIT	0.58	mg/dl		0.30 – 1.20 mg/dl
15-Jul-2011	01200174	SERUM			Default	GPT	51.5	IU/L		0.0 – 42.0 IU/L
15-Jul-2011	01200174	SERUM			Default	GOT	31.5	IU/L		0.0 – 37.0 IU/L
15-Jul-2011	01200174	SERUM			Default	ALB	4.19	g/dl		3.20 – 5.00 g/dl
15-Jul-2011	01200174	SERUM			Default	PRO	7.80	g/dl		6.00 – 8.30 g/dl
20-Jul-2011	02130043	SERUM			Default	GLU	79.8	mg/dl		70.0 – 110.0 mg/dl
20-Jul-2011	02130043	SERUM			Default	UREA	30.2	mg/dl		13.0 – 43.0 mg/dl
20-Jul-2011	02130043	SERUM			Default	CRE	1.19	mg/dl		0.70 – 1.30 mg/dl
20-Jul-2011	02130043	SERUM			Default	UA	6.65	mg/dl		3.40 – 7.00 mg/dl
20-Jul-2011	02130043	SERUM			Default	CHO	220	mg/dl		120 – 250 mg/dl
20-Jul-2011	02130043	SERUM			Default	TRG	124	mg/dl		--
20-Jul-2011	02130110	SERUM			Default	GLU	44.2	mg/dl		70.0 – 110.0 mg/dl
20-Jul-2011	02130110	SERUM			Default	UREA	24.4	mg/dl		13.0 – 43.0 mg/dl
20-Jul-2011	02130110	SERUM			Default	CRE	0.99	mg/dl		0.70 – 1.30 mg/dl
20-Jul-2011	02130110	SERUM			Default	UA	7.80	mg/dl		3.40 – 7.00 mg/dl
20-Jul-2011	02130110	SERUM			Default	CHO	268	mg/dl		120 – 250 mg/dl
20-Jul-2011	02130110	SERUM			Default	TRG	140	mg/dl		--
20-Jul-2011	02130160	SERUM			Default	GLU	192.8	mg/dl		70.0 – 110.0 mg/dl
01-Aug-2011	04	SERUM			Default	GLU	389.6	mg/dl		70.0 – 110.0 mg/dl
18-Jul-2011	04200001	SERUM			Default	GLU	84.5	mg/dl		70.0 – 110.0 mg/dl

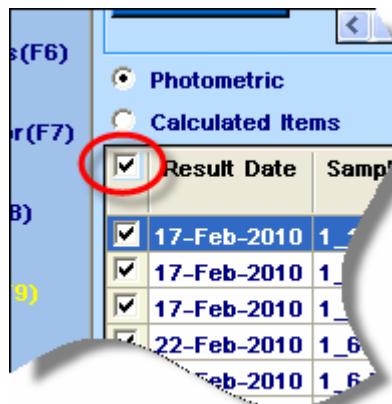
Figure 6-42. Patient report with patient results

- Select the required test using check box individually, select the required Repot Options, and then click PRINT button.
- Now select the required test using check box individually, select the required Repot Options, and then click PRINT button.

On clicking, the report will be generated and displayed on the screen.

Use **PREVIEW** button before printing the report to see the selected records.

To select the entire records, click on the checkbox provided on the top left corner of the grid as shown below.



To select the patients individually, click on the desired check box one by one as shown in the figure below.

F7	<input type="radio"/> Calculated Items	<input type="radio"/> Offline	<input type="radio"/> Rerun			
	Result Date	Sample ID	Sample Type	Patient Name	Age	Category
12	<input checked="" type="checkbox"/>	17-Feb-2010 1_1	SERUM			GLDH
	<input type="checkbox"/>	17-Feb-2010 1_1	SERUM			GLDH
	<input checked="" type="checkbox"/>	17-Feb-2010 1_1	SERUM			GLDH
	<input checked="" type="checkbox"/>	22-Feb-2010 1_6 TLN	SERUM			GLDH
	<input checked="" type="checkbox"/>	22-Feb-2010 1_6 TLN	SERUM			GLDH
	<input type="checkbox"/>	22-Feb-2010 1_6 TLP	SERUM			GLDH
	<input checked="" type="checkbox"/>	22-Feb-2010 1_6 TLP	SERUM			GLDH
	<input checked="" type="checkbox"/>	10-Mar-2010 100310WfALAT TLN	SERUM			ALAT
	<input checked="" type="checkbox"/>	10-Mar-2010 100310WfALAT TLN	SERUM			ALAT
	<input type="checkbox"/>	10-Mar-2010 100310WfALAT TLN	SERUM			ALAT
	<input checked="" type="checkbox"/>	10-Mar-2010 100310WfALAT TLN	SERUM			ALAT
	<input type="checkbox"/>	10-Mar-2010 100310WfALAT TLN	SERUM			ALAT
	<input type="checkbox"/>	10-Mar-2010 100310WfALAT TLN	SERUM			CKMB
	<input type="checkbox"/>	10-Mar-2010 100310WfCKMB TLN	SERUM			CKMB
	<input type="checkbox"/>	10-Mar-2010 100310WfCKMB TLN	SERUM			CKMB
	<input type="checkbox"/>	10-Mar-2010 100310WfCKMB TLN	SERUM			CKMB
	<input type="checkbox"/>	15-Mar-2010 100315 cal u wdf	SERUM			CKMB
	<input type="checkbox"/>	15-Mar-2010 100315 cal u wdf	SERUM			CKMB
		100315 cal u wdf	SERUM			CKMB

The patient records are displayed according to the required selection:

**Doctor Name:** If the user selects Doctor Name, then reports related to that Doctor along with Patients associated with the doctor can be viewed depending on the From and To date selected. Click on **SHOW** to display the selected reports.

**Test:** If the user selects Test, then Patient reports related to that Test can be viewed depending on the From and To date selected. Click on **SHOW** to display the selected reports.

**Patient Name:** If the user selects Patient Name, then the Patient Reports related to Patient Names can be viewed depending on the From and To Date selected. Click on **SHOW** to display the selected reports.

The following options are used to display the patient records:

**From and To:** This option is used to select the date range.

**Location:** If the user selects Location, then Patient Reports related to that Location can be viewed depending on the From and To date selected. Click on **SHOW** to display the selected reports.

**Batch:** It is possible to search the patient results batch wise. Patient Records are displayed depending on the batch number selected. Click on **SHOW** to display the selected reports

The patient results can be viewed and printed depending on the selection of radio button:

**Photometric Tests:** If the user selects this option, then only photometric test results are displayed. By default, this option is selected.

**Calculated Items:** If the user selects this option, then only calculation item results are displayed.

**Offline Results:** If the user selects this option, then only Offline Entry results are displayed.

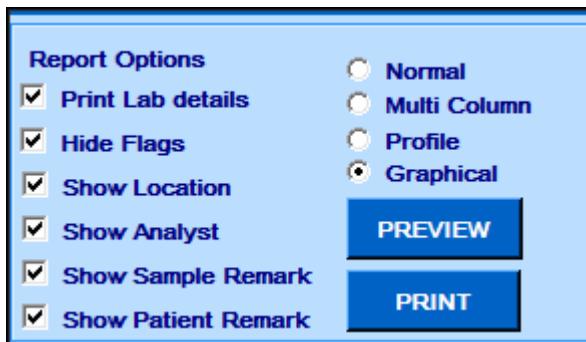
**ISE Results:** If the user selects this option, then only ISE Results are displayed.

**Rerun Results:** If the user selects this option, and then only Rerun results are displayed.

**Recalculated Results:** If the user selects this option, then only Recalculated Results are displayed.

**All:** If the user selects this option, then all results (Photometric Test, Offline Results, ISE Results, Rerun Results, and Recalculated Results) are displayed.

The following are the report options available on the screen:



---

**NOTE: The above report options will be memorized once the patient report is printed.**

---

Using the reports options, you can customize the generated report outputs.

**Print Lab Details:** This option is used when the user needs to print the Lab details. Refer section 7.4.1 *Settings*

*System Parameter Settings* for entering the Lab details.

If the user has clicked on the Print Lab Details checkbox, then the Laboratory details are also printed in reports.

**Hide flags:** This option is used when the user wants to print the Reports without printing the associated flags. If this option is selected, the column **Flag** will not be displayed in the printed patient report.



---

**NOTE: The H and L flag with up and down arrow will be displayed even if the option Hide Flags is selected.**

---

**Show Location:** This option is used when the user wants to print the Reports with or without printing the Location details.

**Show Analyst:** This option is used when the user wants to print the Reports with or without printing Analyst details.

**Show Sample Remarks:** This option is used when the user wants to print the Reports with or without printing the Sample Remarks.

**Show Patient Remarks:** This option is used when the user wants to print the Reports with or without printing the Patient Remarks.

**Five different types of options are available to generate the Report:**

- Normal
- Multi Column
- Profile
- Graphical

See figures in the following page.

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**Normal:** This is a basic type of format available. If all the results are selected, then the photometric results are displayed in one table, followed by calculation item, ISE and Offline Results.

JWL Labs					
202, Second Street, Near Conmax Hall, Florida, USA					
Sample ID	43	Patient ID			
Name	Sam Jones	Sample Type	SERUM		
Category	Male	Collection Date	23-Mar-2011		
Age	-	Reg. Date	23-Mar-2011		
Ref. Dr		Analyst			
Sample Remark			Location		
Sr.No.	Test	Result	Flag	Normal Range	
1	Sr. Cholesterol (CHOD -PAP method)	131.08 mg/dl	L	↓ 140.00-200.00 mg/dl	
2	Sr. Creatinine (Jaffe's method)	1.17 mg/dl		0.70-1.40 mg/dl	
3	Sr. Albumin (BCG dye method)	4.71 g/dl		3.20-5.00 g/dl	
4	SGPT	43.5 IU/L	H	↑ 0.0-42.0 IU/L	
5	Sr. Proteins ( biuret method)	8.12 g/dl		6.00-8.30 g/dl	
Patient Remark					
Further test recommended					
Completion Date 23-Mar-2011 16:42					
Note : Tests have been performed on fully automated analyzer:- EM 200			Print Date 21-Nov-2011 12:23 Page 1 of 1		

Figure 6-43. Patient report – Normal

**Multi Column:** This type of format is used when the user needs to print the results column wise. The results are displayed in a newspaper column format. See figure below.

<b>JWL Labs</b>					
202, Second Street, Near Conmax Hall, Florida, USA					
<b>Sample ID</b>	<b>45</b>		<b>Patient ID</b>		
<b>Name</b>	<b>Calvin Parena</b>		<b>Sample Type</b>	<b>SERUM</b>	
<b>Category</b>	<b>Male</b>		<b>Collection Date</b>	<b>28-Mar-2011</b>	
<b>Age</b>	<b>-</b>		<b>Reg. Date</b>	<b>28-Mar-2011</b>	
<b>Ref. Dr</b>			<b>Analyst</b>		
<b>Sample Remark</b>			<b>Location</b>		
<b>Test</b>	<b>Result</b>	<b>Normal Range</b>	<b>Test</b>	<b>Result</b>	<b>Normal Range</b>
Sr. Cholesterol (CHOD -PAP method)	181.05 mg/dl	140.00 - 200.00 mg/dl	High Density Lipoprotein (turbimetry)	86.33 mg/dl	35.30 - 79.50 mg/dl
Sr. Creatinine (Jaffe's method)	1.02 mg/dl	0.70 - 1.40 mg/dl	Sr. Albumin (BCG dye method)	4.07 g/dl	3.20 - 5.00 g/dl
SGPT	81.8 IU/L	0.0 - 42.0 IU/L	Sr. Proteins ( biuret method)	7.47 g/dl	6.00 - 8.30 g/dl
SGOT	115.4 IU/L	0.0 - 37.0 IU/L	GAMMA GT	1960.0 IU/L	0.0 - 50.0 IU/L
<b>Patient Remark</b>					
Further test recommended			Mary Page		
Completion Date 28-Mar-2011 11:29			Veronica		
Note : Tests have been performed on fully automated analyzer:- EM 200			Print Date	21-Nov-2011 12:30	Page 1 of 1

Figure 6-44. Patient report - Multi column

**Profile:** If the user has selected profiles for scheduling tests from Patient Entry screen, then the user can print Patient Reports as per the various Profiles selected.

<b>JWL Labs</b>			
202, Second Street, Near Conmax Hall, Florida, USA			
<b>Sample ID</b>	<b>68</b>	<b>Patient ID</b>	
<b>Name</b>	<b>Shane Paul</b>	<b>Sample Type</b>	<b>SERUM</b>
<b>Category</b>	<b>Male</b>	<b>Collection Date</b>	<b>28-Mar-2011</b>
<b>Age</b>	-	<b>Reg. Date</b>	<b>28-Mar-2011</b>
<b>Ref. Dr</b>	<b>Analyst</b>		
<b>Sample Remark</b>		<b>Location</b>	
<hr/>			
<b>Profile : --</b>			
<b>Sr.No.</b>	<b>Test</b>	<b>Result</b>	<b>Flag</b>
1	Sr. Cholesterol (CHOD -PAP method)	181.05 mg/dl	
2	High Density Lipoprotein (turbimetry)	86.33 mg/dl	H
3	Sr. Creatinine (Jaffe's method)	1.02 mg/dl	
4	Sr. Albumin (BCG dye method)	4.07 g/dl	
5	SGPT	81.8 IU/L	H
6	Sr. Proteins ( biuret method)	7.47 g/dl	
7	SGOT	115.4 IU/L	H
8	GAMMA GT	1960.0 IU/L	TEC-H,H,AbsLim
<hr/>			
<b>Patient Remark</b> Further test recommended <b>Mary Page</b> Completion Date 28-Mar-2011 11:29 <b>Veronica</b> Note: Tests have been performed on fully automated analyzer:- EM 200 Print Date 21-Nov-2011 12:35 Page 1 of 1			

Figure 6-45. Report screen -Profile

**Graphical:** When the user want to view and print the patient results in Graphical format, then this option can be selected as shown in the following figure.

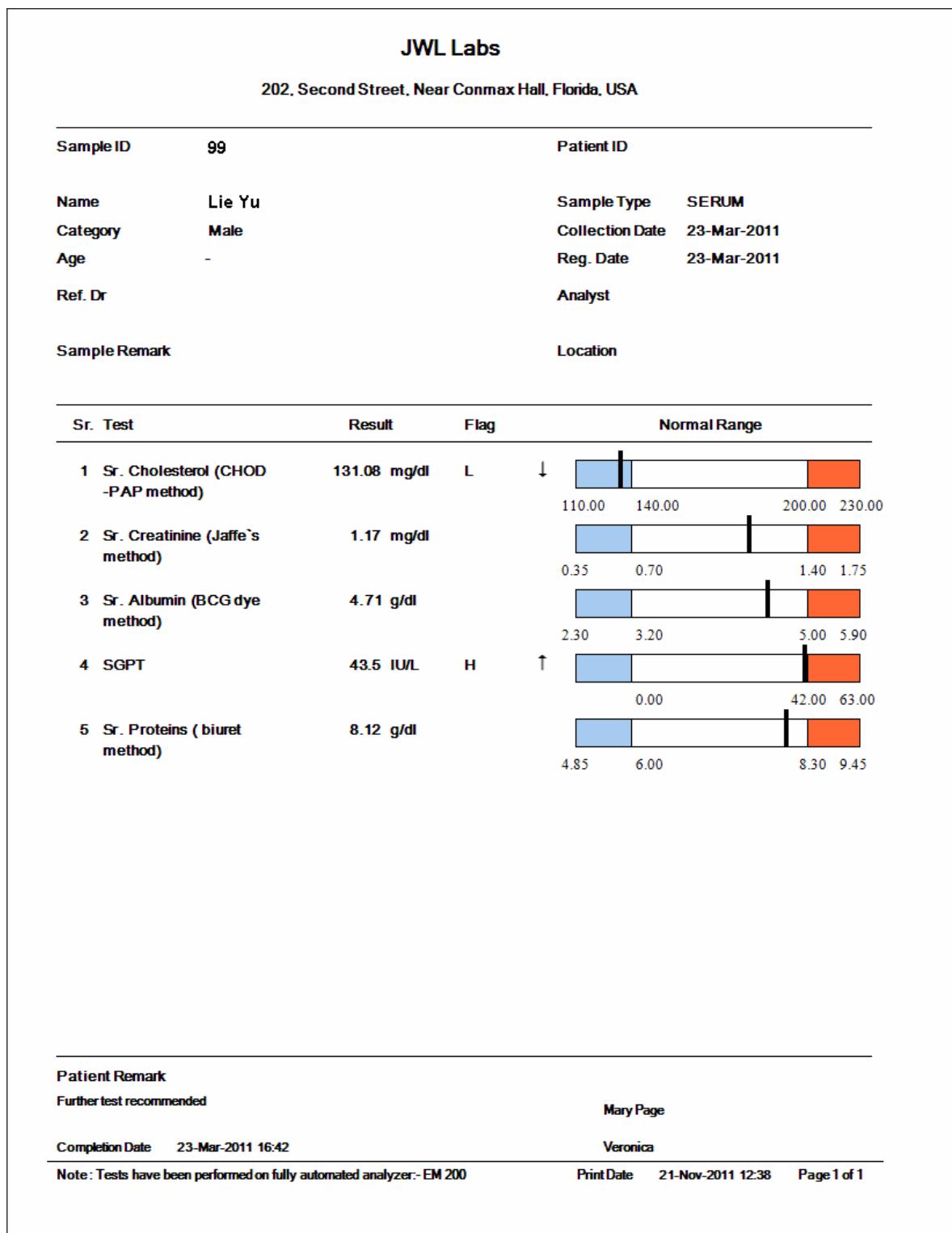


Figure 6-46. Report screen - Graphical



**NOTE: The patient report's footer information, top and bottom margin, and signature will be displayed at the bottom of the report. These settings can be configured through Settings > System Parameters screen.**

The following are the buttons available on the screen:

**PRINT:** This button is used to print the report.

**PREVIEW:** This button displays only those records that are selected for printing.

Preview Record Selection

Result Date	Sample ID	Sample Type	Patient Name	Age	Category	Test	Result	Unit	Flag	Normal Range
14-Jul-2011	1	SERUM		-	Default	SI-H	232.2		H2	--
28-Jun-2011	1	SERUM		-	Default	ALP	2.900	IU/L	L	38.000 - 94.000 IU/L
28-Jun-2011	1	SERUM		-	Default	ALP	2.870	IU/L	L	38.000 - 94.000 IU/L
28-Jun-2011	1	SERUM		-	Default	ALP	2.640	IU/L	L	38.000 - 94.000 IU/L
28-Jun-2011	1	SERUM		-	Default	ALP	2.920	IU/L	L	38.000 - 94.000 IU/L
28-Jun-2011	1	SERUM		-	Default	ALP	2.570	IU/L	L	38.000 - 94.000 IU/L
28-Jun-2011	1	SERUM		-	Default	ALP	2.760	IU/L	L	38.000 - 94.000 IU/L
28-Jun-2011	1	SERUM		-	Default	ALP	2.670	IU/L	L	38.000 - 94.000 IU/L
28-Jun-2011	1	SERUM		-	Default	ALP	2.590	IU/L	L	38.000 - 94.000 IU/L
28-Jun-2011	1	SERUM		-	Default	ALP	0.140	IU/L	L	38.000 - 94.000 IU/L
28-Jun-2011	1	SERUM		-	Default	ALP	0.400	IU/L	L	38.000 - 94.000 IU/L
28-Jun-2011	1	SERUM		-	Default	ALP	0.230	IU/L	L	38.000 - 94.000 IU/L

**PRINT**    **CLOSE**    **CLEAR**    Click on CLEAR to clear selection and close preview.

Figure 6-47. Preview record selection screen



**NOTE: The report options will be memorized once the patient report is printed.**

The following options are available for selection:

**Abnormal Results:** If the user selects this option, then Results with flag are displayed. The sample completion date-time is also printed at the bottom patient report for each sample ID.

**Undo Selection:** This option is used to clear the previous selection.

## 6.8.5. All Results

### 6.8.5.1. Result Reprint

To open this screen, click on **Reports > Result Reprint** button in main menu.

## Operator Manual

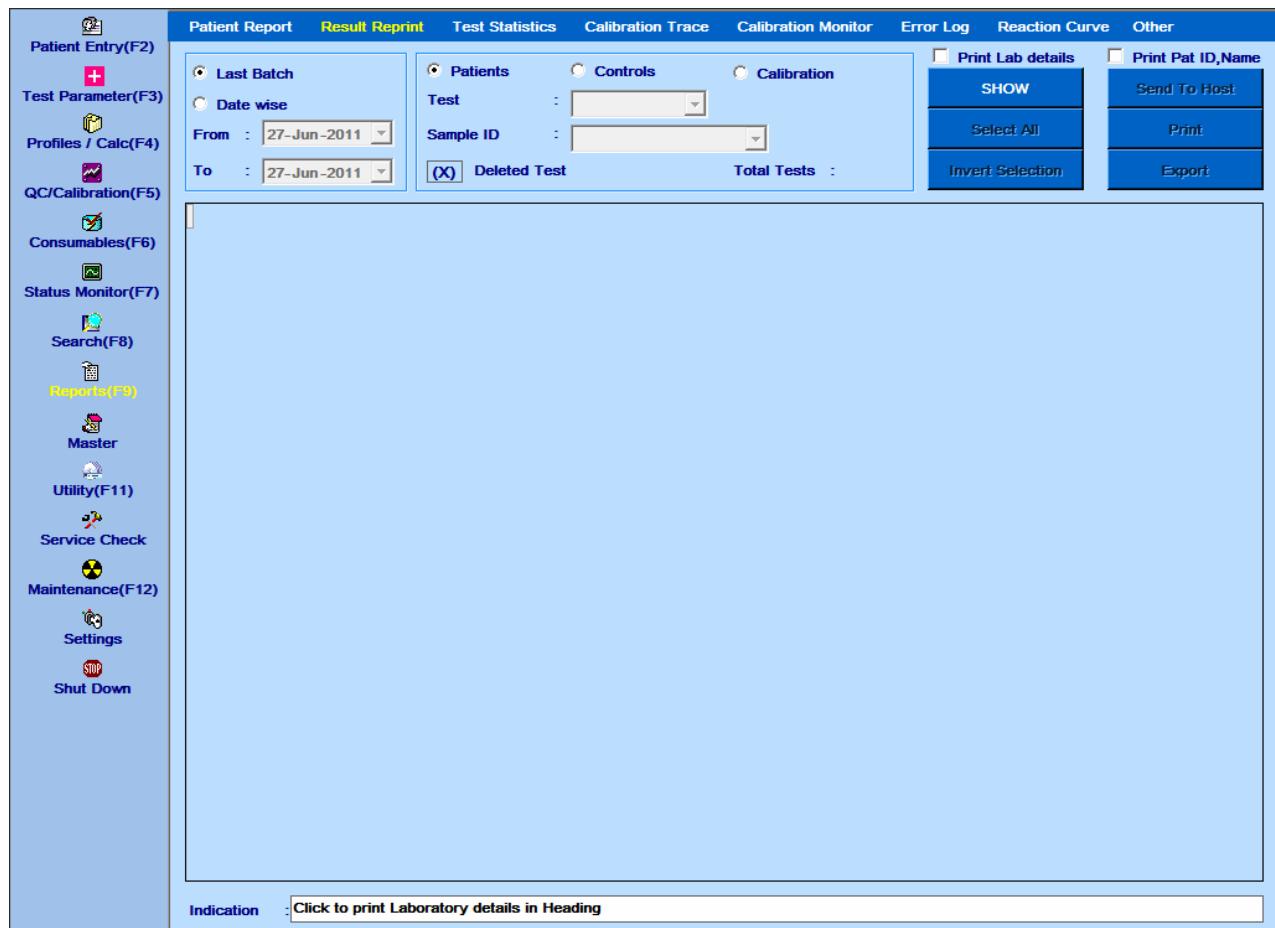


Figure 6-48. Result reprint screen

This menu enables the user to retrieve and print the results date wise or for the last batch. After selecting the required parameters, click on **SHOW** button to display the results.

# Operator Manual

The screenshot shows the software's main window with a left sidebar containing various menu items and their keyboard shortcuts. The main area displays a patient report table with 24 rows of test results.

Sr #	Sample ID	Patient Name	Test	Result	Unit	Flag	Result Date	Curve #
1	201108503093		TP	6.6	g/dl	F	09/14/2011 00:00:01	69822
2	201108503093		URE	15	mg/dl		09/14/2011 00:00:10	69823
3	201108503093		CAL	8.4	mg/dl		09/14/2011 00:00:20	69824
4	201108501094		GLC	123	mg/dl	F	09/14/2011 00:00:28	69825
5	201108502094		ALP	87	U/L	F	09/14/2011 00:00:37	69826
6	201108502094		AMY	39	U/L	F	09/14/2011 00:00:46	69827
7	201108502094		CKMB	37	U/L	F	09/14/2011 00:00:54	69828
8	201108502094		UA	3.1	mg/dl	F	09/14/2011 00:01:03	69829
9	201108502094		CHO	155	mg/dl	F	09/14/2011 00:01:12	69830
10	201108502094		ALB	3.1	g/dl	F	09/14/2011 00:01:21	69831
11	201108502094		GLC	110	mg/dl	F	09/14/2011 00:01:30	69832
12	201108502094		ALT	6	U/L		09/14/2011 00:01:39	69833
13	201108502094		TBIL	0.7	mg/dl	F	09/14/2011 00:01:48	69834
14	201108502094		DBIL	0.2	mg/dl	F	09/14/2011 00:01:57	69835
15	201108502094		CR	1.0	mg/dl	F	09/14/2011 00:02:05	69836
16	201108502094		TG	133	mg/dl	F	09/14/2011 00:02:14	69837
17	201108502094		TP	6.4	g/dl	F	09/14/2011 00:02:23	69838
18	201108502094		URE	13	mg/dl		09/14/2011 00:02:32	69839
19	201108502094		CAL	7.6	mg/dl		09/14/2011 00:02:41	69840
20	201108503094		ALP	82	U/L	F	09/14/2011 00:02:50	69841
21	201108503094		AMY	40	U/L	F	09/14/2011 00:02:59	69842
22	201108503094		CKMB	8	U/L	F	09/14/2011 00:03:07	69843
23	201108503094		UA	2.9	mg/dl	F	09/14/2011 00:03:16	69844
24	201108503094		CHO	153	mg/dl	F	09/14/2011 00:03:25	69845

Indication : Please connect to Archive to view remaining Patient Data.

The multiple options at the top of the screen are described below:

**Latest Batch:** Select this option to display the results of the latest batch.

**Date wise:** Select this option to display results for a specific date or range of dates. Then select the **From** and **To** dates from the drop-down calendar.

**Print Lab Details:** Select this option to print the laboratory details in the header of the printed report.

**Print Pat ID, Name:** On checking this option, the additional column Patient ID and Patient Name column will be displayed on the print report in the landscape orientation. If this option is not selected, the report will be generated in portrait orientation.

**Total Tests:** Displays the total number of tests performed for the selected criteria.

**Send to Host:** This button is visible only if the **Host Connection** checkbox in **Settings > System Parameter** screen is checked. This button is used for sending the selected results to the LIS, after batch run is completed.

**Print:** This button is used for printing the Results on printer or PDF writer.

**Export:** This button is used for export the Results on an excel sheet.

**Report Type:** Any of the three options can be selected.

- Patients

- Controls
- Calibration



**NOTE: During run, patient results of maximum 7 days at a time will be displayed, whereas Calibration and Control results of maximum 30 days at a time will be displayed.**

Depending on the option selected, the results will be displayed on the result grid.

**Test:** All or any one of the tests can be selected from the list

**Sample ID:** All or any one of the sample id can be selected from the list

**Inv. Selection:** Use this button to invert the selection that is made. Clicking on this button will select the unselected results (rows) and vice versa.

**Select All:** Use this button to select all the results displayed on screen.

**Show:** Press show button after selecting Radio button which will display the result of the latest batch.

The columns displayed in the grid are explained below:

Parameters	Description
Sample ID	Displays the Sample ID of the patient
Patient Name	Displays the Patient Name
Test	Displays the Test Name
Result	Displays the Test Result
Unit	Displays the Test Unit
Flag	Displays the Flag associated with the Test Result
Result Date	Displays the date on which the test was performed
Curve No	Displays the Reaction Curve Number

To view the reaction curve, double-click on the reaction curve number in the column "Curve #". A new window with the curve and absorbance readings will be displayed. Click on "Close" button to close this window and go back to the Result Reprint screen.

This facility is available when the batch run is not in progress.

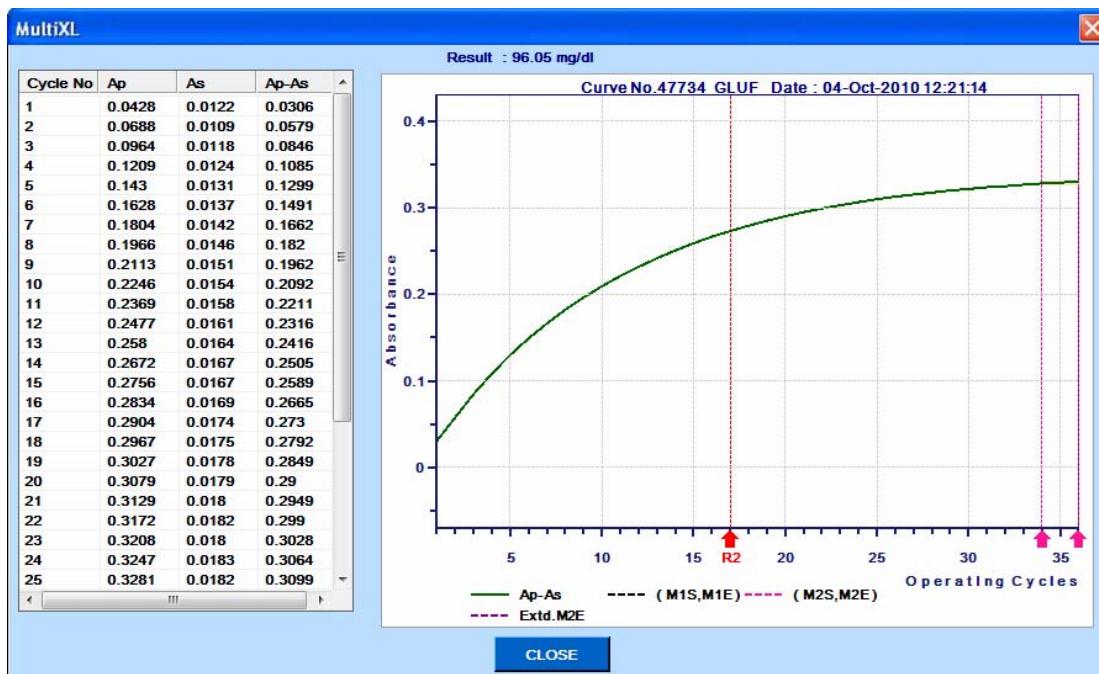


Figure 6-49. Reaction curve from Result reprint screen

### 6.8.5.2. Test Statistics

To open this screen, click on **Reports > Test Statistics** button in main menu.

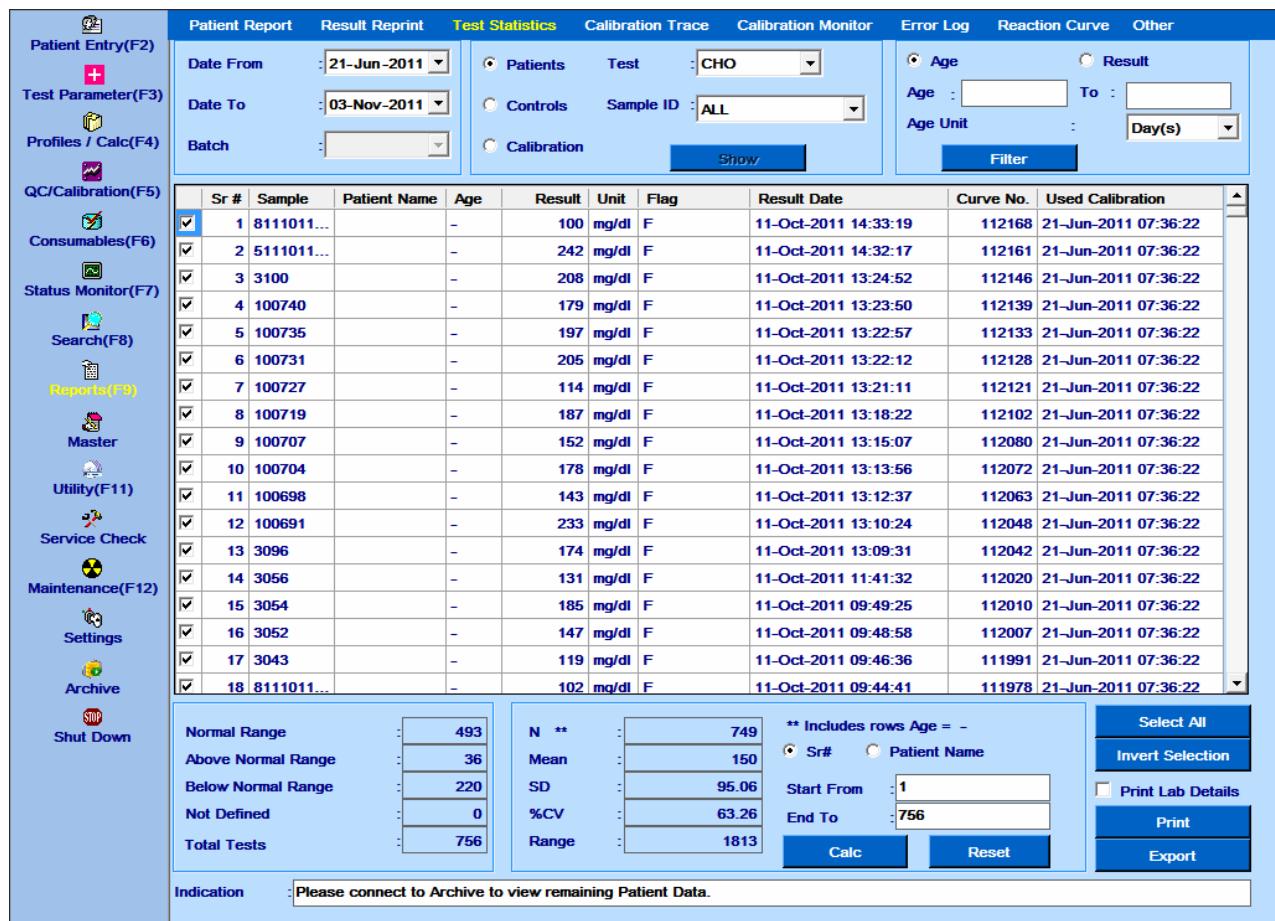


Figure 6-50. Test statistic screen

A description of various parameters available on this screen is given below:

**Date From:** Enter the beginning date for the results to be analyzed.

**Date To:** Enter the ending date for the results to be analyzed.

**Batch:** Use this option to view the results batch wise, when Date From and Date To are the same. Results of the batch number selected from the drop-down list are displayed.

**Report Type:** Using this radio button, select Patient to obtain the details of patient results or select Calibration to obtain calibration results or select Controls to obtain results of controls; for the selected test within the **specified Date Range**.

**Test:** Select the test/chemistry name to view its statistics. Patients, Controls and Calibration results of that test, performed on the analyzer will be displayed.

**Age:** Select this option if test statistics for a particular age group is required.

**Result:** Select this option if test statistics for a particular test value is required.

**Filter:** This button is used to filter the patient results according to **Age** and **Result** wise.

- To filter the patient result Age wise, select **Age** option, and enter the age range into **Age** and **To** textbox. Select appropriate age unit and then click **Filter**.

The screenshot shows a dialog box with the following interface:  
- Two radio buttons at the top: 'Age' (selected) and 'Result'.  
- Input field 'Age : 20' with a numeric value.  
- Input field 'To : 60' with a numeric value.  
- A dropdown menu labeled 'Age Unit' containing 'Day(s)'.  
- A blue 'Filter' button at the bottom.

- Select the **Result** option, and enter the range into Result and To textbox, and then click **Filter** to filter the patient reports Result wise.

The screenshot shows a dialog box with the following interface:  
- Two radio buttons at the top: 'Age' and 'Result' (selected).  
- Input field 'Result : 30' with a numeric value.  
- Input field 'To : 150' with a numeric value.  
- A blue 'Filter' button at the bottom.

If nothing is entered in those boxes, then it will show all the data.

**Print Lab Details:** In case, the user requires the Laboratory details to appear as header on the Test Statistics report, then select this checkbox.

**Sr#:** Use this option to view result statistics of specific rows displayed in the screen. Then enter the Range of Rows in the **Start From** and **End To**.

**Patient Name:** use this option to specify patient name/Consumable for which you want to obtain the statistics. Then enter first few characters of the patient / consumable name.

**The other grid shows the following details:**

**Normal Range:** Displays the total number of results that were within the normal range defined in the **Test Parameters > Reference Ranges** screen.

**Above Normal Range:** Displays the total number of results that were above the normal range defined in the **Test Parameters > Reference Ranges** screen.

**Below Normal Range:** Displays the total number of results that were below the normal range defined in the **Test Parameters > Reference Ranges** screen.

**Not defined:** Displays the total number of results whose reference ranges were not defined in the **Test Parameters > Reference Ranges** screen.

**Total Tests:** Displays total number of results/absorbance's available.

**N:** Displays the total number of tests used for calculating the Mean, SD and %CV for a test.

**Mean:** Displays the average of the result/absorbance that has been selected (checked).

**SD:** Displays the Standard Deviation of the result/absorbance that has been selected.

**%CV:** Displays the %CV (coefficient of variation) of the result/absorbance that have been selected (tick-marked)

**Range:** Displays the Range of the results that fall within the selected criteria. It shows the difference between the minimum and maximum range for the same.

**Sr#:** Use this button to select the range of results/absorbance's for which you want to obtain the statistics. Enter the range in Start From and End To textbox. Once the range is entered, click on **Calc** button to obtain the statistics.

**The following buttons are available on the screen:**

**Select All:** This button is used to select all the sample records for a test.

**Invert Selection:** This button is used to clear all the selections.

**Print:** This button is used for printing the Test Statistics for the selected Test in Report format.

**Export:** This button is used to export the Test Statistic details into the excel sheet and saved in location C:\MultiXLLOG\TestStatistics.

**Calc:** This button is used to recalculate the statistics in the other grid at the left-bottom corner of the screen; as per the result data displayed in screen (based on the sub-filters, such as Sr#, applied to the result data).

**Reset:** This button reset the values entered in the **Start From** and **End To** textbox.

### 6.8.5.3. Reaction Curve

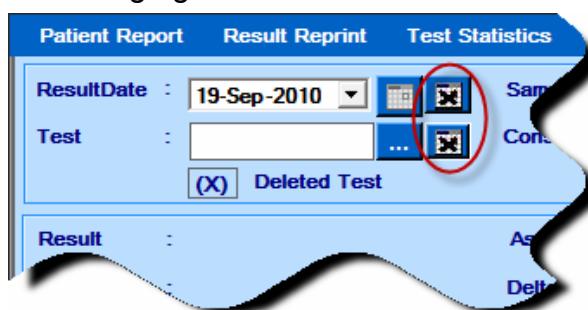
To open this screen, click on **Reports > Reaction Curve** button in main menu.



Figure 6-51. Reports - Reaction curve screen

This screen can be used to view the reaction course (absorbance vs. cycle number) for any reaction. The reaction curve can be viewed Test wise and Sample ID wise for patient results or Test wise and Consumables wise for Blank, Standard/Calibrator and Control Results. Click on the dotted button near the **Test** textbox to select the test. Click on the dotted button near the **Sample ID** textbox or consumable textbox to select Sample ID or Consumable respectively.

Use this to clear the respective selection criteria in the adjoining Textbox, as required. See the following figure.



Alternatively, one can also search a specific Curve number by ticking **Search By Reaction Curve No.** checkbox and then entering the reaction curve number in **Curve No.** textbox (It allows to enter up to 9 digits). The user has to click on **SHOW** to view the reaction curve as per selection.

Reaction Curve number is a unique serial number assigned by the program during analysis. The reaction curve number can be obtained from the from the **Reports > Result Reprint** screen. The absorbance values for the selected time course are displayed in a tabular format as well as graphically.

M1S, M1E, M2S, M2E and Extended M2E and also Ap, As, Ap-As for a particular chemistry are shown on the time course. These points can be identified by legends placed below the time course.

R2 addition line is shown with the red arrow.

The time course display also contains the following details regarding that Reaction Curve:

**Result:** It displays the result of the test selected.

**Flag:** It displays the flag associated with the Result.

**Primary Wavelength:** It displays the primary wavelength to be used for measurement of that test, as set in the **Test Parameter > Test Details** screen.

**Secondary Wavelength:** It displays the secondary wavelength to be used for measurement of that test, as set in the **Test Parameter > Test Details** screen.

**Assay Type:** It displays the Assay Type for that test, as set in the **Test Parameter > Test Details** screen.

**Average O.D./Delta Abs/min:** It displays the Average O.D. for End Point Assays or Delta Abs/min value for Rate Assays; calculated within the specified time intervals for that test. .

**Format:** It allows selecting either to display in the graph only Ap (Absorbance at Primary Wavelength) or only As (Absorbance at Secondary Wavelength) or both Ap and As or Ap-As or All.

An explanation of various columns shown in the table is given below:

Column Name	Description
Cycle	Absorbance cycle numbers are displayed in this column.
Ap	Absorbance of the reaction mixture at primary wavelength after subtraction of cuvette blank absorbance at primary wavelength.
As	Absorbance of the reaction mixture at secondary wavelength after subtraction of cuvette blank absorbance at secondary wavelength
Ap-As	The difference in absorbance at primary and secondary wavelength after subtraction of cuvette blank absorbance (that is, it is the difference of Ap and As).

Click on  to zoom in / zoom out the Y axis (Absorbance) scale to enlarge the graph within the minimum and maximum absorbance for that curve.

Double-click on the Reaction Curve graph to obtain a zoomed view. Double-click again to zoom out. The following figure shows the Zoomed Reaction Curve.

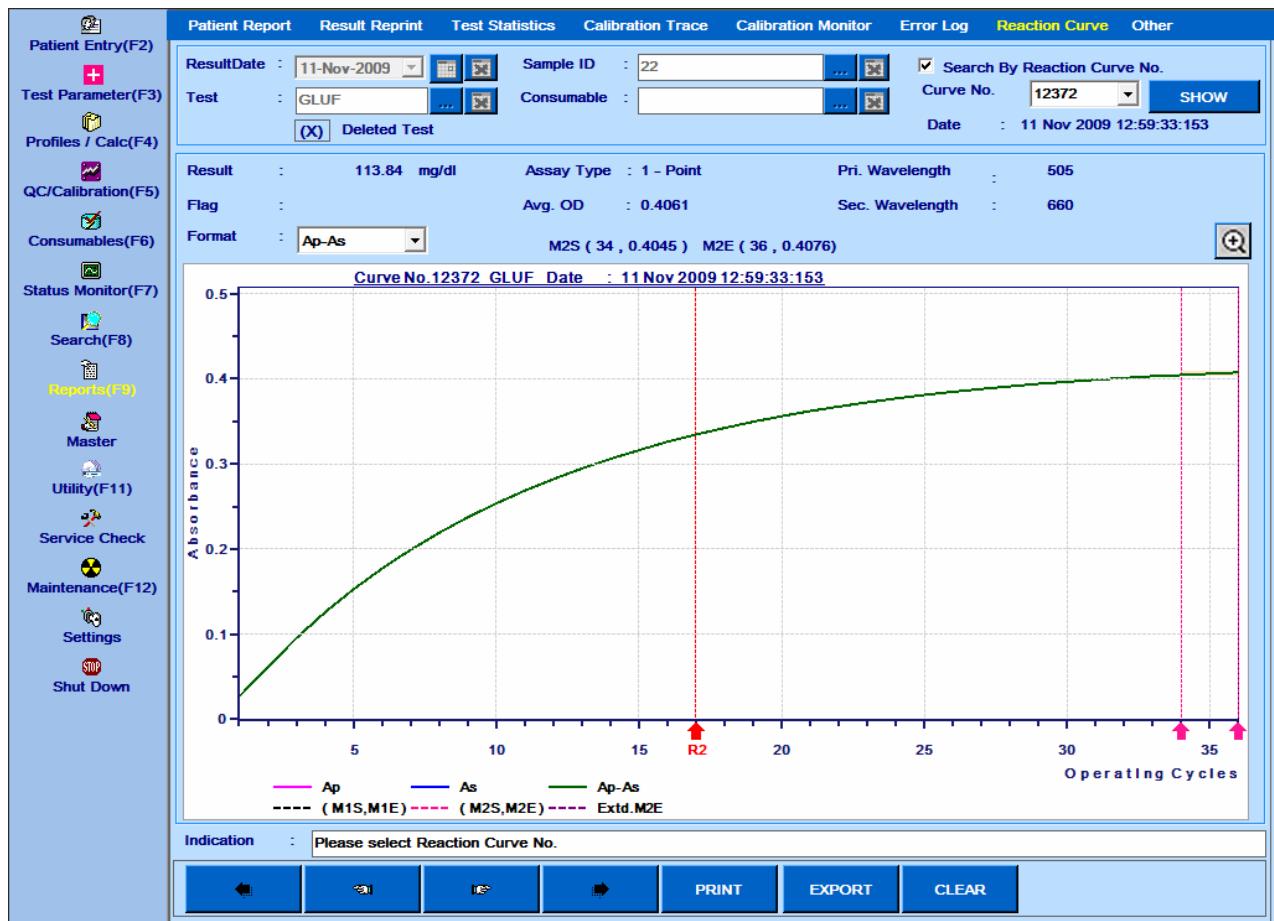


Figure 6-52. Zoomed reaction curve

**Following are the other buttons present on screen:**

**(Move First)** / **(Move Previous)** / **(Move Next)** / **(Move Last)**: These buttons can be used to view the previous or next reaction curve number details.

**PRINT:** Click on this button to print the reaction curve details along with the graph.

**EXPORT:** Click on this button to export the selected reaction curve details along with the graph to the specific location. After exporting the data successfully, the file name along with the path is displayed as a message as well as in Indication textbox in the bottom of the screen.

**CLEAR:** Click on this button to remove the details of the selected reaction curve number.

#### 6.8.5.4. Other

This menu enables the user to view the number of patients, calibration (including blanks and standards/calibrators) and controls, performed on the analyzer for each test for the selected range of dates.

To open this screen, click on **Reports** from the main menu and then select **Other**.

This screen is useful to view the approximate reagent consumption and ISE calibration details. Two options are available on this screen.

- Reagent Consumption
- ISE Calibration

Select the appropriate option as needed. The following screen is displayed when reagent consumption option is selected.

Sr#	Tests	Total Tests [Patients]	Total Tests [Calibration]	Total Tests [Controls]	Total
1	%A1C	3	0	0	3
2	%BA1C	666	0	0	666
3	%HBA1	570	0	0	570
4	A1C	692	70	0	762
5	ALB	348	142	152	642
6	BID	411	153	166	730
7	BIT	393	151	167	711
8	CEC	2	0	0	2
9	CHO	9254	145	157	9556
10	CRE	8533	161	197	8891
11	GLU	10677	145	164	10986
12	GOT	448	140	170	758
13	GPT	449	140	157	746
14	HB	676	28	0	704
15	HBA1C	578	25	0	603
16	HBTOT	589	10	0	599
17	HDLC	2	2	0	4
18	PRO	349	146	164	659
19	TRG	9390	155	201	9746
20	UA	8562	145	161	8868
21	UREA	7876	143	157	8176

Indication : No record found for selected fields.

