Chapter 1
General Information

OVERVIEW

Chapter 1 contains:

- an introduction to this service manual
- cautions and warnings that are applicable to this analyzer
- specifications for the analyzer
- an introduction to the ABBOTT SPECTRUM® SERIES II™ analyzer
- overview of normal operations of the analyzer
  - assay processes
  - modes of operation
  - procedures for calibration run and sample run

Throughout this manual, all references to analyzers are to the ABBOTT SPECTRUM® SERIES II™ Analyzers (including CCx™ Analyzers) unless otherwise noted.

Only human specimens have been tested and approved for analysis with the ABBOTT SPECTRUM® SERIES II™ analyzers.

For *In Vitro* Diagnostic Use.

CHAPTER CONTENTS

HOW TO USE THIS MANUAL

Intended audience

The ABBOTT SPECTRUM® SERIES II™ Analyzer Service Manual was developed to be used by trained Abbott Laboratories Field Service Engineers/Field Service Representatives (FSEs/FSRs). This service manual will assist FSEs/FSRs in operating, troubleshooting and repairing the analyzer. The related manuals described below are also an integral part of the overall operation and troubleshooting information for the analyzer.

The revision status of this manual is the responsibility of the manual holder.

The sample printouts and screen displays are included in this manual for illustrative and example purposes only. This information is not to be used for clinical or maintenance evaluations.

In no event shall Abbott Laboratories or its subsidiaries be liable for any damages incurred in connection with or arising from the use of this manual by persons not fully trained by Abbott Laboratories.

Related documents

ABBOTT SPECTRUM® SERIES II™ Manual Set (1370-37), including:

- **Operation Manual**
- **Maintenance & Troubleshooting Manual**
- **Reagent Manual**

ISE Service Manual (2-54950-02)

Chapter descriptions

Chapter 1: General Information
- How to use this manual
  - Descriptions of each chapter
  - Conventions used in the service manual
- Cautions and warnings
- Analyzer specifications
- Overview of ABBOTT SPECTRUM® SERIES II™ Analyzer and normal operations of the analyzer

Chapter 2: Troubleshooting
- Introduction to the basic troubleshooting method and isolation procedures (troubleshooting flowcharts)
- Alphabetical and numerical cross-reference lists of error codes, banner messages, and observed problems indicating the related Isolation Procedure (IP) and page number
- Isolation procedures for:
  - banner messages
  - error codes
  - observed problems

Chapter 3: Parts Lists (PLs)
- Illustrated parts lists, including:
  - Part number (and catalog or list number, if applicable)
  - Number of the corresponding Removal & Replacement (RR) procedure in Chapter 4
- Supplemental tools and supplies

Chapter 4: Removal & Replacement Procedures (RRs)
- Removal & Replacement procedures, numbered to correspond with the related Parts List in Chapter 3

Chapter 5: Verification Procedures (VPs)
- This chapter contains the procedures required to verify instrument operation after repairs are complete. Verification Procedures (VPs) are also used to assist in troubleshooting. VPs in this chapter include:
  - Adjustments/alignments
  - Calibrations, checks, tests, and verifications
  - Robotics training
  - Additional procedures

Chapter 6: Preventive Maintenance/Total Service Call

Appendix A: Block Diagrams

Appendix B: Jumpers

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Conventions used in this manual

Numbering scheme

Throughout the manual, various messages and procedures are referenced by number. The detailed steps for each procedure are provided once and a reference number is assigned. Elsewhere in the manual, the procedure name and reference number are provided. The reader can use the reference number to locate the detailed procedure and follow the steps as described.

IP Each **Isolation Procedure** number refers to a flowchart or checklist showing tasks to perform to determine the cause of a problem.

RR Each **Removal & Replacement** Procedure number corresponds to the Parts List number and item number for the part being removed/ replaced. For example, RR 1.3 is the procedure for removing and replacing the part that is item 3 on Parts List 1.

VP Each **Verification Procedure** number corresponds to an adjustment, alignment, calibration, check, test, or other verification procedure to perform to ensure proper instrument operation.

Hazard symbols

The Biohazard symbol identifies the actual or potential presence of a biological hazard. Failure to comply with recommended precautions may expose the operator/FSE/FSR to the risk of contamination by biohazardous materials.

The Electrical Shock symbol alerts the reader to the risk of electrical shock. Failure to comply with recommended precautions may expose the operator/FSE/FSR to significant risk of electrical shock.

The Electrostatic Discharge symbol identifies an activity or area in which the FSE/FSR must wear a ground strap while servicing the instrument.

All procedures described in this service manual should be performed with extreme care to minimize these risks.

Notes, Cautions, and Warnings

Notes, cautions, and warning notices are provided in this manual to assist, inform, and warn the reader.

NOTES are shown in italic type, and not contained within boxes.

NOTE: A NOTE provides general information and/or helpful hints. Failure to comply will present no safety, efficacy, or performance issues.

The word CAUTION or WARNING is within a box and indicates the type of information that is contained in the box.

CAUTION !

A CAUTION notice indicates a minor, non-immediate, or potential hazard. Failure to comply may result in unexpected instrument performance or may expose the operator/Field Service Engineer/ Field Service Representative (FSE/FSR) to potentially hazardous conditions.

WARNING !

A WARNING notice indicates clear and present danger to the operator/Field Service Engineer/Field Service Representative (FSE/FSR) and/or the possibility that the instrument could produce questionable results. Failure to comply may result in incorrect instrument performance, instrument failure, the generation of inaccurate or erroneous results and/or hazard to the operator and/or Field Service Engineer/Field Service Representative (FSE/FSR).

CAUTIONS AND WARNINGS

Physical safety

- Keep all protective covers and barriers in place.
- Never allow any part of the body to enter a range of mechanical movement during System operation.
- Do not wear articles of clothing or accessories that could catch on the System.
- Avoid haste. Be especially cautious when performing adjustment, maintenance, cleaning, or repair procedures.

Personal protective equipment

Personal protective equipment includes:
- lab coats
- gloves (latex or hypoallergenic)
- eye protection (safety glasses with side shields)

The Field Service Engineer/Field Service Representative (FSE/FSR) must have his/her own coat, gloves, and safety glasses to use in the event these are not provided by the laboratory account being serviced.

The mandatory use of these items is standard laboratory procedure. Follow 29 CFR 1910.1030 or equivalent biosafety procedures.

Electrical safety

WARNING !

High voltage exists in the analyzer when the Maintenance Power Switch is OFF and the Main Power Switch is ON. The analyzer is wired so that even when the Maintenance Power Switch is turned off, electricity is supplied to the ISE module.

- Periodically inspect electrical cabling into and on the analyzer for signs of wear or damage.
- Do not disconnect any electrical connection while the power is on.
- Keep liquids away from all connectors of electrical or communication components.
- Keep the floor dry and clean under and around the analyzer.
- Disconnect the power cord before servicing.
- In the event of a blown fuse or thrown circuit breaker, determine and correct the cause before attempting to resume operation of the equipment.
- High voltage areas exist near the Main Power Switch and the Maintenance Power Switch. The operator must visually locate the power switches before turning power on or off.
- When Maintenance power is **off** and Main Power is **on**, power remains **on** for the ISE module electronics.
- To prevent damage to electronic components, use proper anti-static precautions.

General biosafety

The OSHA Bloodborne Pathogen Rule, 29 CFR 1910.1030, requires the decontamination of laboratory equipment prior to the following:

- Maintenance
- FSE/FSR service
- Component replacement (for example, Probe change)
- Shipment

Additional decontamination information is contained in this chapter and also in **VP-38**: Analyzer Decontamination.

Surface Decontamination

CAUTION !

This procedure **does not** decontaminate the inside of the analyzer.