Figure 6-53. Other - Reagent consumption

The date range can be selected using **From** and **To** date options.

**SHOW:** This button is used to view the data over the selected date range.

**PRINT:** This button is used to print the **Reagent Consumption** or **ISE Calibration** details report, as selected.

**EXPORT:** On clicking this button, the data will be exported to the appropriate location. After exporting the data successfully, the location will be displayed in the Indication textbox in the bottom of the screen.

On selecting ISE calibration option, the following screen will be displayed:

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The screenshot shows a software interface with a vertical toolbar on the left and a main content area on the right.

**Vertical Toolbar (Left):**

- Patient Entry(F2)
- Test Parameter(F3) (highlighted with a red plus icon)
- Profiles / Calc(F4)
- QC/Calibration(F5)
- Consumables(F6)
- Status Monitor(F7)
- Search(F8)
- Reports(F9)
- Master
- Utility(F11)
- Service Check
- Maintenance(F12)
- Settings
- Shut Down

**Main Content Area (Right):**

At the top of the main area, there are two tabs: "Reagent Consumption" and "ISE Calibration" (highlighted with a blue circular icon).

In the center, there is a header box labeled "ISE CALIBRATION DETAILS". Below it is a table showing ISE calibration details:

Date Time	Na	K	Cl	Li
Jan 6 2011 10:54AM	0	0	0	0
Jan 5 2011 4:01PM	0	0	0	0
Jan 5 2011 4:00PM	0	0	0	0
Dec 24 2010 3:14PM	0	0	0	0
Dec 24 2010 2:46PM	0	0	0	0
Dec 24 2010 2:45PM	0	0	0	0

Figure 6-54. Other - ISE Calibration details

ISE calibration details are displayed in the order of date-time, starting from latest on the top.

## 6.9. Shutdown Options

Click on **Shut Down** from the main menu, the following screen is displayed.



Figure 6-55. Shutdown screen

Following are the two options available on click of Shut Down.

- **Shut Down**

On clicking this button the MultiXL software shuts down.



**NOTE:** \* Only for Analyzer with ISE unit installed.

The analyzer should be kept on as 95 µl of Calibrant-A and 36µl of Calibrant B is automatically dispensed into the ISE unit every 30 minutes to prevent the electrodes from drying. Even under the sleep condition (Front switch OFF), this function is performed.

\* Only if ISE unit is installed.

- **Water Save and Shut Down**

On clicking this button, the MultiXL software minimizes and the water save operation is performed.

Once the water save operation is complete, the MultiXL software automatically shuts down.

During the water save operation, if the application software is closed, a warning message is displayed for confirmation to stop the water save operation and shut down the software.



**NOTE:** On clicking this option, the Status Monitor, Service Check, and Maintenance screen will be disabled.

- **Maintenance and Shut Down**

On clicking this button the auto maintenance activity will be performed and the system will shut down after completing the operation.

If this button is clicked then MultiXL software is minimized and auto maintenance operation is performed.

Refer section *8.4.3.6.2. Operation Performed during Auto maintenance at Shutdown* for more details.

Once the auto maintenance operation is completed, MultiXL software will automatically turn off.



---

**NOTE: During Water Save and Shut Down or Maintenance and Shut Down operation, the Maintenance screen, Service Check screen, and Status Monitor screen will be disabled.**

---

# 7. Alterations of Operational Conditions

This section describes the procedures of setting and altering the operational conditions that determines the functioning of the system. In certain conditions, the behavior of the system can be customized using the respective settings provided in software; such as Test parameter, Calculated Items, Profile Entry, System Parameters, Host Settings, Backup Operation, Carry Over Pairs, Rerun Flags, User Rights, Result Recalculation, Search, Offline Results.

## 7.1. Functional Items

This section addresses how to enter and change the operational conditions and parameters of each functional item. Such functional items are shown below:

Section	Functional item	Description
7.2	Test Parameter	Analytical conditions are predefined. However, a part of them can be altered as applicable. This option includes the definition of Reference Ranges for each test.
7.3.1	Profile Entry	Define profiles with a set of test(s). Profile(s) are used to select at a time and print multiple test(s) in a set.
7.3.2	Calculated Items	Define the equation to compute the (calculated) value using the test result(s) obtained from the analyzer.
7.4.1	System Parameters Settings	Various system settings such as activation of host communication and barcode identification, Temperature range, parameters to customize patient reports are specified in this screen.
7.4.6	Host Setting	This screen is used to configure the Host communication with LIS.
7.4.5	User Rights	This is used to program the User Rights for different users.
7.4.2	Carryover Pairs	Define the Carry over pair with wash type to eliminate the carry over effect of Reagents.
7.4.3	Test Sequence	Define sequence of tests to display on screen and print in Patient Report. Processing sequence of the test(s) can also be set from this screen.
7.4.4	Rerun Flags	Select Flags for which rerun should be performed when such flags are attached to a result.
7.5.1	Backup operation	This screen is used to backup the data, full or partial (only specific data) into file(s). The file(s) then should be copied on an external media such as CD, DVD for future reference.
7.5.2	Offline Results Entry	Define offline results (performed on any other instrument) for existing or new samples.
7.5.3	Re-Calculation of Result(s)	This screen is used to re-calculate the results, after changing the calibration curve or analytical parameters such as limits to flag result.
7.6	Search	Search patients / samples, patient results, calibration / control results, consumables and test from this screen.

## 7.2. Test Parameters

This option is used to define the analytical parameters and the reference ranges of the tests.

Test Parameters are defined using 3 different screens namely Test Details, Test Volumes and Reference Ranges.

### 7.2.1. Test Details

This screen is available on clicking Test Parameter option from the main menu which opens the Test Details screen, as shown below.

Patient Entry(F2)		Test Details		Test Volumes		Reference Ranges							
<b>+ Test Parameter(F3)</b>		<b>* Test</b>	: AMY	Host Name	: AMY	Auto Rerun	: <input checked="" type="checkbox"/>						
<b>Profiles / Calc(F4)</b>		Report Name	: Sr. Amylase (CNP-G3 method)	Decimal Places	: 2	Online Calibration	: <input type="checkbox"/>						
<b>QC/Calibration(F5)</b>		Unit	: U/L	Secondary	: SELECT	Cuvette Wash	: <input type="checkbox"/>						
<b>Consumables(F6)</b>		Wavelength-Primary	: 405	Curve Type	: Linear	Total Reagents	: 1						
<b>Status Monitor(F7)</b>		Assay Type	: RATE - A			* Reagent R1	: AMY R1						
<b>Search(F8)</b>		M1 Start	: 0	M1 End	: 0								
<b>Reports(F9)</b>		<b>* M2 Start</b>	: 4	<b>* M2 End</b>	: 10								
<b>Master</b>		Sample Replicates	: 1	Standard Replicates	: 3								
<b>Utility(F11)</b>		Control Replicates	: 1	Control Interval	: 0								
<b>Service Check</b>		Reaction Direction	: Increasing	React. Abs. Limit	: 0.84								
<b>Maintenance(F12)</b>		Prozone Limit %	: 0	Prozone Check	: Lower								
<b>Settings</b>		Linearity Limit %	: 20	Delta Abs/Min	: 0.0								
<b>STOP</b>		Technical Minimum	: 0.0	Technical Maximum	: 1500.0								
		Y=aX+b	a= : 1	b= : 0	Reagent Abs Max	: 0.0							
		Reagent Abs Min	: 0.0										
<input type="button" value="SET ONLINE CALIBRATION"/> <input type="button" value="DOWNLOAD TEST"/> <input type="button" value="UPLOAD TEST"/> <input type="button" value="SET AUTO RERUN"/> <input type="button" value="COPY TEST"/> <input type="button" value="INITIALIZE TEST(S)"/>													
Tests			GLUF	GLUPP	GLUR	CHO	TRIG	HDLC	LDL	GOT	GPT	CRE	
			ALB	BIDER	BITER	GGTMR	MPR	LDHA	CAA	UACE	LDH	CKN	
			CKMB	PRO	GPTH	MG	GOTH	ALP	GGT	AMY	PHO	BID	
Indication		Please enter Test Name											
		<input type="button" value="◀"/>	<input type="button" value="▶"/>	<input type="button" value="✖"/>	<input type="button" value="▶"/>	<input type="button" value="◀"/>	<input type="button" value="PRINT"/>	<input type="button" value="SAVE"/>	<input type="button" value="CLEAR"/>	<input type="button" value="EDIT"/>	<input type="button" value="DELETE"/>		

Figure 7-1. Test detail screen

Define various parameters such as test name, measurement conditions, analytical method, calibration curve type, time intervals, reagents, limits for various checks on Absorbance or result, etc. as explained below.

Data in this screen is not editable during batch run.

#### 1. Inputs in the screen:

##### a. Test

Enter a short name for the Test, maximum up to 5 characters. This test name is used to select / display test(s) on all screens. A unique name is required for each test as this is the identity.

Enter the name along with appropriate parameters and click on SAVE. The test name will appear at the end of the Test panel in the bottom of the screen.

**b. Report Name**

Enter the full name (50 characters maximum) of the test (assay) that will appear in the patient report. For example, one feeds Aspartate Transaminase in this text box, while AST is entered in text box {Test}.

**c. Host Name**

This field is used to define a 5 character Name assigned in the LIS. This name could be same or different to the Test Name. This field will be available if the Host Connection is activated from the Settings > System Parameters screen.

**d. Total Reagents**

Select the total number of reagents used for the test. The drop-down list gives a selection of 1 or 2 Reagents for single and dual reagent assays respectively.

**e. Reagent R1 and Reagent R2**

Upon selecting the Total number of Reagents, the Reagent Name needs to be selected. This is different from Test Name. Reagent Name is defined in **Consumables > Reagents** screen. Select the name of the Reagent to be used for the test. This is the name that appears in the Utility > Reagent Position screen while viewing / defining the positions of the Reagents placed on Reagent Tray.



---

**NOTE: More than one test can share the same Reagent Name.**

---

**f. Unit**

Select the unit of measurement for the analytes from a drop down list. In case, the desired unit is not found in the list then define a new unit from the **Master > Units** screen.

A list of pre-programmed units is as follows:

- ◆ %
- ◆ µg/dl
- ◆ µg/L
- ◆ µg/ml
- ◆ µIU/ml
- ◆ µKat/L
- ◆ µmol/L

- ◆ µmol/Ls
- ◆ µmol/ml
- ◆ abs
- ◆ g/dl
- ◆ g/l
- ◆ IU/L
- ◆ IU/mL
- ◆ KIU/L
- ◆ mEq/L
- ◆ mg/dl
- ◆ mg/l
- ◆ ml/Min
- ◆ mlu/L
- ◆ mmol/L
- ◆ mU/ml
- ◆ ng/dt
- ◆ ng/L
- ◆ ng/mL
- ◆ nmol/L
- ◆ SEC
- ◆ U/L



---

**NOTE: Define any number of units from Master > Units screen.**

---

**g. Decimal Places**

Enter the number of digits to be displayed and print; after the decimal point of the test results. Enter the number of digits between 0 and 5.

**h. Wave Length**

This is a pull-down option is used to select appropriate primary and secondary wavelengths for absorbance measurement. The measurement wavelengths are selected from 8 fixed values provided. In case of bi-chromatic measurement, the final absorbance is obtained by subtracting the absorbance at the secondary wavelength from that at the primary wavelength. For monochromatic measurements, use "Select" for secondary wavelength.

i) **Primary wavelength**

The analyzer offers a choice of 8 wavelengths with a narrow bandwidth (<8 nm) for programming the wavelength. The choices are 340 nm, 405 nm, 505 nm, 546 nm, 578 nm, 600nm, 660 nm, and 700 nm.

ii) **Secondary wavelength**

When the methodology specifies bi-chromatic measurement for an assay, user can select a secondary wavelength at which the absorbance can has to be measured. The selection is made with the pull-down option provided. The following secondary wavelengths are available in the analyzer: 340 nm, 405 nm, 505 nm, 546 nm, 578 nm, 600nm, 660 nm, and 700 nm.

If bi-chromatic measurement is not desired i.e. for monochromatic measurements, keep the choice as “—SELECT— “ for the value of the secondary wavelength.

i. **Assay Type**

Use this pull-down option to select the assay type among 1POINT, 2POINT, RATE-A and RATE-B. It is recommended to use:

- ◆ 1 POINT for end point chemistries
- ◆ 2 POINT for end point chemistries using sample or reagent blank
- ◆ RATE–A for kinetic/rate assay
- ◆ RATE–B for kinetic/rate assay with differential slope

i) **1 POINT**

The method is used for normal end-point assays using one or two reagents where the final absorbance is used for concentration calculation. Mean of the absorbance's recorded between M2Start and M2End points are taken and this is used for the calculation of the sample results.

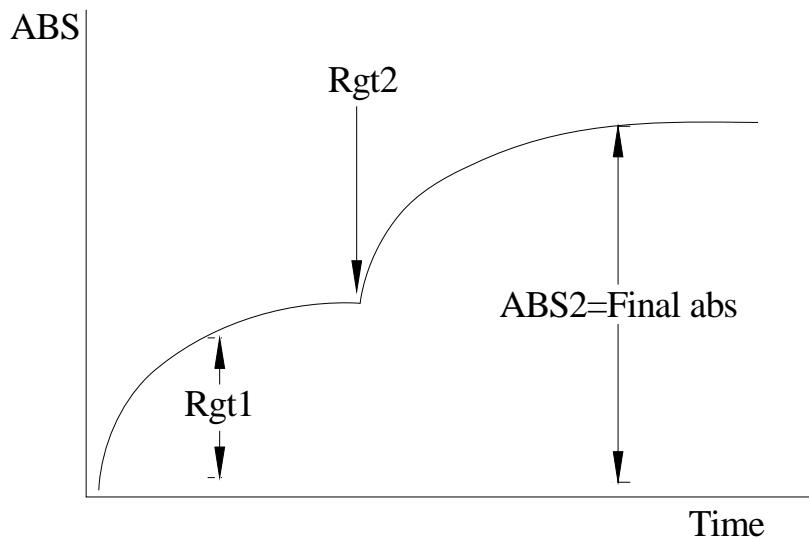


Figure 7-2. One point graph

### ii) 2 POINT

This method is used for end-point analysis when a sample or reagent blank is necessary. In this assay type, the initial absorbance (usually measured after addition of the first reagent) is recorded and subtracted from the final absorbance (which is usually measured after addition of the second reagent). Necessary correction factors to correct the difference in mixture volume are taken into account while subtracting the initial absorbance. The initial absorbance recorded is the mean of the absorbance's recorded between M1Start and M1End and this absorbance is subtracted from the final absorbance, which is the mean of the absorbance's recorded between M2Start and M2End. This differential absorbance is then used for calculation of sample concentration.

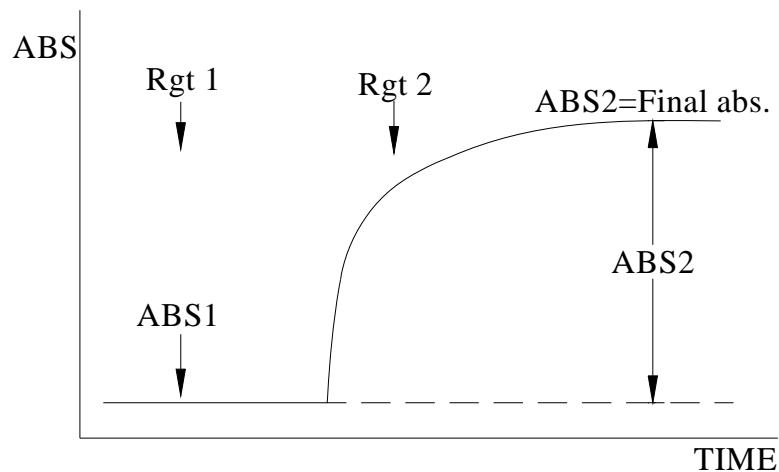


Figure 7-3. Two point graph

**iii) RATE-A**

This method is used for kinetic/rate assays where the change in absorbance per minute is used for result calculation. The slope (absorbance change per minute) is obtained from the absorbance's recorded between M2Start and M2End using the least square linear regression method as per the following formula:

$$\Delta A / \Delta T = \frac{\left[ \frac{1}{n} \sum_{i=1}^n (T_i A_i) \right] - \bar{T} \bar{A}}{\left[ \frac{1}{n} \sum_{i=1}^n (T_i^2) \right] - \bar{T}^2}$$

Where,  $T_i$  is the time in minute and  $A_i$  is the absorbance,  $n$  is the number of points.

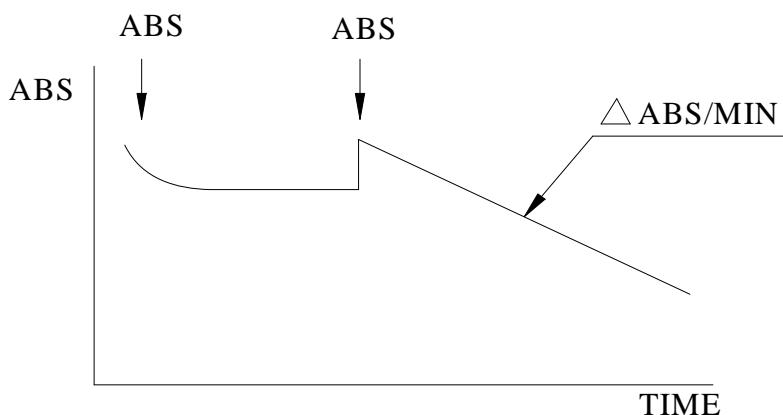


Figure 7-4. Rate A graph

**iv) RATE-B**

This method is used for kinetic/rate assays where differential rate is useful. The initial rate of change in absorbance per minute (usually obtained after addition of the first reagent) is subtracted from the final rate of change of absorbance per minute (usually obtained after addition of the second reagent). Necessary correction factors to correct the difference in mixture volume are taken into account while subtracting the initial rate of change in absorbance per minute. The initial rate of absorbance change per minute is recorded between M1Start and M1End using the least square regression method and is subtracted from the rate of change in absorbance per minute recorded between M2Start and M2End using the least square regression method explained in the section on RATE-A assay type.

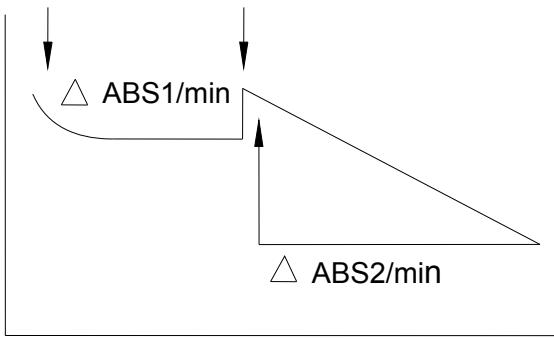


Figure 7-5. Rate B graph

#### j. Curve Type

This pull down list is used for defining the Calibration Curve Type for that test. The available curve types are:

- ◆ Linear
- ◆ K-Factor
- ◆ Linear (Multipoint)
- ◆ Cubic Spline
- ◆ 4P Calibration Logit-Log
- ◆ 5P Calibration Logit-Log
- ◆ Point To Point
- ◆ Exponential
- ◆ Polynomial

#### k. Assay Points

The analyzer records absorbance for a cuvette every 18 seconds over a span of 10 minutes 48 seconds. Operator should select/fix cuvette readings to be used for result calculation. These measurement points are referred to as M1Start, M1End, M2Start and M2End and can be given a value between 1 and 36 (SELECT means “no entry”). The absorbance readings can be obtained from the **Utility > Reaction Curve** screen.

Refer section 2.1.4 *Measurement Operation Table* for the cycle details.

#### M1Start and M1End

These assay points are used to select the time points for measurement of initial absorbance for 2POINT and RATE-B assay types. This absorbance serves as reagent or sample blank. This initial absorbance (or absorbance change per minute) in these assays is subtracted from the final absorbance (or absorbance change per minute) that is

measured between M2Start and M2End points. M1Start and M1End can have values from 1 to 36 for 2POINT and RATE-B assays.

In case of 2POINT chemistries, the mean of the absorbance's obtained between M1Start and M1End is calculated. In case of RATE-B chemistries, the change in absorbance per minute is calculated between M1Start and M1End points using least square linear regression method.

M1End should always be equal to or more than M1Start. The difference between M1End and M1Start should be at least three in case of RATE-B assay. In addition, M1End has to be less than or equal to M2Start. For 1POINT and RATE-A assays, M1Start and M1End should be programmed as "0".

### **M2Start and M2End**

It is essential to program M2Start and M2End parameters for all the tests and these parameters can have values from 1 to 36. M2Start specifies the incubation time point. Similarly, M2End is the time until when the absorbance is recorded for the purpose of concentration calculation.

In case of 1POINT and 2POINT chemistries, the mean of the absorbance's obtained between M2Start and M2End is calculated. In case of RATE-A and RATE-B chemistries, the change in absorbance per minute is calculated between M2Start and M2End points using least square linear regression method.

For 2POINT and RATE-B chemistries, M2Start has to be more than or equal to M1End.

#### **I. Sample Replicates**

Enter the value between 1 to 30 stating the number of repeated sample measurements to be performed for the selected chemistry. Repeated sample measurements are usually used to check repeatability. All samples programmed for this chemistry will be repeated for the programmed number of times. For routine operation, this parameter is programmed as '1'.

#### **m. Standard Replicates**

Enter the value between 1 and 3 stating the number of repeated blank and standard measurements to be performed for the selected chemistry. Average of the two closest replicates would be taken while updating absorbance of Blank and Standard in the Calibration screen.

#### **n. Control Replicates**

Enter a value between 1 and 30, stating the number of repeated control measurements to be performed for the chemistry. Repeated control measurements are usually used to check repeatability.

### **o. Control Interval**

The Control Interval parameter enables the user to define number of samples after which the control serum will run automatically. This interval can be selected between 0 and 1000. The value 0 indicates that control interval is not applicable. A control will run automatically only when the control for the chemistry is defined and available on board.

For example:

Control Interval = 30 means that control serum will be run after every 30th sample analyzed for that chemistry.

### **p. Reaction Direction**

This parameter defines the direction of the absorbance change with time for the reaction mixture. Specify whether the absorbance of the reaction mixture increases or decreases with time.

### **q. React. Abs. Limit (Reaction Absorbance Limit)**

Define the absorbance limit of reaction mixture for Serum/Urine samples. Enter an absorbance limit for reaction mixture, depending on the reaction direction (increasing or decreasing). For rate chemistries, the absorbance limit is that absorbance at which the substrate depletion is detected. The absorbance limit entered would be in direct absorbance and not in terms of delta absorbance per minute. For increasing direction chemistries, enter the maximum allowed final absorbance before substrate depletion takes place. For decreasing direction chemistries, enter the minimum allowed final absorbance before substrate depletion takes place.

If Technical Limits are not entered and if the Reaction Absorbance Limit is exceeded during the course of reaction then the last point of the measurement interval (i.e. M2E) is automatically shifted to the point where this limit has been exceeded to avoid sample rerun phenomenon. This new point is automatically used for calculation of sample concentration.

Also, in the Reaction Curve Screen, the new point would be shown using a dotted line, stated as **Extd. M2E** indicating that the extension logic has been applied to calculate the result.

---

#### **NOTE:**



- 1. If no points are available for slope calculation, then Lim0 flag is issued and the result is NA (not declared).**
  - 2. If only one point is available for slope calculation, then Lim1 flag is issued and the result is NA.**
  - 3. If only 2 points are available for slope calculation, then Lim2 flag is issued along with the result.**
-

Maximum permissible entry is 2.5. In case the reaction absorbance check is not desired, put "0" in the React Abs Limit text box. Extension logic will not be applied if the Reaction Absorbance limit is set to zero.

For rate chemistries, if Technical Limits are entered and if any point between M2S and M2E exceeds the Reaction Absorbance, AbsLim Flag is attached and result will be declared as NA. If option **Auto Rerun** is selected, the test is sent for a decreased rerun.

For end point chemistries, if final O.D calculated exceeds the Reaction Absorbance, AbsLim Flag is attached and result will be declared as NA. If option **Auto Rerun** is selected, the test is sent for a decreased rerun.

r. **Linearity Limit %:**

This parameter is applicable only for Rate-A and Rate-B assay types and monitors the linearity during the reaction. The user can feed any value between 1% to 30%. If the %Linearity exceeds the specified value in the Maximum Reaction Linearity, then a LINXX flag is displayed and result will be declared as NA. This flag is applicable for Patient Samples, Control & Standard / Calibrators and Not for Blank.

For e.g. if the user specified a value of 5% in the Reaction Linearity parameter and if the linearity percentage is exceeded, then flag LIN5 will be issued and result will be declared as NA.

s. **Prozone Limit %**

Specify the minimum limit for the absorbance at the end of an immunoturbidimetric reaction as a percentage of the maximum absorbance observed during the course of a reaction. Prozone limit should be between 0 to 100%. If the percent ratio of the final absorbance (at M2E) with the maximum absorbance in the time course (up to the point M2E) violated the prozone limit, a flag P\* is issued and result will be declared as NA. If the option **Auto Rerun** is selected, the sample is automatically sent for a Decreased volume rerun. If you want to make sure that the absorbance is increasing monotonically in the time course, feed a value of 100(%).



**NOTE: Prozone Limit is applicable only for Non-Linear curves.**

---

t. **Prozone Check**

This displays whether the entered value is an upper limit or lower limit. For increasing reaction direction chemistries, it is displayed as "Lower" and for decreasing reaction direction chemistries; it is displayed as "Upper".

u. **Delta Abs/Min**

This input is used for cancellation of Reaction Linearity Check and is used for low linearity samples. The user needs to enter the delta

absorbance/min for that test where the Linearity Check should not be performed. Once fed, if the delta absorbance/min of the reaction for that test is less than the set limit, then Linearity Check will not be performed.

#### v. Technical Limits

Define the Linearity Limit of the reagents in terms of concentration. For the 1POINT, 2POINT, Rate-A and Rate-B chemistries, feed the minimum and maximum concentrations in the Technical Minimum and Maximum Technical Limit text boxes respectively.

If Tech Limit Min is violated, a flag "TEC-L" is issued and result will be declared as NA. If the option **Auto Rerun** is selected, the sample is automatically sent for an increased volume rerun.

Similarly, if Tech Limit Max is violated, a flag "TEC-H" is issued and result will be declared as NA. If the option Auto Rerun is selected, the sample is automatically sent for a decreased volume rerun.

##### i) Technical Minimum

Define a value ranging from -9999.99 to 9999.99 indicative of the minimum technical limit or the linearity limit of the reagent. For end-point chemistries and rate chemistries, feed the minimum concentration. The concentration entered for Rate Chemistry will automatically be converted



**NOTE: If the Reaction Absorbance Limit parameter is not zero for the RATE ASSAYS types, then the Technical Limit parameters will be masked and vice-versa.**

---

into rate after calibration of that test. This value will be used for comparing with the slope obtained during patient run. Samples that violate this limit are sent for increased volume rerun. If you do not wish to use technical limit minimum, feed a zero value.

##### ii) Technical Maximum

Define a value ranging from -9999.99 to 9999.99 indicative of the maximum technical limit or linearity limit of the reagent. For end-point chemistries and rate chemistries, feed the maximum concentration. The concentration entered for Rate Chemistry will be automatically converted into rate after calibration of that test. This value will be used for comparing with the slope obtained during patient run. Samples that violate the programmed technical limit maximum are sent for Decreased volume rerun. If you do not wish to use technical limit maximum, feed a zero value.



**NOTE: The Technical Limit (Minimum and Maximum), Reaction Absorption Limit, and Linearity Limit parameter are applicable only for Linear and K-Factor curve types.**

---



**NOTE: Technical Limit Minimum or Maximum when '0' (Zero), indicates that the respective check is not required for the test.**

---



**NOTE: If the Reaction Absorbance Limit parameter is not zero for the RATE ASSAYS types, then the Technical Limit parameters will be masked and vice-versa.**

---

w. **Y=aX+b (Instrument correlation factor)**

These fields can be used to perform correlation correction so that the results obtained on this analyzer can be matched with those obtained on some other analyzer. For some assays, the analyzer might give results that are consistently higher or lower than expected or obtained on another analyzer. To match the results with the expected results or the results obtained on another analyzer, a correlation correction can be incorporated in the result calculations. The equation used for correlation correction is:

$$Y = a X + b$$

Where, Y is the corrected result

X is the actual result obtained on this analyzer

a is the multiplication correction factor

b is the offset correction factor

When the results obtained on this analyzer are as expected feed

a = 1 and b = 0.

The following plot shows the relation of results obtained on any two compatible analyzers:

(Here b = 0 and a = 1)

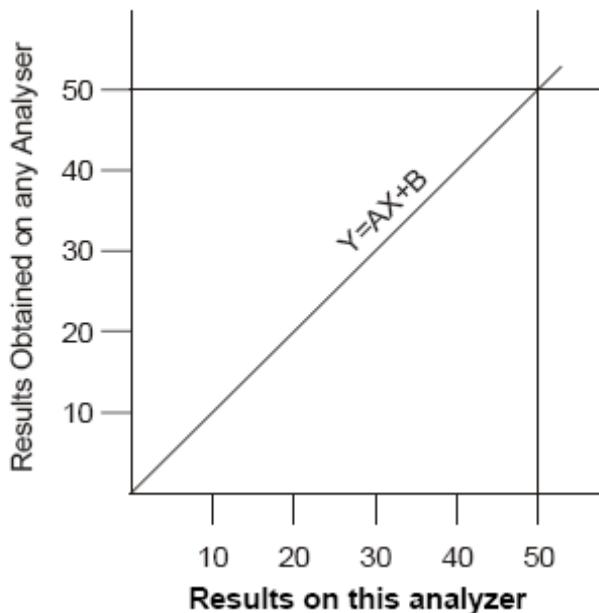


Figure 7-6. Instrument factor

However, when there is a difference in the result between two machines, correlation correction factors a and b can be calculated and fed to obtain consistent results on both the analyzers.

Correction factor a, should have values between 0.0001 and 9999.9 while correction factor b should have values between -99999.99 and 99999.99.

#### x. Reagent Abs Min and Reagent Abs Max

Enter the minimum and maximum absorbance values of the reagent.



**NOTE: Reagent ABS is checked while running Blank during calibration, if RgtABS value is non-zero for the test in Test Parameter.**

This check is applied for Flagging only if RgtAbsMin > 0 for Decreasing direction or RgtAbsMax > 0 for Increasing direction in Test Parameter.

Compare the ABS received after adding Reagent, say A1 (for 1 Reagent chemistry, ABS after adding R1 & for 2 Reagent chemistry, ABS after adding R2) with the Rgt ABS value entered in Test Parameter.

For Decreasing Direction - If A1 (ABS) < RgtABSMIN then attach Flag "RgtAbsMin" to the Blank results.

For Increasing Direction - If A1 (ABS) > RgtABSMAX then attach Flag "RgtAbsMax" to the Blank results.

This check is applicable to -

- Patient and Control results for only single Reagent chemistry.
- Blank for single and dual-reagent chemistries.

#### y. Auto Rerun

Tick this checkbox to set the auto-rerun for the test with appropriate dilution of sample.

One can set the auto rerun for the multiple tests at once using SET AUTO RERUN button. Before selecting the tests for auto rerun, specify the Increase and Decrease Sample Volumes for the test from the **Test Parameter > Test Volumes** screen.

Patient Sample will automatically re-run (performed again) on occurrence of specific flags to the result if:

- ◆ Auto-rerun is selected for the Test
- ◆ Rerun is selected for the flag from **Settings > Rerun Flags** screen.
- ◆ Auto Rerun is selected from PRE-RUN Options in **Status Monitor** screen.

#### z. Cuvette Wash

This check box is used to provide a cuvette wash with special wash solution, after performing the test. This wash is recommended if you are performing special tests like HbA1C, IGG, IGE etc.

The tests for which cuvette wash checkbox is selected, it will be referred to as test requiring cuvette wash with special wash solution.



**NOTE: Ensure that the special wash solution is placed on the reagent tray. Once it is placed, go to the Utility > Reagent Position screen and define the position of the special wash solution in the reagent tray.**

The cuvette will be washed with special wash solution (different from the wash solution used for probe wash); after performing the tests requiring cuvette wash. The special wash solution is common for all the test(s) requiring Cuvette Wash and is not test specific.

#### aa. Online Calibration

Tick this checkbox to trace reagent bottle change. The system will prompt for calibration if the reagent bottle is changed or replaced with new one for the test that is selected for online calibration.

To set the online calibration for multiple test(s) at once, click on **SET ONLINE CALIBRATION** button. Refer section 7.2.1.1 *Online Calibration* for more details.



**NOTE: This option will be disabled if the curve type for the test is set as K-Factor.**

**bb. COPY TEST**

This option is used to copy the test parameters from one test to another. Select the required test from the Test panel and click on COPY TEST button. Enter a new test name and click OK. The new test name will be displayed in the Test panel.

**cc. INITIALIZE TESTS**

This option is used to initialize the test parameters from the existing ones to default settings. The tests with similar Test names are replaced from default ones and the newly added tests are retained as it is. To initialize test parameters, click on INITIALIZE TEST(S) button, select the test(s) to be initialized and confirm by clicking on OK button.

**dd. SET AUTO RERUN**

This option is used to set the auto-rerun for multiple tests at once. Two options are available – Selective or All Test(s). Click on SET AUTO RERUN. The following screen will appear:

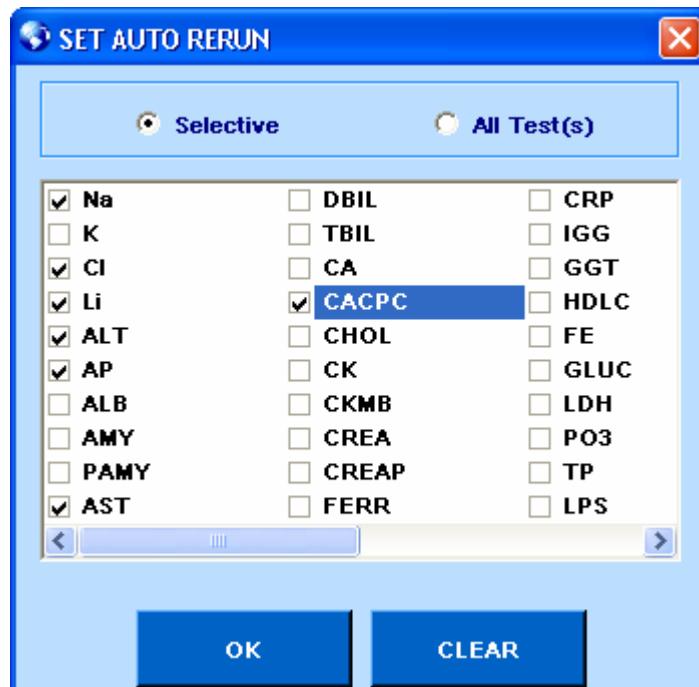
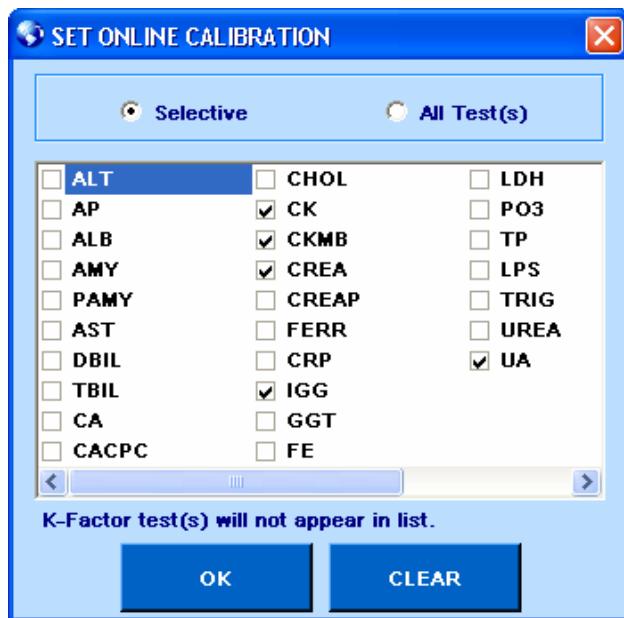


Figure 7-7. Set auto rerun screen

Click on the desired option to choose selective test or all test(s) for auto rerun. If Selective is selected, then user can select test(s) from the list below for setting auto-rerun by clicking on the boxes in the front of tests. Then click on OK button. If All Test(s)" is selected then automatically all the tests in the list below will be selected for auto rerun. Click on OK button to save and apply settings. Click on CLEAR button will close the window without saving changes.

**ee. SET ONLINE CALIBRATION**

Using this button you can set the online calibration for multiple tests at once. The following window will be displayed on clicking:



Check **Selective** radio button for selecting the desired number of tests and **All Test(s)** for selecting the entire tests.

Once selected, click **OK** to confirm.

#### ff. UPLOAD TEST and DOWNLOAD TEST

Using DOWNLOAD TEST button, the parameters of the selected test are stored in a xml file and saved in the C:\MultiXLLOG\DOWNLOAD PARAMETERS. A reagent distributor/manufacturer may enter a new test from test parameter screen, download parameters and send the xml file to distribute parameters to their customers.

This test can be uploaded from xml file in the Test Parameter screen using UPLOAD TEST button, provided the test does not already exist.

#### 2. Following are the description of the buttons on this screen.

	Click this button to view the first record.
	Click this button to view the last record.
	Click this button to view the previous record.
	Click this button to view the next record.
<b>PRINT</b>	This button is used to print the test parameters of the selected test. It contains information about test details, test volumes and test reference ranges.
<b>SAVE</b>	This button is used to save the entered test details.
<b>EDIT</b>	This button is used to edit the details of the selected test.
<b>CLEAR</b>	This button is used to cancel add / edit mode.

<b>DELETE</b>	This button is used to delete the test. Delete is not available for ISE (Na, K, Cl, Li).
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### 7.2.1.1. Procedure for Online Calibration

Online calibration is a feature which is used for tracing the reagent bottle change-over. During test run, when the new reagent bottle is detected, the system will ask for the calibration for newly detected reagent bottles. It is available in the **Test Parameter** screen.

#### 7.2.1.1.1. Setting Online Calibration

For setting the online calibration for the tests for which tracing reagent bottle change-over is desired, follow this procedure:

1. Go to **Test Parameter > Test Details** from the main screen.
2. In the Test Details screen, select the appropriate test for which the online calibration is required.
3. Check the **Online Calibration** option, and click **SAVE**.

On selecting the option, when the run is started from the **Status Monitor > SAMPLE TRAY**, the system will scan the reagent level of all reagents placed on the Reagent Tray.

The screenshot shows the 'Test Details' screen with the following configuration:

- Test:** ALB
- Report Name:** ALBUMIN
- Unit:** g/dl
- Wavelength-Primary:** 600
- Assay Type:** 1 - Point
- M1 Start:** 0
- M2 Start:** 6
- Sample Replicates:** 1
- Control Replicates:** 1
- Reaction Direction:** Increasing
- Prozone Limit %:** 0
- Linearity Limit %:** 0
- Technical Minimum:** 0.0
- Y=aX+b:** a= 1, b= 0
- Reagent Abs Min:** 0.0
- Decimal Places:** 2
- Secondary:** SELECT
- Curve Type:** Linear
- M1 End:** 0
- M2 End:** 10
- Standard Replicates:** 3
- Control Interval:** 0
- React. Abs. Limit:** 0.0
- Prozone Check:** Lower
- Delta Abs/Min:** 0.0
- Technical Maximum:** 7.0
- Reagent Abs Max:** 0.0

On the right side, there are several buttons:

- Auto Rerun:**
- Online Calibration:**  (highlighted with a red oval)
- Cuvette Wash:**
- Total Reagents:** 1
- \* Reagent R1:** ALB R1
- SET ONLINE CALIBRATION** (highlighted with a red oval)
- DOWNLOAD TEST**
- UPLOAD TEST**
- SET AUTO RERUN**
- COPY TEST**
- INITIALIZE TEST(S)**

At the bottom, there is a table titled 'Tests' with columns for various tests like ALB, AMY, BID, etc., and a search bar for 'Indication'.

The software will trace the bottle change-over for the reagents of this test.

For setting the online calibration for multiple tests, use **SET ONLINE CALIBRATION** button.

When the batch run is started, the system will perform the following operations.

1. Reagent Barcode Scan (if selected from PRE-RUN options).
2. Sample Barcode Scan (if selected from PRE-RUN options).
3. Reagent Level Scan (mandatory if **Online Calibration** option is selected for at least 1 test. Otherwise volume scan is performed only if selected from PRE\_RUN options).
  - Prompt for calibration by showing “Calibration Check” screen. This screen contains the list of reagents for which new reagent bottle is detected and calibration is required.
4. Perform Auto-span.
5. When the above requirements are performed, the run will continue.

#### **7.2.1.1.2. Tracing New Reagent Bottles**

System will trace new reagent bottle for the test for which “Online Calibration” is selected. On detecting new reagent bottle, system will prompt for calibration.

New Reagent Bottle will be detected during:

- Reagent Barcode Scan
- Reagent Volume Scan
- Manual Definition of Reagent(s)

#### **Reagent Barcode Scan**

System will detect new reagent bottle on Reagent Barcode scan. Reagent Barcode scan is performed before run start as well as during run on “Add Reagent”. New Reagent Bottle is detected on reading a new barcode.

#### **Reagent Volume Scan**

System will perform Reagent Volume Scan before starting the run, in case Online calibration is selected for at least 1 test (irrespective of the schedules in Work List). System will memorize the reagent volume for each reagent position. Reagent positions for which change in volume is detected during Volume scan on start of the run i.e. reagent volume is increased or decreased with a tolerance of 1 ml.; will be treated as new Reagent Bottle.

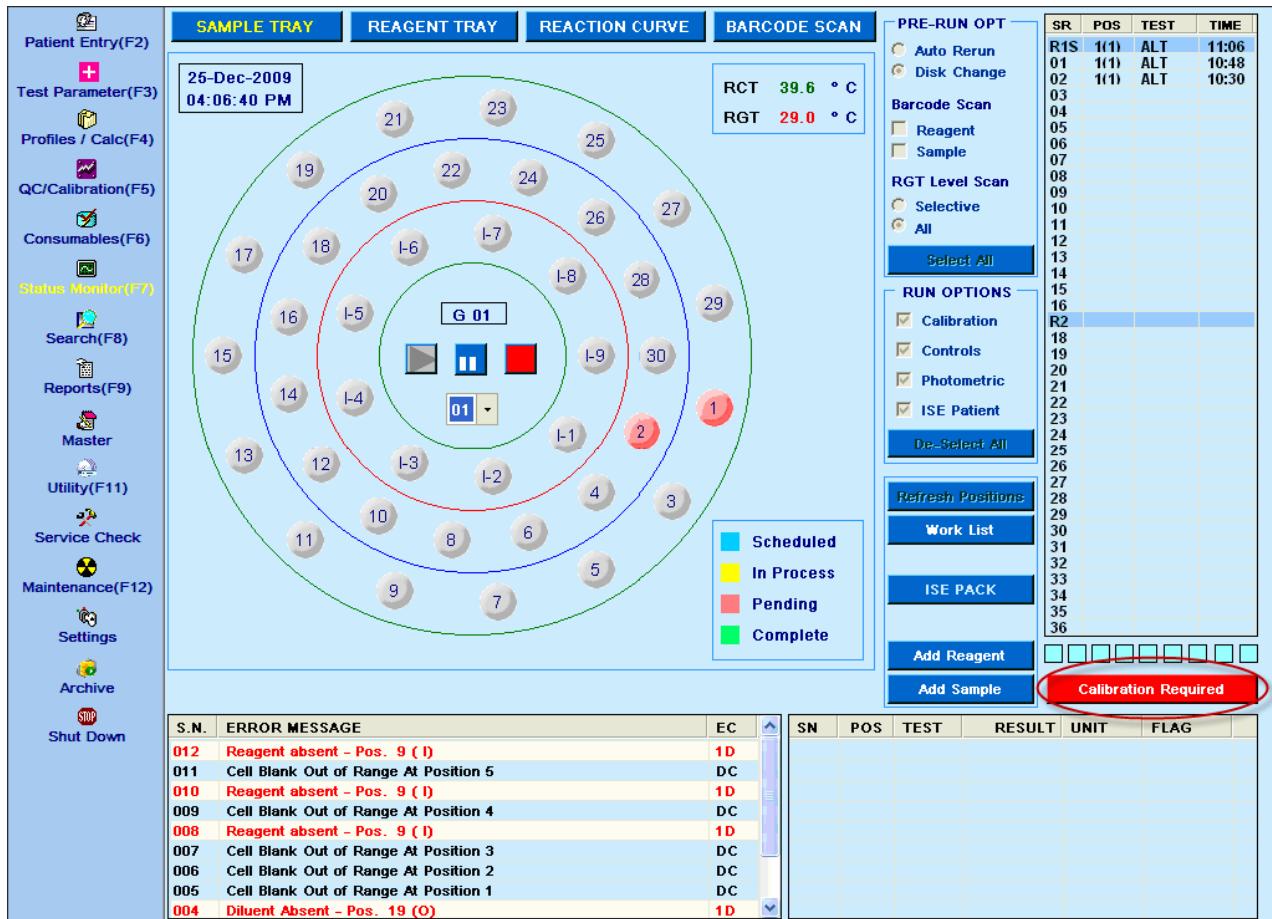
#### **Manual Definition of Reagent(s)**

In manual definition of reagent from **Utility > Reagent Position** screen, add New Reagent or change definition (Edit position). New Reagent Bottle is detected.

### 7.2.1.1.3. Calibration Prompt for New Reagent Bottles

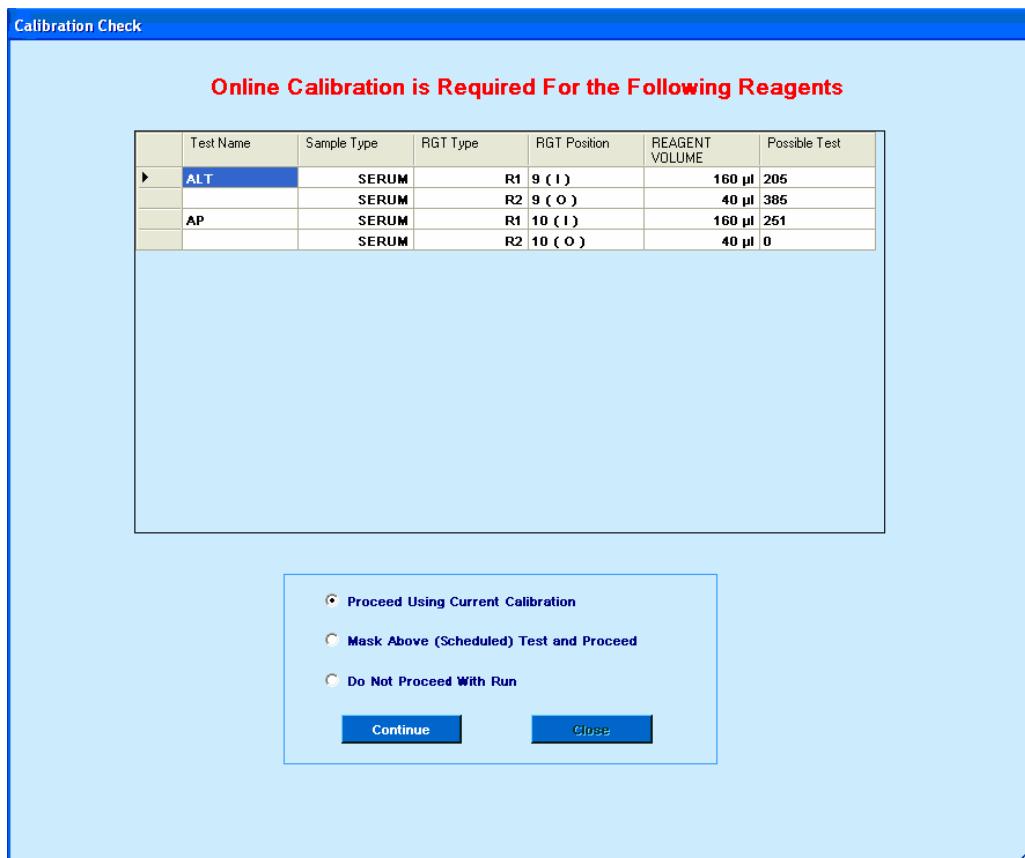
On detecting new reagent bottle, system will prompt for calibration as follows:

- During batch run, when the reagent is found absent or bottle is changed, the **Calibration Required** button will blink on the **Status Monitor** screen. See figure shown below:



Blinking of this button will be stopped in any of following conditions:

- Till it is clicked for calibration or test run completed.
  - If **Emergency Stop** button is pressed from the **Service Check** screen
- On clicking this button, a new window will be displayed showing the list of reagents that requires calibration as shown in figure below.



This screen will show the test(s) for which new reagent bottle is detected and requires calibration. When the calibration prompt is displayed on the start of the run, the following options will be available.

- Proceed using current calibration
- Mask above test and proceed
- Do not proceed with run

The system will function as follows on selecting any of the above options.

- If the user selects **Proceed using current calibration**, then the system will continue with the run. The test(s) in the above list will be performed as part of the work list. The result (of the tests for which calibration prompt is displayed) will be calculated with the available calibration. Such results will be flagged as Cal\*\*.
- If **Mask Above (Scheduled) Test and Proceed** is selected then the Test(s) in the list will be masked. Run will continue with other scheduled Tests in the work list.
- If the user selects **Do not proceed with run** then run will not start. User may take necessary action (schedule calibration) and start the run again.

#### 7.2.1.1.4. Procedure to schedule the masked Test(s) during run

Perform the following steps to re-schedule the masked test(s) during run.

1. Click **Add** reagent to load the reagents on Reagent Tray and load calibrators on Sample Tray; if not available on board.
2. Schedule Calibration for the test from **Calibration > Schedule QC / Calib** screen.
3. Un-mask the Test (patient and control) from the work list.

System will first perform calibration with the Reagent bottle. Control & Patient results will be declared with the new calibration (if successful).



**NOTE: To calibrate new reagent bottle during run: User should load calibrator(s) on Sample Tray before scheduling the calibration. On failing to load calibrators, analyzer will encounter calibrator absent and calibration will be considered as unsuccessful / failed. In such case, results will be calculated using earlier successful calibration and declared with Cal\* flag.**

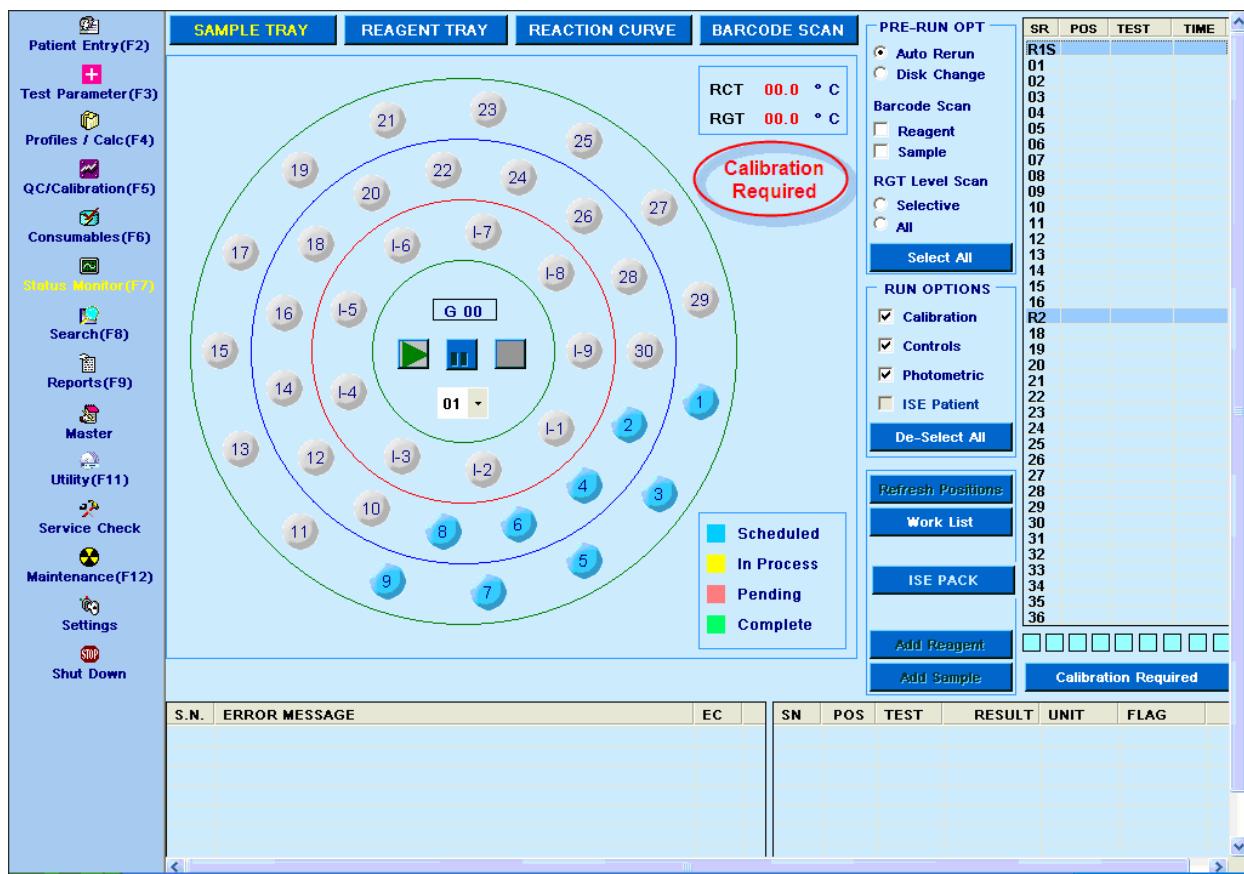
---

#### **7.2.1.1.5. Reagent Absent During Run**

During run, when reagent is found absent then:

1. The **Calibration Required** button on **Status Monitor** will blink till it is clicked or run is completed. On clicking **Calibration Required** button, a new window will open showing the List of Reagent(s) that requires calibration.
2. Remaining Test schedules are added in Pending List.
3. System will not switch over to next Reagent position even if multiple reagent positions are defined / available.
4. User can load reagent and calibrators, schedule calibration and re-schedule patient and control schedules from Pending List by clicking Work List button on Status Monitor. In such case, calibration will be performed first. Patient and control results will be declared using the new calibration.

Alternatively, user can re-schedule the test from Pending List without programming calibration. In such case, result will be calculated using the current (available) successful calibration and declared with Cal\*\* flag.



#### 7.2.1.1.6. Pre-requisite

1. Reagent bottle, once placed on a position is not removed or swapped with the other position.
- 

**NOTE:** Reagent Bottle taken off from Reagent tray and placed with barcoded reagent during Add Reagent operation will be detected as new bottle and will prompt for calibration.
2. User will be able to schedule calibration during run provided the positions are free in Sample Tray. Consumables (with Lot details) required for calibration are defined and available.
  3. Calibrator(s) (multiple calibrators in case of non-linear parameters) are made available on board in the Sample Tray for calibration during run.
  4. User will select Online calibration for the test(s) for which tracing Reagent Bottle change-over is required.
  5. Non-barcoded Reagent Bottle is replaced with another reagent bottle having same reagent of the same volume as that of the earlier bottle; cannot be detected as new bottle.
  6. Recommendation: Select **Online Calibration** option for the test just before the batch when calibration of the test is scheduled. Then onwards, system can easily trace the bottle change. On selecting the option, system will prompt for calibration, ignoring which results will be declared with Cal\*\* flag.

7. Recommendation: While placing multiple Reagent Bottles on the Reagent Tray, place calibrated bottle on the lower position and new un-calibrated reagent bottle on the higher position in the Reagent Tray.

## 7.2.2. Test Volumes Screen

This screen displays the Sample and Reagent Volumes for a test along with the Sample Type. It also includes an option of copying the sample volumes if the CSF, PLASMA or WHOLE BLOOD sample types share the same volumes as Serum sample type. Click on **Test Parameters > Test Volume** to view the following screen.

Tests	ALB	ALP	AMY	BID	BIT	CAA	CHO	CKMB	CKN	CLO	
<<	CO2	CRE	GGT	GLU	GOT	GOTHL	GPT	GPTH	HDLC	LDH	>>
	LDL	MPR	PHO	PRO	MG	TRIG	UA	UREA	A		

**Sample Types**

- SERUM
- URINE
- CSF
- PLASMA
- WHOLE BLOOD
- OTHER

**COPY VOLUMES**

**VIEW VOLUMES**

**Indication**: Select sample type from the list

Buttons: PRINT, SAVE, CLEAR, EDIT, DELETE

Figure 7-8. Test volume screen

The user needs to select a sample type prior to defining the Sample, Standard and Reagent Volume for a test. The Sample and Reagent Volumes may vary for different sample types. However, the Standard volume remains the same for all sample types. During calibration run, standard volume of Sample Type 'Serum' is read for the respective test.

Following is the description of the fields:

### 1. Standard Volume

Specify the Standard volume to be used for calibration i.e. for blank, standard and calibrators.

Usually, the Standard Volume entries will be the same as Normal Serum Volume entries. However, the Standard Volume entries could be different from Normal Serum Volume entries when the calibrator is not to be diluted

but the sample requires dilution. This happens usually for esoteric assays for which the standards available are prediluted and do not require dilution, but the samples need to be diluted.

For example, when the standard is prediluted but sample requires to be diluted 10 times, the standard volume entries might be like {15, 0} and the normal sample volume entries will be like {20, 2x}.

If the standard needs to be diluted, then Auto Dilution procedure should be adopted. The Auto Dilution procedure is available in the **Schedule QC/Calibration** screen under **QC/Calibration** menu. Different dilutions are prepared on board from the base concentration of standard/calibrator using the Geometric series.

## 2. Sample Volume Normal

Specify normal (or default) sample volume for the selected sample type. Different Sample Types can share the same Sample Volumes.

### a. Normal: Sample Volume

This is the volume of the sample to be aspirated for the reaction. When the sample is undiluted, the aspirated sample from the sample container is directly dispensed in the reaction cuvette. When the sample needs to be pre-diluted, the sample from sample container is dispensed in the (dilution) cuvette containing diluent to prepare desired dilution of sample. Then the specified normal volume of diluted sample is aspirated from dilution cuvette and dispensed into reaction cuvette.

Enter a value between 2 to 70  $\mu\text{l}$  when the sample is undiluted. In case of pre-diluted sample, enter a value between 2 to 20  $\mu\text{l}$ . The total volume of sample and reagents should be more than or equal to 180  $\mu\text{l}$ .

### b. Normal: Dilution Ratio

Define a dilution ratio if predilution of the sample is required. The available range is from 2x to 150x in steps of 1x. Default will be 1x and this will mean that pre-dilution is not required. A dilution ratio Nx means 1 part of sample and (N-1) part of diluent. The sample is diluted on board.

## 3. Sample Volume Decrease

Specify sample volumes (lower than normal) to carry out an automatic rerun of the sample (with reduced sample volume) in case of a hyperactive sample or when the Sample is requested as Decrease in the Patient Entry screen.

### a. Decrease: Sample Volume

This is the volume of the sample to be aspirated for the reaction. When the sample is undiluted, the aspirated sample from the sample container is directly dispensed in the reaction cuvette. When the sample needs to be pre-diluted, the sample from sample container is dispensed in the (dilution) cuvette containing diluent to prepare desired dilution of sample.

Then the specified decrease volume of diluted sample is aspirated from dilution cuvette and dispensed into reaction cuvette.

Enter a value between 2 to 70 µl when the sample is undiluted. In case of pre-diluted sample, enter a value between 2 to 20 µl. The total volume of sample and reagents should be more than or equal to 180 µl.

b. **Decrease: Dilution Ratio**

Define a dilution ratio if pre-dilution of the sample is required. The available range is from 2x to 150x in steps of 1x. Default will be 1x and this will mean that pre-dilution is not required. A dilution ratio Nx means 1 part of sample and (N-1) part of diluent. The sample is diluted on board.

4. **Sample Volume Increase**

Specify sample volumes (higher than normal) to carry out an automatic rerun of the sample in case of a sample with low reactivity or if the sample is requested as Increase on the **Patient Entry** screen.

a. **Increase: Sample Volume**

This is the volume of the sample to be aspirated for the reaction. When the sample is undiluted, the aspirated sample from the sample container is directly dispensed in the reaction cuvette. When the sample needs to be pre-diluted, the sample from sample container is dispensed in the (dilution) cuvette containing diluent to prepare desired dilution of sample. Then the specified increase volume of diluted sample is aspirated from dilution cuvette and dispensed into reaction cuvette.

Enter a value between 2 to 70 µl when the sample is undiluted. In case of pre-diluted sample, enter a value between 2 to 20 µl. The total volume of sample and reagents should be more than or equal to 180 µl.

b. **Increase: Dilution Ratio**

Define a dilution ratio if pre-dilution of the sample is required. The available range is from 2x to 150x in steps of 1x. Default will be 1x and this will mean that pre-dilution is not required. A dilution ratio Nx means 1 part of sample and (N-1) part of diluent. The sample is diluted on board.

5. **RGT1/RGT2 Volume**

Assign volume of reagent (in µL) to be aspirated for Reagent 1 and/or Reagent 2. Volume for Reagent 1 is set between 50 and 300 µl and for Reagent 2 between 10 and 200 µl. If a single reagent test is used, then RGT 2 Volume field is not shown on the screen.

6. **R1/R2 Reagent Mix Speed**

There are 3 options available to set the stirrer speed, after adding R1 and R2 in order to mix the reagent and the sample. They are Low, Medium and High.

## 7. COPY VOLUMES

This button is used to copy the volumes from current sample type to other sample type(s) of the selected test. Multiple sample type selection is available for copying volumes.

**Follow the procedure to copy the test volumes:**

- a. To copy, select the test from the **Test Parameter > Test Volume** screen.
- b. Now click on the **COPY VOLUMES**. On clicking, the **Copy Volume** window will be displayed.

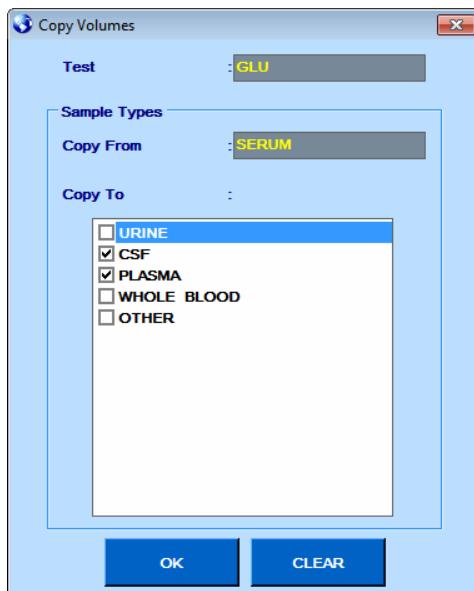


Figure 7-9. Copy volume

- c. Select the required sample types, and click **OK**.

This will copy the sample volumes details to the multiple sample types as selected in the **Copy Volume** window.

- d. You can edit the sample details using **EDIT** button if required.



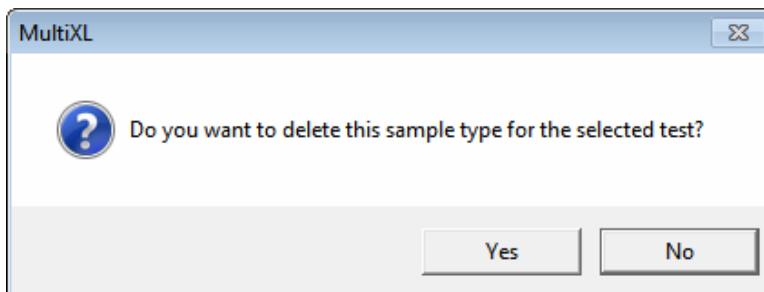
**NOTE: The sample types cannot be deleted using EDIT button. To delete the Sample types, use DELETE button.**

**Use the following procedure to delete the sample type from the particular test:**

- a. Select the required test from the **Test Volume** screen, and click on the sample type to delete.

b. Now click on **DELETE** button.

On clicking, a warning message will be displayed as below.



c. Click **Yes** to delete.

This will delete the volume details of the selected sample type for the selected test.

During batch run, the Copy Volume option is available for the Sample types for which volume detail is not defined. Sample Types for which volume detail is already defined are excluded from the List of "Copy To" Sample Types.

## 8. VIEW VOLUMES

This button is used to view the volumes programmed as per the different sample types. The following screenshot gives the serum volume details.

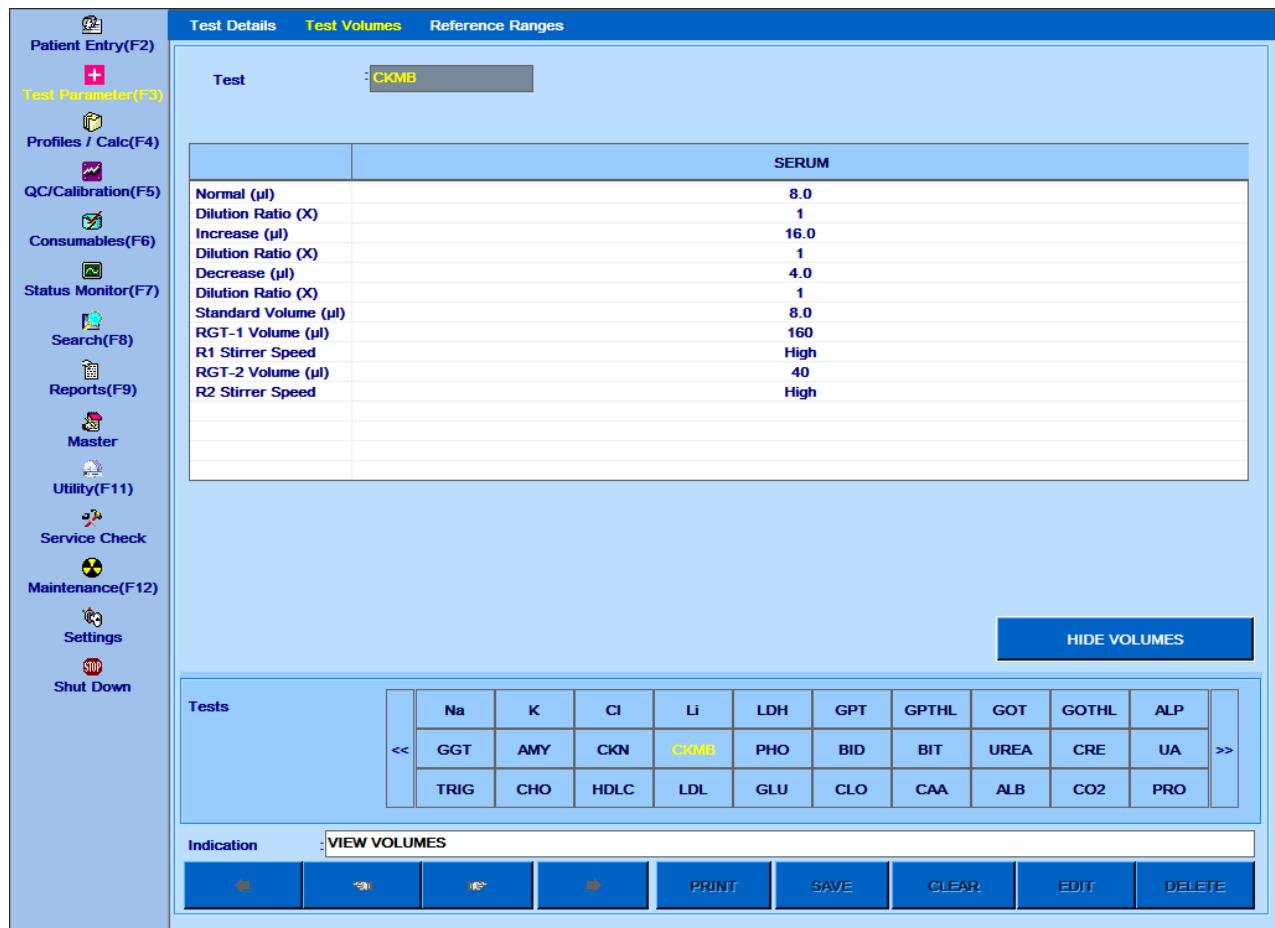


Figure 7-10. View sample volume screen

## 7.2.3. Reference Ranges Screen

To open this screen, click on **Test Parameter > Reference Ranges** on the main screen. The following screen will be displayed.

## Operator Manual

**Test Details**   **Test Volumes**   **Reference Ranges**

Test : GLU  
Sample Type : SERUM

Reference Range : DEFAULT  
Category : Default

Reference Range - Decimal Places : 3		
	Lower Limit (mg/dl)	Upper Limit (mg/dl)
★ Normal	89.00	90.00
Panic	0.00	0.00

**Sample Types**

- SERUM
- URINE
- CSF
- PLASMA
- WHOLE BLOOD
- OTHER

**COPY REFERENCE RANGES**  
**VIEW REFERENCE RANGES**

Tests	Na	K	Cl	Li	GPT	LDH	GPTL	GOT	GOTH	ALP	
<<	GGT	AMY	CKN	CKMB	PHO	BID	BIT	UREA	CRE	UA	>>
	TRIG	CHO	HDLC	LDL	GLU	CLO	CAA	ALB	CO2	PRO	

Indication : Select Reference Range

◀ ▶ ⌂ ⌃ PRINT SAVE CLEAR EDIT DELETE

Figure 7-11. Reference range screen

This screen is used to define the normal ranges and panic limit values for the patients for category such as Male, Female, Child, Other.

It is also used to copy the reference ranges of one sample type to different sample types.

Following are the description of the parameters used in the screen:

### 1. Test

It displays the test as selected from the Tests panel.

### 2. Sample Type

It displays the sample type as selected from the list of available Sample Types.

### 3. Reference Range

This drop down list is used to display the default reference ranges for the tests.

### 4. Category

This drop-down list is used to select the category (gender). The available options are: Default, Male, Female, Child, and Other.

## 5. Normal (Lower Limit and Upper Limit)

Define the expected values or normal range for serum/urine/other samples being assayed. These limits are used to issue H or L flag, which indicate a higher concentration than normal or lower concentration than normal respectively. Normal range values for both Male and Female subjects can be specified for different age groups. Additionally, default normal range values can also be defined for Male, Female, Child and Other subjects. The default normal range is applied if the age of the patient is not known.

Use this to enter the expected values range for different sample types for different assays.



---

**NOTE: For correct H and L flags, the patient's Category and Gender should be set before the patient's sample is analyzed.**

---

## 6. Panic (Lower Limit and Upper Limit)

Define the minimum and maximum concentration limits beyond which the serum or urine sample or other sample will go for a “same” rerun. A same rerun means that if the sample was programmed for a normal volume run, the rerun too will be performed using a normal sample volume. Similarly, if the sample was programmed for Decreased or Increased volume run, the rerun will be performed using a Decreased or Increased volumes respectively.

For an automatic rerun to take place due to Panic Limit violation, the option Auto Rerun should be selected for the respective test in Test Parameter > Test Details screen. When the sample result violates the Panic Limit Minimum or Maximum, a flag “PANH” or “PANL” is issued with the result respectively. The rerun result is flagged “#” to indicate a rerun.

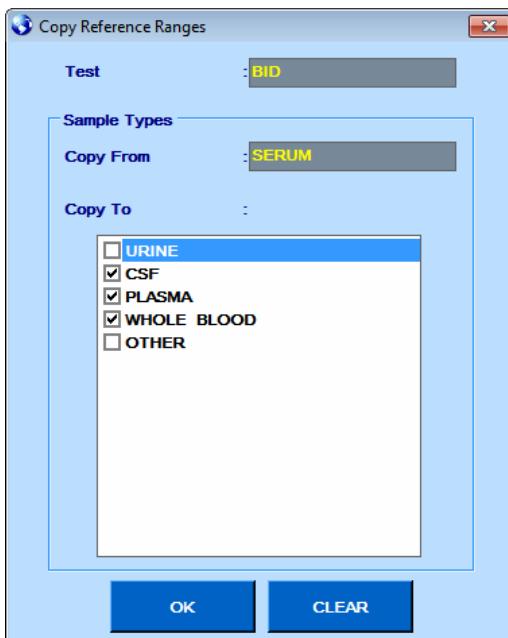
Following is the description of the buttons available on the right side of the screen:

### a. COPY REFERENCE RANGE

This button is used to copy the reference ranges from current sample type to other sample types. Multiple sample types can also be selected.

Follow the procedure to copy the Reference ranges:

- i) Select the test from the **Test Parameter > Reference Range** screen.
- ii) Click on the **COPY REFERENCE RANGES**. On clicking, the **Copy Reference Ranges** window will be displayed.



- iii) Select the required sample types, and click **OK**.

This will copy the sample reference range details to the multiple sample types as selected in the **Copy Reference Ranges** window.

- iv) You can edit the sample details using **EDIT** button if required.



---

**NOTE:** The sample types can not be deselected using **EDIT** button. To de-select the Sample types, use **DELETE** button in the Reference Ranges screen.

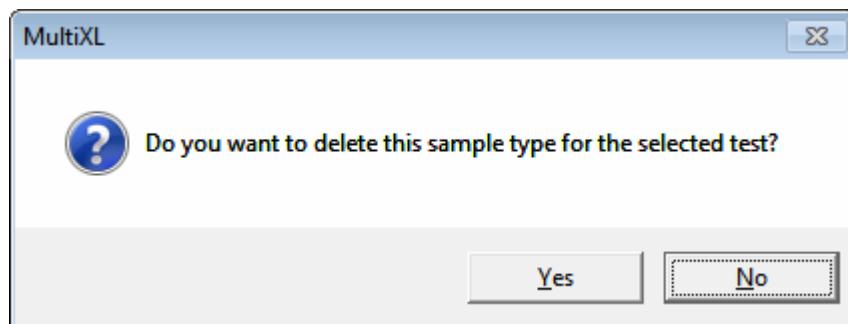
---

**Use the following procedure to delete the reference range of a sample type for a particular test:**

- i) Select the required test from the **Reference Range** screen, and click on the sample type to delete.

ii) Click on **DELETE** button.

On clicking, a warning message will be displayed as below.



iii) Click **Yes** to delete.

This will delete the selected sample type.

## b. **VIEW REFERENCE RANGE**

This button is used to view the reference ranges programmed as per the different sample types. The following screenshot gives the reference range details.

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		Patient Entry(F2)		Test Details		Test Volumes		Reference Ranges						
 Patient Entry(F2)   Test Parameter(F3)   Profiles / Calc(F4)   QC/Calibration(F5)   Consumables(F6)   Status Monitor(F7)   Search(F8)   Reports(F9)   Master   Utility(F11)   Service Check   Maintenance(F12)   Settings   Shut Down	Test		CKMB		Sample Type		SERUM							
	Range		Normal Lower Limit		Normal Upper Limit		Panic Lower Limit		Panic Upper Limit					
	Category: DEFAULT		0.0		25.0		0.0		0.0					
	DEFAULT		0.0		25.0		0.0		0.0					
	Category: MALE		0.0		25.0		0.0		0.0					
	DEFAULT		0.0		25.0		0.0		0.0					
	Category: FEMALE		0.0		25.0		0.0		0.0					
	DEFAULT		0.0		25.0		0.0		0.0					
<b>HIDE REFERENCE RANGES</b>														
Tests		<<	Na	K	Cl	Li	LDH	GPT	GPTL	GOT	GOTL	ALP	>>	
			GGT	AMY	CKN	CKMB	PHO	BID	BIT	UREA	CRE	UA		
			TRIG	CHO	HDLC	LDL	GLU	CLO	CAA	ALB	CO2	PRO		
Indication		VIEW REFERENCE RANGES												
						PRINT		SAVE		CLEAR		EDIT		DELETE

Figure 7-12. View reference ranges

## 7.3. Profile/Calc

### 7.3.1. Profile Entry

To open this screen, click on **Profiles/Calc** from the main menu and then select **Profiles**. The following screen will be displayed.

The screenshot shows the 'Profiles' screen with the following interface elements:

- Left Sidebar:** A vertical menu with icons and labels for various functions: Patient Entry(F2), Test Parameter(F3), Profiles / Calc(F4) (highlighted in yellow), QC/Calibration(F5), Consumables(F6), Status Monitor(F7), Search(F8), Reports(F9), Master, Utility(F11), Service Check, Maintenance(F12), Settings, and Shut Down.
- Top Header:** 'Profiles' and 'Calculated Items'.
- Profile Input:** Fields for 'Profile' (with a red asterisk) and 'Profile Report Name'.
- TESTS Table:**

Sr. #	Test	Test Report Name
1	CKN	Creatine Kinase
2	CLO	Chloride
3	BID	Bilirubin Direct
4	BIT	Bilirubin Total
- Profiles and Tests Selection Matrix:**

Profiles	<<	CBC	ASD								>>	
Tests	<<	Na	K	Cl	Li	LDH	GPT	GPTHL	GOT	GOTHL	ALP	>>
	GGT	AMY	CKN	CKMB	PHO	BID	BIT	UREA	CRE	UA	PRO	
	TRIG	CHO	HDLC	LDL	GLU	CLO	CAA	ALB	CO2	PRO		
- Indication:** 'Click and Select Test' with a dropdown arrow.
- Bottom Buttons:** Back, Forward, Print, Save, Clear, Edit, Delete.

Figure 7-13. Profile entry screen

This screen is used to create profile for selection through **Patient Entry** screen. Profile is a group of tests that can be requested through a single click during the patient entry details.

One or more profiles can be selected for a patient at the same time. If more than 10 profiles are entered, the user can browse to the next profiles using (Prev / Next) arrow buttons.

#### 7.3.1.1. Procedure to Create a Profile

The profile can be created from the {Profiles} screen.

The procedure is given below:

1. Open **Profiles/Calc** screen.
2. Enter the profile name and profile report name in the respective text box.
3. Add the required tests by clicking on the test name from the Tests panel.

4. Click on **SAVE** to save the Profile.
5. Once the profile is saved, the name will be displayed in the Profiles grid.

### 7.3.2. Calculated Item

To open this screen, click on **Profiles/Calc** from the main menu and then select **Calculated Items** screen. The following screen will be displayed.

The screenshot shows the 'Calculated Items' screen. On the left is a vertical menu bar with icons and labels for various functions: Patient Entry(F2), Test Parameter(F3), Profiles / Calc(F4), QC/Calibration(F5), Consumables(F6), Status Monitor(F7), Search(F8), Reports(F9), Master, Utility(F11), Service Check, Maintenance(F12), Settings, and Shut Down. The main area has tabs for 'Profiles' and 'Calculated Items'. Under 'Calculated Items', there are fields for 'Calculated Item' (name), 'Host Name', 'Report Name', 'Unit (%)', 'Decimal Places', and a 'Formula' field containing 'A/(B-A)'. Below this are five rows for selecting chemistries (A-E) and coefficients (a-d). A table for 'Sample Type' is partially visible. At the bottom is a toolbar with buttons for 'Calculated Items' (navigation), 'Indication' (text input: 'Please enter Calculated Item Name'), and various function keys like PRINT, SAVE, CLEAR, EDIT, and DELETE.

Figure 7-14. Calculation screen

This screen enables the user to define a calculation item involving one or more chemistries (up to 5 chemistries). It is also possible to define the formula as per your requirement using the **Master > Calculation Formula** screen.

If the calculation items are selected in the **Patient Entry** screen, then the test(s) required to calculate the value are selected (scheduled) automatically. The calculated items are printed along with the test result in the Patient Report printout.

A description of various inputs available on the screen is given below.

**Calculated Item:** Define the name of the calculated item, up to 5 characters. This name will be shown in a separate grid in **Patient Entry** screen.

**Report Name:** Enter the full name of the calculated item (i.e., A/G ratio). This name is printed on the patient report.

**Formula:** The user can select the desired calculation formula from the drop down list. If new formula is required, you can create your own formula using **Master > Calculation Formula** screen. See section *7.7.8 Master - Calculation Formula* for more details.

**Unit:** Select the unit to be printed along with the Calculated Item.

**Host Name:** Enter the name of the calculated item, as defined in LIS (for host communication). This text box is visible only if Host connection is activated from System Parameters screen.

**Decimal Places:** Enter the number of decimal places for the calculated item.

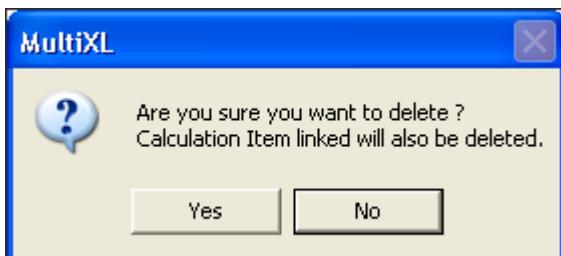
Once the formula is selected, the user can select the tests associated with the calculated item, according to the variables in the selected formula. Additionally, the user can also use another calculated item (nested calculation items) for defining a new calculation item.

The user can select the normal ranges or panic limits (if desired) for the calculation item depending on the Sample Type selected. Options are available for defining the normal range for patient Category Type – Default, Male, Female, Child or Other.

CEC Calculation item is provided by default. For this calculation item, only the Report Name, Host name, Unit, Decimal Places and Normal Ranges can be modified. Test is always CRE (Creatinine) and cannot be altered.



**NOTE: The calculation item will be deleted if you delete any one of the chemistries involved in the calculation item's group. The following message will be displayed if the DELETE button is pressed from the Test Parameter > Test Details screen. See figure below:**



## 7.4. Settings

### 7.4.1. System Parameter Settings

To open this screen, click on **Settings** from the main screen and then select **System Parameters**. The following screen will be displayed.

Figure 7-15. System parameter settings screen

This is one of the most important and useful sub-menu available on the **Settings** screen. This screen allows the user to configure behavior of the analyzer hardware and application software.

A description of the options available to the user is given in the table below. These settings can be modified after clicking on the **EDIT** button at the bottom of the screen. **EDIT** button is not available during batch run.

Item	Description
Laboratory Name	It displays the default laboratory name which will appear as header in the printed patient reports. The default laboratory name can be changed through <b>Master &gt; Laboratory</b> screen. Refer section 7.7.4. <i>Master – Laboratory</i> for more details.
Default Language	The default language for the software screen can be set using this button. Refer section 4.8 <i>Display Language Settings</i> for more details.
Clear Screen upon Save	This drop-down list is used for selecting the clearing of the input screens such as Patient Entry, upon Save operation. The available

	<p>options are Yes, No, and User Confirmation.</p> <p>On selecting option Yes, the screen will be cleared upon Save.</p> <p>On selecting option No, the screen will not be cleared upon Save and will display the saved data. Click on CLEAR button in the respective screen to add new data.</p> <p>On selecting option User Confirmation; every time upon Save, user will be prompted to choose the option to clear the screen.</p>
Confirmation Message	<p>This checkbox is used to select the availability of confirmation message. Default is checked. If it is checked, on performing any critical operation such as SAVE or DELETE, a confirmation message will be displayed.</p>
Auto Copy Calibration	<p>This checkbox is used to automatically copy the calibration details across test(s) with same assay type and specific curve type (either both linear or both non-linear requiring the same number of calibrators); sharing the same Reagents.</p> <p>This option will be useful for the test(s) created using COPY TEST option in Test Parameter screen.</p>
Patient Report	<p>This option allows the user to print the Patient Report automatically during the batch run, as soon as all the results of a sample are available. Patient Report can be printed with or without the header.</p> <p>The following options are available for selection:</p> <ul style="list-style-type: none"> <li>▪ OFF</li> <li>▪ Normal with Header</li> <li>▪ Normal without Header</li> <li>▪ Multicolumn with Header</li> <li>▪ Multi column without Header</li> <li>▪ Profile with Header</li> <li>▪ Profile without Header</li> <li>▪ Graphical with Header</li> <li>▪ Graphical without Header</li> </ul> <p>Select <b>OFF</b>, in case automatic Patient Report printing is not required.</p> <p>Patient Report can be printed in any of the 4 different formats, with or without the header.</p> <p>Make sure to select the desired Report Options from the <b>Reports &gt; Patient Report</b> screen. This will determine whether or not to print Location (area), Analyst, Sample Remarks and Patient Remarks on the Patient Report.</p> <p><b><u>IMPORTANT: Set Printer ON, when Online Report or Patient Report is selected to print.</u></b></p>
Online Report	<p>Tick this checkbox to print the results (list in columnar format) during batch run.</p>
Print Negative Result	<p>Tick this checkbox to print the negative results as it is. On un-ticking this checkbox, the negative results will be printed as 0 (zero) in Patient Report, instead of negative value.</p> <p>However, irrespective of the option selected; the screen will always display the results as it is (negative) and the Online (results) Report will also print negative values.</p>
Footer	<p>Enter the foot note to be printed in the Patient Report (at the bottom). See <i>Figure 6-46. Report screen - Graphical.</i></p>

Signature	Two text boxes are available to add the signature on the printed patient report. It will be displayed in the footer (or bottom) of the printed patient reports.
Top Margin(inch) and Bottom Margin(inch)	Set the top and bottom margin for the printed patient report. The extra space will be added to the top and bottom of the printed patient reports, as per margin selected.
Analyzer Port	Select the COM Port of the PC, at which the Analyzer is connected. Default port is COM 1.
Host Connection	<p>This option is used to activate the data transmission (patient demographics, work list and test results) with LIS. Default is checked. Un-checking this option will close the LIS connection from the analyzer PC.</p> <p>When Host connection is activated, configure other parameters from the Host settings screen.</p>
Open Channel Test	<p>This drop-down list is used to select setting for test parameters. Three options are available <b>Open</b>, <b>SemiClosed</b> and <b>Closed</b>.</p> <ul style="list-style-type: none"> <li>▪ If <b>Open</b> option is selected, all the inputs on the test parameter screen are editable and also new tests can be added.</li> <li>▪ If <b>Semi-Closed</b> option is selected, only some of the inputs on the test parameter screen are editable for the pre-defined tests. A new test can be added.</li> <li>▪ If <b>Closed</b> option is selected, the inputs on the test parameter screen are non-editable. A new test cannot be added.</li> </ul> <p>This option may be used to secure the Test Parameter screen.</p>
RCT Temperature	It displays the RCT Temperature in °C. The default value is 37 °C.
RCT Temperature Range	This field is used to set the allowable fluctuation in RCT Temperature. User can enter the range between 0 and 0.5.
RGT Temperature	This field displays the RGT Temperature in °C. This value is 8 °C.
RGT Temperature Range	This field is used to set the allowable fluctuation in RGT Temperature. Default value is 4°C. User can enter the range between 0 and 4.
Sample Barcode	<p>This option is used to select the availability of Sample Barcode. Default is ticked (available).</p> <p>When the sample barcode identification is not desired, un-tick this option &amp; SAVE. In such case, in Patient Entry screen, the Barcode option will be disabled and entry of sample position is mandatory.</p>
Reagent Barcode	<p>This option is used to select the availability of Reagent Barcode. Default is ticked (available).</p> <p>When this option is un-ticked, Reagent Barcode scan in Status Monitor is not available. Reagents should be defined manually from Utility &gt; Reagent Position screen.</p>
ISE Module	<p>This option is used to select the availability of ISE.</p> <p>When un-ticked, ISE options are not available for scheduling &amp; for batch run.</p>
Minimum Cell Blank	Enter the Minimum Cell Blank Absorbance from 0.01 to 0.05. If the absorbance of the cell blank falls below this limit, then the colour of the cuvette Absorbance value in the <b>Maintenance &gt; Cell Blank</b> screen will change to Blue. Default value is 0.03.
Maximum Cell Blank	Enter the Maximum Cell Blank Absorbance from 0.1 to 0.2. If the absorbance of the cell blank falls above this limit, then the colour of the cuvette Absorbance value in the <b>Maintenance &gt; Cell Blank</b> screen will

	change to Red. Default value is 0.2.
Extrapolation	Specify the desired percentage to extrapolate the calibration graph to a particular percentage. Value between 0 to 20% can be entered. If the value is 0, the graph is not extrapolated.
Container Type	Set the default container type from the list. The selected option will appear as the default container type while adding samples in the Patient Entry screen.
Li in ISE	Using this option Lithium (Li) test can be disabled or enabled. If this option is ticked then Lithium is activated and Lithium results will be displayed when ISE is performed.

## 7.4.2. Carry Over Pairs

Analyzer typically uses probes to dispense reagents, and these probes are exposed with different types of reagents. Likewise, cuvettes are exposed to the same variety of different reagents as they are used over and over during batch run. A very real concern with analyzers is reagent carryover, that is, reagent from an initial assay clinging to a reagent probe and contaminating the reaction mixture of the next test immediately following the initial assay.

This contamination can be eliminated using Carryover Pairs screen. To open this screen, click on **Settings > Carry Over Pairs**.

The following screen will be displayed.

Sr #	Contaminant(1st) Test	Contaminated(2nd) Test	Skip Cuvette	System Wash	Wash	Wash Cycles	R1 Volume	R2 Volume
1	ALB	TRIG	Yes	No	Reagent 1 Wash	3	50	0
2	ALB	TGER	Yes	No	Reagent 1 Wash	3	50	0
3	TRIG	ALB	Yes	No	Reagent 1 Wash	3	50	0
4	TRIG	LDHA	Yes	No	Reagent 1 Wash	3	50	0
5	TRIG	LIPAS	Yes	No	Reagent 1 Wash	3	50	0
6	LDHA	PHO	Yes	No	Reagent 1 Wash	3	50	0
7	TGER	ALB	Yes	No	Reagent 1 Wash	3	50	0
8	TGER	LDHA	No	No	Reagent 1 Wash	3	50	0
9	TGER	LIPAS	Yes	No	Reagent 1 Wash	3	50	0

Figure 7-16. Carry over pair screen

On this screen, the user can define the forbidden pair for a particular chemistry. The following parameters are available for selection:

Item	Description
Contaminant Test(1 <sup>st</sup> )	The user can enter the contaminant chemistry.
Contaminated Test(2 <sup>nd</sup> )	The user can enter the chemistry that could get contaminated
Skip Cuvette	This option is used to skip the cuvette along with the probe wash. Whenever a contaminated test comes under a cuvette where the contaminant test has been run, the cuvette will be skipped automatically.
Wash	The user can select whether for that pair, a <b>Reagent 1 or Reagent 2 Wash</b> or a <b>Detergent Wash</b> or both <b>Reagent 1 and Reagent 2</b> washes are required. The option <b>No Wash</b> can be selected if wash is not required.
System Wash	The user can select this option for a pair. In System Wash, the Arm will be washed internally and externally with internal DI water after picking up contaminant test using trough. The system wash will be applied to Reagent 1 Arm, Reagent 2 Arm, Sample Arm, Stirrer 1, and Stirrer 2. When this option is selected, the <b>Wash</b> drop down list will be disabled.
Wash Cycles	The user can define the number of cycles depending on the type of wash selected. The cycle number varies from 1 to 4.
R1/R2 Volume	If reagent Wash is selected, then the user can define the R1 and R2 volume to be aspirated from the contaminated test for cleaning the probe.



**NOTE: For Detergent Wash, prepare Wash Solution (preferably phosphate-free neutral 1%Extran or 0.025% Hypochlorous Acid). Also, the same pair cannot be programmed for 2 different type of wash.**

### 7.4.3. Test Sequence Screen

To open this screen, click on **Settings** from the main menu and then select **Test Sequence**. The following screen will be displayed.

Four options available for displaying the test sequences:

- Test display sequence
- Test process sequence
- Print sequence for patient reports
- Profile print sequence for patient reports

#### 7.4.3.1. TEST DISPLAY SEQUENCE

This option is used to set the sequence of tests. The sequence of test can be displayed in alphabetical order (ascending and descending) or you can set the

order as per requirement. It also provides a drag-and-drop mechanism to let you directly rearrange the test in a sequence within the grid.

Click on a row to select a test and click **MOVE UP** or **MOVE DOWN** as appropriate. Alternatively, user may select multiple tests by CTRL + Click and then drag-and-drop the selection at the row desired.

To set the test display sequence, select option TEST DISPLAY SEQUENCE. Click on SORT ASCENDING or SORT DESCENDING button as appropriate, and then click SAVE to confirm the settings. Once the test display sequence is set, the test(s) will appear in the specified sequence in the following screens:

- Patient Entry
- Reports
- Search
- Test Parameter > Test Details
- Test Parameter > Test Volumes
- Test Parameter > Reference Ranges
- QC Calibration > Calibration

Sr #	TEST	TEST REPORT NAME
1	GLUF	Blood Sugar - fasting (by GOD-POD method)
2	GLUPP	Blood Sugar - post lunch (by GOD-POD method)
3	GLUR	Random Blood Sugar (by GOD-POD method)
4	CHO	Sr. Cholesterol (CHOD -PAP method)
5	TRIG	Sr. Triglycerides(glycerol phosphate oxidase mthd)
6	HDLC	High Density Lipoprotein (turbimetry)
7	LDL	Low Density Lipoprotein - direct
8	GOT	S.G.O.T - (I.F.C.C.method)
9	GPT	S.G.P.T - (I.F.C.C method)
10	CRE	Sr. Creatinine (Jaffe's method)
11	ALB	Sr. Albumin (BCG dye method)
12	BIDER	Sr. Bilirubin (Direct) - diazo method
13	BITER	Sr. Bilirubin (Total) - diazo method
14	GGTMR	Sr. GAMMA GT - Szasz method.
15	MPR	Micro-Protein
16	LDHA	Sr. Lactate Dehydrogenase
17	CAA	Sr. Calcium - Arsenazo III method
18	UACE	Sr. Uric Acid - modified Trinder method.
19	LDH	LACTATE DEHYDROGENASE
20	CKN	Sr. Creatine Kinase - modified IFCC method.
21	CKMB	CK-MB
22	PRO	Sr. Proteins ( biuret method)
23	GPTHL	SGPT
24	GOTHL	SGOT
25	MG	MAGNESIUM
26	ALP	ALKALINE PHOSPHATASE
27	GGT	GAMMA GT
28	AMY	Sr. Amylase (CNP-G3 method)
29	PHO	Sr. PHOSPHORUS
30	BID	Bilirubin Direct

Indication : Set Frequently Tests on Top using Test Display Sequence.

**SORT ASCENDING**  
**SORT DESCENDING**  
**MOVE UP**  
**MOVE DOWN**

**PRINT**    **SAVE**    **CLEAR**    **EDIT**    **DELETE**

### 7.4.3.2. TEST PROCESS SEQUENCE

This option is used to set the test process sequence during run or on the test grid. This function is useful in avoiding forbidden pairs that may come together during the run. This function will work only for same patients. In order to avoid the carry over between patients, then use Forbidden Pairs program.

To set the test process sequence, select option **TEST PROCESS SEQUENCE**. Click on **SORT ASCENDING** or **SORT DESCENDING** button as appropriate, and then click **SAVE** to confirm the settings.

The two different modes are available to define the test sequence:

- **SORT ASCENDING/DESCENDING:** This button is used to sort the tests alphabetically in ascending or descending order.
- **MOVE UP/ MOVE DOWN:** This button is used to move the desired test up or down. The user needs to select the test and then click on the Move up or Move down depending on how the order for display or processing should be done. Also, you can use drag and drop to move the test up and down.