NOTE: This decontamination procedure should be used when preparing the analyzer for shipping/transporting.

Use the following procedure to decontaminate the surface of the analyzer:

1. From Main Menu:
   SPECIAL PROCEDURES
   ROBOTICS
   HOME ROBOTICS
   (to flush the probes and mix arm tip, and purge waste and reagents from the tubing)
2. Remove all samples, reagents, controls, calibrators, standards, cuvettes, and other disposables from the instrument. Dispose of in accordance with local, state, and federal regulations governing the treatment of regulated medical waste.
3. Empty all waste containers and rinse with disinfectant or water.
4. Wipe the surface of the instrument with a detergent solution to remove any soiling. Then wipe the unit down with a tuberculocidal disinfectant, such as 10% chlorine bleach solution.

Handling controls, calibrators, reagents, and samples

CAUTION !

Consider all clinical specimens and reagents, controls, calibrators, etc., that contain human blood or serum and contaminated instruments as potentially infectious. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in the 29 CFR 1910.1030, or other equivalent biosafety procedures.

Special handling precautions should be followed on these sample types:

Fibrin: Fibrin in serum specimens can cause assay results to be either erroneously high or low. This may be due to partial obstruction of the Sample Arm probe tip or ISE Sample Probe. Excess sample deposits caused by partial aspiration of fibrin clot-laden serum can also cause obstruction. To prevent fibrin formation in serum samples:

1. Review and adhere to any instructions or precautions accompanying serum separator tubes.
2. Use serum filters available to aid in the removal of fibrin.
3. Inspect patient samples for fibrin clots or unspun gel material prior to placing the sample in the sample cups.

Anticoagulants: If plasma is desired for ISE assays, Lithium Heparin should be used as an anticoagulant. Sodium Heparin can cause falsely elevated results.

Preservatives to be avoided

Some preservatives in reference and quality control material should be avoided because they may damage the electrodes and affect results.

Preservative	Reason to avoid
Ammonium bicarbonate	will cause high sodium results and low potassium results
Azides	will cause chloride to drift high
Chloraphenol	is toxic to the chloride electrode
Ethylene glycol	will destroy all electrodes

Spills

Consider all samples, reagents, calibrators and controls that contain human blood or serum as potentially infectious. Clean up spills of potentially infectious materials in accordance with established biosafety practices. A generally accepted procedure for cleaning such spills is to absorb the spill with toweling or other absorbent material, wipe the area with a detergent solution, and then wipe the area with an appropriate tuberculocidal disinfectant, such as 10% chlorine bleach solution.

Disposal

Sharps/Contaminated Sharps
Sharps, such as contaminated probes, must be placed in an appropriately marked, puncture–resistant container prior to treatment and disposal.

CAUTION !

Use caution when contacting the Sample Probe, Reagent Probe, and Mix Arm Tip. They are sharp and potentially contaminated with infectious materials. Avoid any unnecessary contact with the probes or the Mix Arm tip.

Waste Treatment
Dispose of all clinical specimens, reagents, controls, calibrators, standards, cuvettes, and other disposables that may be contaminated in accordance with local, state, and federal regulations governing the treatment of regulated medical waste.

Solid Waste: Generally accepted procedures for the treatment of potentially infectious solid waste include incineration or autoclaving. If an autoclave is used, the effectiveness of the decontamination cycle must be verified.

Liquid Waste: Liquid waste containing acid should be neutralized prior to the addition of a disinfectant and disposal. Addition of disinfectant to the waste container helps inactivate the infectious organisms that may collect with the waste.

SPECIFICATIONS

Physical requirements

Environmental requirements	
Room temperature	20°C to 28°C
Storage temperature	- 20°C to 80°C
Humidity	10% to 90% relative humidity (non-condensing)
Shipping	10g vibration
Additional considerations	No drafts or direct sunlight

Clearance requirements		
Right side	18 inches	45.72 cm
Left side	18 inches	45.72 cm
Rear	10 inches	25.40 cm
Top	12 inches	30.48 cm

Entryway requirements		
Minimum doorway width	33 inches	83.82 cm
Minimum hallway width	77 inches	195.58 cm
Minimum turning radius	77 inches	195.58 cm

CAUTION !