---

**NOTE: Define Test Process Sequence to reduce / eliminate the carryover effect of reagents. For each sample, the tests will be performed in the order of processing sequence during run.**

---

### 7.4.3.3. PRINT SEQUENCE FOR PATIENT REPORTS

This option is used to set the sequence of test to be printed on the patient reports. The following screen shows the sample printed patient report for a sample ID, with tests arranged in an alphabetical sequence.

Main Report | DFG | My Laboratory Address1

Sample ID	2	Patient ID	
Name		Sample Type	SERUM
Category	-	Collection Date	04-Mar-2011
Age		Reg. Date	04-Mar-2011
Ref. Dr		Analyst	
Sample Remark		Location	

Sr.No.	Test	Result	Flag	Normal Range
1	ALBUMIN	10.53 g/dl	TEC-H,H	↑ 0.45 - 0.55 g/dl
2	Alkaline Phosphatase	8 IU/L	L,LIN20	↓ 28 - 78 IU/L
3	Amylase	12 U/L	LIN20	0 - 80 U/L
4	Anti-Streptolysin(O)	NA IU/mL	MONO	--
5	Bilirubin Direct	0.00 mg/dl		0.00 - 0.20 mg/dl
6	Bilirubin Total	-40.00 mg/dl	L	↓ 0.30 - 1.20 mg/dl

Current Page No.: 2 | Total Page No.: 158 | Zoom Factor: 100%

To set the test sequence, select option **PRINT SEQUENCE FOR PATIENT REPORTS**. Click on **SORT ASCENDING** or **SORT DESCENDING** button as appropriate, and then click **SAVE** to confirm the settings. Also, you can use drag and drop to move the test up and down.

#### 7.4.3.4. PROFILE PRINT SEQUENCE FOR PATIENT REPORTS

This option is used to set the sequence of profile to be printed on the patient reports. The following screen shows the sample printed patient report for a sample ID, with profiles arranged in an alphabetical sequence.

Main Report

DFG					
My Laboratory Address1					
Sample ID	1	Patient ID			
Name		Sample Type	SERUM		
Category	-	Collection Date	04-Mar-2011		
Age	-	Reg. Date	04-Mar-2011		
Ref. Dr		Analyst			
Sample Remark		Location			
<hr/>					
Profile : --					
Sr.No.	Test	Result	Flag	Normal Range	
1	ALBUMIN	10.53 g/dl	TEC-H,H	↑	0.45 - 0.55 g/dl
2	Lactate Dehydrogenase	80 IU/L	TEC-H,L,AbsLim,RgtAb sMin	↓	226 - 456 IU/L
<hr/>					
Profile : Lipid Profile					
Sr.No.	Test	Result	Flag	Normal Range	
1	Bilirubin Direct	0.00 mg/dl		0.00 - 0.20 mg/dl	
2	Bilirubin Total	-40.00 mg/dl	L	↓	0.30 - 1.20 mg/dl
3	Low Density Cholesterol	0.00 mg/dl		0.00 - 130.00 mg/dl	

Current Page No.: 1      Total Page No.: 156      Zoom Factor: 100%

To set the print sequence, select option **PROFILE PRINT SEQUENCE FOR PATIENT REPORTS**. Click on **SORT ASCENDING** or **SORT DESCENDING** button as appropriate, and then click **SAVE** to confirm the settings. Also, you can use drag and drop to move the test up and down.



**NOTE: Use Test Sequence screen to define Test Processing Sequence. The sequence will be followed during batch run while performing the tests for each Sample. This will reduce the carryover effect.**

#### 7.4.4. Rerun Flags

This screen allows user to select the flags for which auto-rerun of the test is required during batch run.

If a particular flag is de-selected for re-run, then auto-rerun will not be performed when the flag is issued along with the result for that test, even though auto-rerun is selected for the test from **Test Parameter** screen.

Click on **Setting > Rerun Flags**, the following screen appears as follows:

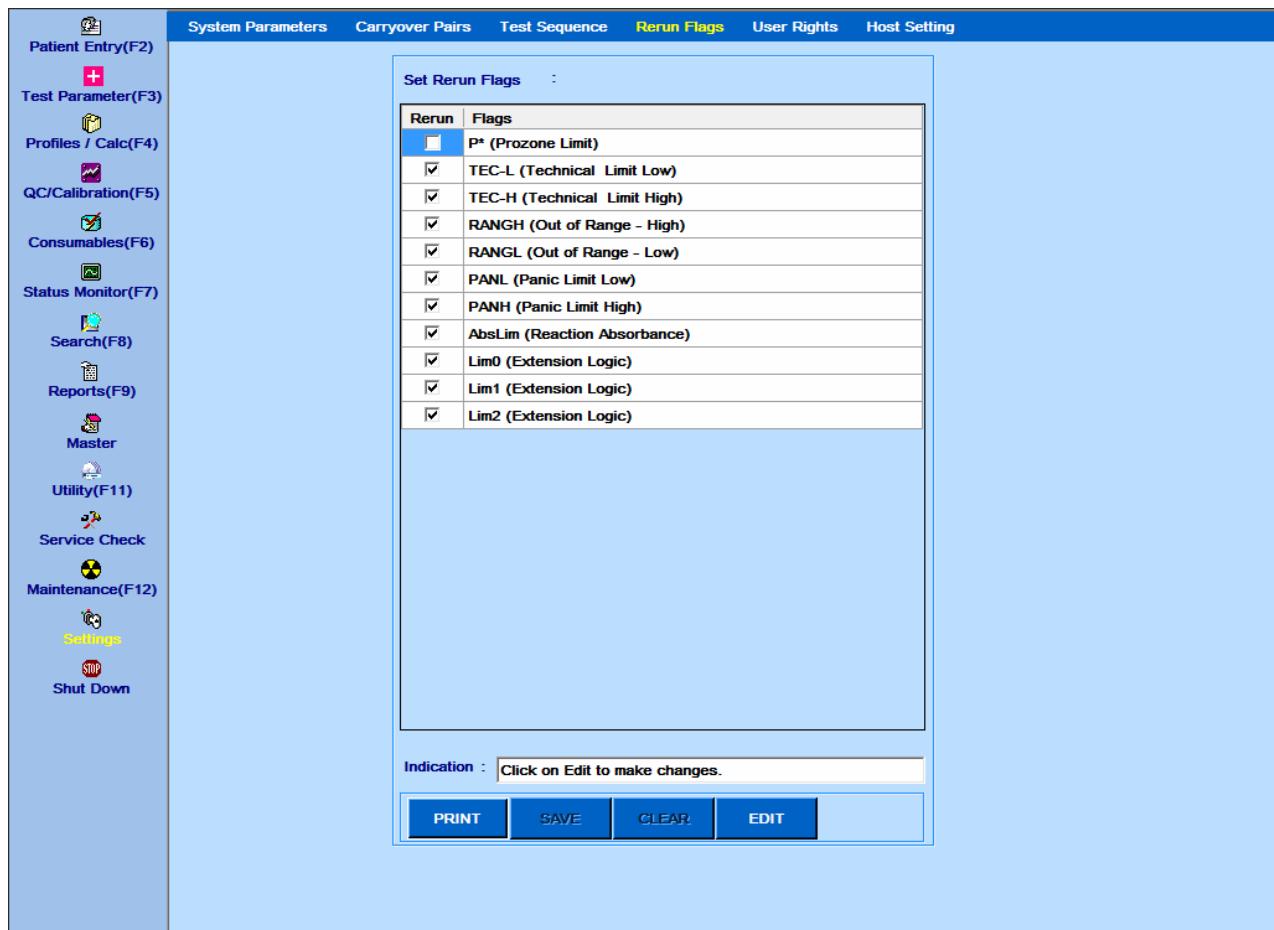


Figure 7-17. Rerun flags screen

Following are the explanation of the buttons on the screen:

**PRINT:** This button to be clicked to print the details whether a particular flag is set for rerun

**SAVE:** This button to be clicked to save the details

**CLEAR:** This button to be clicked to undo the changes done

**EDIT:** This button to be clicked to change the setting for the flags

## 7.4.5. User Rights

This screen allows the administrator to create new user login with respective password and provide access rights for the menu options to the new user and existing users.

The following screen is displayed on clicking **Setting > User Rights**:

Sr#	Module	Full Access
1	Patient Entry	<input checked="" type="checkbox"/>
2	Test Parameter	<input checked="" type="checkbox"/>
3	Profiles / Calc	<input checked="" type="checkbox"/>
4	QC/Calibration	<input checked="" type="checkbox"/>
5	Consumables	<input checked="" type="checkbox"/>
6	Status Monitor	<input checked="" type="checkbox"/>
7	Search	<input checked="" type="checkbox"/>
8	Reports	<input checked="" type="checkbox"/>
9	Master	<input checked="" type="checkbox"/>
10	Utility	<input checked="" type="checkbox"/>
11	Service Check	<input checked="" type="checkbox"/>
12	Maintenance	<input checked="" type="checkbox"/>
13	Settings	<input checked="" type="checkbox"/>

Figure 7-18. User rights - User name list screen

- To create a new user, click on the **CLEAR** button and then enter the user name in the **User Name** textbox.
- Now enter the type of user using **User Type** drop down list. Four options are available:
  - **Super-User**
  - **User**
  - **Analyst**
  - **Doctor**
- Enter the following details:
  - **On Panel**
  - **Address**

- **City**
- **State**
- **Country**
- **Zip Code**
- **Telephone**
- **Email ID**
- **Login ID**
- **New Password**
- **Confirm Password**



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**NOTE: User must enter the details for the parameters that are marked with red asterisk.**

---

4. Once all the data are entered, click on the **SAVE** button.

The user ID will be created.

5. To provide access rights to the existing user, click on the search button. On clicking, the Help window will be displayed containing the list of user id records. Now, select the name of the user by double click on the appropriate record and click **EDIT** button.

A screenshot of a Windows-style 'HELP' dialog box. The title bar says 'HELP'. Inside, there's a search input field labeled 'Search :'. Below it is a table with two columns: 'User Name' and 'Login ID'. The table contains five rows of data:

User Name	Login ID
Guest	Guest
S.SMITH	SS
B.WILLIAMS	BW
M.TYLOR	MT

At the bottom, there's an 'Indication' field with the text 'Enter record to be searched.'

- The screen on next the page gives the options available for the user. Check or uncheck the Full Access check box as per requirement, and click **SAVE** to confirm.

The settings will be saved for that user id.



**NOTE: You must replace the old password with the new password before saving the settings.**

Sr#	Module	Full Access
1	Patient Entry	<input checked="" type="checkbox"/>
2	Test Parameter	<input checked="" type="checkbox"/>
3	Profiles / Calc	<input checked="" type="checkbox"/>
4	QC/Calibration	<input checked="" type="checkbox"/>
5	Consumables	<input checked="" type="checkbox"/>
6	Status Monitor	<input checked="" type="checkbox"/>
7	Search	<input checked="" type="checkbox"/>
8	Reports	<input checked="" type="checkbox"/>
9	Master	<input checked="" type="checkbox"/>
10	Utility	<input checked="" type="checkbox"/>
11	Service Check	<input checked="" type="checkbox"/>
12	Maintenance	<input checked="" type="checkbox"/>
13	Settings	<input checked="" type="checkbox"/>

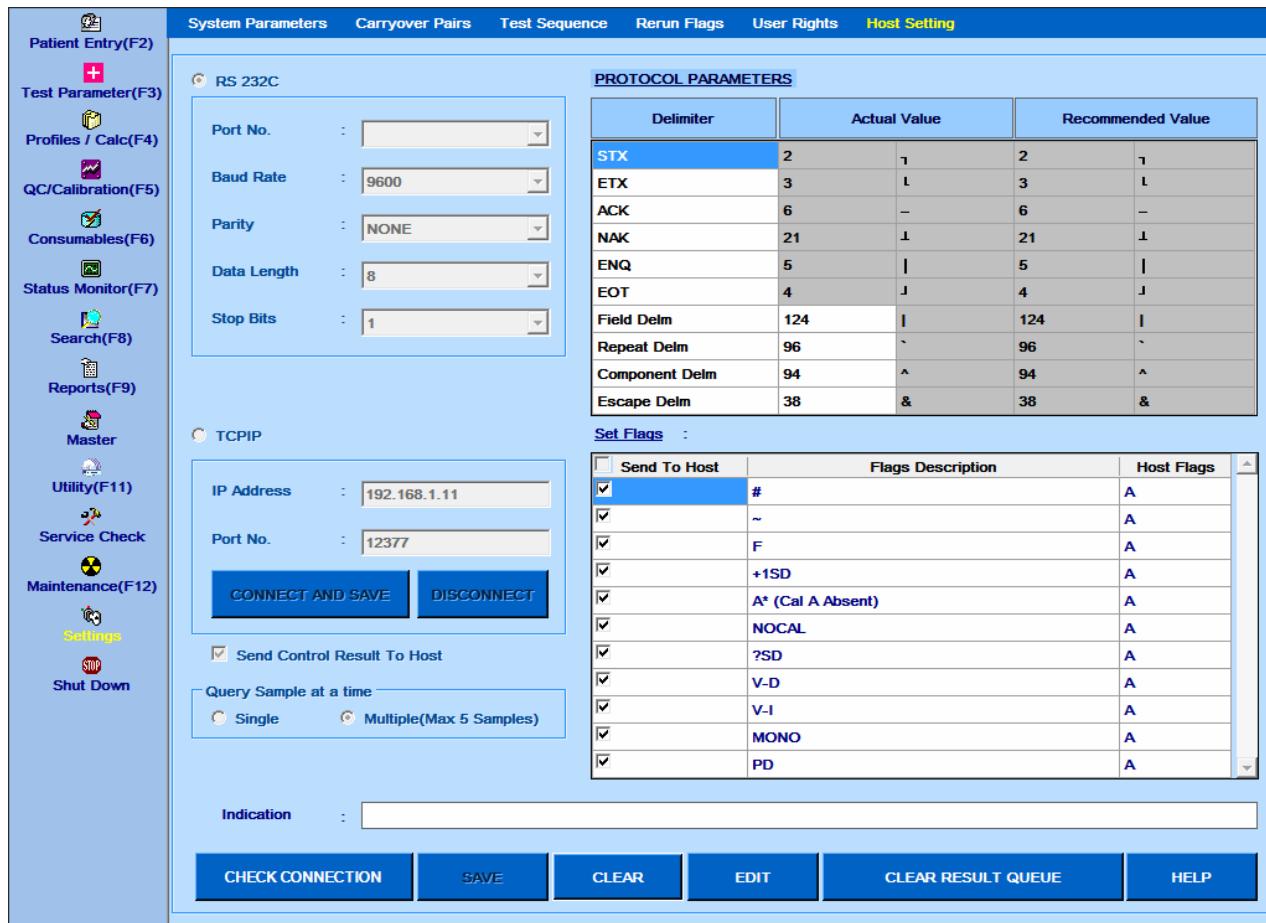
Figure 7-19. User right –user edit option screen

- To change the password, first select the user from the record using  button, and then click **EDIT** button. Now enter the old password, new password, and confirm password. Click **SAVE** to confirm the settings.
- If the user has forgotten the password, click on **EDIT**, select the **FORGOT PASSWORD** check box and then enter the New Password and Confirm Password.

#### 7.4.6. Host Settings

This screen is used to define the settings required to establish the Host communication between the analyzer PC and LIS. To open this screen, click on the **Settings**, and then select **Host Settings**.

MultiXL communicates with LIS through Serial Port or TCP/IP. Separate serial port (other than the one used for communication with analyzer) is required to enable the communication through serial cable. To enable communication through TCP/IP, the analyzer PC should be connected to local network.



Two communication mediums are available in the Host Settings screen for communicating with the host. They are:

- **RS 232C (serial communication)**
- **TCP/IP**

To enable communication through serial cable, select the **RS 232C** option, and enter the appropriate details in the following:

- **Port No.**
- **Baud rate**
- **Parity**
- **Data Length**
- **Stop Bits**

The baud rate, parity, data length, and start bit settings on the host must match with the analyzer's PC. The communication is initiated through serial port as configured on the Port No.

To enable the communication through TCP/IP, select the TCP/IP option, and enter the following parameters:

- **IP Address**
- **Port No.**

After entering the details, click on **CONNECT AND SAVE**. On clicking, the connection between the LIS and host will be established, and data will be saved.

**DISCONNECT** button is used to disconnect the connection.

The following option available on the screen:

- **Send Control Result to Host:** Tick this option to automatically send the control results obtained during batch run to LIS. Refer ASTM HOST help file for more details.

**Query Sample at a time:** After Sample Barcode Scan, MultiXL application will request LIS for downloading test details for the samples scanned during run or Sample Barcode Scan. MultiXL will query either 1 sample or 5 samples at a time. Select appropriate option from the following, in consultation with LIS vendor.

- ◆ Single
- ◆ Multiple(Max 5 Samples)

The following additional buttons available on this screen are:

**CHECK CONNECTION:** This button is used to check the communication between Host and analyzer PC.

**SAVE:** This button is used to save the settings.

**CLEAR:** This button is used to clear the changes.

**EDIT:** This button is used to edit the changes.

**CLEAR OFFLINE RESULT QUEUE:** On clicking this button, the ongoing result data to LIS will be stopped.

**HELP:** This button displays the ASTM HOST help file in more details.

## 7.5. Utility

### 7.5.1. Backup

To open this screen, click on **Utility** from the main menu and then select **Backup**. The following screen will be displayed.

**Backup Mode:** The display changes according to the selection and provides necessary guidance to perform the operation.

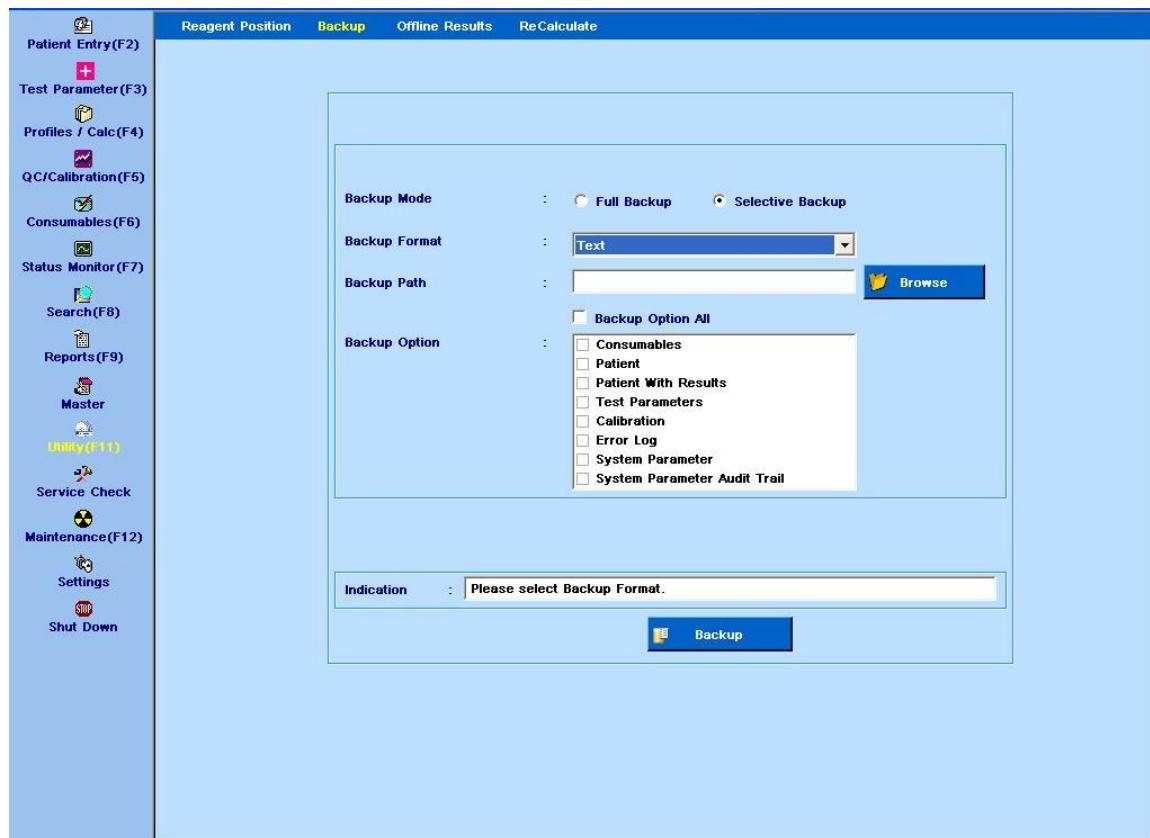


Figure 7-20. Backup screen

### Method to backup data:

**Backup Mode:** Two options are available. Full Backup and Selective Backup. Only Full backup is restorable. Selective backup is used to extract partial data for reference and cannot be restored back.

**Backup Format:** This drop down list is used to select the Mode of Backup. Available options are Text, XML, XLS, and CSV. These options are available if the **Selective Backup** option is selected.

- XML: This mode of backup stores the Backup Parameters in XML format.
- Text: This mode of backup stores the Backup Parameters in Text format.
- XLS: This mode of backup stores the Backup Parameters in Excel format.
- CSV: This mode of backup stores the Backup Parameters in Excel format.

The option **Database** will be displayed if **Full Backup** option is selected. Using this option, a complete database file is created in .BKP format that can be stored in the appropriate location using **Browse** button.

**Backup Path:** Click on the **Browse** button to select the path or directory where the Parameters will be backed up. It is not recommended to take the backup on the desktop.

**Database:** This mode of backup copies the entire database and stores it on the hard disk at the path selected by user using **Browse** button.

**Backup Option:** A list of parameters is available for Backup if the user selects the Selective Backup mode. The user can either check all the parameters using Backup Option/All checkbox or make a selection individually using the checkbox placed against each parameter.

After the above operations have been done, click on **Backup** button to take a backup of selected parameters.



**Important: Take Full Backup periodically, to avoid loss of data in case of PC crash.**

**Store the backup file .BKP, created through Full Backup; in an external media like CD/DVD.**

## 7.5.2. Offline Results

This screen enables the user to enter data for any patient without having to actually perform a test on the analyzer. In this case, the application software is simply used to print the patient report. To open this screen click on **Utility > Offline Results**.

Figure 7-21. Offline results screen

A description of the inputs available on this screen is given in the following table:

Item	Description
Date	Select the date for the patient result. Current date is displayed by default.
Laboratory	By clicking on the dotted button, select the name of the Laboratory from the available list. Use <b>Master &gt; Laboratory</b> screen to add a new laboratory.
Instrument	By clicking on the dotted button, select the name of the Instrument (from the available list) on which the test is conducted. Add a new instrument name from <b>Master &gt; Instrument</b> screen.
Sample ID	By clicking on the dotted button, select the Sample ID, if already defined from <b>Patient Entry</b> screen or directly enter the sample id in this textbox.
Sample Type	Select the Sample Type from drop down list.
Patient Name	Enter the name of the patient. The name of the patient will be displayed automatically if the Sample ID is selected using the dotted button.
Age	It displays the patient's age.
Category	This list displays the Category (Gender) of the patient.
Test	Select the required test name from drop down list or enter a new test name up to 5 characters.
Report Name	Enter the Report Name of the selected test, for printing in Patient Report.
Unit	Select / enter the Unit of measurement for the test.
Normal Lower Limit	Enter the Lower Limit of the Normal Reference Range for the Test. By default, the reference range will be displayed when the test available in Test Parameter is selected from the list of <b>Tests</b> .
Normal Upper Limit	Enter the Upper Limit of the Normal Reference Range for the Test. By default, the reference range will be displayed when the test available in Test Parameter is selected from the list of <b>Tests</b> .
Result	Enter the result for the Test.
Flag	Select / enter the Flag associated with the Result.

On clicking **PRINT** button, the patient report will be generated. This result can also be printed from **Reports > Patient Report** screen along with other results of the patient.

### 7.5.3. Result Recalculation

To open, click on the **Utility**, and then select **Recalculate**. The following screen will be displayed.

Sample ID	Test	Result	Flag	Recal Result	Recal Flag	Curve No
1702 MV NaP ...	NaPNZ	101.8		100.0		11359
1702 MV NaP ...	NaPNZ	106.7		105.7		11358
1702 MV NaP ...	NaPNZ	99.7		109.0		11376
1702 MV NaP ...	NaPNZ	99.8		112.0		11377
1702 MV NaP ...	NaPNZ	108.6		113.4		11378
1702 MV NaP ...	NaPNZ	109.9		118.9		11379
1702 MV NaP ...	NaPNZ	104.7		113.5		11381
1702 MV NaP ...	NaPNZ	99.7		116.8		11380
1702 MV NaP ...	NaPNZ	110.3		107.2		11383
1702 MV NaP ...	NaPNZ	112.7		112.6		11382
1702 MV NaP ...	NaPNZ	108.7		108.7		11385
1702 MV NaP ...	NaPNZ	115.3		115.3		11384
1702 MV NaP ...	NaPNZ	104.4		104.4		11386
1702 MV NaP ...	NaPNZ	106.0		106.0		11387
1702 MV NaP ...	NaPNZ	100.0		100.0		11389
1702 MV NaP ...	NaPNZ	105.7		105.7		11388
1702 MV NaP ...	NaPNZ	109.0		109.0		11391
1702 MV NaP ...	NaPNZ	112.0		112.0		11390
1702 MV NaP ...	NaPNZ	113.4		113.4		11393
1702 MV NaP ...	NaPNZ	118.9		118.9		11392
1702 MV NaP ...	NaPNZ	113.5		113.5		11395
1702 MV NaP ...	NaPNZ	116.8		116.8		11394
1702 MV NaP ...	NaPNZ	107.2		107.2		11360
1702 MV NaP ...	NaPNZ	112.6		112.6		11361

Figure 7-22. Recalculate screen

This screen is useful in recalculating results if any changes are made in the test parameters or calibration data after analysis. This is particularly useful because one does not have to rerun a sample if a mistake was made in Test Parameters or the Calibration Table.

Recalculate option is not available during batch run.

Results of deleted Sample IDs cannot be re-calculated.

Results of the test(s) having flags for Sample/Reagent absent cannot be re-calculated.

To obtain recalculated result:

1. Select Result date or Batch number or Test or Sample ID. Sample ID option will be disabled if Calibration or Control radio button is selected.
2. Select any of the three options, Patients or Calibration or Controls.
3. Click on **SHOW** button to view all the results.
4. Select the result(s) for which re-calculation is required. Click on the **Recalculate** button. The re-calculated result and flag (revised as per re-calculated value) are displayed along with the original result and flag.
5. Recalculated test results can be sent to Host by selecting the results and clicking on the **Send To Host** button.



**NOTE: The Send To Host button will be enabled only if:**

- Patient or Control checkbox are selected for showing results.**
- Host Connection should be activated.**



**NOTE: During run, the Send to Host button is not available in the Re-calculated screen and Result Reprint screen.**

## 7.6. Search

To open this screen, click on **Search** from the main screen. It is used to search Consumables, Test Parameters, Patient Information, Sample Information and Results. The following screen will be displayed.

### 7.6.1. Search – Patient and Samples

Category	Age	Sample ID	Collection	Reg.Date	Area	Doctor	Analyst	Sample	Patient	Operator ID	Modified On
	7	24 Jul 2009	24 Jul 2009					SERUM		Guest	24 Jul 2009
	10	24 Jul 2009	24 Jul 2009					SERUM		Guest	24 Jul 2009
	12	24 Jul 2009	24 Jul 2009					SERUM		Guest	24 Jul 2009
	13	24 Jul 2009	24 Jul 2009					SERUM		Guest	24 Jul 2009
	19	24 Jul 2009	24 Jul 2009					SERUM		Guest	24 Jul 2009
	20	24 Jul 2009	24 Jul 2009					SERUM		Guest	24 Jul 2009
	24	24 Jul 2009	24 Jul 2009					SERUM		Guest	24 Jul 2009
	25	24 Jul 2009	24 Jul 2009					SERUM		Guest	24 Jul 2009
	26	24 Jul 2009	24 Jul 2009					SERUM		Guest	24 Jul 2009
	28	24 Jul 2009	24 Jul 2009					SERUM		Guest	24 Jul 2009
	20a	24 Jul 2009	24 Jul 2009					SERUM		Guest	24 Jul 2009
	Pat SALB	30 Jul 2009	30 Jul 2009					SERUM		Guest	30 Jul 2009
	Pat SALB1	30 Jul 2009	30 Jul 2009					SERUM		Guest	30 Jul 2009
	Pat SALB2	30 Jul 2009	30 Jul 2009					SERUM		Guest	30 Jul 2009

Figure 7-23. Patient search form

Search for Patients and Sample details can be made using the above form.

Various filters can be applied during Search.

The following parameters are available:

- Search by entering the Patient Name

- Search by Patient ID.
- Search by selecting a Doctor
- Search by selecting a Sample Type
- Search by entering the Sample ID
- Search by Collection Date

To select the date range, click on the calendar icon near the **Collection Date** and **To** text box. To remove the date selection, click on 'X' i.e. the second icon near the Collection Date text box.

- Search by Registration Date

To select the date range, click on the calendar icon near the **Registration Date** and **To** text box. To remove the date selection, click on 'X' i.e. the second icon near the Registration Date text box.

- Advanced Search using 2 or more combinations from above.

The above selection can be cleared using **Reset** button.

The search results are displayed in the grid. In the search result, you can able to see the name of the operator and the modified date in **Operator ID** and **Modified On** column.

## 7.6.2. Patient Results Search

Patient Name	Doctor	Test	Flag	Result Date	Sample ID	Batch	Sample ID
	MALB			22 Jul 2009 11:33:36:560	U 1	1	SERUM
	MALB			22 Jul 2009 11:33:54:480	U 1	1	SERUM
	MALB			22 Jul 2009 11:34:12:590	U2	1	SERUM
	MALB			22 Jul 2009 11:34:30:577	U2	1	SERUM
	MALB			22 Jul 2009 11:34:48:670	U3	1	SERUM
	MALB			22 Jul 2009 11:35:06:653	U3	1	SERUM
	MALB			22 Jul 2009 12:32:51:903	MV22072009	2	SERUM
	MALB			22 Jul 2009 12:33:09:873	MV22072009	2	SERUM
	MALB	TEC-L,RANGI		22 Jul 2009 12:33:27:997	MV22072009	2	SERUM
	MALB	TEC-L,RANGI		22 Jul 2009 12:33:45:950	MV22072009	2	SERUM
	MALB			22 Jul 2009 12:34:04:047	MV22072009	2	SERUM
	MALB			22 Jul 2009 12:34:22:030	MV22072009	2	SERUM
	MALB	TEC-L,RANGI		22 Jul 2009 12:34:40:200	MV22072009	2	SERUM
	MALB	TEC-L,RANGI		22 Jul 2009 12:34:58:120	MV22072009	2	SERUM

Figure 7-24. Patient results search form

Search for Patient Results can be made using the above form.

Various filters can be applied during Search.

The following parameters are available:

- Search by entering the Patient Name
- Search by entering the Patient ID
- Search by selecting a Doctor
- Search by selecting a Test
- Search by entering the Flag associated with the test
- Search by Sample Type
- Search by entering Sample ID
- Search by selecting the Result Date

To select the date range, click on the calendar icon near the **Result Date** and **To** text box. To remove the date selection, click on 'X' i.e. the second icon near the Result Date text box

- Advanced search using 2 or more combinations from above.

The above selection can be cleared using **Reset** button.

The results are displayed in the grid. If you are searching the result by entering the result date, the **Result Date** column, in the search result will displays date and time.

## 7.6.3. Calib / Control Results Search

Consumable	Consumable	Lot No	Test	Flag	Result Date	Batch	Result	Unit
Blank	NaCl	1	MALB		22 Jul 2009 11:28:11:873	1	0.0088	—
Blank	NaCl	1	MALB		22 Jul 2009 11:28:29:733	1	0.0090	—
Blank	NaCl	1	MALB		22 Jul 2009 11:28:47:967	1	0.0088	—
Calibrators	TC ALB L1	10783	MALB		22 Jul 2009 11:29:05:857	1	0.0112	—
Calibrators	TC ALB L1	10783	MALB		22 Jul 2009 11:29:23:920	1	0.0114	—
Calibrators	TC ALB L1	10783	MALB		22 Jul 2009 11:29:41:903	1	0.0110	—
Calibrators	TC ALB L2	10784	MALB		22 Jul 2009 11:30:00:000	1	0.0207	—
Calibrators	TC ALB L2	10784	MALB		22 Jul 2009 11:30:17:983	1	0.0224	—
Calibrators	TC ALB L2	10784	MALB		22 Jul 2009 11:30:36:077	1	0.0250	—
Calibrators	TC ALB L3	10785	MALB		22 Jul 2009 11:30:54:077	1	0.0672	—
Calibrators	TC ALB L3	10785	MALB		22 Jul 2009 11:31:12:153	1	0.0675	—
Calibrators	TC ALB L3	10785	MALB		22 Jul 2009 11:31:30:153	1	0.0616	—
Calibrators	TC ALB L4	10786	MALB		22 Jul 2009 11:31:48:280	1	0.1585	—
Calibrators	TC ALB L4	10786	MALB		22 Jul 2009 11:32:06:230	1	0.1563	—

1870 Results Found  
Indication Select Search option to view results  
Search Reset

Figure 7-25. Calib/Control results form

Search for Calib / Control Results can be made using the above form.

Various filters can be applied during Search.

This search includes following:

- Blank
- Standards
- Calibrators
- Controls

Following filters are used for the search:

- Search by entering the Test Name
- Search by selecting Flags
- Search by selecting the Result Date

To select the date range, click on the calendar near the **Result Date From** and **Result Date To** text box. To remove the date selection, click on 'X' i.e. the second icon near the Result Date From text box.

- Search by Lot No
- Advanced search using 2 or more combinations from above.

The above selection can be cleared using **Reset** button.

The results are displayed in the grid. The **Result Date** column will display date and time.

#### 7.6.4. Consumables Search

Consumable	Consumable Type	Lot No	Manufacturer	Expiry Date
blk	Blank	1	ERBA	31 Dec 9990
blk1	Blank	1	ERBA	31 Dec 9990
blk2	Blank	1	ERBA	31 Dec 9990
blk3	Blank	1	ERBA	31 Dec 9990
calib	Calibrators	1	ERBA	25 Jun 2010
calib1	Calibrators	1	ERBA	25 Jun 2010
calib2	Calibrators	3	ERBA	25 Jun 2010
calibrator	Calibrators	1	ERBA	26 Jun 2010
ctrl	Controls	1	ERBA	24 Jun 2009
ctrl1	Controls	1	ERBA	26 Jun 2010
ctrl2	Controls	1	ERBA	26 Jun 2010
ctrl3	Controls	1	ERBA	26 Jun 2010
dil	Diluent/Serum Dil.	1	ERBA	31 Dec 9990
ALB	Reagents	9100803	ERBA	31 Dec 2011
....	Reagents	4	ERBA	25 Jun 2010

Figure 7-26. Consumable search form

Search for Consumables can be made using the above form.

Various filters can be applied during Search.

The user has a choice of searching the entire consumables or selecting one consumable at a time.

The following parameters are available:

- Search by entering Manufacturer Name
- Search by selecting the Expiry Date

To select the date range, click on the icon near the **Expiry Date** and **To** text box. To remove the date selection, click on 'X' i.e. the second icon near the Expiry Date text box.

This is not applicable to Blanks, Diluent or Wash Solution

- Search by Lot No.
- Search by Consumable Type

The above selection can be cleared using **Reset** button.

The results are displayed in the grid.

### 7.6.5. Test Search

Test	Primary	Secondary	Assay Type	Curve Type	Direction	Unit	Decimal	
Na	0	0	-	-	-	mmol/L	2	0
K	0	0	-	-	-	mmol/L	2	0
Cl	0	0	-	-	-	mmol/L	2	0
Li	0	0	-	-	-	mmol/L	2	0
ALT	340	405	RATE - A	Linear	DECREASING	U/L	1	0
AP	406	700	RATE - A	Linear	INCREASING	U/L	1	0
ALB	578	700	1 - Point	Linear	INCREASING	g/dl	2	0
AMY	406	700	RATE - A	Linear	INCREASING	U/L	1	0
PAMY	406	700	RATE - A	Linear	INCREASING	U/L	1	0
AST	340	405	RATE - A	Linear	DECREASING	U/L	1	0
DBIL	546	660	2 - Point	Linear	INCREASING	mg/dl	2	1
TBIL	546	660	2 - Point	Linear	INCREASING	mg/dl	2	1
CA	660	700	2 - Point	Linear	INCREASING	mg/dl	2	1
CHOL	606	700	4 - Point	Linear	INCREASING	mmol/L	2	0

Figure 7-27. Test details search form

Search for Test Details can be made using the above form.

Various filters can be applied during Search.

The user has a choice of searching the entire consumables or selecting one consumable at a time.

The following parameters are available:

- Search by selecting Primary Wavelength
- Search by selecting Secondary Wavelength
- Search by selecting Assay Type
- Search by selecting Curve Type
- Search by Reaction Direction
- Advanced Search using 2 or more combinations from above.

The above selection can be cleared using **Reset** button.

The results are displayed in the grid. The information about the curve type, direction, M1 start, and M2 start will not be displayed for the ISE tests.

## 7.7. Master

This screen can be selected from the main menu to enter the master details for Area, Doctor, Analyst, Laboratory, Manufacturer, Reference Range, Unit, Calculation Formula and Instrument.

### 7.7.1. Master – Area

This screen is used to enter the Area (Location) from which the samples are collected. This list of area is available in **Patient Entry** screen and hence for each patient a particular area can be selected. This selected area (location) is printed in Patient Report.

Click on **Master > Area** to view this screen as shown below:

Sr #	AREA
1	BIOGENICS
2	BIOLOGIC TD

Figure 7-28. Master - Area screen

- To Edit a row:
  - a. Select the Area from the grid.
  - b. Click on **EDIT** button.
  - c. Change the Area name.
  - d. Click on **SAVE** button.
  - e. The updated Area will hence be displayed in the grid.

- To Add a row:
  - a. Click on **CLEAR** button.
  - b. Enter the Area name.
  - c. Click on **SAVE** button.
  - d. The updated Area will hence be displayed in the grid.
- To Delete a row:
  - a. Select the Area from the grid.
  - b. Click on **DELETE** button.

The deleted Area will not be displayed in the grid.

To Print the list of Area, click on **PRINT** button.

### 7.7.2. Master – Doctor

This screen is used to enter the name and demographics of referring Doctor. This list of doctor is available in **Patient Entry** screen and hence for each patient a particular doctor can be selected. Click on **Master > Doctor** to view this screen as shown below:

The screenshot shows a software interface for managing medical records. On the left is a vertical toolbar with various icons and labels:

- Patient Entry(F2)
- Test Parameter(F3)
- Profiles / Calc(F4)
- QC/Calibration(F5)
- Consumables(F6)
- Status Monitor(F7)
- Search(F8)
- Reports(F9)
- Master
- Utility(F11)
- Service Check
- Maintenance(F12)
- Settings
- Shut Down

The main window has a header with tabs: Area, Doctor, Analyst, Laboratory, Mfg, Reference Range, Unit, Calculation Formula, and Instrument. Below the header is a search bar labeled "SEARCH :". A large input field contains the text "Dr. James Hawkins". To the right of this field is a table titled "DOCTOR" with three rows of data:

Sr #	DOCTOR	TEL NO.
1	Dr. James Hawkins	
2	Dr. Ramoun D Jones	
3	Sara E. Strawn PT	

At the bottom of the screen, there is an "Indication" message: "Click on row to view / modify the record." Below this is a row of five buttons: PRINT, SAVE, EDIT, CLEAR, and DELETE.

Figure 7-29 Master – Doctor screen

- To Edit a row:
  - a. Select the Doctor's name from the grid.
  - b. Click on **EDIT** button.
  - c. Change the Doctor's name and its demographics.
  - d. Click on **SAVE** button.
  - e. The updated Doctor's name will be hence displayed in the grid.
- To Add a row:
  - a. Click on **CLEAR** button.
  - b. Enter the Doctor's name and its demographics.
  - c. Click on **SAVE** button.
  - d. The updated Doctor's name will be hence displayed in the grid.
- To Delete a row:
  - e. Select the Doctor from the grid.
  - f. Click on **DELETE** button.

The deleted Doctor's name will not be displayed in the grid.

To Print the list of Doctor, click on **PRINT** button.

### 7.7.3. Master – Analyst

This screen is used to enter the name and demographics of Analyst. This list of analyst is available in **Patient Entry** screen and hence for each patient a particular analyst can be selected. Click on **Master > Analyst** to view this screen as shown below:

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The screenshot shows the 'Master - Analyst' screen. On the left is a vertical menu bar with icons and labels for various functions: Patient Entry(F2), Test Parameter(F3), Profiles / Calc(F4), QC/Calibration(F5), Consumables(F6), Status Monitor(F7), Search(F8), Reports(F9), Master, Utility(F11), Service Check, Maintenance(F12), Settings, and Shut Down.

The main area has a header with tabs: Area, Doctor, Analyst (which is selected), Laboratory, Mfg, Reference Range, Unit, Calculation Formula, and Instrument.

A search bar labeled 'SEARCH : [ ]' is followed by a list of demographic fields: Analyst (with value 'Amy Selinger'), Address, City, Country, State, Zip Code, Email, and Tel No. Below these fields is a note: 'Indication : Click on row to view / modify the record.'

To the right of the search area is a grid table with columns 'Sr #', 'ANALYST', and 'TEL NO.'.

Sr #	ANALYST	TEL NO.
1	Amy Selinger	
2	Diana Fassett	
3	Polkinghorn BS	

At the bottom of the screen are five buttons: PRINT, SAVE, EDIT, CLEAR, and DELETE.

Figure 7-30. Master - Analyst screen

- To Edit a row:
  - a. Select the Analyst from the grid.
  - b. Click on **EDIT** button.
  - c. Change the Analyst's name and its demographics.
  - d. Click on **SAVE** button.
  - e. The updated Analyst will be hence displayed in the grid.
- To Add a row:
  - a. Click on **CLEAR** button.
  - b. Enter the Analyst's name and its demographics.
  - c. Click on **SAVE** button.
  - d. The updated Analyst will be hence displayed in the grid.
- To Delete a row:
  - a. Select the Analyst from the grid.
  - b. Click on **DELETE** button.

The deleted Analyst will not be displayed in the grid.

To Print the list of Analyst, click on **PRINT** button.

#### 7.7.4. Master – Laboratory

This screen is used to enter new or edit the existing Laboratory name with their details. These details will be printed as a header in the patient reports.

There is always a default row with laboratory name as **My Laboratory** marked with \*\* sign. This row can not be deleted but it can be edited. The name and address of this row is printed as header in the patient reports. See example of printed reports in *Figure 6-43. Patient report – Normal*.

The list of laboratories will be displayed in **Utility > Offline Results** screen under **Laboratory** textbox for selection.

Click on **Master > Laboratory** to view this screen as shown below.

Sr #	LABORATORY
1	BLCC LABS
2**	JWL LABS
3	MICROBIO LABS

Figure 7-31. Master – Laboratory screen

There is always a default row with laboratory name as My Laboratory marked with \*\* sign. This row can't be deleted but it can be edited. The name and address of this row is printed as header in the patient reports.

- To Edit a row:
  - Select the Laboratory name from the grid.

- b. Click on **EDIT** button.
  - c. Change the Laboratory name or the other laboratory details.
  - d. Click on **SAVE** button.
  - e. The updated Laboratory name will hence be displayed in the grid.
- To Add a row:
    - a. Click on **CLEAR** button.
    - b. Enter the laboratory name and other laboratory details.
    - c. Click on **SAVE** button.
    - d. The updated Laboratory name will hence be displayed in the grid.
  - To Delete a row:
    - a. Select the Laboratory name from the grid.
    - b. Click on **DELETE** button.

The deleted Laboratory name will not be displayed in the grid.

To Print the list of laboratory, click on **PRINT** button.

## 7.7.5. Master – Manufacturer

This screen is used to enter new or edit the existing Manufacturer name. This list of manufacturer will be displayed in **Consumables** screen and hence for each consumable a particular manufacturer can be selected.

Click on **Master > Manufacturer** to view this screen as shown below:

The screenshot shows a software application window titled "Master - Manufacturer". On the left is a vertical toolbar with icons for various functions like Patient Entry, Test Parameter, Profiles / Calc, QC/Calibration, Consumables, Status Monitor, Search, Reports, Master (highlighted in blue), Utility, Service Check, Maintenance, Settings, Archive, and Shut Down. The main area has a header with tabs: Area, Doctor, Analyst, Laboratory, Mfg (which is selected and highlighted in blue), Reference Range, Unit, Calculation Formula, and Instrument. Below the header are two search fields: "SEARCH : [ ]" and "★ Mfg : ERBA". To the right of these fields is a note: "NOTE : \*\* in Sr # Indicates default record." Below the note is a grid table with columns "Sr #" and "MFG". The data in the grid is:

Sr #	MFG
1	BIOSYSTEMS
2**	ERBA
3	RANDOX
4	SMP

At the bottom of the screen, there is an "Indication" message: "Cannot Delete this Record." Below this are five buttons: PRINT, SAVE, EDIT, CLEAR, and DELETE.

Figure 7-32. Master - Manufacturer screen

There is always a default manufacturer present marked with \*\* sign. This row can't be deleted but it can be edited i.e. the name can be changed.

- To Edit a row:
  - a. Select the Manufacturer from the grid.
  - b. Click on **EDIT** button.
  - c. Change the Manufacturer name in **Mfg** text box.
  - d. Click on **SAVE** button.
  - e. The updated Manufacturer will be displayed in the grid.
- To Add a row:
  - a. Click on **CLEAR** button.
  - b. Enter the Manufacturer.

- c. Click on **SAVE** button.
- d. The updated Manufacturer will be displayed in the grid.
- To Delete a row:
  - a. Select the Manufacturer from the grid.
  - b. Click on **DELETE** button

The deleted Manufacturer will not be displayed in the grid.

To Print the list of Manufacturer, click on PRINT button.

### 7.7.6. Master – Reference Range

This screen is used to enter the min and max Years, Months, Days for a reference range. This list of reference range is available in **Test Parameter > Reference Ranges** screen and hence for each test a particular reference range can be selected and the min / max values can be entered.

Click on **Master > Reference Range** to view this screen as shown below:

Sr #	REFERENCE RANGE
1**	DEFAULT

Figure 7-33. Master - Reference ranges screen

There is always a default row present marked with \*\* sign. This row can't be deleted, it can only be selected.

- To Edit a row:

- a. Select the reference range from the grid.
  - b. Click on **EDIT** button.
  - c. Change the reference range.
  - d. Click on **SAVE** button.
  - e. The updated reference range will be hence displayed in the grid.
- To Add a row:
    - a. Click on **CLEAR** button.
    - b. Enter the min and max reference range.
    - c. Click on **SAVE** button.
    - d. The updated reference range will be hence displayed in the grid.
  - To Delete a row:
    - a. Select the reference range from the grid.
    - b. Click on **DELETE** button.

The deleted reference range will not be displayed in the grid.

To Print the list of reference range, click on **PRINT** button.

### 7.7.7. Master – Unit

This screen is used to enter the Unit. This list of units will be displayed in **Test Parameters > Test Details** and **Profiles/Calc > Calculated Item** screen and hence for each test a particular unit can be selected.

Click on **Master > Unit** to view this screen as shown below:

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The screenshot shows the 'Master - Unit' screen of the EM 200 software. On the left, a vertical sidebar lists the following menu items with their corresponding icons:

- Patient Entry(F2)
- Test Parameter(F3)
- Profiles / Calc(F4)
- QC/Calibration(F5)
- Consumables(F6)
- Status Monitor(F7)
- Search(F8)
- Reports(F9)
- Master
- Utility(F11)
- Service Check
- Maintenance(F12)
- Settings
- Shut Down

The main area contains the following controls and displays:

- SEARCH :** A text input field.
- \* Unit :** A text input field.
- Indication :** A text input field containing the placeholder "Enter Unit to be searched."
- Buttons:** A row of five buttons: PRINT, SAVE, EDIT, CLEAR, and DELETE.
- Unit Grid:** A scrollable grid showing a list of units with columns for Sr # and UNIT. The grid contains 26 entries, numbered 1 to 26, with their respective unit names.