To avoid damage to the analyzer when moving it through an entry:

Analyzer **cannot** be tilted on its end.

Analyzer (serial # 2956 or above) may be tilted at an angle greater than 45°.

Analyzer (serial # 2955 or below) **must not** be tilted at an angle greater than 45°.

Electrical requirements

Electrical characteristics	220 VAC	110 VAC
Input	220 VAC ± 10% 60 Hz ±1% 50 Hz ±1% International	110 VAC ± 10% 60 Hz ±1% 50 Hz ±1% International
Power consumption	1800 Volt Amps	1800 Volt Amps

Power outlets characteristics	220 VAC	110 VAC
Continuous ground	Required	Required
Separate conduit with no other electrical wires	Required	Required
20 Amp dedicated line with its own circuit breaker	Required	Required
Line to Ground Line to Neutral Ground to Neutral Ground to Conduit *NOTE: Use test plug to ensure proper outlet configuration.*	110 V ±10% 220 V ±10% 110 V ±10% ≤ 0.5 VAC	110 V ±10% 110 V ±10% ≤ 0.5 VAC ≤ 0.5 VAC
Circuit breaker measurements (with breaker open) Line to Ground Line to Neutral Ground to Neutral	 ≤ 0.5 VAC ≤ 0.5 VAC ≤ 0.5 VAC	 ≤ 0.5 VAC ≤ 0.5 VAC ≤ 0.5 VAC

Water quality requirements

Customer water supply to water quality station (WQS)	
Water type	≥ 1 MΩ resistivity deionized Free of gas and air bubbles
Flow rate: Momentary Continuous	700 mL/minute (for a maximum usage of 8L/hour) 800 mL/minute
Inlet pressure (to WQS)	20 psi ± 10%
Outlet pressure (to analyzer)	5 to 7 psi
Minimum support equipment	0-60 psi input gauge 0-30 psi output gauge Input and output cutoff valves Air purge valve Filter Water quality light Flush valve Pressure regulator
Filtration	Solids filter with deionizer system
Tubing: inlet outlet	0.375 inch (0.95 cm) poly 0.125 inch (0.32 cm) Tygon® [15 feet (4.57m) is supplied with accessory kit]
Usage	Water is dispensed into incubator and mix and reagent wash cups

Sample Diluent Reservoir (Sample Diluent Bottle)	
Water type	Type II water
Usage	15 µL dispensed into sample. Washes the sample probe.
Monitoring	Weight-sensitive platform. Filled by operator during daily maintenance.

The Water Quality Station must be installed within 3 feet (91.4 cm) of a 110 VAC electrical outlet.

Drainage requirements

Drainage requirements	
Location	Within 15 feet (4.57 m) of analyzer. At or below analyzer base. Cannot be higher than 30 inches (76 cm) off the floor. Flexible drain line must not droop or loop prior to the drain.
Line dimensions: output of deionization system	0.25 inches (0.64 cm) I.D. by 0.375 inches (0.95 cm) O.D. flexible polyethylene tubing
Tubing color	To prevent bacterial growth, the tubing must be black, gray, or neutral color.
Flow rate	Able to handle continuous rate of 0.2 gallons (700 mL) per minute without any back pressure.
Drain vent	Drain vent is required. Proper ventilation required to ensure the above flow rate is achieved.