Sr #	UNIT
1	%
2	µg/dl
3	µg/L
4	µg/ml
5	µU/ml
6	µKat/L
7	µmol/L
8	µmol/Ls
9	µmol/ml
10	abs
11	g/dl
12	g/l
13	IU/L
14	IU/mL
15	KIU/L
16	mEq/L
17	mg/dl
18	mg/l
19	ml/Min
20	mlu/L
21	mmol/l
22	mU/mL
23	ng/dt
24	ng/L
25	ng/L
26	ng/mL

Figure 7-34. Master - Unit screen

- To Edit a row:
  - a. Select the Unit from the grid.
  - b. Click on **EDIT** button.
  - c. Change the Unit.
  - d. Click on **SAVE** button.
  - e. The updated Unit will be hence displayed in the grid.
- To Add a row:
  - a. Click on **CLEAR** button.
  - b. Enter the Unit.
  - c. Click on **SAVE** button.
  - d. The updated Unit will be hence displayed in the grid.
- To Delete a row:
  - a. Select the Unit from the grid.
  - b. Click on **DELETE** button.

The deleted Unit will not be displayed in the grid.

To Print the list of Unit, click on **PRINT** button.

### 7.7.8. Master – Calculation Formula

This screen is used to enter calculation formula. This list of calculation formula will be displayed in **Calculated Item** screen and hence for each calculation item a particular calculation formula can be selected.

Click on **Master > Calculation Formula** to view this screen as shown below:

Sr #	CALCULATION FORMULA
1	A/(B-A)
2	A+B
3	A-B
4	A/a
5	(A/B)*a+b
6	((A-B)/A)*a
7	(a*A+b*B+c*C+d)
8	(A/B)*100
9	a*A+b*B+c
10	a*A+b
11	(A/B)*e^(f/1440)
12	A/B
13	A-(B+C/5)

Figure 7-35. Master - Calculation formula screen

There are 13 default calculation formulas. These formulas can be used or can also be deleted if not required.

- To Edit a row:
  - a. Select the calculation formula from the grid.
  - b. Click on **EDIT** button.
  - c. Change the calculation formula.

A, B, C, D, E: Used for test names.  
a, b, c, d, e : Used for Coefficients.

0 to 9: Used in formula for calculation.

Various arithmetic operators are available to be used in the formula.

Backspace – Used to clear one previous character.

Clear Formula – Used to remove the complete formula.

- d. Click on **SAVE** button.
- e. The updated calculation formula will be hence displayed in the grid.
- To Add a row:
  - a. Click on **CLEAR** button.
  - b. Enter the calculation formula.
  - c. Click on **SAVE** button.
  - d. The updated calculation formula will be hence displayed in the grid.
- To Delete a row:
  - a. Select the calculation formula from the grid.
  - b. Click on **DELETE** button.

The deleted calculation formula will not be displayed in the grid.

To Print the list of calculation formula, click on **PRINT** button.

### 7.7.9. Master – Instrument

This screen is used to enter instrument details. This list of instrument will be displayed in Offline Results screen and hence for each offline result a particular instrument can be selected.

Click on **Master > Instrument** to view this screen as shown below:

The screenshot displays the 'Master - Instrument' screen of a laboratory management software. On the left, a vertical sidebar lists various menu items with corresponding icons:

- Patient Entry(F2)
- Test Parameter(F3)
- Profiles / Calc(F4)
- QC/Calibration(F5)
- Consumables(F6)
- Status Monitor(F7)
- Search(F8)
- Reports(F9)
- Master
- Utility(F11)
- Service Check
- Maintenance(F12)
- Settings
- Shut Down

The main area contains the following elements:

- A top navigation bar with tabs: Area, Doctor, Analyst, Laboratory, Mfg, Reference Range, Unit, Calculation Formula, and **Instrument**.
- A search bar labeled "SEARCH : [ ]".
- A search bar labeled "★ Instrument : [ ]".
- A results grid table titled "Instrument" with columns "Sr #", "InstrumentName". It contains three rows of data:
 

Sr #	InstrumentName
1	Electron Microscope
2	erba
3	Microscope
- An indication message at the bottom: "Indication : Instrument saved successfully!".
- At the bottom, there are five buttons: PRINT, SAVE, EDIT, CLEAR, and DELETE.

Figure 7-36. Master - Instrument screen

- To Edit a row:
  - a. Select the Instrument from the grid.
  - b. Click on **EDIT** button.
  - c. Change the Instrument.
  - d. Click on **SAVE** button.
  - e. The updated Instrument will be hence displayed in the grid.
- To Add a row:
  - a. Click on **CLEAR** button.
  - b. Enter the Instrument.
  - c. Click on **SAVE** button.
  - d. The updated Instrument will be hence displayed in the grid.
- To Delete a row:
  - a. Select the Instrument from the grid
  - b. Click on **DELETE** button.

The deleted Instrument will not be displayed in the grid.

To Print the list of Instrument, click on **PRINT** button.

## 7.8. MultiXL – Archive Database

In MultiXL, when the size of the data exceeds to particular threshold level, the **Archive** option will be visible on the main screen which enables you to archive the data from the Live database to the Archive database.

Also, this option is always available, once the archive is done.



**NOTE: Only Patient results will be archived. The Calibration, Control and Consumables data will remain in the MultiXL (Live) Database. Master data (for example: Reference Ranges, Area, Doctor, Unit etc) will be copied (new additions as well as changes in data) from MultiXL (Live Database) to MultiXL Archive Database, whenever Data is archived.**

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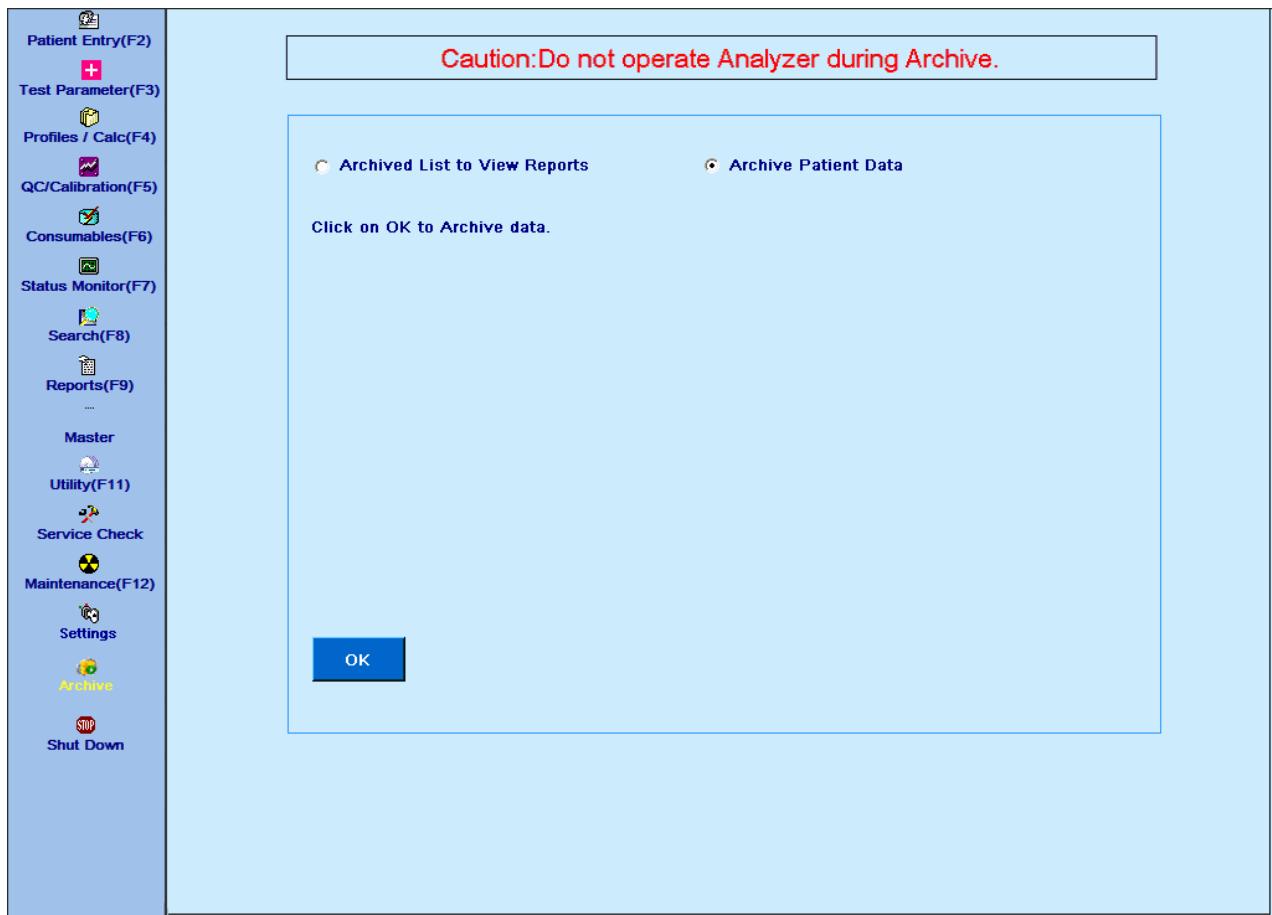
### 7.8.2. Archiving Data

Use the following procedure to archive the data:

1. Click on the **Archive** option.



On clicking, the following screen will be displayed.

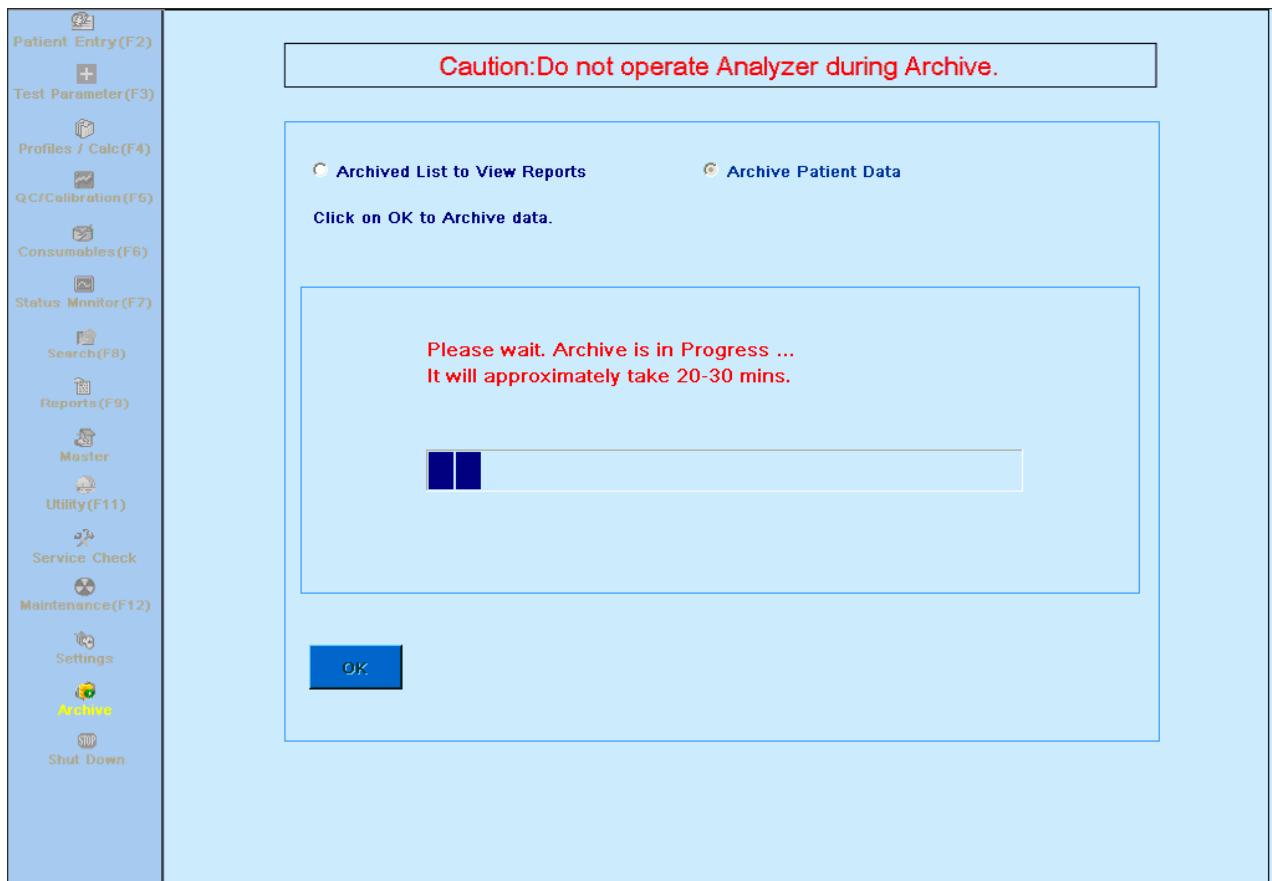


2. In this screen, two options are available.

- **Archived List to View Reports**
- **Archive Patient Data**

3. Select the **Archive Patient Data** option, and click on **OK**.

On clicking, the archive process started and the status will be displayed on the status bar.



**NOTE: During the archive process, all other menus will be disabled.**

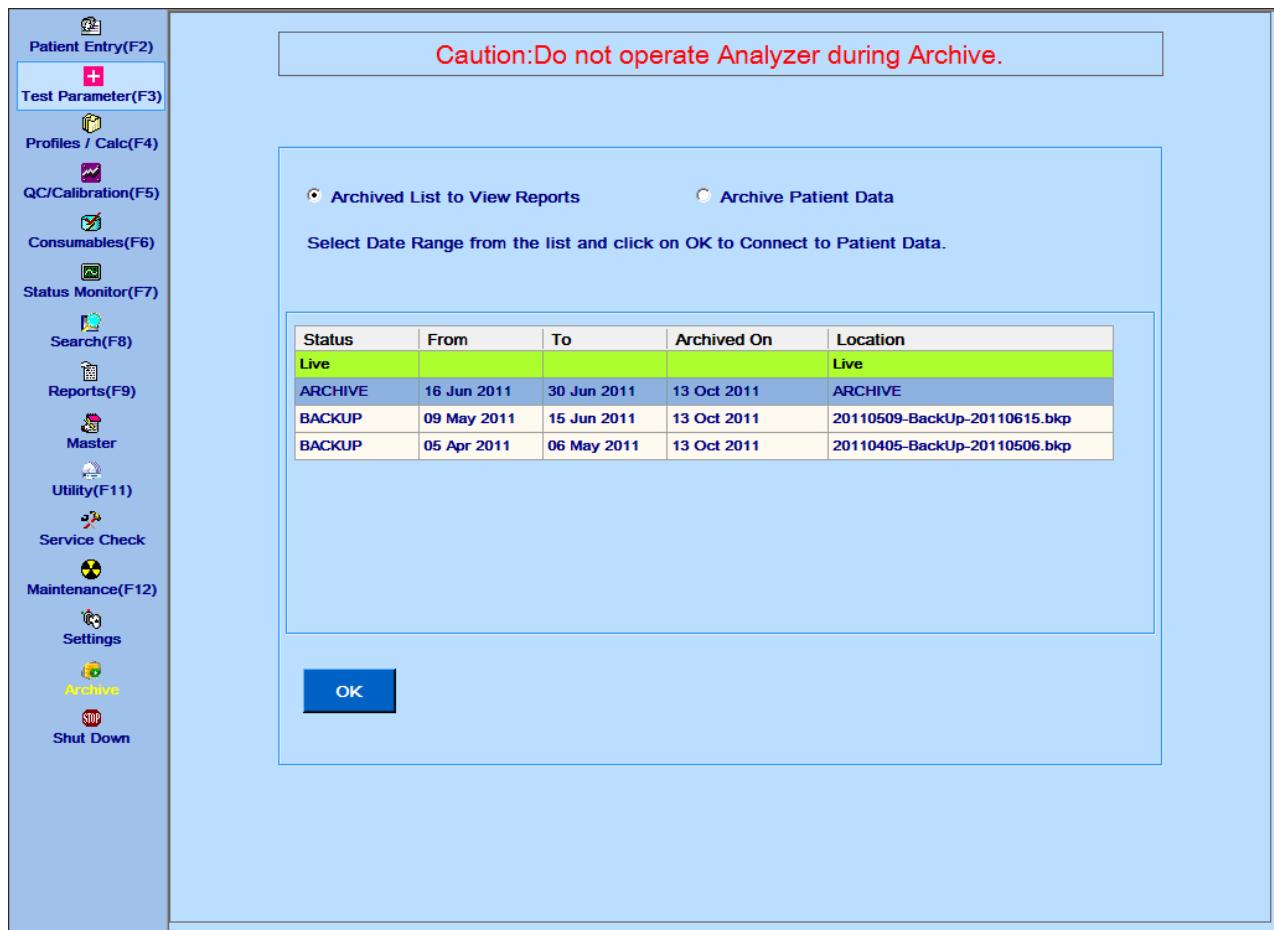
4. After completing the archive process, a message "**Archived data successfully**" will be displayed on the screen.

### 7.8.3. Viewing Archived Data

Use the following steps to view the archived data:

1. Click on the **Archive** option.

On clicking, the following screen will be displayed.



2. Select the **Archived List to View Reports**, and then select the desired archive to connect to archive database to view the reports.
3. Click **OK**.

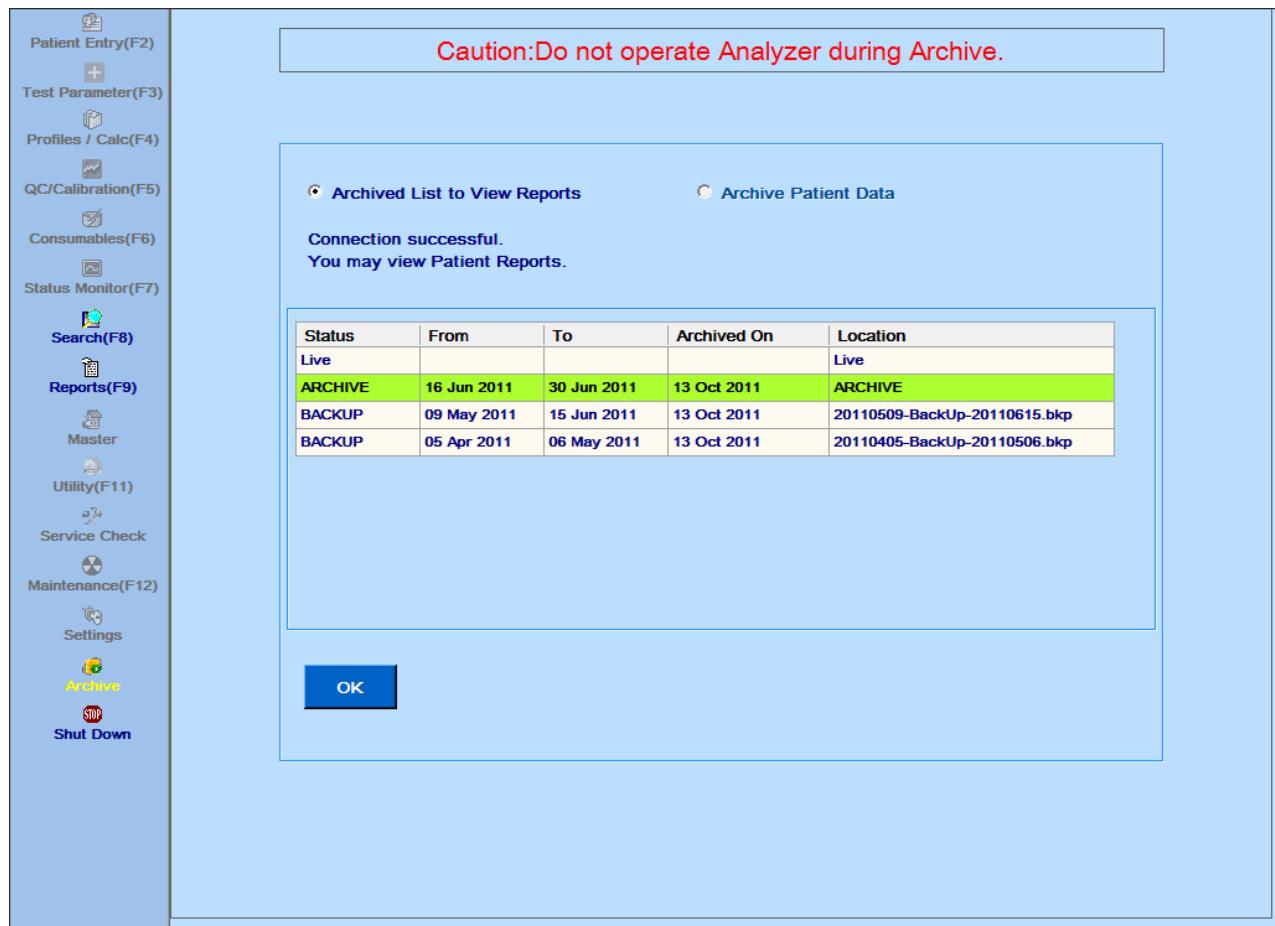
On clicking, a message will be displayed “**Connection successful. You may view the Patient Reports**”.




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**NOTE: During this time you can not access other menus apart from Reports, Search and Shut down.**

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- After connecting to archive database, you will be able to connect to Live database again by selecting **Live** record from the list and click on **OK** button.

## 7.8.4. Observations

When the archive database is connected, the patient data can be viewed only in the following screen:

- **Reports > Patient Report**
- **Reports > Result Reprint**
- **Reports > Test Statistics**
- **Reports > Error Log**
- **Reports > Reaction Curve**
- **Reports > Other > Reagent Consumption**
- **Search > Patient Results**

Other main menu screens are not accessible for the user except the following screens:

- **Search**
- **Reports**
- **Archive**
- **Shutdown**

During batch run, the Archive screen will not be accessible.

## 8. Maintenance

This section provides the necessary and minimal maintenance procedures in order to ensure that the analyzer operates correctly and provides the accurate measurement results.

### 8.1. Maintenance Intervals

The Clinical Chemistry Analyzer has been designed to require very little user maintenance compared to the other analyzers of the same class. Regular cleaning and periodic maintenance as per the schedule keeps the analyzer in good working condition without any trouble. For example, clean the cuvettes externally once every few months as per the cleaning procedure.

For easy understanding, different tables are included in this section.

Table 1 is the maintenance schedule for operator. This table should be used as a reference for performing daily, weekly, quarterly and annual maintenance.

Table 2 is the replacement schedule for different consumables.

Regular maintenance of the analyzer will ensure trouble free operation and consistent quality test results throughout its working. Hence, the user should perform daily Cuvette rinsing.

#### 8.1.1. Daily Maintenance

Start of the day procedure	
Serial Number	Description
1	Fill the DI water can.
2	Fill the cleaning solution can.
3	Clean the probes tips and stirrer paddle with tissue paper soaked in alcohol.
4	Perform the sample and reagent probe wash.
5	Replace the printer paper if necessary.
6	Perform Prime, Cuvette Wash and Probe Wash operations & Check Cell Blanks.
7	Perform the photometer check and verify that the auto span check has passed successfully. (Observe after 30 minutes warm-up).
8	Verify the reagent tray and reaction tray temperature.
9	In case of ISE unit, ensure that there is enough CAL A and CAL B solution
10	Replenish or replace the reagents if necessary.

<b>End of the day Procedure</b>	
<b>Serial Number</b>	<b>Description</b>
1	Remove and discard all sample / standard and controls cups or tubes from the sample tray.
2	Carry out Acid and Alkali Wash (Auto Wash) if Latex based chemistries are used during the day
3	Perform Water save.
4	Take a back up of all patient reports.
5	Turn off the main switch located on the front right hand side of the analyzer (in case ISE and if reagent cooling required, leave left hand side switch on).
6	Empty the Waste and Bio-hazardous waste cans.
7	Clean analyzer external surface to remove residues of serum, reagents etc.

### 8.1.2. Weekly Maintenance

<b>Serial Number</b>	<b>Description</b>
1	Clean and fill the DI water can.
2	Clean the Cleaning solution can.
3	In case of ISE unit, ensure that there is enough CAL A and CAL B solution.
4	Clean the stirrer paddles and laundry probes with alcohol.
5	Check the syringe assembly and surrounding tubes.
6	Clean the computer, trolley, monitor, keyboard and printer external surface.
7	Clean the area around the analyzer, and discard any unwanted item. (Maintain proper room cleanliness).
8	Clean the sample or reagent probe.
9	Clean the Sample tray.
10	Clean the Reagent tray
11	Perform an auto span check and note down the gain values for all the wavelengths.
12	Perform a cuvette rinse and check cuvette blanks
13	Perform a precision check and note down the %CV for an end point and kinetic test.
14	Clean the barcode reader window in the piece of RGT base unit

### 8.1.3. Quarterly Maintenance

<b>Serial Number</b>	<b>Description</b>
1	Clean the Waste can.
2	Clean the Bio hazardous waste can.
3	Clean and fill the DI water can.
4	Clean the cleaning solution can.
5	In case of ISE unit, ensure that there is enough CAL A and CAL B solution

6	Clean the computer, monitor, keyboard and printer external surface.
7	Clean the area around the analyzer, and discard any unwanted item (maintain proper room cleanliness).
8	Clean the Sample or Reagent probe.
9	Clean the stirrer paddle.
10	Clean the laundry probes.
11	Clean the Sample tray.
12	Clean the Reagent tray.
13	Clean the fans.
15	Clean the bar code readers.
16	Perform the auto span check and note down the gain values for all the wavelengths.
17	Perform a cuvette rinse.
18	Perform a precision check and note down the %CV for an end point and kinetic test.
19	Replace the lamp.
20	Clean the internal surface free of dust.
21	Perform an auto span check and note down the gain values for all the wavelengths.
22	Carry out site verification for temperature, line voltage, electrical ground, ventilation, external interferences, room lighting, and laboratory cleanliness practice. Refer section 3.4 Site Requirement for more details.
23	Make a detailed entry of the maintenance carried out and site verifications performed in the error log book.

#### 8.1.4. Annual Maintenance

Serial Number	Description
1	Clean the Waste can.
2	Clean the Bio hazardous waste can.
3	Clean and fill the DI water can.
4	Clean the cleaning solution can.
5	In case of ISE unit, ensure that there is enough CAL A and CAL B solution
6	Replace External Tubings to the Waste, Bio Hazardous Waste, Cleaning Solution And DI Water Cans.
7	Clean the Analyzer External Surface.
8	Clean the computer, monitor, keyboard and printer external surface.
9	Clean the area around the analyzer, and discard any unwanted item (maintain proper room cleanliness).
10	Check and replace the sample probe if necessary.
11	Check and replace the stirrer paddle.
12	Replace the laundry probes.
13	Clean the Sample tray.
14	Clean the Reagent tray.

15	Check and replace the syringe dilutor assembly.
16	Clean the fans.
17	Clean the bar code readers.
18	Perform the auto span check and note down the gain values for all the wavelengths.
19	Perform a cuvette rinse.
20	Perform a precision check and note down the %CV for an end point and kinetic test.
21	Replace the lamp.
22	Clean the internal surface free of dust.
23	Perform an auto span check and note down the gain values for all the wavelengths.
24	Carry out site verification for temperature, line voltage, electrical ground, ventilation, external interferences, room lighting, and laboratory cleanliness practice. Refer section 3.4 Site Requirement for more details.
25	Make a detailed entry in the error log book, of the maintenance carried out and site verifications.



**NOTE: Average life span of the Lamp is 1000 hours. Replacement of Lamp depends on its usage and ON Time.**

Average life of water filter is 3 months. Replacement of water filter depends on quality of DI water used.

## 8.2. Replacement Schedule for Spares and Consumable

Serial Number	Spares/Consumables	3 Months	6 Months	9 Months	12 Months
1	SAMPLE PROBE				✓
2	STIRRER PADDLE		✓		✓
3	CUVETTE DRYER BLOCK (TEFLON)		✓		✓
4	LAUNDRY DISPENSE TUBINGS		✓		✓
5	LAUNDRY ASPIRATION TUBINGS		✓		✓
6	LAUNDRY PROBE ASSY				✓
7	PHOTOMETER LAMP	✓	✓	✓	✓

## 8.3. Consumables-Diluents and Wash Solutions

The screenshot shows a software interface for managing consumables. On the left is a vertical menu bar with icons and labels for various functions: Patient Entry(F2), Test Parameter(F3), Profiles / Calc(F4), QC/Calibration(F5), Consumables(F6), Status Monitor(F7), Search(F8), Reports(F9), Master, Utility(F11), Service Check, Maintenance(F12), Settings, Archive, and Shut Down.

The main area contains a table titled "Consumables" with the following data:

Sr #	Consumable	Lot	Manufacturer
1	DII	1236	fsdfsd
2	DII	dil123	fsdfsd

Below the table, a message says "Indication : Select Consumable for the selected Consumable Type". At the bottom are five blue buttons labeled PRINT, ADD, SAVE, EDIT, and CLEAR.

Figure 8-1. Consumable screen - diluents and wash solution

Using this screen, the user can program various diluents for Serum or Urine from **Consumables > Diluents** screen. The user can add a new diluent name by clicking on the dotted button alongside Consumable name.

1. Once the diluent is added, the user can click on the new button to add the Manufacturer name of the diluent. Lot No. is not mandatory.
2. Similar option is given for adding the Wash solution, which is used when carry-over pairs are programmed.



**NOTE: Diluents can be placed on any position of the Reagent Tray. However, the Diluent and Wash Solution bottles should be 50 ml or 20 ml container types only (either large or small).**

## 8.4. Preventative Maintenance

### 8.4.1. Actions Taken in the Event of Trouble

When any abnormal conditions are found in the analyzer, the operator is requested to check the following items:

1. Preparation and preservation methods of reagents.
2. Preparation and preservation methods of sample.
3. Operational procedures of the analyzer and maintenance work.



**NOTE: When such an abnormal condition is considered to be caused by an electrical or mechanical failure, do not try to carry out the inspection of the analyzer by your own and call for service at our customer service department.**

#### 8.4.1.1. Information Requested by Our Customer Service Department

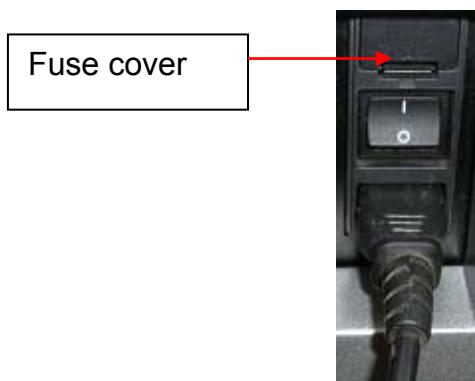
When any technical service will be called for at our customer service department, the following information is requested to be prepared.

- Trouble in assembly.
  - Serial number of analyzer in use.
  - Method code in question.
  - Explanation of encountered trouble.
  - Serial number and lot number of reagent, calibrator and QC sample in use.
  - A few calibration results that were carried out recently.
  - A few measurement results of QC sample, that were carried out recently.
  - Measurement results.
- Trouble in analyzer.
  - Serial number of analyzer in use.
  - Software version numbers in use (PC, Mechanical and Sub-CPU).
  - Explanation of the relevant alarm and problem, and any other information about the analyzer in use and maintenance.

#### 8.4.1.2. Malfunction at the Time of Operation

If the analyzer cannot be activated, follow the procedures shown below:

1. Check that the main switch located on the left hand side of the analyzer is at "ON" position.
2. Check that the main fuses are not burnt.
3. When the main fuses are checked, turn the main switch off without fail and then pull out the plug of power supply cable from its receptacle on the analyzer. Open up the fuse cover and pull the fuses out.
4. Check that the circuit breaker of the power supply system to which the analyzer is connected is not cut off.



#### 8.4.1.3. Anomalous Measurement Results

There may be two cases that analytical errors are noticed, by error flag or unexpected results. In the following cases, troubleshooting is requested.

1. Error flag is set to the calibration results.
2. Error flag is set to the measurement results of QC sample or normal sample.
3. The measurement results of QC sample are out of range of judgment criteria. Investigate which situation shown below is applicable to the error in the measurement results of calibration, QC sample or normal sample. Based on the investigation, further check may be requested.
4. The resultant values obtained from measurements of a specific method are high for all samples.
5. The resultant values obtained from measurements of a specific method are low for all samples.
6. Erroneous results are randomly derived from the measurement.
7. Two or more anomalous measurement results are observed:
  - a. From all methods,
  - b. Or randomly.

#### **8.4.1.4. Check for Preparation of Reagent, Calibrator or QC Sample**

Perform the following checks in order to track down the cause for high, low or random resultant measurement results. When a reagent, calibrator or QC sample is prepared, read the respective statement of virtues carefully and follow its instruction.

1. Preparation of reagent.
  - a. Was there any change of the reagent?
  - b. Is the term of validity of the prepared reagent still valid?
  - c. Was the reagent prepared according to the correct procedures?
  - d. Was the reagent prepared using fresh, non-bacteria contaminated and DI water or appropriate diluent?
2. Preparation of QC sample.
  - a. Was the volume used for preparation correct?
  - b. Was the sample preserved as recommended?
  - c. Is the term of validity of the sample still valid?
  - d. Was the sample prepared using a pipette calibrated in terms of volume?
  - e. Is the term of validity of the sample lot still valid?
  - f. Was the sample prepared using appropriate diluent?
3. Preparation of calibrator.
  - a. Was there any change of the lot number?
  - b. Was the calibrator prepared using volume correctly?
  - c. Was the calibrator preserved as recommended?
  - d. Is the term of validity of the calibrator still valid?
  - e. Was the calibrator prepared using a pipette calibrated in terms of volume?
  - f. Was the calibrator prepared using appropriate diluent?

Further checks are requested to track down the cause referring to the following lists after the above checks have been completed.

#### 8.4.1.5. High Resultant Values from a Specific Method for all Samples

Serial Number	Cause	Corrective action
1	Incorrect calibration results.	<ul style="list-style-type: none"> <li>Check the preparation of the calibrator.</li> <li>Check that the calibration settings are correct.</li> <li>The calibration is performed again if necessary.</li> </ul>
2	Too high inside temperature of RCT unit.	<ul style="list-style-type: none"> <li>Check the temperature shown in Service Check &gt; Temperature &gt; Read.</li> <li>Call for service at our customer service department when the indicated temperature deviates from the specified value of <math>37 \pm 0.2^\circ\text{C}</math>.</li> </ul>
3	Improper preparation of reagent.	Check the preparation of the reagent.
4	Improper preparation of calibrator.	Check the preparation of the calibrator.

#### 8.4.1.6. Low Resultant Values from a Specific Method for all Samples

Serial Number	Cause	Corrective action
1	Expiration of the term of validity of reagent.	<ul style="list-style-type: none"> <li>See the statement of virtues that comes together with the reagent kit for its stability.</li> </ul>
2	Improper preparation of reagent.	<ul style="list-style-type: none"> <li>Check the preparation of the reagent.</li> </ul>
3	Improper preservation of reagent.	See the statement of virtues that comes together with the reagent kit for its proper preservation method.
4	Too low inside temperature of RCT unit.	<ul style="list-style-type: none"> <li>Check the temperature shown in Service Check &gt; Temperature &gt; Read.</li> <li>Call for service at our customer service department when the indicated temperature deviates from the specified value of <math>37 \pm 0.2^\circ\text{C}</math>.</li> </ul>
5	Improper preparation of calibrator.	Check the preparation of the calibrator.
6	Excessive volume of reagent dispensed.	Check if there is any leakage or drip at junction of reagent sampling system.

#### 8.4.1.7. Randomly Derived Erroneous Measurement Results

Serial Number	Cause	Corrective action
1	Fibrin clots formed on specific sample tube or sample cup.	Clean the SPT nozzle.
2	Insufficient water or solution supply from respective external tank.	Check if the tip of water or solution tube is positioned below the water or solution level. Call for service at our customer service department in case of trouble.
3	Insufficient stirring.	Check if the stirrer rotates in the center of cuvette and at the correct speed.

#### 8.4.1.8. Anomalous Resultant Values from all Methods for a Sample

Serial Number	Cause	Corrective action
1	Improper preparation of reagent.	Prepare newly the reagent referring to the statement of virtues that comes together with the reagent kit.
2	Expiration of term of validity, contamination or paleness of reagent.	Newly prepare the reagent referring to the statement of virtues that comes together with the reagent kit.

### 8.4.2. Equipment Malfunction

It may be difficult for the user to deal with the problem, the troubleshooting of which is beyond the scope of user. In such a case, call for service at our customer service department.

#### 8.4.2.1. Detection of mechanical problem

All the mechanical movements are controlled and monitored by the computer. When a problem arises, the computer becomes aware of it and generates the visual error message to call the operator's attention.

In the event of the problem that may affect the performance of the analyzer, the sampling stop or emergency stop will be executed. In the case of sampling stop mode, the analyzer carries on and completes the processing of the sample that is not affected by the problem. In the case of problem that may affect the entire measurements of sample, the emergency stop will be executed.

The **Report > Error Log** screen can be used to view all the errors occurred on the analyzer during the test run or service check. This data is generally useful for servicing/diagnostic purposes.

The period of Error List can be selected using From and To Date Calendar. For further details see section 8.4.2.3 *Error Log*.

Remedial actions for all error conditions are given below in section 8.4.2.2 *Error Messages for each unit*.



**NOTE: When user clicks on Start Run button on Status Monitor, if any error is detected during initialization of the instrument then the error message will be displayed in the error grid on the Screen. In such case, the instruments will stop. The user has to take the corrective action.**

Problem may arise, which is not monitored by the computer. An alarm message may not be indicated on the display for such a problem. Such a problem includes abrasion of parts, leakage in the sampling system, etc. When this type of problem occurs, decide whether the processing of sample is carried on or the measurement is terminated, considering that such problem may result in damage to the analyzer or erroneous outcome of measurements.

#### 8.4.2.2. Error messages for each unit

Assembly	Error code	Flags	Error Description	Possible Failures	Corrective Action to be Taken
Arm	11	@R1	Arm Rotational error - Trough to Reagent 1 position	1. Sample position Opto signal	1. Switch OFF the analyzer; Rotate arm by hand and make sure that nothing is obstructing Arm rotation.
				2. Interface board and its connectors	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to reagent inner> Execute commands.
				3. Up/Down and rotation stepper motor and its connection	3. If the initialization or rotation fails, call Service Engineer.
Arm	12	@R1	Arm Rotational error - Reagent 1 position to Trough	1. Sample position Opto signal	1. Switch OFF the analyzer; Rotate arm by hand and make sure that nothing is obstructing Arm rotation.
				2. Interface board and its connectors	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to reagent inner> <Reagent outer/inner to trough> Execute commands.
				3. Up/Down and rotation stepper motor and its connection	3. If the initialization or rotation fails, call Service Engineer.
					4. If the initialization or VOD generation fails, call the Service Engineer.
Arm	13		Arm VOD error	1. VOD Opto Sensor	1. Check the arm alignment in [Service Check]. If it is

					hitting at the edge, then align the probe using the calibration facility.
			(During service check)	2. The connectors	2. Remove the cover of the arm and check and clean the VOD opto.
				3. Sample arm position in Trough during Reagent 1 operation	3. Go to Service Check: Arm Menu. Click on <Initialize> button. Push the probe gently to cut the VOD opto so as to generate a VOD Error will be generated and Arm initializes.  4. If the initialization or VOD generation fails, call the Service Engineer
Arm	14	@R1	Arm Up error - Trough during reagent 1 operation	1. Arm VOD opto, arm position optos, up/down optos and rotation optos  2. Probe assembly	1. Switch OFF the analyzer; Move SPT arm up and down by hand and make sure that nothing is obstructing SPT movement  2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm Down in Trough> Execute commands
				3. Interface card and its connector	3. If the initialization or up/down movement fails, call Service Engineer
				4. Up/down and rotation stepper motor and its connections	4 . If the initialization or rotation fails, call Service Engineer
Arm	15	@R1	Arm Down error - Reagent 1 position	1. Arm VOD opto & arm optos  2. Interface card and its connector  3. Probe goes down but doesn't find LLS signal due to problem in LLS card or its connector  4. Probe assembly	1. Switch OFF and then switch ON the instrument. Check if the error comes again  2. Remove the cover of the sample arm and check and clean obstacle opto  3. Check the Arm assembly  4. If still it is giving error, call Service Engineer
Arm	16	@R1	Arm Up error - Reagent 1 position	1. Arm VOD opto, arm position optos, up/down	1. Switch OFF the analyzer; Move SPT arm up and down by hand and make

				optos and rotation optos	sure that nothing is obstructing SPT movement
				2. Probe assembly	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to Reagent outer> Execute <Arm Down> Execute <Arm Up> Execute commands
				3. Interface card and its connector	3. If the initialization or up/down movement fails, call Service Engineer
				4. Up/down and rotation stepper motor and its connections	4. If the initialization or rotation fails, call Service Engineer
Arm	17		Arm rotation error	1. Arm position Opto signal	1. Switch OFF the analyzer; Rotate arm by hand and make sure that nothing is obstructing Arm rotation
			(During service check)	2. Interface board and its connectors	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to sample outer> Execute <Sample Outer to R1 Cuvette> Execute <R1 Cuvette to Trough> Execute commands
				3. Up/Down and rotation stepper motor and its connection	3. If the initialization or rotation fails, call Service Engineer
Arm	18		Arm up/down error (During service check)	1. Arm VOD opto, arm position optos, up/down optos and rotation optos	1. Switch OFF the analyzer; Move arm up and down by hand and make sure that nothing is obstructing Arm movement
				2. Probe assembly	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm Down in Trough> Execute <Arm Up> Execute commands
				3. Interface card and its connector	3. If the initialization or up/down movement fails, call Service Engineer
				4. Up/down and rotation stepper motor and its connections	

Arm	19	@R1	Arm Down error - Trough during reagent 1 operation	1. Arm VOD opto & arm optos	1. Switch OFF and then switch ON the instrument. Check if the error comes again
				2. Interface card and its connector	2. Remove the cover of the sample arm and check and clean obstacle opto
				3. Probe goes down but doesn't find LLS signal due to problem in LLS card or its connector	3. Check the Arm assembly
				4. Probe assembly	4. If still it is giving error, call Service Engineer
Arm	1A	!R1	Arm VOD error - Reagent Pos.	1. VOD Opto Sensor	1. Check the arm alignment in [Service Check]. If it is hitting at the edge, then align the probe using the calibrate facility.
				2. The connectors	2. Remove the cover of the arm and check and clean VOD opto
				3. Arm position in Reagent tray at R1 position	3. Go to Service Check: Arm Menu. Click on <Initialize> button. Push the probe gently to cut the VOD opto so that VOD Error will be generated and Arm initializes.
					4. If the initialization or VOD generation fails, call the Service Engineer
Arm	1A	!D	Arm VOD error - Diluent Pos.	1. VOD Opto Sensor	1. Check the arm alignment in [Service Check]. If it is hitting at the edge, then align the probe using the calibrate facility.
				2. The connectors	2. Remove the cover of the arm and check and clean VOD opto
				3. Arm position in Reagent tray at Diluent position	3. Go to Service Check: Arm Menu. Click on <Initialize> button. Push the probe gently to cut the VOD opto so that VOD Error will be generated and Arm initializes.
					4. If the initialization or VOD generation fails, call the Service Engineer
Arm	1B	R1**	R1 Liquid Level found	1. Liquid Level Detector	Call the Service Engineer

			different at Pos.		
Arm	1C	!R1!	Arm VOD error - Trough during Reagent 1 operation	1. VOD Opto Sensor	1. Check the arm alignment in [Service Check]. If it is hitting at the edge, then align the probe using the calibrate facility.
				2. The connectors	2. Remove the cover of the arm and check and clean VOD opto
				3. Sample arm position in Trough during Reagent 1 operation	3. Go to Service Check: Arm Menu. Click on <Initialize> button. Push the probe gently to cut the VOD opto so that VOD Error will be generated and Arm initializes.
					4. If the initialization or VOD generation fails, call the Service Engineer
Arm	1C	!D!	Arm VOD error – Dilution pos.	1. VOD Opto Sensor	1. Check the arm alignment in [Service Check]. If it is hitting at the edge, then align the probe using the calibrate facility.
				2. The connectors	2. Remove the cover of the arm and check and clean VOD opto
				3. Sample arm position in Trough during Reagent 1 operation	3. Go to Service Check: Arm Menu. Click on <Initialize> button. Push the probe gently to cut the VOD opto so that VOD Error will be generated and Arm initializes.
					4. If the initialization or VOD generation fails, call the Service Engineer
Arm	1D	R1*	Reagent 1 absent - Pos.	1. Reagent is not kept in the reagent bottle or reagent bottle not kept at the defined position	1. Place the reagent at the required reagent position
				2. Reagent is below the Dead volume	2. Check the level of Reagent and ensure that it is above the Dead volume
				3. Arm position in reagent tray	3. Call Service Engineer
				4. LLS circuit and its connector problem	

Arm	1D	D*	Diluent absent - Pos.	1. Reagent is not kept in the reagent bottle or reagent bottle not kept at the defined position	1. Place the reagent at the required reagent position
				2. Reagent is below the Dead volume	2. Check the level of Reagent and ensure that it is above the Dead volume
				3. Arm position in reagent tray	3. Call Service Engineer
				4. LLS circuit and its connector problem	
Arm	1E	@R1	Arm Initialize Rotational error	1. Sample position Opto signal	1. Switch OFF the analyzer; Rotate arm by hand and make sure that nothing is obstructing Arm rotation
				2. Interface board and its connectors	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> command
				3. Up/Down and rotation stepper motor and its connection	3. If the initialization fails, call Service Engineer
Arm	1F	@R1	Arm Initialize Up/Down error	1. Arm VOD opto, arm position optos, up/down optos and rotation optos	1. Switch OFF the analyzer; Move SPT arm up and down by hand and make sure that nothing is obstructing SPT movement
				2. Probe assembly	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm Down in Trough> Execute commands
				3. Interface card and its connector	3. If the initialization or up/down movement fails, call Service Engineer
				4. Up/down and rotation stepper motor and its connections	
Arm	BB	!S	Arm VOD error at ISE unit	1. Arm VOD opto, arm position optos, up/down optos and rotation optos	1. Switch OFF and then switch ON the instrument. Check if the error comes again
				2. Probe assembly	2. Remove the cover of the sample arm and check and clean obstacle opto

				3. Interface card and its connector	3. Check the Arm assembly
				4. Probe assembly	4. If still it is giving error, call Service Engineer
Arm	21	@R2	Arm Rotational error - Trough to Reagent 2 position	1. Sample position Opto signal	1. Switch OFF the analyzer; Rotate arm by hand and make sure that nothing is obstructing Arm rotation
				2. Interface board and its connectors	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to reagent outer> Execute commands
				3. Up/Down and rotation stepper motor and its connection	3. If the initialization or rotation fails, call Service Engineer
Arm	22	@R2	Arm Rotational error - Reagent 2 position to R2 Cuvette	1. Sample position Opto signal	1. Switch OFF the analyzer; Rotate arm by hand and make sure that nothing is obstructing Arm rotation
				2. Interface board and its connectors	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to reagent outer> Execute <Reagent outer/inner to R2 cuvette> Execute commands
				3. Up/Down and rotation stepper motor and its connection	3. If the initialization or rotation fails, call Service Engineer
Arm	23	@R2	Arm Rotational error - R2 Cuvette to Trough	1. Sample position Opto signal	1. Switch OFF the analyzer; Rotate arm by hand and make sure that nothing is obstructing Arm rotation
				2. Interface board and its connectors	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to reagent outer> Execute <Reagent outer/inner to R2 cuvette> Execute commands
				3. Up/Down and rotation stepper motor and its connection	3. If the initialization or rotation fails, call Service Engineer

Arm	24	@R2	Arm Up error - Trough during Reagent 2 operation	1. Arm VOD opto, arm position optos, up/down optos and rotation optos	1. Switch OFF the analyzer; Move SPT arm up and down by hand and make sure that nothing is obstructing SPT movement
				2. Probe assembly	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm Down in Trough> Execute commands
				3. Interface card and its connector	3. If the initialization or up/down movement fails, call Service Engineer
				4. Up/down and rotation stepper motor and its connections	
Arm	25	@R2	Arm Down error - Reagent 2 position	1. Arm VOD opto & arm optos	1. Switch OFF and then switch ON the instrument. Check if the error comes again
				2. Interface card and its connector	2. Remove the cover of the sample arm and check and clean obstacle opto
				3. Probe goes down but doesn't find LLS signal due to problem in LLS card or its connector	3. Check the Arm assembly
				4. Probe assembly	4. If still it is giving error, call Service Engineer
Arm	26	@R2	Arm Up error - Reagent 2 position	1. ARM up/down opto, ARM position opto, ARM Home opto, ARM direction opto	1. Switch OFF the analyzer; Move SPT arm up and down by hand and make sure that nothing is obstructing SPT movement
				2. Arm assembly opto connector(FRC)	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to Reagent outer> Execute <Arm Down> Execute <Arm Up> Execute commands
				3. Interface card and its connector	3. If the initialization or up/down movement fails, call Service Engineer
				4. Up/down and rotation stepper	

				motor and its connections	
Arm	27	@R2	Arm Down error - Cuvette during Reagent 2 operation	1. Arm VOD opto & arm optos	1. Switch OFF and then switch ON the instrument. Check if the error comes again
				2. Interface card and its connector	2. Remove the cover of the sample arm and check and clean obstacle opto
				3. Probe goes down but doesn't find LLS signal due to problem in LLS card or its connector	3. Check the Arm assembly
				4. Probe assembly	4. If still it is giving error, call Service Engineer
Arm	28	@R2	Arm Up error - R2 Cuvette	1. Arm VOD opto, arm position optos, up/down optos and rotation optos	1. Switch OFF the analyzer; Move SPT arm up and down by hand and make sure that nothing is obstructing SPT movement
				2. Probe assembly	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Trough to R2 cuvette> Execute <Arm Down> Execute <Arm Up> Execute commands
				3. Interface card and its connector	3. If the initialization or up/down movement fails, call Service Engineer
				4. Up/down and rotation stepper motor and its connections	
Arm	29	@R2	Arm Down error - Trough during Reagent 2 operation	1. Arm VOD opto & arm optos	1. Switch OFF and then switch ON the instrument. Check if the error comes again
				2. Interface card and its connector	2. Remove the cover of the sample arm and check and clean obstacle opto
				3. Probe goes down but doesn't find LLS signal due to problem in LLS card or its connector	3. Check the Arm assembly
				4. Probe assembly	4. If still it is giving error, call Service Engineer

Arm	2A	!R2	Arm VOD error – Reagent Pos.	1. VOD Opto Sensor	1. Check the arm alignment in [Service Check]. If it is hitting at the edge, then align the probe using the calibrate facility.
				2. The connectors	2. Remove the cover of the arm and check and clean VOD opto
				3. Sample arm position in Reagent tray at R2 position	3. Go to Service Check: Arm Menu. Click on <Initialize> button. Push the probe gently to cut the VOD opto so that VOD Error will be generated and Arm initializes.
					4. If the initialization or VOD generation fails, call the Service Engineer
Arm	2B	R2!	Arm VOD error - Cuvette during Reagent 2 operation	1. VOD Opto Sensor	1. Check the arm alignment in [Service Check]. If it is hitting at the edge, then align the probe using the calibration facility.
				2. The connectors	2. Remove the cover of the arm and check and clean VOD opto
				3. Sample arm position in Cuvette during Reagent 2 operation	3. Go to Service Check: Arm Menu. Click on <Initialize> button. Push the probe gently to cut the VOD opto so that VOD Error will be generated and Arm initializes.
					4. If the initialization or VOD generation fails, call the Service Engineer
Arm	2C	!R2!	Arm VOD error - Trough during Reagent 2 operation	1. VOD Opto Sensor	1. Check the arm alignment in [Service Check]. If it is hitting at the edge, then align the probe using the calibration facility.
				2. The connectors	2. Remove the cover of the arm and check and clean VOD opto
				3. Sample arm position in Trough during Reagent 2 operation	3. Go to Service Check: Arm Menu. Click on <Initialize> button. Push the probe gently to cut the VOD opto so that VOD Error will be generated and Arm initializes.
					4. If the initialization or VOD generation fails, call the Service Engineer

Arm	2D	R2*	Reagent absent – Pos.	1. Reagent is not kept in the reagent bottle or reagent bottle not kept at the defined position	1. Place the reagent at the required reagent position
				2. Reagent is below the Dead volume	2. Check the level of Reagent and ensure that it is above the Dead volume
				3. Arm position in reagent tray	3. Call Service Engineer
				4. LLS circuit and its connector problem	
Arm	2E	R2**	R2 Liquid Level found different at Pos.	1. Liquid Level Detector	Call the Service Engineer
Arm	1F/2F/3F	@R2	Arm Initialize Up/Down error	1. Arm VOD opto, arm position optos, up/down optos and rotation optos	1. Switch OFF the analyzer; Move SPT arm up and down by hand and make sure that nothing is obstructing SPT movement
				2. Probe assembly	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm Down in Trough> Execute commands.
				3. Interface card and its connector	3. If the initialization or up/down movement fails, call Service Engineer
				4. Up/down and rotation stepper motor and its connections	
Arm	31	@S	Arm Rotational error - Trough to Sample	1. Sample position Opto signal	1. Switch OFF the analyzer; Rotate arm by hand and make sure that nothing is obstructing Arm rotation
				2. Interface board and its connectors	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to sample outer> Execute commands
				3. Up/Down and rotation stepper motor and its connection	3. If the initialization or rotation fails, call Service Engineer

Arm	3A6/3A 7	!DILN	Arm Rotational Error - Trough to Dilution Cuvette	1. Sample position Opto signal	1. Switch OFF the analyzer; Rotate arm by hand and make sure that nothing is obstructing Arm rotation
				2. Interface board and its connectors	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to reagent outer> Execute commands
				3. Up/Down and rotation stepper motor and its connection	3. If the initialization or rotation fails, call Service Engineer
Arm	32	@S	Arm Rotational error - Sample to Cuvette	1. Sample position Opto signal	1. Switch OFF the analyzer; Rotate arm by hand and make sure that nothing is obstructing Arm rotation
				2. Interface board and its connectors	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to sample outer> Execute <Sample Outer to R1 Cuvette> Execute commands
				3. Up/Down and rotation stepper motor and its connection	3. If the initialization or rotation fails, call Service Engineer
Arm	320/321 /322	@S	Arm Rotational Error - Sample to Cuvette	1. Sample position Opto signal	1. Switch OFF the analyzer; Rotate arm by hand and make sure that nothing is obstructing Arm rotation
				2. Interface board and its connectors	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to reagent outer> Execute commands
				3. Up/Down and rotation stepper motor and its connection	3. If the initialization or rotation fails, call Service Engineer
Arm	323/324 /325	@S	Arm Rotational Error - Sample to ISE	1. Sample position Opto signal	1. Switch OFF the analyzer; Rotate arm by hand and make sure that nothing is obstructing Arm rotation
				2. Interface board and its connectors	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give

					<Initialize> and <Arm Up> Execute <Arm trough to reagent outer> Execute commands
				3. Up/Down and rotation stepper motor and its connection	3. If the initialization or rotation fails, call Service Engineer
Arm	326	@S	Arm Rotational Error - Dilution Cuvette to Cuvette	1. Sample position Opto signal	1. Switch OFF the analyzer; Rotate arm by hand and make sure that nothing is obstructing Arm rotation
				2. Interface board and its connectors	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to reagent outer> Execute commands
				3. Up/Down and rotation stepper motor and its connection	3. If the initialization or rotation fails, call Service Engineer
Arm	327	@S	Arm Rotational Error - Dilution Cuvette to ISE	1. Sample position Opto signal	1. Switch OFF the analyzer; Rotate arm by hand and make sure that nothing is obstructing Arm rotation
				2. Interface board and its connectors	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to reagent outer> Execute commands
				3. Up/Down and rotation stepper motor and its connection	3. If the initialization or rotation fails, call Service Engineer
Arm	328		Arm Rotational error - Reagent 1 position to Cuvette	1. Sample position Opto signal	1. Switch OFF the analyzer; Rotate arm by hand and make sure that nothing is obstructing Arm rotation
				2. Interface board and its connectors	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to reagent outer> Execute commands
				3. Up/Down and rotation stepper motor and its connection	3. If the initialization or rotation fails, call Service Engineer

Arm	33	@S	Arm Rotational error - Cuvette to Trough	1. Sample position Opto signal	1. Switch OFF the analyzer; Rotate arm by hand and make sure that nothing is obstructing Arm rotation
				2. Interface board and its connectors	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to sample outer> Execute <Sample Outer to R1 Cuvette> Execute <R1 Cuvette to Trough> Execute commands
				3. Up/Down and rotation stepper motor and its connection	3. If the initialization or rotation fails, call Service Engineer
Arm	330/331 /332	@S	Arm Rotational Error - Cuvette to Trough	1. Sample position Opto or Home opto signal	1. Switch OFF the analyzer; Rotate arm by hand and make sure that nothing is obstructing Arm rotation
				2. Interface board and its connectors	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to sample outer> Execute <Sample Outer to R1 Cuvette> Execute <R1 Cuvette to Trough> Execute commands
				3. Up/Down and rotation stepper motor and its connection	3. If the initialization or rotation fails, call Service Engineer
Arm	333/334 /335	@S	Arm Rotational Error - ISE to Trough	1. Sample position Opto or Home opto signal	1. Switch OFF the analyzer; Rotate arm by hand and make sure that nothing is obstructing Arm rotation
				2. Interface board and its connectors	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to sample outer> Execute <Sample Outer to R1 Cuvette> Execute <R1 Cuvette to Trough> Execute commands
				3. Up/Down and rotation stepper motor and its connection	3. If the initialization or rotation fails, call Service Engineer

Arm	336	@S	Arm Rotational Error - Cuvette to Trough	1. Sample position Opto or Home opto signal	1. Switch OFF the analyzer; Rotate arm by hand and make sure that nothing is obstructing Arm rotation
				2. Interface board and its connectors	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to sample outer> Execute <Sample Outer to R1 Cuvette> Execute <R1 Cuvette to Trough> Execute commands
				3. Up/Down and rotation stepper motor and its connection	3. If the initialization or rotation fails, call Service Engineer
Arm	337	@S	Arm Rotational Error - ISE to Trough	1. Sample position Opto or Home opto signal	1. Switch OFF the analyzer; Rotate arm by hand and make sure that nothing is obstructing Arm rotation
				2. Interface board and its connectors	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to sample outer> Execute <Sample Outer to R1 Cuvette> Execute <R1 Cuvette to Trough> Execute commands
				3. Up/Down and rotation stepper motor and its connection	3. If the initialization or rotation fails, call Service Engineer
Arm	338		Arm Rotational error - Cuvette to Trough	1. Sample position Opto or Home opto signal	1. Switch OFF the analyzer; Rotate arm by hand and make sure that nothing is obstructing Arm rotation
				2. Interface board and its connectors	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to sample outer> Execute <Sample Outer to R1 Cuvette> Execute <R1 Cuvette to Trough> Execute commands
				3. Up/Down and rotation stepper motor and its connection	3. If the initialization or rotation fails, call Service Engineer

Arm	34	@S	Arm Up error - Trough during sample operation	1. Arm VOD opto, arm position optos, up/down optos and rotation optos	1. Switch OFF the analyzer; Move arm up and down by hand and make sure that nothing is obstructing Arm movement
				2. Probe assembly	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm Down in Trough> Execute <Arm Up> Execute commands
				3. Interface card and its connector	3. If the initialization or up/down movement fails, call Service Engineer
				4. Up/down and rotation stepper motor and its connections	
Arm	356/357	@S	Arm Down Error - Dilution Cuvette	1. Sample position Opto signal	1. Switch OFF the analyzer; Rotate arm by hand and make sure that nothing is obstructing Arm rotation
				2. Interface board and its connectors	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to reagent outer> Execute commands
				3. Up/Down and rotation stepper motor and its connection	3. If the initialization or rotation fails, call Service Engineer
Arm	35	@S	Arm Down error - Sample position	1. Arm VOD opto & arm optos	1. Switch OFF and then switch ON
				2. Interface card and its connector	Check the instrument. Check if the error comes again
				3. Probe goes down but doesn't find LLS signal due to problem in LLS card or its connector	2. Remove the cover of the sample arm and check and clean obstacle opto
				4. Probe assembly	3. Check the Arm assembly
					4. Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up>

					Execute <Arm trough to Sample outer> Execute <Arm Down> Execute commands
					5. If still it is giving error, call Service Engineer
Arm	36	@S	Arm Up error - Sample position	1. Arm VOD opto, arm position optos, up/down optos and rotation optos	1. Switch OFF the analyzer; Move SPT arm up and down by hand and make sure that nothing is obstructing SPT movement
				2. Probe assembly	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to Sample outer> Execute <Arm Down> Execute <Arm Up> Execute commands
				3. Interface card and its connector	3. If the initialization or up/down movement fails, call Service Engineer
				4. Up/down and rotation stepper motor and its connections	
Arm	366/367	@S	Arm Up Error - Dilution Cuvette	1. ARM up/down opto,ARM position opto ,ARM Home opto ,ARM direction opto	1. Switch OFF the analyzer; Move SPT arm up and down by hand and make sure that nothing is obstructing SPT movement
				2. Arm assembly opto connector(FRC)	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to Reagent outer> Execute <Arm Down> Execute <Arm Up> Execute commands
				3. Interface card and its connector	3. If the initialization or up/down movement fails, call Service Engineer
				4. Up/down and rotation stepper motor and its connections	
Arm	37	@S	Arm Down error - Sample Cuvette	1. Arm VOD opto & arm optos	1. Switch OFF and then switch ON the instrument. Check if the error comes again
				2. Interface card and its connector	2. Remove the cover of the sample arm and check and

					clean obstacle opto
				3. Probe goes down but doesn't find LLS signal due to problem in LLS card or its connector	3. Check the Arm assembly
				4. Probe assembly	4. If still it is giving error, call Service Engineer
Arm	370/371 /372	@S	Arm Down Error - Cuvette	1.ARM up/down opto,ARM position opto ,ARM Home opto ,ARM direction opto	1. Switch OFF the analyzer; Move SPT arm up and down by hand and make sure that nothing is obstructing SPT movement
				2. Arm assembly opto connector(FRC)	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to Reagent outer> Execute <Arm Down> Execute <Arm Up> Execute commands
				3. Interface card and its connector	3. If the initialization or up/down movement fails, call Service Engineer
				4. Up/down and rotation stepper motor and its connections	
Arm	373/374 /375	@S	Arm Down Error - ISE	1.ARM up/down opto, ARM position opto, ARM Home opto, ARM direction opto	1. Switch OFF the analyzer; Move SPT arm up and down by hand and make sure that nothing is obstructing SPT movement
				2. Arm assembly opto connector(FRC)	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to Reagent outer> Execute <Arm Down> Execute <Arm Up> Execute commands
				3. Interface card and its connector	3. If the initialization or up/down movement fails, call Service Engineer
				4. Up/down and rotation stepper motor and its connections	

Arm	376	@S	Arm Down Error - Cuvette	1.ARM up/down opto,ARM position opto ,ARM Home opto ,ARM direction opto	1. Switch OFF the analyzer; Move SPT arm up and down by hand and make sure that nothing is obstructing SPT movement
				2. Arm assembly opto connector(FRC)	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to Reagent outer> Execute <Arm Down> Execute <Arm Up> Execute commands
				3. Interface card and its connector	3. If the initialization or up/down movement fails, call Service Engineer
				4. Up/down and rotation stepper motor and its connections	
Arm	377	@S	Arm Down Error - ISE	1.ARM up/down opto,ARM position opto ,ARM Home opto ,ARM direction opto	1. Switch OFF the analyzer; Move SPT arm up and down by hand and make sure that nothing is obstructing SPT movement
				2. Arm assembly opto connector(FRC)	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to Reagent outer> Execute <Arm Down> Execute <Arm Up> Execute commands
				3. Interface card and its connector	3. If the initialization or up/down movement fails, call Service Engineer
				4. Up/down and rotation stepper motor and its connections	
Arm	378		Arm Down Error - Cuvette	1.ARM up/down opto,ARM position opto ,ARM Home opto ,ARM direction opto	1. Switch OFF the analyzer; Move SPT arm up and down by hand and make sure that nothing is obstructing SPT movement
				2. Arm assembly opto connector (FRC)	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to Reagent outer> Execute <Arm Down> Execute <Arm Up> Execute

					commands
				3. Interface card and its connector	3. If the initialization or up/down movement fails, call Service Engineer
				4. Up/down and rotation stepper motor and its connections	
Arm	38	@S	Arm Up error - Sample Cuvette	1. Arm VOD opto, arm position optos, up/down optos and rotation optos	1. Switch OFF the analyzer; Move SPT arm up and down by hand and make sure that nothing is obstructing SPT movement
				2. Probe assembly	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to Sample outer> Execute <Sample outer to R1 cuvette> Execute <Arm Down in R1 cuvette> Execute <Arm Up> Execute commands
				3. Interface card and its connector	3. If the initialization or up/down movement fails, call Service Engineer
				4. Up/down and rotation stepper motor and its connections	
Arm	380/381 /382/ 386/388	@S	Arm Up Error - Cuvette	1.ARM up/down opto,ARM position opto ,ARM Home opto ,ARM direction opto	1. Switch OFF the analyzer; Move SPT arm up and down by hand and make sure that nothing is obstructing SPT movement
				2. Arm assembly opto connector(FRC)	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to Reagent outer> Execute <Arm Down> Execute <Arm Up> Execute commands
				3. Interface card and its connector	3. If the initialization or up/down movement fails, call Service Engineer
				4. Up/down and rotation stepper motor and its connections	

Arm	383/384 /385 /387	@S	Arm Up Error - ISE	1.ARM up/down opto,ARM position opto ,ARM Home opto ,ARM direction opto	1. Switch OFF the analyzer; Move SPT arm up and down by hand and make sure that nothing is obstructing SPT movement
				2. Arm assembly opto connector(FRC)	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to Reagent outer> Execute <Arm Down> Execute <Arm Up> Execute commands
				3. Interface card and its connector	3. If the initialization or up/down movement fails, call Service Engineer
				4. Up/down and rotation stepper motor and its connections	
Arm	39	@S	Arm Down error - Trough during sample operation	1. Arm VOD opto & arm optos	1. Switch OFF and then switch ON the instrument. Check if the error comes again
				2. Interface card and its connector	2. Remove the cover of the sample arm and check and clean obstacle opto
				3. Probe goes down but doesn't find LLS signal due to problem in LLS card or its connector	3. Check the Arm assembly
				4. Probe assembly	4. If still it is giving error, call Service Engineer
Arm	398		Arm Down error - Trough during Cuvette wash	1.ARM up/down opto,ARM position opto ,ARM Home opto ,ARM direction opto	1. Switch OFF the analyzer; Move SPT arm up and down by hand and make sure that nothing is obstructing SPT movement
				2. Arm assembly opto connector(FRC)	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm trough to Reagent outer> Execute <Arm Down> Execute <Arm Up> Execute commands
				3. Interface card and its connector	3. If the initialization or up/down movement fails, call Service Engineer

				4. Up/down and rotation stepper motor and its connections	
Arm	3A	!S	Arm VOD error - Sample Pos.	1. VOD Opto Sensor	1. Check whether the selected option is tube and instead of tube a cup is placed
				2. The connectors	2. Check the Arm alignment in [Service Check]. If it is hitting at the edge, then align the probe using the calibrate facility.
				3. Sample arm position in Sample tray	3. Remove the cover of the sample arm and check and clean VOD opto
					4. Go to Service Check: Arm Menu. Click on <Initialize> button. Push the Probe gently to cut the VOD opto so that VOD Error will be generated and Arm initializes.
					5. If the initialization or VOD generation fails, call the Service Engineer
Arm	3A6/ 3A7	!DILN	Arm VOD error - Dilution Cuvette.	1. VOD Opto Sensor	1. Check the Arm alignment in [Service Check]. If it is hitting at the edge, then align the probe using the calibrate facility.
				2. The connectors	2. Remove the cover of the arm and check and clean VOD opto
				3. Sample arm position in Dilution cuvette	3. Go to Service Check: Arm Menu. Click on <Initialize> button. Push the probe gently to cut the VOD opto so that VOD Error will be generated and Arm initializes.
					4. If the initialization or VOD generation fails, call the Service Engineer
Arm	3B	S!	Arm VOD error - During Sample dispense	1. VOD Opto Sensor	1. Check the arm alignment in [Service Check]. If it is hitting at the edge, then align the probe using the calibrate facility.
				2. The connectors	2. Remove the cover of the arm and check and clean VOD opto

				3. Sample arm position in Dispense cuvette	3. Go to Service Check: Arm Menu. Click on <Initialize> button. Push the probe gently to cut the VOD opto so that VOD Error will be generated and Arm initializes.
					4. If the initialization or VOD generation fails, call the Service Engineer
Arm	3B	DILN!	Arm VOD error - During Diluted Sample dispense	1. VOD Opto Sensor	1. Check the arm alignment in [Service Check]. If it is hitting at the edge , then align the probe using the calibrate facility.
				2. The connectors	2. Remove the cover of the arm and check and clean VOD opto
				3. Sample arm position in Dispense cuvette during dilution	3. Go to Service Check: Arm Menu. Click on <Initialize> button. Push the probe gently to cut the VOD opto so that VOD Error will be generated and Arm initializes.
					4. If the initialization or VOD generation fails, call the Service Engineer
Arm	3B0/ 3B1/ 3B2/	!S	Arm VOD Error - Cuvette	1. VOD Opto Sensor	1. Check whether the selected option is tube and instead of tube a cup is placed
				2. The connectors	2. Check the Arm alignment in [Service Check]. If it is hitting at the edge, then align the probe using the calibrate facility.
				3. Sample arm position in Sample tray	3. Remove the cover of the sample arm and check and clean VOD opto
					4. Go to Service Check: Arm Menu. Click on <Initialize> button. Push the Probe gently to cut the VOD opto so that VOD Error will be generated and Arm initializes.
					5. If the initialization or VOD generation fails, call the Service Engineer
Arm	3B3/ 3B4/ 3B5/ 3B7	S!	Arm VOD Error - ISE	1. VOD Opto Sensor	1. Check whether the selected option is tube and instead of tube a cup is placed

				2. The connectors	2. Check the Arm alignment in [Service Check]. If it is hitting at the edge, then align the probe using the calibrate facility.
				3. Sample arm position in Sample tray	3. Remove the cover of the sample arm and check and clean VOD opto
					4. Go to Service Check: Arm Menu. Click on <Initialize> button. Push the Probe gently to cut the VOD opto so that VOD Error will be generated and Arm initializes.
					5. If the initialization or VOD generation fails, call the Service Engineer
Arm	3B6	!DILN	Arm VOD Error - Cuvette	1. VOD Opto Sensor	1. Check whether the selected option is tube and instead of tube a cup is placed
				2. The connectors	2. Check the Arm alignment in [Service Check]. If it is hitting at the edge, then align the probe using the calibrate facility.
				3. Sample arm position in cuvette during dilution	3. Remove the cover of the sample arm and check and clean VOD opto
					4. Go to Service Check: Arm Menu. Click on <Initialize> button. Push the Probe gently to cut the VOD opto so that VOD Error will be generated and Arm initializes.
					5. If the initialization or VOD generation fails, call the Service Engineer
Arm	3B8		Arm VOD Error - Cuvette during Cuvette wash	1. VOD Opto Sensor	1. Check whether the selected option is tube and instead of tube a cup is placed
				2. The connectors	2. Check the Arm alignment in [Service Check]. If it is hitting at the edge, then align the probe using the calibrate facility.
				3. Sample arm position in cuvette during cuvette wash	3. Remove the cover of the sample arm and check and clean VOD opto

					4. Go to Service Check: Arm Menu. Click on <Initialize> button. Push the Probe gently to cut the VOD opto so that VOD Error will be generated and Arm initializes.
					5. If the initialization or VOD generation fails, call the Service Engineer
Arm	3C	!S!	Arm VOD error - Trough during Sample operation	1. VOD Opto Sensor	1. Check the arm alignment in [Service Check]. If it is hitting at the edge, then align the probe using the calibrate facility.
				2. The connectors	2. Remove the cover of the arm and check and clean VOD opto
				3. Sample arm position in Trough during sample operation	3. Go to Service Check: Arm Menu. Click on <Initialize> button. Push the probe gently to cut the VOD opto so that VOD Error will be generated and Arm initializes.
					4. If the initialization or VOD generation fails, call the Service Engineer
Arm	3C	!DILN!	Arm VOD error - Trough during Sample Dilution operation	1. VOD Opto Sensor	1. Check the arm alignment in [Service Check]. If it is hitting at the edge, then align the probe using the calibrate facility.
				2. The connectors	2. Remove the cover of the arm and check and clean VOD opto
				3. Sample arm position in Trough during sample operation	3. Go to Service Check: Arm Menu. Click on <Initialize> button. Push the probe gently to cut the VOD opto so that VOD Error will be generated and Arm initializes.
					4. If the initialization or VOD generation fails, call the Service Engineer
Arm	3D	S*	Sample absent - Pos.	1. Sample is not kept in the sample tube / cup at that particular position	1. Place the sample at the required sample position
				2. Sample tube / cup absent at that particular position	2. Check the level of Sample and ensure that it is above the Dead volume

				3. LLS circuit and its connector problem	3. Call Service Engineer
				4. Sample is below the Dead volume	
				5. Arm position in sample tray	
Arm	3E	S**	Sample Liquid Level found different at Pos.	1. Liquid Level Detector	Call Service Engineer 1. The test of the Patient Sample will be added to Pending list.
Arm	3F	@S	Arm Initialize Up/Down error	1. Arm VOD opto, arm position optos, up/down optos and rotation optos	1. Switch OFF the analyzer; Move SPT arm up and down by hand and make sure that nothing is obstructing SPT movement
				2. Probe assembly	2. Then switch ON the instrument; Go to [Service Check: Arm] menu; Give <Initialize> and <Arm Up> Execute <Arm Down in Trough> Execute commands
				3. Interface card and its connector	3. If the initialization or up/down movement fails, call Service Engineer
				4. Up/down and rotation stepper motor and its connections	
Syringe	41		R1 Syringe Initialize error	1. Syringe position opto	1. Switch OFF the analyzer; Move the Syringe up and down by hand and make sure that nothing is obstructing the movement
				2. Interface card and its connector	2. Then switch ON the instrument; Go to [Service Check: Syringe]; Give <Initialize> and <Aspirate/Dispense> commands
				3. Syringe up/down motor	3. If the initialization or aspirate/dispense movement fails, call Service Engineer
Syringe	42	@R1	R1 Syringe Up/Down error	1. Syringe position opto	1. Switch OFF the analyzer; Move the Syringe up and down by hand and make sure that nothing is obstructing the movement

				2. Interface card and its connector	2. Then switch ON the instrument; Go to [Service Check: Syringe]; Give <Initialize> and <Aspirate/Dispense> commands
				3. Syringe up/down motor	3. If the initialization or aspirate/dispense movement fails, call Service Engineer
Syringe	52	@R2	R2 Syringe Up/Down error	1. Syringe position opto	1. Switch OFF the analyzer; Move the Syringe up and down by hand and make sure that nothing is obstructing the movement
				2. Interface card and its connector	2. Then switch ON the instrument; Go to [Service Check: Syringe]; Give <Initialize> and <Aspirate/Dispense> commands
				3. Syringe up/down motor	3. If the initialization or aspirate/dispense movement fails, call Service Engineer
Syringe	61	@SYR	Syringe Initialize error	1. Syringe position opto	1. Switch OFF the analyzer; Move the Syringe up and down by hand and make sure that nothing is obstructing the movement
				2. Interface card and its connector	2. Then switch ON the instrument; Go to [Service Check: Syringe]; Give <Initialize> and <Aspirate/Dispense> commands
				3. Syringe up/down motor	3. If the initialization or aspirate/dispense movement fails, call Service Engineer
Syringe	62		Sample Syringe Up/Down error	1. Syringe position opto	1. Switch OFF the analyzer; Move the Syringe up and down by hand and make sure that nothing is obstructing the movement
				2. Interface card and its connector	2. Then switch ON the instrument; Go to [Service Check: Syringe]; Give <Initialize> and <Aspirate/Dispense> commands
				3. Syringe up/down motor	3. If the initialization or aspirate/dispense movement fails, call Service

					Engineer
Reagent Tray	71	RGT1	Reagent tray Initialize Rotational error	1. Position opto assembly of RGT tray	1. Switch OFF the analyzer; Rotate RGT by hand and make sure that nothing is obstructing the rotation
				2. Stepper motor and its connections	2. Then, switch ON the instrument; Go to [Service Check: Reagent Tray]; Give <Initialize> command.
				3. Interface card and its connector	3. If initialization fails, call Service Engineer
Reagent Tray	72	RGT1	Reagent tray Rotational error during run	1. Position opto assembly of RGT tray	1. Switch OFF the analyzer; Rotate RGT by hand and make sure that nothing is obstructing the rotation
				2. Stepper motor and its connections	2. Then, switch ON the instrument; Go to [Service Check: Reagent Tray]; Give <Initialize> command.
				3. Interface card and its connector	3. If initialization fails, call Service Engineer
Reagent Tray	7F	RGT3	RGT Interlock error	ARM assembly UP opto & Direction opto.	<p>1. Make sure that arm assembly is not down in RGT tray during service check for reagent i.e service command</p> <p>1) RGT initialize 2) RGT tray rotate to "X" position. If arm assembly is not down then check up opto &amp; direction opto signal.</p> <p>2. Check opto connectors are connected properly or not.</p>
Reagent Tray	V1		"Bottle over-filled at Pos. N", where N = Position No.	1. Scanned Reagent volume is more than 47ml for Large bottle	Decrease the Reagent volume at the required position
				2. Scanned Reagent volume is more than 23 ml for Small bottle	Decrease the Reagent volume at the required position
Sample Tray	81		Sample tray Initialize Rotational error	1. Position opto assembly of ASP	1. Switch OFF the analyzer; Rotate ASP by hand and make sure that nothing is obstructing the rotation
				2. Stepper motor and its connections	2. Then, switch ON the instrument; Go to [Service Check: Sample Tray]; Give <Initialize> command.
				3. Interface card and its connector	3. If initialization fails, call Service Engineer

Sample Tray	82	ASP2	Sample tray Rotational error during run	1. Position opto assembly of ASP	1. Switch OFF the analyzer; Rotate ASP by hand and make sure that nothing is obstructing the rotation
				2. Stepper motor and its connections	2. Then, switch ON the instrument; Go to [Service Check: Sample Tray]; Give <Initialize> command.
				3. Interface card and its connector	3. If initialization fails, call Service Engineer
Sample Tray	8F	ASP3	ASP Interlock Error	ARM assembly UP opto & Direction opto & ARM home opto	1. Make sure that arm assembly is not down in ASP tray during service check for ASP tray i.e service command 1) ASP initialize 2) ASP tray rotate to "X" position  2. Check opto connectors are connected properly or not.
RCT Tray	91	RCT1	RCT tray Initialize Rotational error	1. Position opto assembly of RCT tray	1. Switch OFF the analyzer; Rotate RCT by hand and make sure that nothing is obstructing the rotation
				2. Stepper motor and its connections	2. Then switch ON the instrument; Go to [Service Check: RCT Tray]; Give <Initialize> command
				3. Interface card and its connector	3. If initialization fails, otherwise call Service Engineer
				4. Arms are down in RCT	
RCT Tray	92	RCT2	RCT tray Rotational error during run	1. Position opto assembly of RCT tray	1. Switch OFF the analyzer; Rotate RCT by hand and make sure that nothing is obstructing the rotation
				2. Stepper motor and its connections	2. Then switch ON the instrument; Go to [Service Check: RCT Tray]; Give <Initialize> command
				3. Interface card and its connector	3. If initialization fails, otherwise call Service Engineer
				4. Arms are down in RCT	
System Error	98	SYS!	SYS error	1. Error in communication between PC and Analyzer during schedule transmission.	1. Test will be added in pending list. Reschedule the test and perform.

					2. In case frequent occurrence of error, contact Service Engineer.
Hardware Error	99	HErr	Hardware Error	Check the assembly which gave error prior to Hardware Error.	Take the corrective action for the error which occurred prior to Hardware Error
RCT Tray	9F	RCT3	RCT Interlock error	ARM assembly UP opto & Direction opto & ARM home opto	<p>1. Make sure that arm assembly is not down in RCT tray during service check for RCT tray i.e service command</p> <p>1) RCT initialize 2) RCT tray rotate to "X" position</p> <p>2. Check opto connectors are connected properly or not.</p>
CRU	A1	@CRU	CRU Initialization error	1. CRU Position opto signal	1. Switch OFF the analyzer; Move CRU up and down by hand and make sure that nothing is obstructing the CRU movement
				2. RCT Position opto signals	2. Then switch ON the instrument; Go to [Service Check: CRU Unit]; Give <Initialize> and <Up/down> commands
				3. Interface card and its connector	3. If the initialization or up/down movement fails, otherwise call Service Engineer
				4. Stepper motor and its connections	
				5. RCT alignment	
CRU	A2	@CRU	CRU Up/Down error	1. CRU Position opto signal	1. Switch OFF the analyzer; Move CRU up and down by hand and make sure that nothing is obstructing the CRU movement
				2. RCT Position opto signals	2. Then switch ON the instrument; Go to [Service Check: CRU Unit]; Give <Initialize> and <Up/down> commands
				3. Interface card and its connector	3. If the initialization or up/down movement fails, otherwise call Service Engineer
				4. Stepper motor and its	

				connections	
				5. RCT alignment	
CRU	A3	@CRU	CRU Down Opto Fail	CRU down opto	1. Make sure the down opto is working i.e CRU down opto LED is ON when when OPTO is open and CRU down opto LED is OFF when CRU opto is cut by interrupter. Also ensure that the logic low signal is reaching to CPU board when opto is open i.e LED is ON & logic high (3.3v) signal reaches the CPU board when opto is cut i.e LED is OFF.
					2. Check opto connectors are connected properly or not.
CRU	A4	@CRU	CRU Up Opto Fail	CRU up opto	1. Make sure the up opto is working i.e CRU up opto led is ON when when OPTO is open and CRU up opto led is OFF when CRU opto is cut by interrupter. Also ensure that the logic low signal is reaching to CPU board when opto is open i.e LED is ON & logic high (3.3v) signal reaches the CPU board when opto is cut i.e LED is OFF.
					2. Check opto connectors are connected properly or not.
CRU	AF	@CRU	CRU Interlock Error	RCT_POSITION_ OPTO and CRU_UP_OPTO and CRU_DOWN_OP TO	1. Make sure RCT_position opto is ON and CRU_UP_OPTO is OFF and CRU_DOWN_OPTO is ON before CRU goes down in RCT when down command is executed during service check. 2) Ensure RCT position opto is ON when cru goes down in RCT during run.
					2. Check opto connectors are connected properly or not.
Stirrer	B1	@STR 1	Stirrer Up/Down error for Reagent 1	1. Position opto assembly of stirrer	1. Switch OFF the analyzer; Rotate stirrer by hand and make sure that nothing is obstructing the rotation

				2. Interface card and its connector	2. Then switch ON the instrument; Go to [Service Check: Stirrer]; Give <Initialize> and <Stirrer Up> Execute <Stirrer Arm Trough to R1 Cuvette> Execute <Down in Cuvette> Execute <Stirrer Up> Execute <R1 Cuvette to Trough> commands
				3. Stepper motor	3. If the initialization or rotation fails, call Service Engineer
Stirrer	B2	@STR 1	Stirrer Rotational error for Reagent 1	1. Position opto assembly of stirrer	1. Switch OFF the analyzer; Rotate stirrer by hand and make sure that nothing is obstructing the rotation
				2. Interface card and its connector	2. Then switch ON the instrument; Go to [Service Check: Stirrer]; Give <Initialize> and <Stirrer Up> Execute <Stirrer Arm Trough to R1 Cuvette> Execute <R1 Cuvette to Trough> commands
				3. Stepper motor	3. If the initialization or rotation fails, call Service Engineer
Stirrer	BF	@STR 3	Stirrer Interlock Error	RCT_POSITION_OPTO and STR_HOME_OPTO and STR_DIRECTION_OPTO'	Make sure RCT_POSITION_OPTO is ON when stirrer down in cuvette command is executed during service check 2. Check opto connectors are connected properly or not.
Stirrer	C1	@STR 2	Stirrer Up/Down error for Reagent 2	1. Position opto assembly of stirrer	1. Switch OFF the analyzer; Rotate stirrer by hand and make sure that nothing is obstructing the rotation
				2. Interface card and its connector	2. Then switch ON the instrument; Go to [Service Check: Stirrer]; Give <Initialize> and <Stirrer Up> Execute <Stirrer Arm Trough to R2 Cuvette> Execute <Down in Cuvette> Execute <Stirrer Up> Execute <R2 Cuvette to Trough> commands
				3. Stepper motor	3. If the initialization or rotation fails, call Service Engineer

Stirrer	C2	@STR 2	Stirrer Rotational error for Reagent 2	1. Position opto assembly of stirrer	1. Switch OFF the analyzer; Rotate stirrer by hand and make sure that nothing is obstructing the rotation
				2. Interface card and its connector	2. Then switch ON the instrument; Go to [Service Check: Stirrer]; Give <Initialize> and <Stirrer Up> Execute <Stirrer Arm Trough to R2 Cuvette> Execute <R2 Cuvette to Trough> commands
				3. Stepper motor	3. If the initialization or rotation fails, call Service Engineer
Controller	D1		SRAM Memory Error	1. Interface Board (CPU).	1. Switch OFF the Analyzer and Switch it on after few minutes.
Pressure	G1		Low Pressure Level	1. Malfunctioning of pressure unit	Check the pressure unit for any leakage or blockage in the tubing
				2. Leakage/Blockage in pressure tubing	
Pressure	G2		High Pressure Level	1. Malfunctioning of pressure unit	Check the pressure unit for any leakage or blockage in the tubing
				2. Leakage/Blockage in pressure tubing	
Reagent Tray	H1	RGT!	RGT Cover Open	1. Reagent tray cover placement	1. Check the placement of Reagent Cover
				2. The logic levels at the baseboard connectors	2. Check the logic levels at the baseboard connectors/connector connections and verify for proper functionality.
				3. Connector connections	
Cleaning Can	I1		Low Cleaning Solution Level	1. Cleaning solution Level	1. Check the Cleaning solution Level
				2. Sensor output of Level Sensors	2. Check the Sensor Output of Level Sensor
Waste Can	J1		Empty Waste Reservoir/Waste Tank full to Capacity	1. Waste Level	1. Check the Waste Level
				2. Sensor output of Level Sensors	2. Check the Sensor Output of Level Sensor
Bio-Waste Can	K1		Bio-Waste Tank Full to Capacity	1. Bio-Waste Level	1. Check the Bio-Waste Level
				2. Sensor output of Level Sensors	2. Check the Sensor Output of Level Sensor

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Pressure	L1		Low DI Water Level	1. Malfunctioning of pressure unit	Check the pressure unit for any leakage or blockage in the tubing
				2. Leakage/Blockage in pressure tubing	
DI Water Can	M1		DI Water Tank Level less than or equal to 50%	1. DI Water Level	1. Check the DI Water Level
				2. Sensor output of Level Sensors	2. Check the Sensor Output of Level Sensor
Photometer	N1		PDC Operational ERROR	1. PDC Card.	1. Goto Service Check and give Emergency Stop Command.
				2. Interface Board and its connector.	2. Switch OFF the Analyzer and Switch it on after few minutes.
Photometer	N2		PDC Communication ERROR	1. PDC Card.	1. Goto Service Check and give Emergency Stop Command.
				2. Interface Board and its connector.	2. Switch OFF the Analyzer and Switch it on after few minutes.
Barcode Scanner	P1		Reagent Barcode Scanner Failure	1. Reagent Barcode Scanner	1. Check the Reagent barcode scanner
				2. Reagent barcode scanner connections	2. Check the Reagent barcode scanner connections
				3. Interface board and its connections	
Barcode Scanner	Q1		Sample Barcode Scanner Failure	1. Sample Barcode Scanner	1. Check the Sample barcode scanner
				2. Sample barcode scanner connections	2. Check the Sample barcode scanner connections
				3. Interface board and its connections	
Reagent Tray	R1	RGTE!!	RGTE Cover open for 5 minutes under standby	1. Reagent tray cover placement	1. Check the placement of Reagent Cover
				2. The logic levels at the baseboard connectors	2. Check the logic levels at the baseboard connectors/connector connections and verify for proper functionality.
				3. Connector connections	

Reaction Tray	T9	@TMP	RCT Temperature out of range	1. RCT heater and its connections	1. Go to [Service Check: RCT Temp]; Give <Read> command. RCT temperature should be displayed along with the RCT sensor status
				2. Interface board and its connections	3. If the temperature is not coming within range, call Service Engineer
				3. RCT sensors and its connections	
Reaction Tray	DC	DC*	Reaction performed in Dirty Cuvette	1. Cuvettes dirty	Retest the result.

#### 8.4.2.3. Error Log

The error log screen is used to display the list of errors that is occurred during machine operation. The list of errors can be filtered according to the type of operation by selecting option **All**, **Run**, **Service**, **Maintenance**, **Host**, and **Auto-Startup**. This data is generally useful for service/diagnostic purposes.

To open, go to **Reports > Error Log** button. The following screen will be displayed:

Date	Batch	Error Code	Description	Action
14 Mar 2011 11:45:34:107		G1	Low Pressure Level	PAUSE-P
14 Mar 2011 12:28:13:747		1D	Reagent absent - Pos. 2	
14 Mar 2011 12:28:31:640		1D	Reagent absent - Pos. 6	
14 Mar 2011 12:29:26:950		1D	Reagent absent - Pos. 21	
14 Mar 2011 12:29:44:390		1D	Reagent absent - Pos. 26	
14 Mar 2011 15:19:00:390		G1	Low Pressure Level	PAUSE-P
14 Mar 2011 16:03:48:170	2	1D	Reagent absent - Pos. 9	
14 Mar 2011 18:07:02:357		G1	Low Pressure Level	PAUSE-P
15 Mar 2011 13:19:42:030	1	1B	R1 LLD Sensing Failure at Pos. 9	
15 Mar 2011 15:34:57:403		G1	Low Pressure Level	PAUSE-P
15 Mar 2011 15:54:20:590	2	3E	Sample LLD Sensing Failure at Pos. 5	
15 Mar 2011 17:04:30:060	3	1B	R1 LLD Sensing Failure at Pos. 7	PAUSE-P
15 Mar 2011 19:29:50:547		G1	Low Pressure Level	PAUSE-P
16 Mar 2011 11:44:07:357		1D	Reagent absent - Pos. 2	
16 Mar 2011 11:44:24:763		1D	Reagent absent - Pos. 6	
16 Mar 2011 11:45:37:327		1D	Reagent absent - Pos. 26	
16 Mar 2011 11:56:35:747	1	1B	R1 LLD Sensing Failure at Pos. 17	
16 Mar 2011 11:56:53:733	1	1B	R1 LLD Sensing Failure at Pos. 17	
16 Mar 2011 12:01:42:543	1	3D	Sample absent - Pos. I-2	
16 Mar 2011 12:04:06:920	1	1D	Reagent absent - Pos. 34	
16 Mar 2011 12:08:55:747	1	2D	Reagent absent - Pos. 32	
16 Mar 2011 12:12:50:343	1	2D	Reagent absent - Pos. 10	
16 Mar 2011 12:35:21:703	2	1D	Reagent absent - Pos. 33	
16 Mar 2011 12:36:15:840	2	3D	Sample absent - Pos. I-1	
16 Mar 2011 12:37:09:937	2	3D	Sample absent - Pos. I-2	
16 Mar 2011 12:41:04:590	2	2D	Reagent absent - Pos. 31	
16 Mar 2011 12:46:11:403	2	3D	Sample absent - Pos. 3	

Indication : Click on Show to view data as per selection.

Figure 8-2. Error log screen

1. The user can select the date range by changing the **From** and **To**.
2. The user can select operation (Service, Maintenance, Host, Auto-Startup, Run, and All operations) during which the errors occurred.
3. Once the above selection is done, user needs to click on **Show** button to view all the errors.
4. The **Error Code** drop down list is used to filter the records according to the required error code.
5. In the grid following are the different parameters present:
  - **Date** - Date and Time of the occurrence of the error.
  - **Batch No** - During run, if there was any error then in which batch it occurred.
  - **Error Code** – Displays the error code to identify the type of error occurred.
  - **Description** - Description of the error occurred.
  - **Action** - Action taken on the error occurrence is displayed in this column.

The column “Action” represents the severity of the error, which is as follows:

**Pause-P** states that the sampling will be paused on occurrence of such errors during run. User may take corrective action and resume sampling by clicking on the Resume button from Status Monitor.

**Pause-R** states that the sampling will be paused on occurrence of such errors during run. On occurrence of such errors, resume sampling in same batch is not possible. Once the results of all the tests in progress are declared, the batch run will stop. When the batch run is completed, user should take corrective action and then start the run again.

**STOP** states that the analyzer will stop the batch run immediately on occurrence of such errors.

Errors having blank Action states that they are warnings.

Error description is displayed along with the date and time and also batch no if applicable.
6. To print the details of the error log, user can click on **Print** button.
7. Use **EXPORT** button to save the records in the excel sheet. On clicking, the details will be automatically copied in the excel sheet and the file is saved in the particular location. The location will be displayed in the **Indication** text box.

#### 8.4.2.4. Measurement result error flags

The measurement result flags printed out together with the measurement result are shown in the following list.