Drain types	
Floor	**If local, state, and federal regulations allow, this is the recommended type.** Ensure that the end of the drain line is not submerged in fluid.
Sink	This type can be connected in 2 ways: 1. Tubing connection(s) added on the output side of the drain trap (prevents backflow to the sink). 2. Drain line(s) can be placed in a manner so that waste drips into the drain.
Canister with submersible pump	A 5 gallon canister with a submersible pump will empty the canister as the fluid level rises. Ensure that the end of the drain line is not submerged in fluid.
Carboy	This type is acceptable; however, care must be taken to ensure that there is proper ventilation for the fluid to drip into the carboy. Ensure that the end of the drain line is not submerged in fluid. The line(s) cannot be submerged into the carboy. Ensure that the carboy is emptied periodically.

Follow local, state, and federal regulations governing the treatment of regulated medical waste at the site where analyzer is serviced.

Analyzer specifications

Physical dimensions	Without Base	With Base
Height	32.50 inches 82.55 cm	63.00 inches 160.02 cm
Length	68.00 inches 172.72 cm	68.00 inches 172.72 cm
Width	32.25 inches 81.92 cm	32.25 inches 81.92 cm
Weight	500 pounds 273 kg	800 pounds 364 kg
BTU output	5982 BTU/hour (approximately)	

General characteristics	
Instrument type	Discrete, multiple-access
Tests on-line	31
Programmable test capacity	127
Test parameters	66
Modes of operation	Flexible Batch (Flex-B) Batch Random Tandem STAT (dispensed in Random mode)

Dispensing characteristics	Volume	Accuracy	Precision
Sample volume	1.25 µL 2.50 µL 5.0 µL to 25 µL	98.0 % 98.5 % 99.0 %	98.5 % 99.0 % 99.5 %
Reagent volume	25 µL to 486 µL	99.5 %	99.5 %
Sample carryover	≤ 0.5 %		

Reaction temperatures
25.0 ºC ± 0.1 ºC
30.0 ºC ± 0.1 ºC
37.0 ºC ± 0.1 ºC

Optical characteristics	
Light source	Tungsten-halogen lamp
Light path	1.000 ± 0.006 cm
Detector	Linear diode array
Analytical modes	Polychromatic Bichromatic Monochromatic
Spectral range	340 nm to 660 nm
Wavelengths available	340 nm 404 nm 500 nm 604 nm 364 nm 412 nm 516 nm 636 nm 380 nm 452 nm 548 nm 652 nm 484 nm 564 nm 660 nm 572 nm
Wavelength resolution	± 4 nm
Linearity	0 to 2.5A ± 2% at all wavelengths
Noise	Less than ± 0.0003A @ 1.2A
Long-term drift	0.0004A
Resolution	Better than 0.0001A

Computer characteristics	
Processor type	Distributive with 17 CPUs
Programming	Multi-tasking
Interface	Uni-directional and Bi-directional
Volatile memory	560 Kbytes
Non-volatile memory	934 Kbytes
Baud rate	75 - 1200 bps

Printer specifications
Refer to printer operations manual.

ABBOTT SPECTRUM® SERIES II™ SYSTEM OVERVIEW

The ABBOTT SPECTRUM® SERIES II™ analyzer is a Clinical Chemistry analyzer using optical assay and Ion Selective Electrode (ISE) assay technologies to quantify selected analytes in biological fluids.

The ABBOTT SPECTRUM® SERIES II™ System includes:

- Analyzer (illustrated below)
- Water Quality Station
- Printer
- Line conditioner