Serial Number	Flags	Cause
1	#	This flag is issued to indicate that the result obtained is from a rerun. This flag is issued for all rerun results
2	~	When Linearity Extension Logic method is used to reduce the measurement range to match absorbance range setting, this flag should be given
3	F	This flag is used to indicate that correlation correction has been used to calculate the final result. That is, this flag is issued if in the equation $Y = aX + b$ , $a$ is not equal to 1 or $b$ is not equal to zero.
4	-1SD	This flag is issued with control results to indicate that the result is below 1SD limit
5	+1SD	This flag is issued with control results to indicate that the result is above 1SD limit
6	-2SD	This flag is issued with control results to indicate that the result is below 2SD limit
7	+2SD	This flag is issued with control results to indicate that the result is above 2SD limit
8	-3SD	This flag is issued with control results to indicate that the result is below 3SD limit
9	+3SD	This flag is issued with control results to indicate that the result is above 3SD limit
10	NOCAL	This flag is issued with patient or control result and indicates that calibration is not available to calculate results; may be something is wrong with the calibration table. The calibration table needs to be checked and corrected to calculate a result (e.g. no calibration is present or number of standards provided for multipoint calibration is less than required).
11	?SD	This flag is issued with control result and indicates that the target Mean and SD values have not been defined in Quality Control screen for the control. Therefore, flags such as “±1SD”, “±2SD”, “±3SD” cannot be given
12	V-D	This flag is issued with patient results and indicates a Decreased volume run
13	V-I	This flag is issued with patient results and indicates a Increased volume run
14	MONO	This flag is issued with patient and control results when, for the concerned test, the absorbance's of the calibrators are not changing monotonically with the concentration of the calibrators in the calibration table.
15	PD	This flag is issued with blank, patient, calibrator and control results to indicate that the sample was prediluted
16	P*	This flag is issued with patient and control serum results to indicate that prozone (antigen excess) has occurred.
17	TEC-L	Lower technical limit violated. Measured value (for End-point) or absorbance slope (for Rate chemistry) is lower than the set

		minimum technical limit. Minimum Technical Limit, "0" (zero) indicates that minimum technical limit should not be checked.
18	TEC-H	Upper technical limit violated. Measured value (for End-point) or absorbance slope (for Rate chemistry) is higher than the set maximum technical limit. Maximum Technical Limit, "0" (zero) indicates that maximum technical limit should not be checked.
19	RANGH	<p>1. This flag is issued with patient and control serum results to indicate that the absorbance of the sample is higher than the absorbance of the highest concentration calibrator in the calibration table for increasing direction test.</p> <p>2. This flag is also issued with patient and control serum results if the absorbance of the sample is lower than the absorbance of the highest concentration calibrator in the calibration table for decreasing direction test.</p>
20	RANGL	<p>1. This flag is issued with patient and control serum results to indicate that the absorbance of the sample is lower than the absorbance of the blank (or lowest concentration calibrator) in the calibration table for increasing direction test.</p> <p>2. This flag is also issued with patient and control serum results if the absorbance of the sample is higher than the absorbance of blank (or lowest concentration calibrator) for a decreasing direction test.</p>
21	H	Measured value is larger than upper limit set for normal value range for the corresponding age, sample type and category.
22	L	Measured value is smaller than lower limit set for normal value range for the corresponding age, sample type and category.
23	CALC!	<p>Calculation Item calculation does not take place for any of the following reasons</p> <ol style="list-style-type: none"> <li>Denominator is 0 (zero) in the process of calculation for compensation.</li> <li>The test to be used for Calculation Item has not been measured yet.</li> <li>Any test to be used for Calculation Item has data/calibration alarms (such as Chk Calib)</li> <li>Any test to be used for Calculation Item errors (S*, R1* etc)</li> </ol>
24	ABSLIM	This flag is issued for End-Point Chemistries and Rate A chemistries (For Rate-Chemistries, this flag will be issued when Technical limit field is set). In this case Extension Logic will not be performed. The result "NA" is associated with the flag.
25	PANL	Low Panic value error. This flag is issued with a sample result to indicate that the patient result is lower than the programmed Panic Limit Min. ISE tests too will be sent for a rerun
26	PANH	High Panic value error. This flag is issued with a sample result to indicate that the patient result is higher than the programmed Panic Limit Max. ISE tests too will be sent for a rerun
27	LINxx	Linearity abnormal (checked only for Rate A and Rate B assays). When the reaction during measurement points M2S and M2E is non-linear beyond the set limit for linearity of

		reaction this flag is given and the percent linearity of reaction is indicated by a two digit number xx after "LIN".
28	Lim0	This flag is applicable for Rate Chemistries, only during the extension logic and when Reaction Absorbance Limit is present. If there are no points available for calculation, then this flag is issued
29	Lim1	This flag is applicable for Rate Chemistries, only during the extension logic and when Reaction Absorbance Limit is present. If there is only one point available for calculation, then this flag is issued
30	Lim2	This flag is applicable for Rate Chemistries, only during the extension logic and when Reaction Absorbance Limit is present. If there are 2 points available for calculation, then this flag is issued
31	???	This flag is issued when the denominator becomes zero during calculation or an overflow error occurs in logarithmic or exponential calculation
32	Rgt Abs Min	This flag indicates that the reagent 1 absorbance is lower than the programmed Reagent Absorbance Min. This flag is not applicable for Patient & Control results of 2-Reagent chemistry.
33	Rgt Abs Max	This flag indicates that the reagent 1 absorbance is greater than the programmed Reagent Absorbance Max. This flag is not applicable for Patient & Control results of 2-Reagent chemistry.
34	COMM*	This flag is issued with the result if any reading is missed out between the measurement point (M1 Start and M2 Start) due to communication failure.
35	@TMP	This flag is issued when the RCT temperature was out of range while the measurement was in process.
36	TO	This flag indicates Time Out while receiving result from the machine.
37	Cal*	This flag is issued with the patient and control results to indicate that the results are being calibrated with previous calibration data.
38	Cal**	This flag is issued to indicate the result with Un-Calibrated Reagent. (Applicable only if Online Calibration is selected for the test).
39	EVH	Extrapolation % is set in system parameters This flag is issued when patient sample result is calculated by extrapolating calibration curve on higher side (concentration of the patient result is higher than highest calibrator).
40	EVL	Extrapolation % is set in system parameters This flag is issued when patient sample result is calculated by extrapolating calibration curve on lower side (concentration of the patient result is lower than lowest calibrator).

### **8.4.3. Maintenance Menu**

To open maintenance screen, go to main screen, and click on the **Maintenance** on the left side of screen. The following screen will be displayed:

Figure 8-3. Maintenance screen

Using this screen, the routine maintenance of the analyzer is performed using the following function:

- Span
    - Manual Span
    - Auto Span
  - Wash
  - Dead Volume Calibration
  - ISE (available only if ISE is installed on the analyzer)
  - Auto Maintenance

### 8.4.3.1. Auto Span

This screen is useful to view and adjust the photometer gains at different wavelengths. The analyzer adjusts the photometer gains automatically if you selects Auto Span option and clicks on **START** button.

If the gain obtained during autospan is within the factory set limits, it is indicated by a green background. And if the gain is not within the limits, then it is indicated by red background.

The photometer gains can also be adjusted manually, however it is not recommended.

SPAN								
<input type="radio"/> MANUAL SPAN	<input checked="" type="radio"/> AUTO SPAN	Cuv : 01			Gain Value			
Wavelength		340	405	505	546	578	600	660
Gain		810	599	659	516	576	511	536
<b>START</b>								



**NOTE: If the absorbance of the DI Water placed inside the cuvette is not between 0.05-0.085 Abs, then following corrective measures should be taken.**

- Check the cuvette
- Perform cuvette rinse to ensure that the cuvettes are clean
- Check the particular wavelengths and the photometer lamp.
- Call the service engineer

The Auto Span option will be the default option when the Maintenance screen is clicked first time. Later it can be change, as appropriate.

### 8.4.3.2. Manual Span

This screen is useful to view the filter absorbance and voltages at different wavelengths. It is also used to view the photometer stability at different wavelengths.

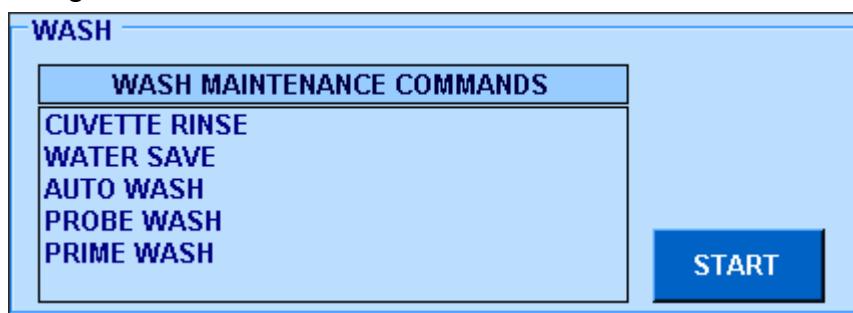
SPAN								
<input type="radio"/> MANUAL SPAN	<input checked="" type="radio"/> AUTO SPAN	Cuv : 39						
Wavelength		340	405	505	546	578	600	660
Voltage ( volts )								
Absorbance ( abs )								
<b>START</b>								

Following is the procedure:

1. Select a wavelength using which the absorbance and voltage needs to be checked. The yellow color indicates that the wavelength is selected.
2. Click on **START** button. Continuous online update of voltage and absorbance takes place and is displayed on the screen.
3. Click on **STOP** once the check is performed.
4. User can select another wavelength to check the voltage and the absorbance at the other wavelength. Again user needs to click on **START** to start the reading and **STOP** to stop the reading.

#### 8.4.3.3. Wash Screen

The following screenshot shows the wash screen:



##### 8.4.3.3.1. Cuvette Rinse

On selecting **CUVETTE RINSE** option, the user can perform a Cuvette Wash of all 45 cuvettes by clicking on the **START** button. This wash is done using DI Water. At the end of cuvette rinse operation, the cell blanks are updated automatically and can be viewed in the **Maintenance > Cell Blank** screen:

# Operator Manual

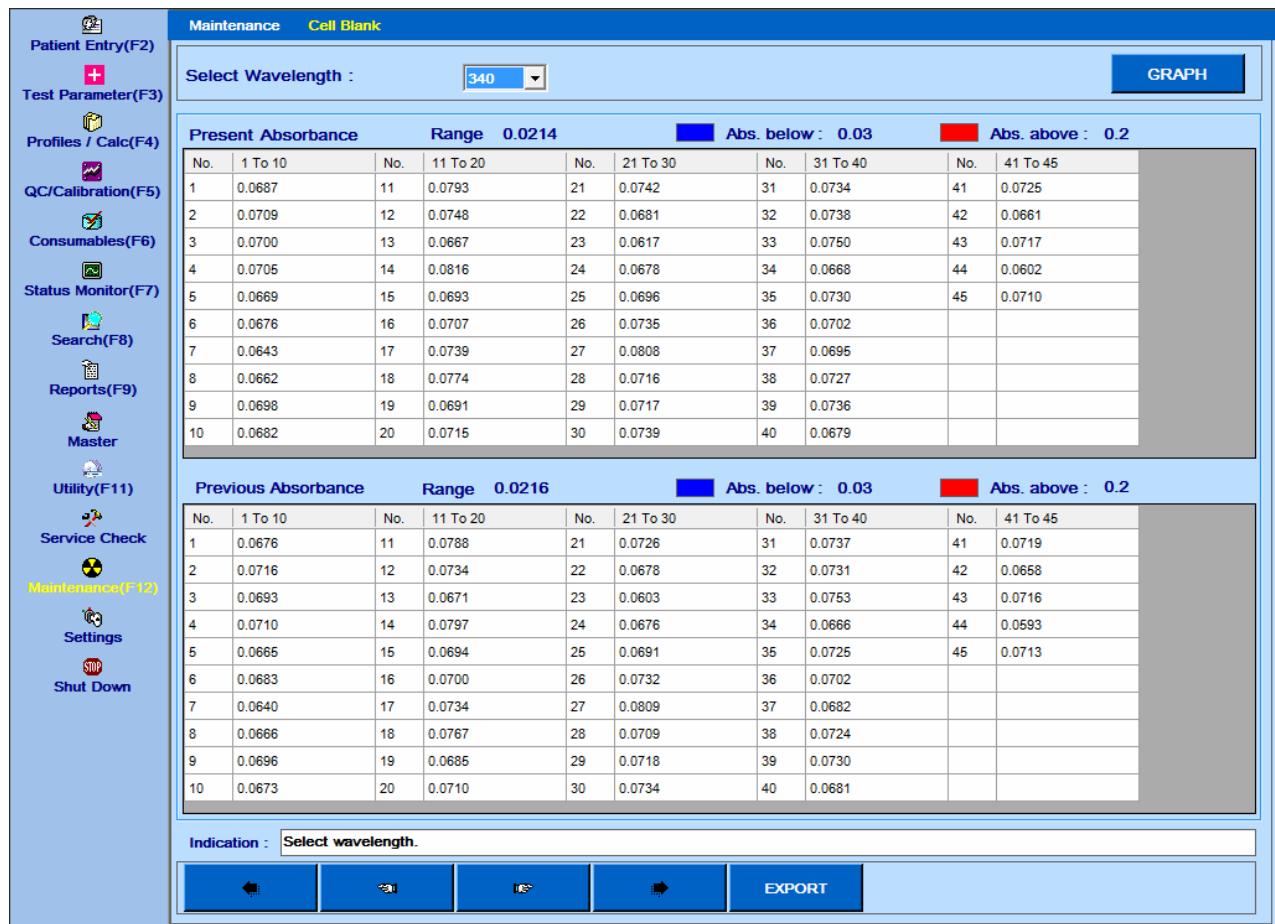


Figure 8-4. Cell blank screen

This menu enables the user to view the cuvette blank absorbance values (obtained with DI water in the cuvette) at any particular wavelength.

The screen displays the cuvette blank for the requested wavelength. Wavelength can be selected by the pull-down option provided on the left side of the screen.

The  and  buttons can also be used to view the cuvette blanks for the next and previous wavelength. There is also a **GRAPH** button available, through which the cell blank reading for particular wavelength can be viewed in a graphical format. The cuvette blank table consists of three sections.

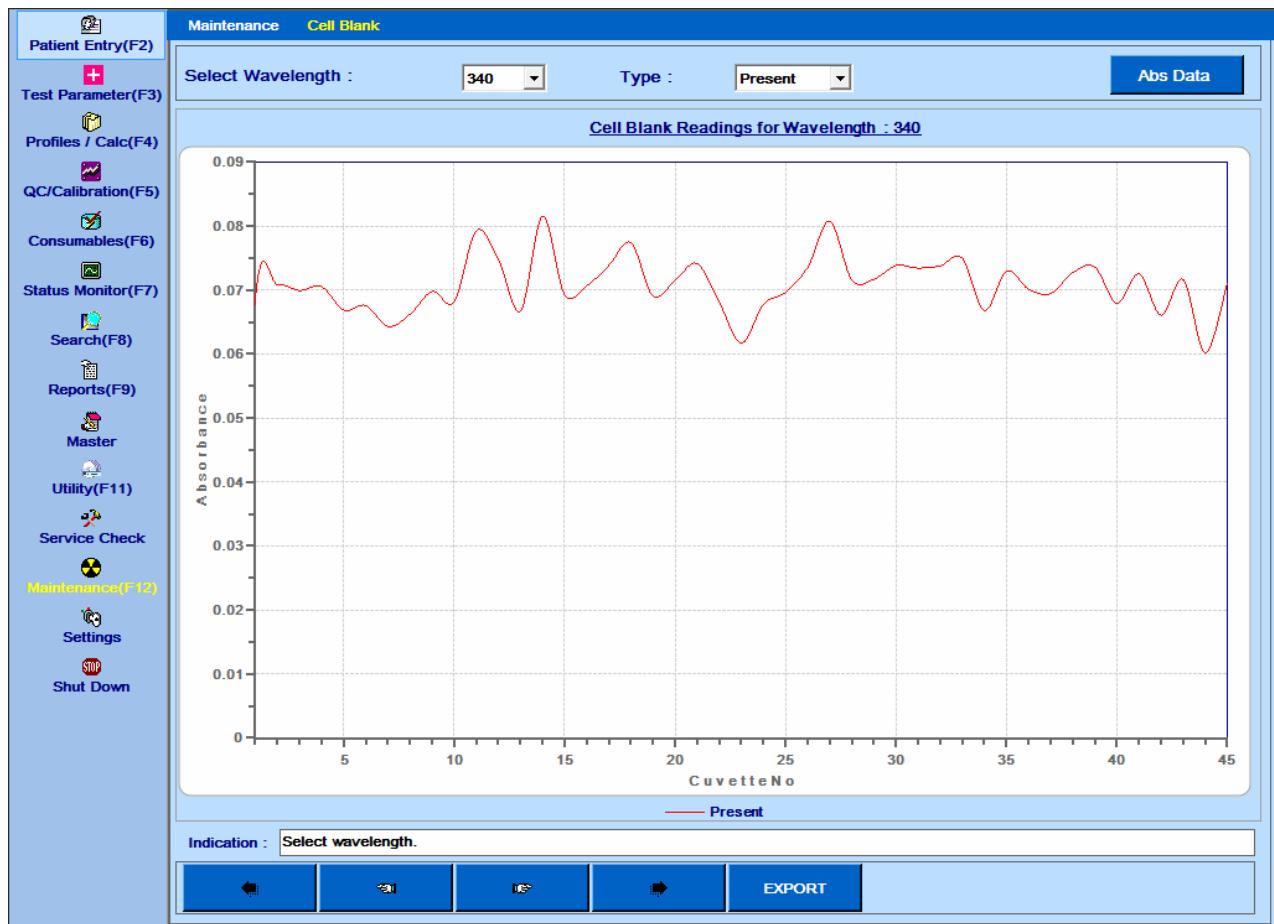


Figure 8-5. Cell blank graph

**Present abs:** It is the absorbance of the cuvettes with de-ionized water measured after the last run or Cuvette Rinse.

**Previous abs:** It is the absorbance of the cuvettes with de-ionized water measured after the second last run or Cuvette Rinse.

**Graph:** On clicking **GRAPH** button, the user can view the absorbances in graphical format for the required wavelength. To view the graph, you need to select the required wavelength from the **Select Wavelength** drop-down list, and then select the appropriate graph type from the Type option.

Three options are available to view the graph:

- **Present:** This option will displays the previous absorbance graph obtained for the selected wavelengths.
- **Previous:** This option will displays the present absorbance graph obtained for the selected wavelengths.
- **Both:** The comparison of both graphs (previous and present) can be viewed using this option.

The maximum and minimum acceptable value of the cuvette blank absorbance can be set in the **Settings > System Parameter** menu. If the absorbance of the cuvette blank exceeds the set maximum blank absorbance, then that particular

cuvette absorbance is indicated by Red background. On the other hand, if the absorbance of the cuvette blank is below the minimum acceptable absorbance, then it is indicated by Blue background.

The values on the cuvette blank value table display should not exceed 0.1 normally. Cuvette Rinse and/or Auto Wash procedure from **Maintenance** menu must be performed if the cuvette blanks are higher than the maximum limit. If the Cuvette O.D.s exceed 0.2 Absorbance, the cuvette should be replaced with a new cuvette or should be cleaned externally using fresh water.

This procedure should be done daily before starting the batch.

#### 8.4.3.3.2. Water Save

This option enables the operator to wash the reaction tray cuvettes with some cleaning solution and fill all cuvettes with DI water at the end of a day's work or at beginning of the day.

This operation can be performed any time using Water Save option.

To perform this, select **WATER SAVE**, and click **START**.

On clicking this button, the analyzer first washes all the 45 cuvettes with the cleaning solution through laundry probes, and then using the Arm probe, the analyzer fills DI water in all the 45 cuvettes. This water remains in the cuvettes until the next run or cuvette wash/rinse.

Overnight filling of the cuvettes with DI water is helpful in loosening the dirt on the cuvette walls.

Perform water save daily, at the end of the day's work.



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**NOTE: Poor quality DI water should not be used for Water Save, as bacteria growth can take place inside the cuvettes.**

---

#### 8.4.3.3.3. Auto Wash

The cuvettes, arm probes, and stirrer can be cleaned with external detergents or cleaning solution through Auto Wash option.

Usually, the Cleaning A and Cleaning B solutions with concentration of 0.1N is used for this operation.

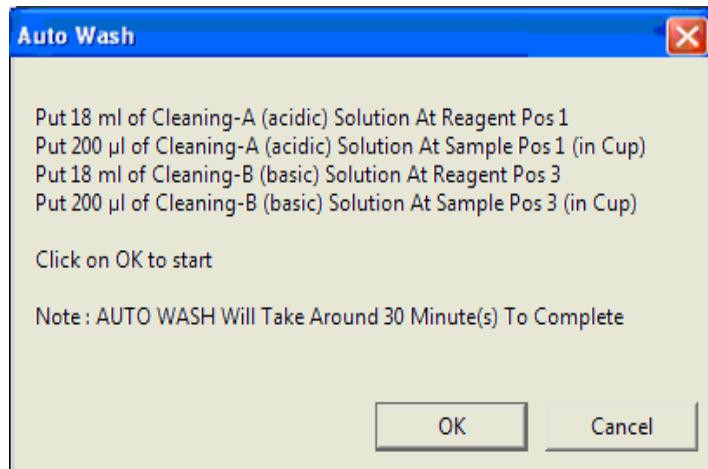
However, any other detergent or cleaning solution with appropriate concentration can be used for this operation. These solutions are not kept in the detergent Can but in reagent bottles on the Reagent Tray and in sample tubes on the Sample Tray.

Auto Wash option can be used instead of Cuvette Rinse option, when operator wants to use external detergents/solutions to clean the cuvettes, probe, and stirrer.

1. Place 18 ml of Cleaning A (acidic) solution at position 1 and Cleaning B(basic) solutions at positions 3 on the reagent tray (in 50 ml large bottles).

2. Place 200  $\mu$ l of Cleaning A (acidic) solution at position 1 and Cleaning B solutions at positions 3 on the sample tray (in 2 ml Cups).
3. Click on **START** button.

On clicking, a message box will be displayed indicating the user for placing cleaning solution.



4. Click **OK** to perform auto wash.

At the end of the procedure, the user can check the Updated Cuvette Blanks by going to the **Maintenance > Cell Blank** screen. If the user wants to stop the operation, click on the **STOP** button which will be active after the **START** button is clicked.

It is recommended to perform this procedure once a week or when needed. If one is using latex based assays regularly, it is recommended to perform a Cuvette Wash daily with Cleaner A and Cleaner B solutions.

- Cleaning A Solution: HCl (Acidic)
- Cleaning B Solution: NaOH (Basic)

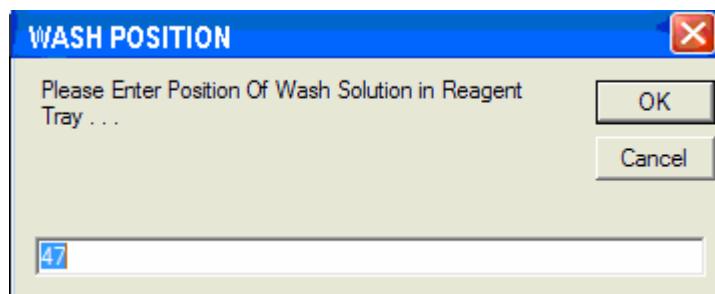
#### 8.4.3.3.4. Probe Wash

This option enables the operator to wash the Sample Probe with some cleaning solution at the end of a day's work or at beginning of the day. This operation can be performed any time using this option.

1. Select the desired number of cycles from 01 – 09.
2. Click **START** button.

On clicking, a prompt window will be displayed for the user to enter/confirm the position of the cleaning solution on the reagent tray.

In case, if the cleaning solution is already defined through **Utility > Reagent Position**, on clicking **START** the prompt window will displays the position number where the wash solution is placed. You can edit the wash solution position by entering new position number. Refer figure below.



Enter the cleaning solution position, and click **OK**, the Probe picks up the appropriate volume of cleaning solution (in  $\mu\text{l}$ ) and dispenses it in the drain with internal and external cleaning.

The Probe wash action is repeated based on the number of cycles selected.

3. After the action is completed the analyzer gets initialized.

#### 8.4.3.3.5. Prime Wash

This option is used at the beginning of the day before the Cuvette Rinse operation. The syringe valve of the Probe is kept ON (depending on the time set by the user: One or two minutes) to remove the air trapped inside the tubings. Also, the valves of the CRU tubings are kept open to remove the air trapped in them. The following operation occurs after the button is clicked:

1. Machine Initializes.
2. CRU goes in DOWN position in the RCT.
3. The syringe valves for CRU and Probe open sequentially.
4. The priming continues for "x" minutes.
5. After the priming operation is completed, the CRU initializes to home position.

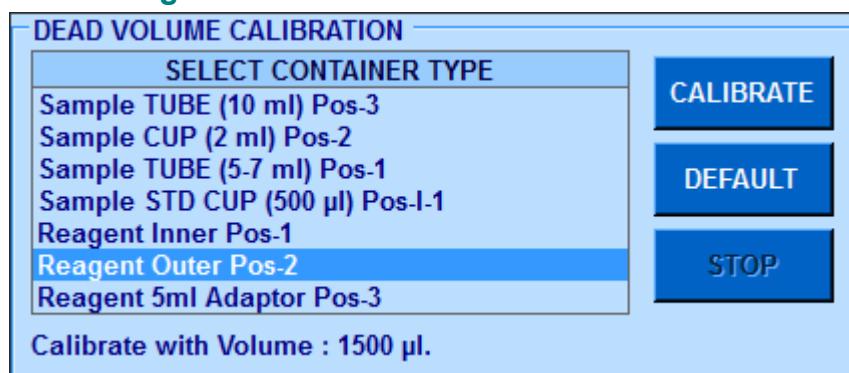
### 8.4.3.4. Dead Volume Calibration

This screen enables the user to calibrate the Dead Volume for Sample Containers and Reagent Bottles.

This procedure should be carried out at time of software installation (application or analyzer embedded).

The procedure to carry out the Dead Volume Calibration is given below:

#### 8.4.3.4.1. For Reagent Bottle Calibration



The following steps should be performed to carry out the Sample container calibration:

1. Select the appropriate Reagent bottle type available from the SELECT CONTAINER TYPE list for Dead Volume Calibration.
2. Pipette the exact amount displayed in **Calibrate with Volume** for the dead volume in the Reagent Bottle.
3. Place the Reagent bottle according to the bottle type on the position specified in the list.
4. Click **CALIBRATE** button.

If the reagent volume present in the specified reagent bottle is not approximately equal to the volume with which it is to be calibrated, then message "Calibrated Value Out of Range of Specified Value" is displayed.

Once the calibration process is completed, a message is displayed whether the calibration is successful or failed.

If the calibration is successful then the values are automatically stored in the software.

#### 8.4.3.4.2. For Sample tube and Cup Calibration

**DEAD VOLUME CALIBRATION**

SELECT CONTAINER TYPE	
<b>Sample TUBE (10 ml) Pos-3</b>	
Sample CUP (2 ml) Pos-2	
Sample TUBE (5-7 ml) Pos-1	
Sample STD CUP (500 µl) Pos-I-1	
Reagent Inner Pos-1	
Reagent Outer Pos-2	
Reagent 5ml Adaptor Pos-3	

**CALIBRATE**

**DEFAULT**

**STOP**

**Calibrate with Volume : 450 µl.**

The following steps should be done to carry out the Reagent Bottle calibration:

1. Select the appropriate Sample tube available from the SELECT CONTAINER TYPE list for Dead Volume Calibration.
2. Place the containers according to the container type on the position specified in the list.
3. Pipette the exact amount of volume in **Calibrate with Volume** for dead volume in sample tube.
4. Click **CALIBRATE** button.
5. Once the calibration process is completed then it is automatically stored in the software.



**NOTE: During calibration, if assembly error occurs; then the error message “Dead Volume Calibration Failed” will be displayed on the error message grid.**

#### 8.4.3.4.3. For Default Calibration

**LOAD DEFAULT DEAD VOLUME CALIBRATION**

S.No	CONTAINER TYPE
<input type="checkbox"/> 1	Sample TUBE (10 ml)
<input type="checkbox"/> 2	Sample CUP (2 ml)
<input type="checkbox"/> 3	Sample TUBE (5-7 ml)
<input type="checkbox"/> 4	Sample STD CUP (500 µl) P
<input type="checkbox"/> 5	Reagent Inner
<input type="checkbox"/> 6	Reagent Outer
<input type="checkbox"/> 7	Reagent 5ml Adaptor

**Select All**

**OK**

**CANCEL**

The following steps should be done to reset the Dead Volume Calibration to Default:

User should click on **DEFAULT** button.

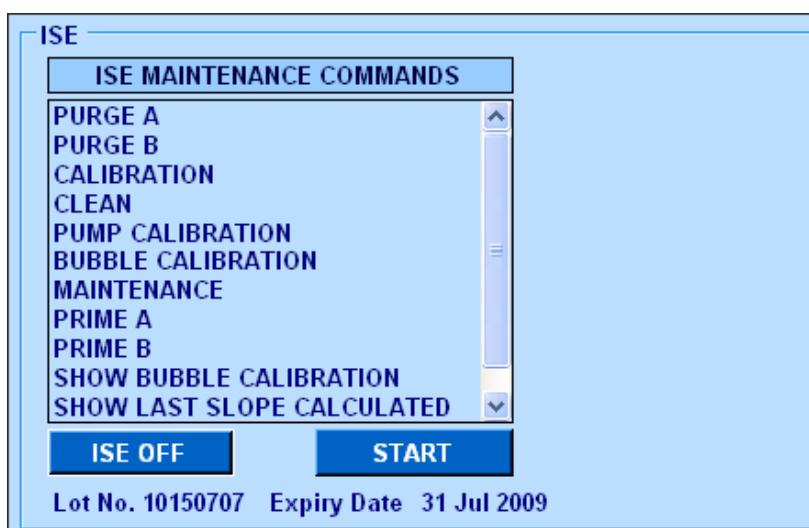
1. Select the Container Types from the list for which the Dead volume calibration needs to be reset.
2. User can click on **OK** to reset the selected containers.



**NOTE: If the Application Software is changed, then the Dead Volume Calibration settings are updated automatically and it can also be updated from the instrument from Service Check > Read Current command. If any hardware program is changed, then the Dead Volume Calibration should be repeated again.**

#### 8.4.3.5. ISE

This option is available only when Ion Selective Electrode unit is installed on the analyzer to perform routine maintenance, purging, cleaning and calibration on the ISE unit.



The following ISE maintenance commands are explained below:

When the **ISE ON** button is clicked, the system will check for the volume of CAL A and CAL B. Once it is done, the lot number and expiry date of the ISE reagent pack will be displayed in the **Lot No.** and **Expiry Date**.

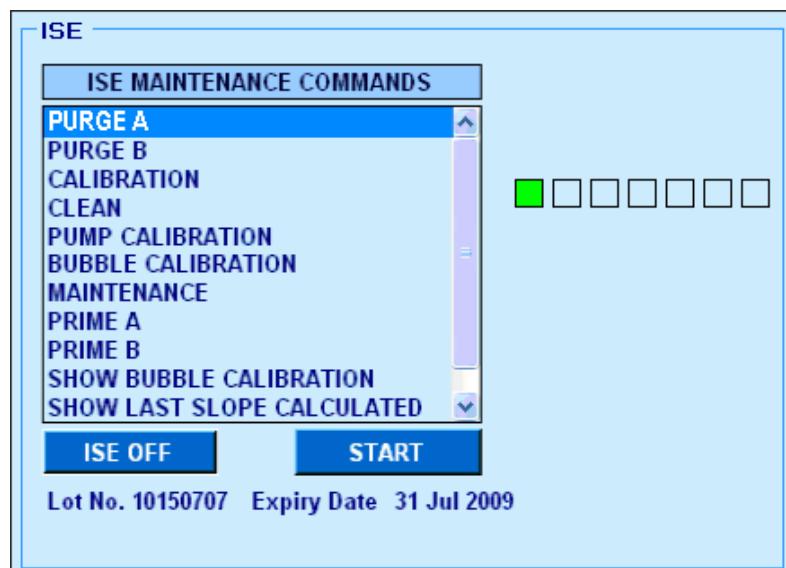
There are various ISE commands available for ISE maintenance. To start the maintenance, click on the appropriate command and then click **START**.

The following are the explanation of each command:

- **PURGE A**

This is used to purge Calibrant A solution through the tubing from the reagent module to the ISE Module. The ISE Module pumps Calibrant A from the reagent module through the ISE Module to wash out the flow path.

On successful PURGE A cycle, it is indicated by green colored box, if it is failed, then red colored box will be displayed on the right side of the ISE maintenance screen.



- **PURGE B**

This is used to purge Calibrant B solution through the tubing from the reagent module to the ISE Module. The ISE Module pumps Calibrant B through the ISE Module to wash out the flow path.

On successful PURGE B cycle, it is indicated by green colored box, if it is failed, then red colored box will be displayed on the right side of the ISE maintenance screen.

- **CALIBRATION**

This cycle is used to calibrate the electrodes (Na, K, Cl, and Li) of ISE Module. The ISE calibration range is as follows:

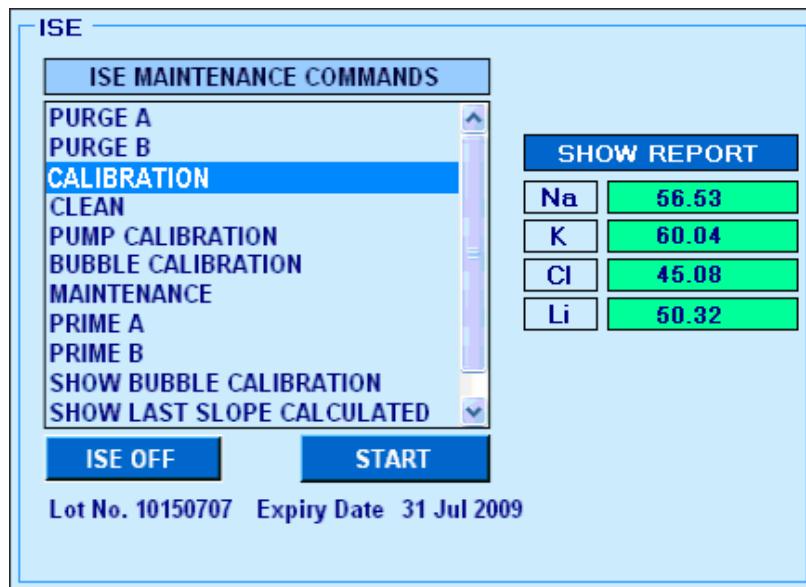
Na :52-64

K :52-64

Cl :40-55

Li :47-64

On successful calibration cycle, if the values are in range, it is indicated by green colored box. If it is not in range, then coral (deep pink) colored box will be displayed.



On clicking **SHOW REPORT**, it will display the last 30 calibration values. See figure as shown below.

Date	Time	Na	K	Cl	Li
Oct 19 2011	6:24PM	47.37	72.9	0	0
Oct 17 2011	3:31PM	47.37	72.9	0	0
Oct 17 2011	3:31PM	47.37	72.9	0	0
Oct 17 2011	3:30PM	47.37	72.9	0	0
Oct 17 2011	2:29PM	52.67	72.9	45.33	0
Oct 17 2011	2:29PM	47.37	72.9	0	0
Oct 17 2011	2:28PM	47.37	72.9	0	0
Oct 17 2011	2:18PM	47.37	72.9	0	0
Oct 17 2011	2:18PM	47.37	72.9	0	0
Oct 17 2011	2:17PM	47.37	72.9	0	0
Oct 17 2011	2:12PM	47.37	72.9	0	0

### ● CLEAN

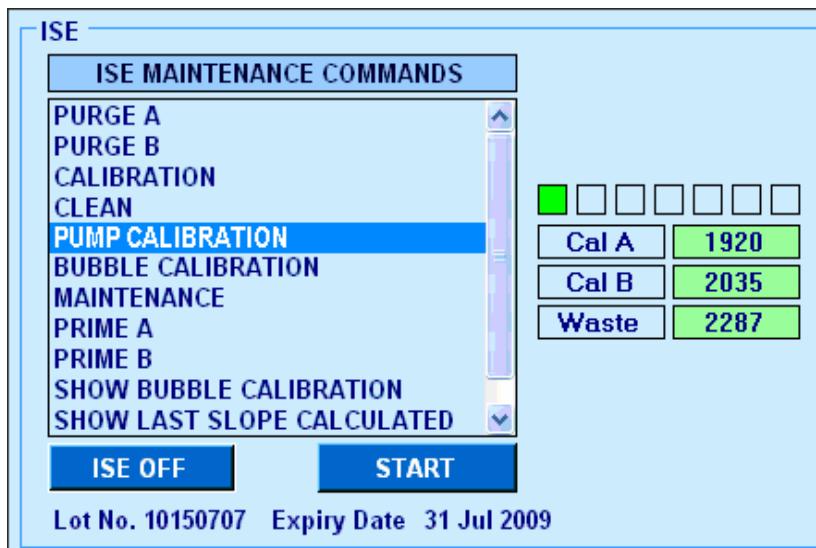
This command is used to remove protein build-up from the ISE Module electrodes. The Clean command should be performed once per 24-hour period.

On successful operation, it is indicated by green colored box, if it is failed, then Coral (deep pink) colored box will be displayed.

### ● PUMP CALIBRATION

This cycle is used to calibrate the peristaltic pumps of the ISE Module.

On successful operation, it is indicated by green colored box, if it is failed, then Coral (deep pink) colored box will be displayed.



- **BUBBLE CALIBRATION**

The bubble calibration command is used to allow the module to reestablish a baseline for detecting air-liquid interfaces. It can also be used as a diagnostic tool to see if the bubble detector is functioning properly.

On successful operation, it is indicated by green colored box, if it is failed, then Coral (deep pink) colored box will be displayed.

- **MAINTENANCE**

This is used to clear fluid from the flow path of the ISE Module, and to pause the Sip Cycle.

The Sip Cycle is used to refresh the Calibrant A in front of the electrodes. Every 30 minutes after the last sample is run, the ISE Module will automatically run a Sip Cycle. No command is required from the host analyzer to initiate a Sip Cycle. The ISE Module automatically clears the flow path, next the ISE Module dispenses 36 µL of Calibrant B into the Sample Entry Port, and it pulls it past the electrodes using the waste pump. The ISE Module then dispenses 95 µL of Calibrant A into the sample entry port, and positions it in front of the electrodes.

On successful operation, it is indicated by green colored box, if it is failed, then coral (deep pink) colored box will be displayed.

- **PRIME A**

This command is used to prime Calibrant A solution from the reagent pack. It is performed after installing the new ISE Reagent Pack.

- **PRIME B**

This command is used to prime Calibrant B solution from the reagent pack. It is performed after installing the new ISE Reagent Pack.

- **SHOW BUBBLE CALIBRATION**

This command is used to display the bubble calibration values.

- **SHOW LAST SLOPE CALCULATED**

This command is used to display last calibration values for the Na, K, Cl, and Li.

- **SHOW ISE PUMP CALIBRATION**

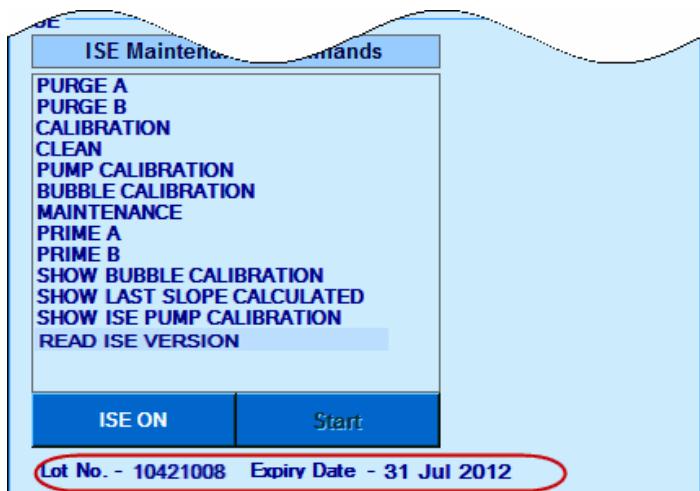
This command is used to display the ISE pump calibration values.

- **READ ISE VERSION**

This command is used to display the ISE module software version.

On clicking **ISE ON** button, the system will check for the (calculated) volume of Calibrant A and Calibrant B.

- In case, if the remaining (calculated) volume of any Calibrant is less than 10% of the total Volume then the message “ISE Reagent Pack Volume Low (Less than 10% of Total Volume)” will be displayed in error grid and logged in the database. This message is only for the user information.
- In case, if the remaining (calculated) volume of any Calibrant is below the respective threshold level, then the alert message “ISE Reagent Pack Volume Very Low (Less than 3 Days Sip)” will be displayed with RED background in error grid.



Once the check is completed, the ISE reagent pack **Lot Number** and **Expiry date** will be displayed in the Maintenance screen.

However, you can proceed with RUN and other maintenance activities.

#### **8.4.3.5.1. Checking ISE Pack Details**

The ISE pack details can be view by **ISE PACK** button, through the **Status Monitor** screen. These details are viewable only before starting the run as this option is disabled during the run.

On clicking this button, the ISE reagent pack information will be displayed which contains.

- Lot Number, Installation Date and Expiry Date of current ISE Reagent Pack

- Details of all ISE Calibration values
- Remaining ISE Reagent Volume Indicator (approximate remaining volume of Calibrant A and Calibrant B; whichever is lesser).

**SAMPLE TRAY REAGENT TRAY REACTION CURVE BARCODE SCAN**

**ISE REAGENT PACK DETAILS**

Installation Date: 04 May 2008 Expiry Date: 31 Jul 2009  
Lot No.: 10150707

**ISE CALIBRATION DETAILS**

Date Time	Na	K	Cl	Li	Lot No.	Exp. Date
May 4 2011 10:35AM	59.74	0	47.15	0	10611009	30 Sep 2012
May 4 2011 10:33AM	59.08	0	46.98	0	10611009	30 Sep 2012
May 4 2011 10:31AM	68.49	0	47.33	0	10611009	30 Sep 2012
May 4 2011 10:30AM	61.73	0	48.12	0	10611009	30 Sep 2012
May 4 2011 10:28AM	79.64	0	49.72	0	10611009	30 Sep 2012
May 4 2011 10:19AM	91.35	0	67.5	0	10611009	30 Sep 2012

**REMAINING ISE REAGENT VOLUME INDICATOR**

**PRE-RUN OPT**

Auto Rerun  
 Disk Change

**Barcode Scan**

Reagent  
 Sample

**RGT Level Scan**

Selective  
 All

**Select All**

**RUN OPTIONS**

Calibration  
 Controls  
 Photometric  
 ISE Patient

**De-Select All**

**ISE PACK** (This button is circled in red)

**Refresh Positions**

**Work List**

**Add Reagent**

**Add Sample**

**Calibration Required**

**SR POS TEST TIME**

SR	POS	TEST	TIME
R1S			
01			
02			
03			
04			
05			
06			
07			
08			
09			
10			
11			
12			
13			
14			
15			
16			
R2			
18			
19			
20			
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35			
36			



**NOTE:** The system detects New / Change in ISE Reagent Pack only on interacting with ISE module (by clicking ISE ON from the Maintenance screen or on starting the ISE run) or during Auto Maintenance operations. Hence, if the user clicks ISE Details button just after (physically) installing the New ISE Reagent Pack, system will displays the ISE Details of the earlier Reagent Pack.



**NOTE:** On detecting (and registering) new ISE Reagent Pack, Backup of ISE inventory data of earlier Reagent Pack will be taken by the system on the analyzer PC.



**NOTE:** During ISE Sampling (Serum/Urine Samples), ISE inventory is updated even on the occurrence of Time Out/Error received in ISE result string from analyzer.

### 8.4.3.6. Auto Maintenance

By default, the auto maintenance actions are performed automatically at the beginning of the day when the application is started first time. This is an automatic service action that does not require manual intervention.

This operation can be initiated any time from the AUTO MAINTENANCE option from the Maintenance screen:



There are some series of actions performed during the auto maintenance startup and shut down operation.

#### 8.4.3.6.1. Operation performed during Auto Maintenance at Startup

Startup
1. Priming of laundry unit and SRPT probe with DI water for one minute (automatic step).
2. Auto Span operation (automatic step).
3. Cuvette rinse operation (automatic step).
4. Perform priming of SRPT syringe for one minute (automatic step).

#### 8.4.3.6.2. Operation performed during Auto Maintenance at Shutdown

Shutdown
1. Analyzer initialization.
2. Volume scan of cleaning solution.
3. Cuvette rinse operation of 11 cuvettes.
4. Probe cleaning with cleaning solution for 3 times.
5. Internal and External probe cleaning with DI water in trough for 3 times.
6. Probe cleaning with DI water for 3 times.
7. Water save operation
8. Shutdown

#### 8.4.3.6.3. Steps to initiate Auto Maintenance at Startup

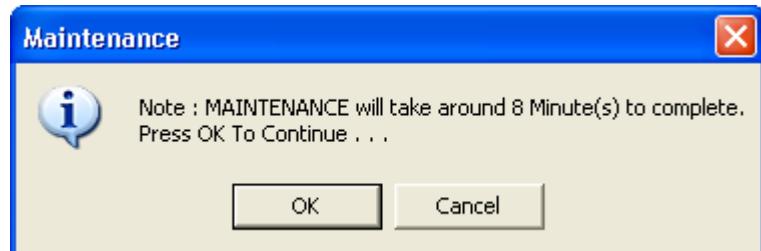
To perform auto startup action manually, do the following:

1. In the **Maintenance** screen, select **START-UP** from the AUTO MAINTENANCE frame.



2. Click **START**.

On clicking, the following window will be displayed.



3. Click **OK** to continue with the maintenance.

This will start the auto maintenance operation.

#### 8.4.3.6.4. Steps to initiate Auto Maintenance at Shutdown

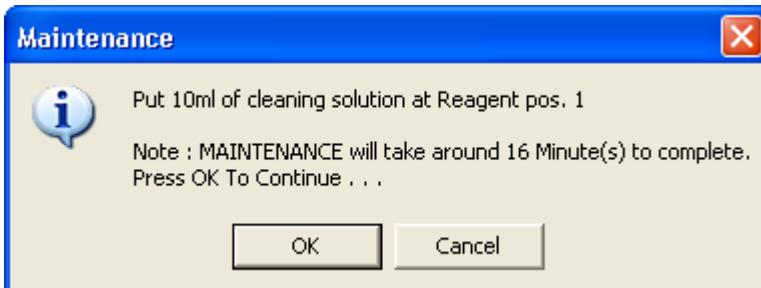
To perform auto shutdown manually, do the following:

1. In the **Maintenance** screen, select **SHUTDOWN** from the AUTO MAINTENANCE frame.



2. Click **START**.

On clicking, the following window will be displayed.



Put the required amount of cleaning solution on the mentioned reagent and sample position, and then click **OK**.

This will start the maintenance operation and the instrument will be shutdown once it is completed.

## 9. Introduction to ISE Module

The ISE (Electrolyte Measurement System) is placed inside the chemistry analyzer, and it measures the concentration of  $\text{Li}^+$ ,  $\text{Na}^+$ ,  $\text{K}^+$ , and  $\text{Cl}^-$  in serum, plasma and diluted urine.

The ISE unit consists of ISE module, ion electrode and three pumps, two for supply and other for waste. ISE Reagent pack containing Calibrant A and Calibrant B is attached to the ISE module.

ISE module	This module consists of electrodes (Na, K, Cl, Li and Reference) and pumps. Measurement of concentration is done at electrodes and rinses/calibrates after every measurement Communication to the analyzer is carried out through RS232C.
Ion electrode	This unit consists of Na, K, Cl, Li and Reference electrodes.
Cal A pump	This pump supplies Calibrant-A into ISE module.
Cal B pump	This pump supplies Calibrant-B into ISE module.
Waste pump	This pump drains liquid from ISE module.

All waste liquid are discharged into the external tank for high concentration waste liquid.

The Module is completely self-contained. All sample and Calibrant positioning within the module is controlled by an integral microprocessor, which assures reliable electrode operation and maximum lifetime. The electrolyte measurement system's microprocessor applies proprietary mathematical algorithms to electrode output voltages, converting them to clinical units of mmol/L.

## 9.1. Part Location

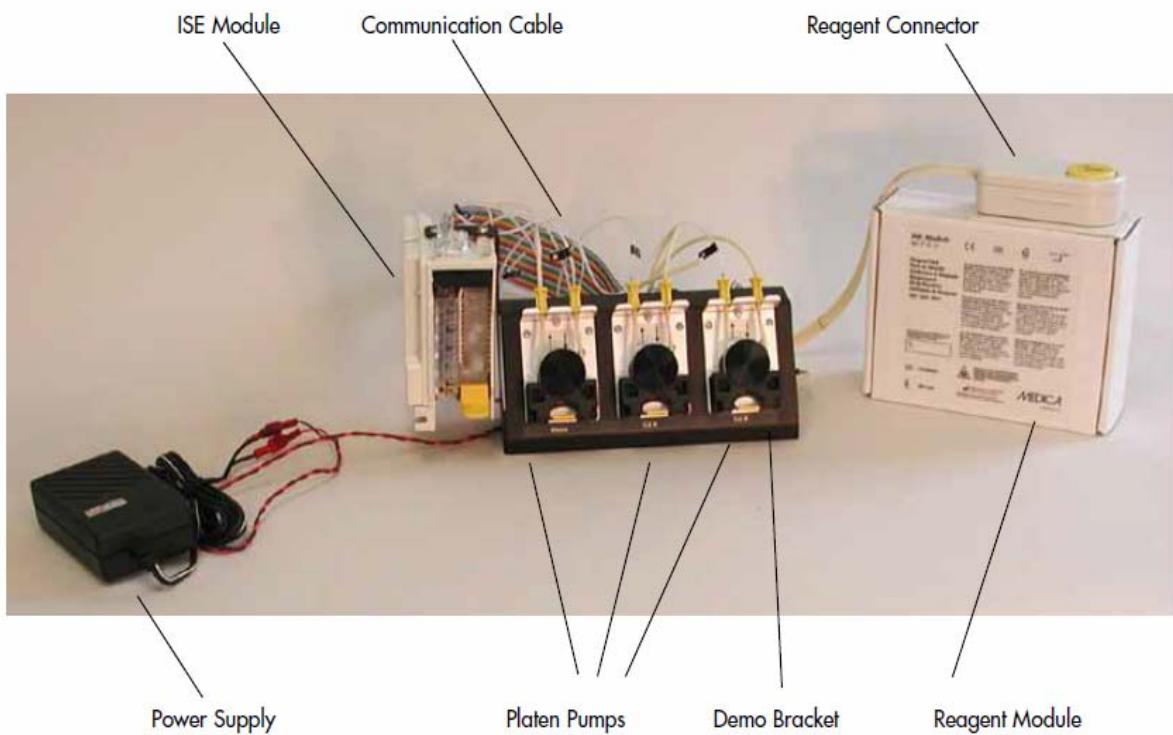


Figure 9-1. Front View

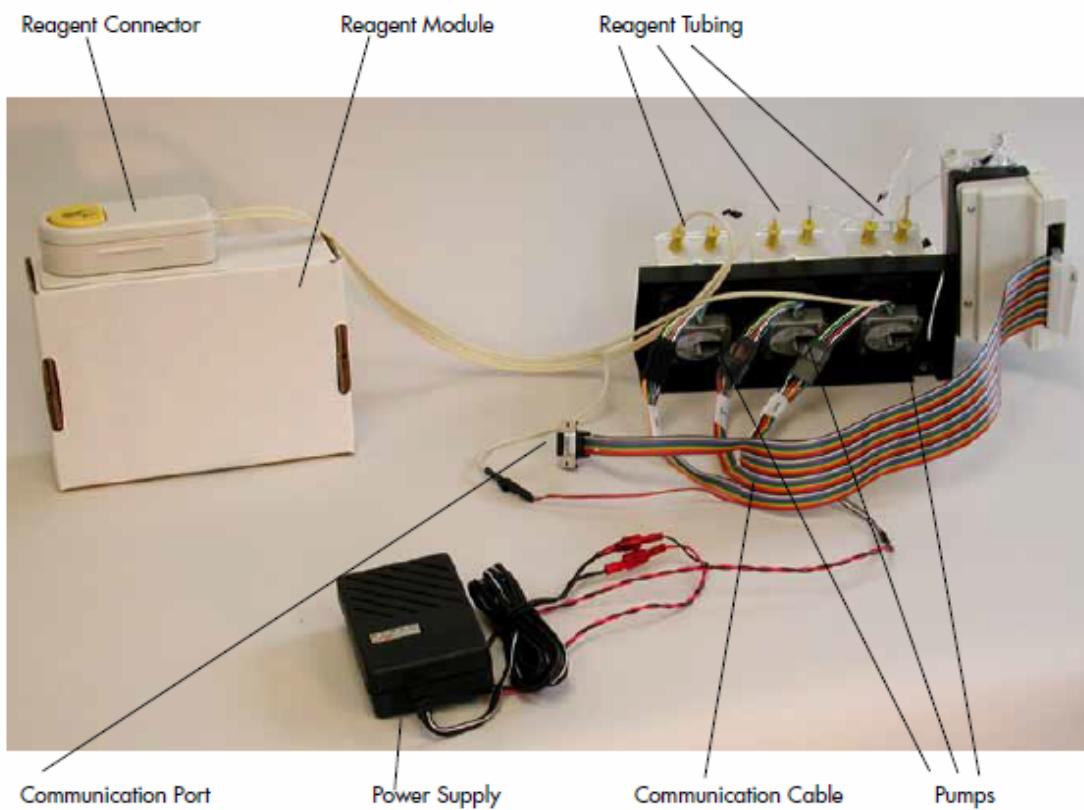


Figure 9-2. Rear View

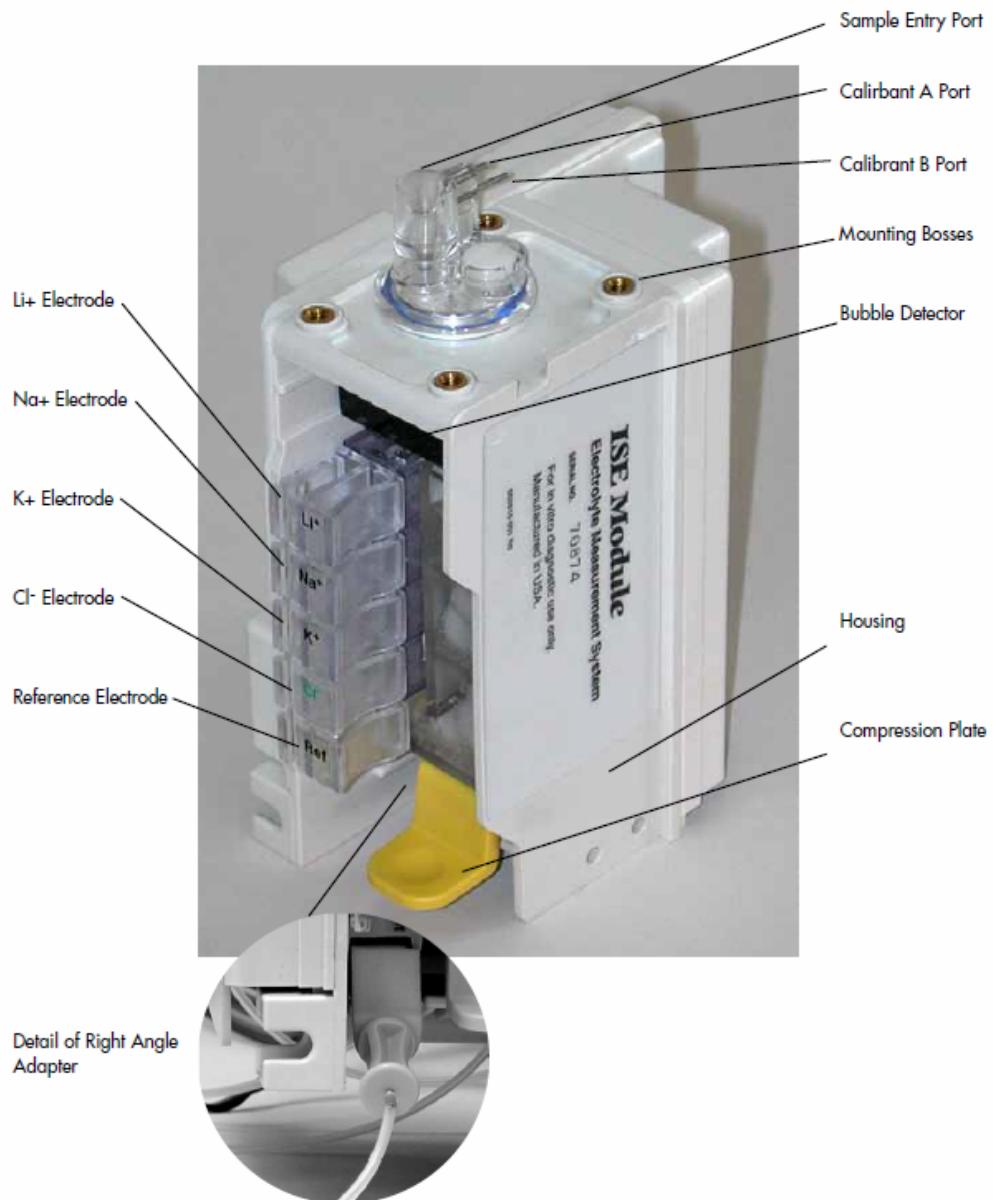


Figure 9-3. ISE Module

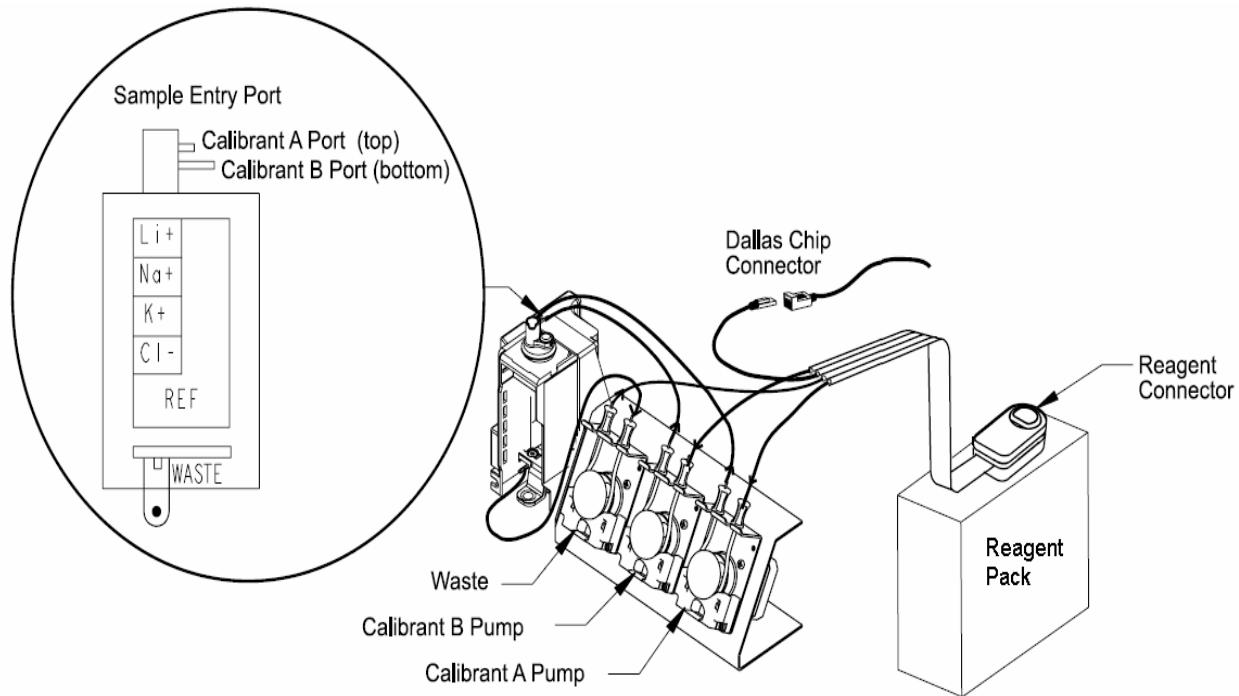


Figure 9-4. Interconnection tubing diagram

## 9.2. ISE Technical Specification

Sample type	Serum, Plasma or Urine (Urine requires dilution)
Sample size	70 µl serum 140 µl diluted urine
Analysis time	Serum – 35 seconds, including one point calibration Urine – 40 seconds, including one point calibration
Throughput	Serum – 100 samples per hour Urine – 90 samples per hour
Power	24V DC, 1.0A (SMPS, four channel ISE)
Module Size	161 mm high x 65.5 mm wide x 98.6 mm deep
Reagent Pack includes	Calibrant A, Calibrant B
Other Reagents	Cleaning Solution, Urine Diluent
Operating Ambient Temperature	15°C - 32°C

## 9.3. ISE Measurement Theory

The electrolyte measurement system measures Sodium, Potassium, Chloride, and Lithium ions in biological fluids using ion selective electrode technology. A diagram of the electrode measurement system.

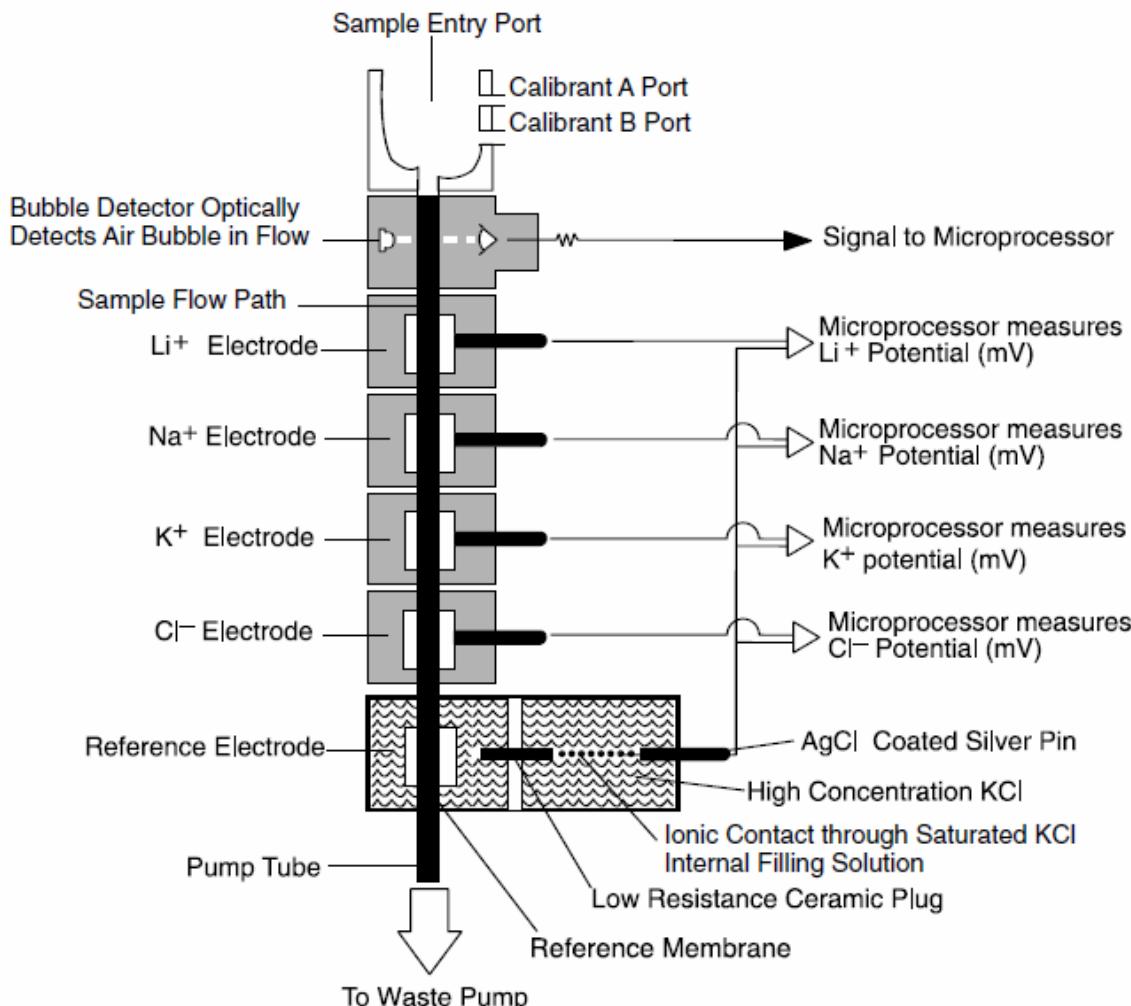


Figure 9-5. Schematic diagram for electrolyte measurement system

The flow-through electrodes use selective membrane tubing, specially formulated to be sensitive to the respective ions. The potential of each electrode is measured relative to a fixed, stable voltage established by the double junction Silver/Silver-chloride reference electrode. An ion-selective electrode develops a voltage that varies with the concentration of the ion to which it responds. The relationship between the voltage developed and the concentration of the sensed ion is logarithmic, as expressed by the Nernst equation:

$$E = E_o + \frac{RT \log(\alpha C)}{nf}$$

Where:

$E$  = the potential of the electrode in sample solution

- E<sub>o</sub> = the potential developed under standard conditions  
RT/nF = A temperature dependent “constant”, termed the slope  
log = Base ten logarithm function  
 $\alpha$  = Activity coefficient of the measured ion in the solution  
C = Concentration of the measured ion in the solution

## 9.4. Electrodes and Reagents Used

### Electrodes used in the ISE module:

The electrodes are maintenance-free. Cleaning Solution, aspirated from an operator designated sample cup, is used at least once a day at the end of the day in order to minimize protein buildup in the fluid lines and electrodes. A pump calibration should be performed each day. A two-point calibration of the ISE module is also done at least once a day at the beginning of the first sample run. If the user is running more than 50 samples a day, cleaning and calibration must be performed after completion of 50 samples.

The entire double-junction reference electrode is disposable. The reference electrode is filled with saturated KCl so that no filling solution must be added during the lifetime of the electrode. The lifetime of the reference electrode is 6 months or 10,000 samples. No addition of internal filling solution is required for this electrode.

Electrodes require Calibrant A sampling at 30-minute intervals for reliable operation, but this is completely controlled by the electrolyte measurement system without any need for operator intervention.

It is not necessary to regulate the electrode housing temperature if its environmental temperature does not exceed 32 degree C.

### Reagents used in the ISE Module:

The sample is aspirated from a sample cup and dispensed into the sample port at the top of the ISE module by the sample probe. The sample is then positioned in front of the sensors using the double detector and the waste pump.

Four reagents are needed to operate the ISE module:

**Calibrant A:** It is used in both two-point and single-point calibrations for serum sample analysis. Calibrant A is pumped into the sample entry port by the Calibrant A pump and then positioned in front of the electrodes by the waste pump. Calibrant A solution is also used for Pump and Bubble Calibration.

**Calibrant B:** It is used in two-point and single-point calibrations for urine sample analysis. Calibrant B is pumped into the sample entry port by the Calibrant B pump and then positioned in front of the electrodes by the waste pump.

**Cleaning Solution:** It is used once a day to prevent protein buildup on the electrodes and fluid path. It must be used more frequently if the ISE Module performs greater than 50 sample measurements per day. 100  $\mu$ L of cleaning

solution must be aspirated by the host analyzer from a sample cup on the host analyzer and dispensed into the sample entry port. The sample cup must be covered to eliminate evaporation..

**Urine Diluent:** It is required for the urine samples. Urine samples are diluted on-board by 10 times (1 part sample to 9 parts urine diluent) to perform urine measurement. The operator must keep the urine diluent on the Reagent Tray.

## 9.5. Urine ISE Dilution Rerun

Urine ISE sample should be Re-run with different Dilution ratio (increase / decrease Sample volume), based on the Result flags in the order of K, Na then Cl.

The ISE Urine sample is performed with 10X dilution during its first run. During ISE-rerun, the 3X and 15X dilutions may be performed, depending upon the flag attached to the result (based on increased or decreased sample volume).

On receiving the result, the test will go for rerun on the following conditions:

- If the sample result is attached with PANH flag, then sample will go for rerun with normal dilution that is 1:9 (10X). If the sample result is attached with RANGH flag, then the sample will go for rerun with decreased sample volume that is 1:14 (15X) dilution.
- After receiving the result for the sample replicates, if both the replicates are attached with different flag that is RANGH (requiring decrease rerun) and RANGL (requiring increase rerun). But the priority of RANGH is higher so this sample will go for a Re-run with decrease sample volume. The number of replicates sent to Rerun will be the same as number of replicates sent during the 1st (original) determination.



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**NOTE: The software will display re-run result (after applying the volume correction) for only those tests having flags that required re-run. The Attach Rerun Flag ("#") and Volume Increase/ Volume Decrease Flag ("V-I"/ "V-D") will be displayed after correcting the results. Flags H, L, PANH, PANL , RANGH and RANGL will be applicable to ISE results**

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## 9.6. Storage and Usage of the Reagents

1. Store all solutions in a dark and cool place at room temperature.
2. Don't preserve the reagents such as or cleaning solution once they are dispensed to sample cup.
3. Don't use the expired solution.
4. When opening new bottle for a solution, don't mix remaining solution from the previous bottle.
5. Reagent Pack has one month of on board stability.

## 9.7. Turning Off the Power

As Calibrant-A and Calibrant-B is automatically dispensed into ISE unit every 30 minutes to prevent electrodes from drying out; it is not recommended to turn off the main power supply of the analyzer. Switch off only the analyzer at the end of the day. This will keep the above function activated.

When the Calibrant remains in fluid path for over two hours without flowing, the Na ion from reference electrode can reach Na electrode and saturate the membrane resulting in effected Na measurement.

When the power to the analyzer needs to be turned off for a reason such as maintenance, follow the procedure below to purge Calibrant-A solution in the path. Also refer to the procedure when turning off the power for more than several hours, as it requires storage of the electrodes.

## 9.8. Shutdown Procedure

### 9.8.1. Preparing the ISE Module for Storage

If the laboratory plans to store the ISE module for a period greater than one week, during which the analyzer will not be connected to power, the following steps should be performed:

Before removing the electrodes, they should be cleaned using the cleaning solution and then running 3 Purge A cycles from the **Maintenance > ISE**.

### 9.8.2. Reference, $\text{Na}^+$ and $\text{Cl}^-$ Electrodes

1. Depress the compression plate and remove all electrodes, including the reference electrode from the ISE Module.
2. Place the  $\text{Na}^+$  and  $\text{Cl}^-$  electrodes into individual sealed bags.
3. Reinsert the Reference Electrode flow path line with yellow flag, if available, and then put into individual sealed bags.

### 9.8.3. $\text{K}^+$ and $\text{Li}^+$ Electrode

1. Aspirate a small volume of Calibrant A from the top port of the reagent pack into a syringe fitted with a blunt needle.
2. Inject sufficient Calibrant A into the lumen of the  $\text{K}^+$  and  $\text{Li}^+$  electrodes until fluid fills the lumen.
3. Cover both ends of the lumen (both sides of the  $\text{K}^+$  and  $\text{Li}^+$  electrodes) with tape to hold the Calibrant A in place.
4. Insert the  $\text{K}^+$  and  $\text{Li}^+$  electrodes into a sealed bag.

### 9.8.4. Reagent Pack

Remove the Reagent pack from the analyzer and discard it.

## 9.8.5. Analyzer Tubing

Remove all the fluidic tubing and thoroughly rinse with DI water.

## 9.8.6. Analyzer Re-activation

- Remove all electrodes from the sealed bags.
- Remove tape from K<sup>+</sup> and Li<sup>+</sup> electrode.
- If necessary, soak the reference electrode in warm water until the lumen of the electrode has been cleared of salt build-up.
- Install electrodes into the ISE Module.
- Connect new reagent pack to the ISE Module.
- Use Prime Cycles to prime the Calibrants.
- Calibrate analyzer.

## 9.9. ISE Calibration

It is mandatory to perform calibration (two points) before ISE measurement. It is recommended to make it a routine operation to run calibration before running first sample of the day.

One point calibration is automatically performed at each sample processing by Calibrant-A and Calibrant-B is used for two-point calibration.

The calibration is required at the following cases:

**IMPORTANT:**

- The power switch of analyzer is turned off.
- Eight hours have passed since the last ISE calibration.
- Environmental temperature has changed more than 4 degree C since the last ISE calibration.
- More than 50 samples are processed after ISE Calibration in the morning.

### 9.9.1. Procedure for ISE Calibration

Before starting analysis of sample for electrolytes, user should first clean and calibrate the ISE module.

The following sequence should be used for ISE unit calibration:

1. Install the Reagent Pack and connect it to the ISE module. If the Reagent Pack is already in place, shake it gently.
2. Pour the Cleaning solution into the sample cup and place on the ISE2 position of the standard sample tray.
3. Go to the **Maintenance** from the main menu screen.

4. Click **ISE ON** button.
5. Select **PURGE A** and click **START**.

On clicking, the ISE Module pumps 100  $\mu\text{l}$  of Calibrant A from the reagent pack and dispenses it into the sample entry port to wash out the electrode flow path. Repeat the procedure if required.

6. Select **PURGE B** and click **START**.

On clicking, the ISE Module pumps 100  $\mu\text{l}$  of Calibrant B from the reagent pack and dispenses it into the sample entry port to wash out the electrode flow path. Repeat the procedure if required.

7. Select **PURGE A** and click **START**.

8. On clicking, the ISE Module pumps 100  $\mu\text{l}$  of Calibrant A from the reagent pack and dispenses it into the sample entry port to wash out the electrode flow path. Repeat the procedure if required.

9. After completion of purge cycles, select **CLEAN**, and then click **START**. On clicking, the analyzer dispenses 100  $\mu\text{l}$  of cleaning solution and 180  $\mu\text{l}$  of Calibrant A in the sample entry port during the cleaning process.

10. After cleaning cycle is over, perform 6 to 8 **PURGE A** cycles. Now the system is ready for calibration.

11. Select **CALIBRATION** and click **START**.

This command is used to calibrate the electrodes of the ISE Module. The ISE Module then cycles Calibrant B and Calibrant A solutions in front of the electrodes and measures the millivolt output of the electrodes for each of the respective solutions.

These millivolt readings are then used to set up a relationship between sample concentration and electrode millivolt output. The change in millivolts per change in concentration is the slope of the electrode. The slope of the electrodes is reported in mv/dec (millivolts per decade change in concentration), and should be within the following limits:

$\text{Li}^+$  47-64 mV/dec

$\text{Na}^+$  52-64 mV/dec

$\text{K}^+$  52-64 mV/dec

$\text{Cl}^-$  40-55 mV/dec

After the calibration process is completed, electrode calibration slopes are displayed on the right side of screen. If any error occurs during the calibration process, the error code is also displayed in the error message grid. If the slopes are within range then a box with green color is displayed. If slopes are out of range then a box with coral (deep pink) color is displayed. The previous calibration details with date and time along with the slope values can be viewed. To view them select **CALIBRATION**, and then click **SHOW REPORT**.

If the electrode calibration slopes are in the acceptable range, the electrolyte measurement system is ready for the sample analysis.

For Serum samples 70 µl and for Urine 140 µl (10 times diluted with urine diluent) of sample is required for the Electrolyte measurement.

The slope is defined as:

$$Slope = \frac{E_B - E_A}{\log(C_B/C_A)}$$

Where CA = Calibrant A concentration in mmol/L

CB = Calibrant B concentration in mmol/L

EA = ISE Potential developed in Calibrant A solution in mV

EB = ISE Potential developed in Calibrant B solution in mV

12. To perform Pump Calibration, select **PUMP CALIBRATION** and click on **START**.

175 µl of Calibrant A solution and 375 µl of Calibrant B solution are dispensed in the sample port. Once the process is completed successfully, values for all the 3 pumps CAL A, CAL B and Waste are displayed. If the values are between 1500 and 3000, calibration is displayed OK with green colored box else it is displayed NOK with red colored box.

13. To perform Bubble Calibration, select the option **BUBBLE CALIBRATION** and click on **START** button. 75 µl of Calibrant A solution is dispensed in the sample port. Bubble calibration allows the module to reestablish a baseline for detecting air-liquid interface. It can be used as a diagnostic tool to see if the bubble detector is functioning properly. If the process is successful without any error it's displayed OK with green colored box else it is displayed NOK with red colored box.

## 9.10. ISE Maintenance Schedule

The ISE Module has been designed to require very little operator maintenance. The only daily maintenance required is to run the cleaning solution after the last sample of the day or after 50 patient samples, whichever is first.

### Recommended Component Replacement Schedule (low volume user)

Li <sup>+</sup> Electrode	: 6 months
Pump Tubing	: 6 months
Na <sup>+</sup> Electrode	: 6 months
K <sup>+</sup> Electrode	: 6 months
Cl <sup>-</sup> Electrode	: 6 months
Reference Electrode	: 6 months

Fluidic Tubing : 12 months

**Recommended Component Replacement Schedule (high volume user, greater than 100 samples/day)**

Li<sup>+</sup> Electrode : 3,000 samples

Pump Tubing : 6 months

Na<sup>+</sup> Electrode : 10,000 samples

K<sup>+</sup> Electrode : 10,000 samples

Cl<sup>-</sup> Electrode : 10,000 samples

Reference Electrode : 10,000 samples

Fluidic Tubing : 12 months

## 9.11. Acceptable Calibration Ranges

The following are the acceptable calibration values displayed at the bottom of the screen after completion of an ISE calibration.

Na<sup>+</sup> :Slope 52 to 64 milli volt / Decade

K<sup>+</sup> :Slope 52 to 64 milli volt / Decade

Cl<sup>-</sup> :Slope 40 to 55 milli volt / Decade

Li<sup>+</sup> :Slope 47 to 64 milli volt / Decade

## 9.12. Troubleshooting

Symptom	Cause	Corrective actions
System does not respond	1. No power	
	2. Communication failure	Turn off power, reapply power.
	3. RS232 cable is disconnected or damaged	Reconnect or replace cable.
	4. ISE Module connector has been damaged	Replace board.
	5. Component failure on board	Replace board.
Low Slope Na <sup>+</sup> or K <sup>+</sup> <52 mV/decade Cl <sup>-</sup> <40mV/decade, Li <sup>+</sup> <47mV mV/decade or High Slope Na <sup>+</sup> ,	1. Misalignment of electrodes	Remove electrodes. Inspect o-rings. Reassemble properly.
	2. Calibrator solutions	Replace Reagent pack
	3. Electrode (low slope)	Replace electrodes.
	4. Air bubble on reference electrode membrane	Remove electrode, tap to dislodge bubble, replace, and recalibrate

Symptom	Cause	Corrective actions
K+, or Li+>64 mV/decade Cl- >55 mV/decade	5. Reference electrode 6. ISE Module or Fluid temperatures exceed 32° C (high slope)	Replace reference electrode and retest Change ISE Module location if ambient temperature is too great.
Noise Error Flag Single electrode	1. Electrode.	Replace problem electrode and recalibrate
	2. Electrical noise spike from environmental source	a) Find source of spike and eliminate. b) Check grounding of ISE module.
	3. Component failure on ISE Module board	Replace Board.
Noise Error Flag Multiple electrodes	1. Reference Electrode	Replace reference electrode and recalibrate
	2. Electrical noise spike from environmental source	a) Check for electrical noise coincident with activation. b) Check grounding of ISE Module
	3. Component failure on ISE Module board.	Replace board.
Drift Error Flag Single Electrode	1. May occur when new electrode Purge the Calibrant A is installed. If the electrode is new it may initially drift as it rehydrates over the course of 15 minutes	Purge the Calibrant A and recalibrate the module.
	2. Electrode	Replace the electrode and recalibrate.
Drift Error Flag Multiple Electrode	1. May occur when new electrode or reagent pack is installed on system.	Purge the Calibrant A and recalibrate the ISE Module
	2. Reference electrode	Replace reference electrode and recalibrate
	3. Electrical spikes from environmental source	a) Find source of spike and eliminate b) Check the grounding of ISE Module.
	4. Component failure on ISE Module board	Replace the board
Air in Sample	1. Insufficient sample pipetted into the ISE Module sample entry port.	Host instrument must deliver 70µl. Increase dispensed sample volume.
	2. Fluid leaks.	Determine source of leak and resolve
	3. Sample not positioned properly.	a) Electrode not seated properly. Remove electrode. Inspect o-rings and reassemble. b) Replace pump tubing.
	4. Pump tubing obstructed.	Replace pump tubing.

Symptom	Cause	Corrective actions
	4. Bubble in sample.	Host must deliver sample free of bubbles.
Air in Sample and Cal A	1. Cal B and Cal A are segmented with air	a) Electrodes are not properly seated or compressed. Check compression plate, spring and seal. Remove and reassemble electrodes.
	2. Fibrin or salt is plugging the electrode flow path.	a) Use Cleaning procedure for module. b) Remove electrode and clean or replace electrode with plugged flow path. Reinstall electrodes and recalibrate.
	3. Bubble detector is malfunctioning	Replace bubble detector.
	4. Waste pump is malfunctioning	Replace Waste Pump.
	5. Dirty sample cup	Clean with cotton swab and DI water.
Air in Cal B and Air in Cal A	1. Cal B and Cal A are segmented with air	a) Electrodes are properly seated. Check compression plate, spring and seal. b) Ensure that all electrodes and o-rings are properly installed. c) Ensure tubing between reagent pack and sample entry port is connected properly. d) Replace tubing between reagent pack and sample entry port. e) Reagent low or out. f) Use Cleaning procedure for module.
	2. Fibrin or salt is plugging the electrode flow path.	a) Use Cleaning procedure for module. b) Remove electrodes and clean or replace electrode with plugged flow path. Reinstall electrodes and recalibrate.
	3. Bubble detector is malfunctioning	Replace bubble detector.
	4. Waste pump is malfunctioning	Replace waste pump
	5. Bubble detector malfunction	Replace bubble detector
Air in Cal A	1. Calibrant A	Replace reagent pack with new one, prime and recalibrate
	2. Tubing from reagent module is disconnected, plugged or crimped	Reconnect or replace tubing.

Symptom	Cause	Corrective actions
	3. Calibrant A pump is not working properly	a) Check electrical connections. b) Replace pump tubing c) Replace motor d) Replace pump.

## 9.13. Procedure for Installing New Reagent Pack

The MultiXL application automatically detects the newly installed ISE reagent pack if it is replaced or installed. For detection of new ISE reagent pack, follow the prerequisites.

- MultiXL software with ISE Reagent Pack Inventory feature with the New ISE Reagent Pack. For existing partially utilized pack, the inventory will not be correct .



**NOTE: Software is using a counter to calculate ISE inventory. Any manipulation, like releasing and attaching the reagent pack connector, will falsify the inventory.**

- ISE Reagent Pack from one analyzer should not be interchanged with Pack on other analyzer. In such event, the inventory will not be correct.
- ISE Module should be always ON (for periodic sip cycles).

Follow this procedure for installing the new reagent pack:

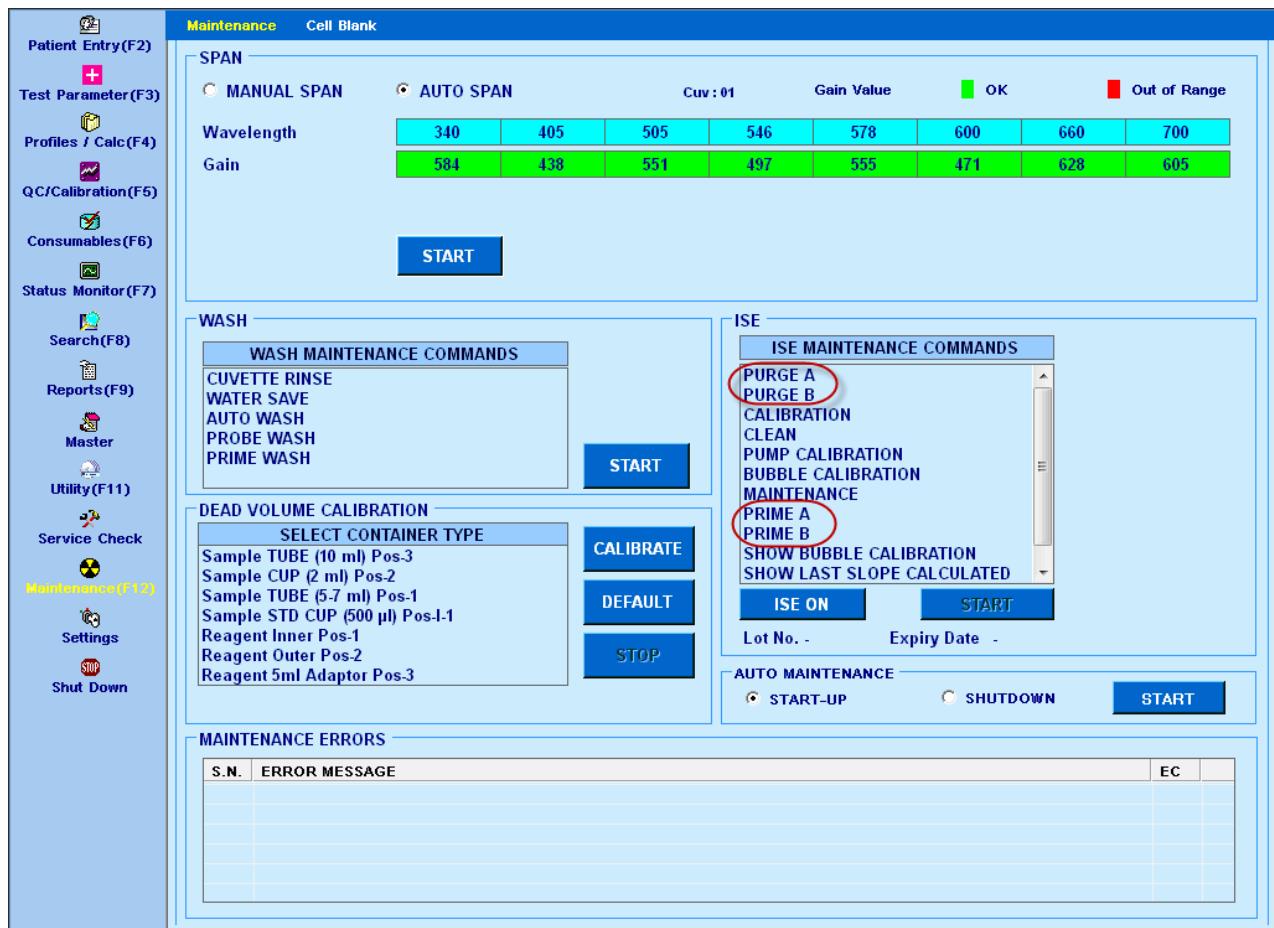
1. Connect the new Reagent Pack on the analyzer.
2. Click on **ISE ON** button in the **Maintenance** screen. The software will automatically detect the new pack and perform some series of ISE maintenance commands automatically till ISE module sends OK status (air removed), The following maintenance commands are
  - PURGE A and PURGE B maximum up to 10 times
  - PRIME A and PRIME B up to 9 times



**NOTE: During this operation, the following error message may be displayed on the error grid:**

- Air in Calibrant A. ISE tubing may be bent, closed or not attached or
- Air in Calibrant B. ISE tubing may be bent, closed or not attached.

This will help the user in detection of bended or closed tubing. In this case, correct the closed or bent tubings and again perform the PRIME A and PRIME B commands manually through the **Maintenance > ISE MAINTENANCE COMMANDS**. See figure below.



3. Once the auto priming operation performed correctly, the lot number and expiry date of the new reagent pack will be displayed on the **Lot No.** and **Expiry Date** information along with the following details:

- ISE Pack Installation Date
- Distributor code (This information is stored in the reagent pack's dallas chip and not visible to user.)
- Volume of Cal A and Cal B in full Pack.

The above information can be checked through **ISE Pack** button available on the **Status Monitor** screen. See section 8.4.3.5.1 *Checking ISE Pack Details* for more information.

4. Perform Calibration with the new reagent pack and check the values.



**NOTE: On detecting (and registering) new ISE Reagent Pack, Backup of ISE inventory data of earlier Reagent Pack will be taken by the system on the analyzer PC.**

## 9.14. Error Message for ISE Unit

The following error codes with description will be displayed on the Maintenance error grid, if any error occurred during the ISE operation.

Assembly	Error Code	Description	Possible Failure	Corrective Actions
ISE	ID	ISE Pack - Installation Date Mismatch. Inventory may not be Correct	Reagent pack expired or invalid	Change ISE Pack
ISE	IE	ISE Pack - Expired	--	Change ISE Pack
ISE	IL	ISE Reagent Pack Volume Low (Less than 10% of Total Volume)	Required volume insufficient	Change ISE Pack
ISE	IN	ISE Pack - No Dallas Chip	Dallas chip absent	Ensure reagent connector properly connected on Dallas chip
ISE	IR	ISE Pack - Dallas Read Error	Dallas chip absent	Change ISE Pack
ISE	IT	ISE Pack - Time Out Occurred	Dallas chip absent	1. Check ISE module connection 2. Ensure reagent connector properly connected on Dallas chip
ISE	IU	ISE Pack - Unknown Distributor	--	Change ISE Pack
ISE	IV	ISE Reagent Pack Volume Very Low (Less than 3 Days Sip)	Required volume insufficient	Change ISE Pack
ISE	IW	ISE Pack - Dallas Write Error	No Dallas chip, date already written	Ensure reagent connector properly connected on Dallas chip
ISE	ISES*	Air in Sample / Urine	1. Required volume insufficient 2. Tubing leakage	1. Change ISE Pack 2. Ensure proper tubing
ISE	ISEA*	Air in Calibrant A	1. Required volume insufficient 2. Tubing leakage	1. Change ISE Pack 2. Ensure proper tubing
ISE	ISEB*	Air in Calibrant B	1. Required volume insufficient 2. Tubing	1. Change ISE Pack 2. Ensure proper tubing

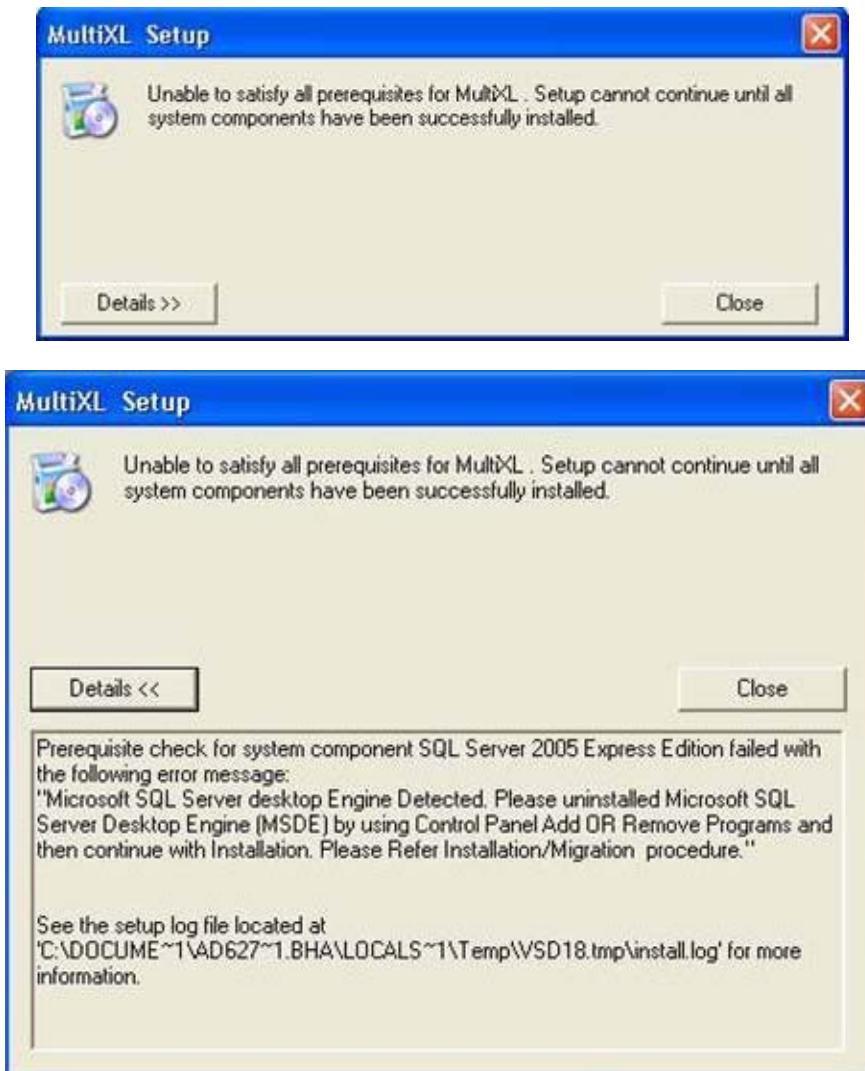
			leakage	
ISE	ISEC*	Air in Cleaner	1. Required volume insufficient 2. Tubing leakage	1. Change ISE Pack 2. Ensure proper tubing
ISE	ISEM*	Air in Segment	1. Required volume insufficient 2. Tubing leakage	1. Change ISE Pack 2. Ensure proper tubing
ISE	ISEP*	Pump Cal	1. Required volume insufficient 2. Tubing leakage 3. Motor problem	1. Change ISE Pack 2. Ensure proper tubing 3. Check motor wiring 4. Change motor
ISE	ISEF*	No Flow	1. Motor problem 2. Tube choked/bent	1. Check motor wiring 2. Change motor 3. Replace Tubing
ISE	ISED*	Bubble Detector	1. Bubble Detector module problem	Change ISE Module
ISE	ISER*	Dallas Read	1. Dallas chip absent 2. Dallas chip connection improper	Change ISE Pack
ISE	ISEW*	Dallas Write	No Dallas chip, date already written	Ensure reagent connector properly connected on Dallas chip
ISE	ISET*	Time Out	Dallas chip absent	1. Check ISE module connection 2. Ensure reagent connector properly connected on Dallas chip

## 10. Appendix

### 10.1. Troubleshooting

1. If you are getting “Operating System error 5 (Access denied)” while performing above mention steps then refer section SQL Server 2005 Configuration file for SQL Server 2005 Settings.
2. Incase Microsoft SQL Server Desktop Engine is already installed then below mention screen will appear. Installer will not proceed with the MultiXL installation until user Uninstall Microsoft SQL Server Desktop Engine (MSDE) from Control Panel à Add / Remove Program.

Please refer Migration Guide for Database Engine MSDE to SQL Server Express 2005 from the Installation CD.



3. In case of Windows 7 operating system while installing MultiXL application below mention screen may appear. Please click on Run Program button to continue with the MultiXL Installation.



### 10.1.1. SQL Server 2005 Configuration

Use the following procedure if you are getting “Operating System error 5 (Access denied)” during Create Database operation or Backup operation in MultiXL /Database Utility.

1. Click on **Start > Programs > Microsoft SQL Server 2005 > Configuration Tools > SQL Server 2005 Manager**.
2. In the right panel, select **SQL Server (SQLEXPRESS)** and choose **Properties** option. The following screen will be displayed.



3. Change **Built -In Account** setting by choosing **Local System** from highlighted drop down box.

4. Click on **Apply** button. This will display confirmation message for the Account Change. Click on **YES** and wait for few minutes. This will restart the SQL Server Services.



5. After applying the setting "Apply" button will be disabled. Then close all the windows and continue with MultiXL or Database Utility.



## 10.2. Revision History

Revision	Date	Revision Description	Author
2010.00.01	30-October-2010	Changes incorporated as per ASW version 2010.01	Sarang Dumbre
2010.01	07-May-2011	Updated the software installation procedure as per software version 2010.02	Prasad Patil
2011.01	27-December-2011	<p>Document has been updated as per software version 2011.01.03 and above.</p> <p>The following list of features added in the manual:</p> <ul style="list-style-type: none"> <li>▪ Detection of Reagent Bottle Over Filled</li> <li>▪ Option Stock Over for Consumable Lot is provided for selection.</li> <li>▪ One step installer in installation procedure</li> <li>▪ Copy Calibration</li> <li>▪ Archive database feature</li> <li>▪ Application software will be launched automatically at PC startup</li> <li>▪ Option added in Maintenance screen under ISE to read the ISE version.</li> <li>▪ Technical specification table and features updated</li> <li>▪ All software images updated as per the latest Software.</li> </ul>	Sarang Dumbre