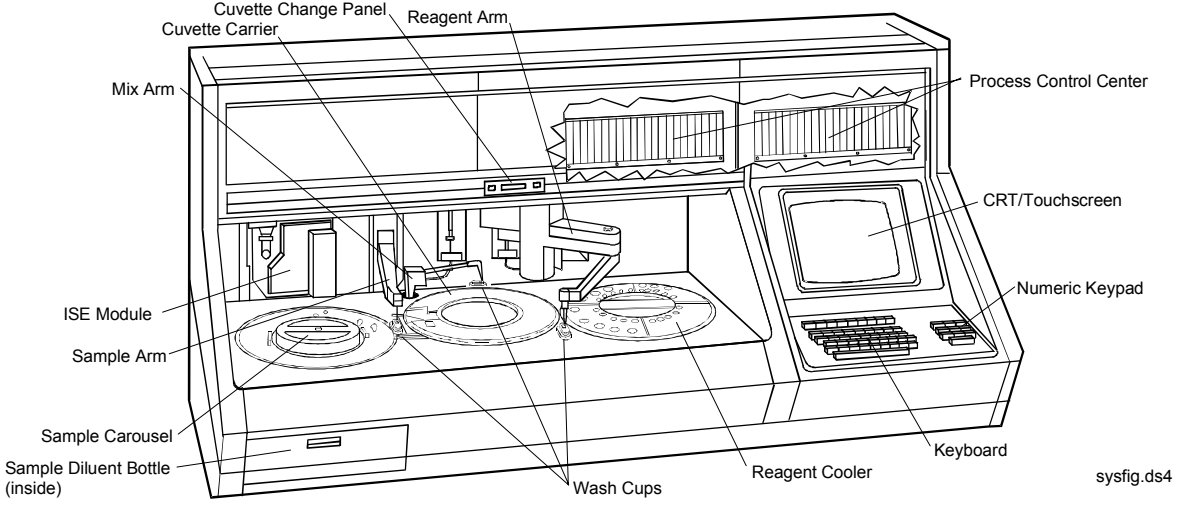


Figure 1 - 1: Front View of Analyzer (doors removed)

Process Control Center

The Process Control Center monitors and controls operation of the system. This center consists of:

- System Control Center that performs these functions:
  - coordinates data entry and test requests from the operator
  - schedules optimized test runs based upon available reagents, calibration data, and reaction parameters
  - calculates and stores optical assay results from photometer readings and electrolyte results from the ISE
  - collates and reports patient results
- Real Time Processor that coordinates all robotic, electromechanical, and optical processes in the system.

Operator input is done via the Keyboard and the CRT/Touchscreen.

The **Keyboard** is used to:

- enter information required by the analyzer
- access special functions

Cursor control keys (arrows) move the cursor, alphanumeric keys are used to input information, and pressing the ENTER key instructs the analyzer to store the information.

The **CRT/Touchscreen** is used to control analyzer operation. An object touching, then moving away from the screen registers when the object interrupts the infrared grid. Touching a field on the screen causes the field to highlight. The field stays highlighted to indicate the most recent item that was entered. To correct an item, touch the field again, then enter the appropriate data.

Process Area

Reagents and samples are handled in the process area. This area includes:

- Incubator Optics Assembly
- ISE Module
- Cuvette Carrier Assembly
- Reagent Cooler Assembly
- Robotic arms (Mix Arm, Reagent Arm and Sample Arm)
- Sample Carousel Drive Assembly
- Wash Cups

The **Sample Carousel** consists of removable inner and outer rings.

Ring	Positions	Function
Outer	1 - 48	Patient and quality control samples
Inner	49 - 72	Calibrators, standards, and STAT samples

The **Sample Arm** aspirates and transfers aliquots of sample from a cup (or tube, if equipped with a Primary Sample Tube Carousel) to individual cells in the Cuvette Carrier.

The **ISE Module** draws samples directly from the Sample Carousel to perform sodium, potassium, and chloride measurements using Ion Selective Electrode (ISE) technology. For further information on the ISE Module, refer to the ISE Service Manual.

The **Mix Arm** tip agitates the sample and reagent that have been dispensed into the cuvette cell, to ensure homogeneity.

The **Cuvette Carrier**, located in the temperature-controlled Incubator (25ºC, 30ºC, or 37ºC), contains the cuvettes with which optical testing is performed.

The **Reagent Arm** transfers reagent from the appropriate cartridge into individual cuvette cells.

The **Reagent Cooler** accommodates reagent cartridges. Capacity is:
- maximum of 20 single-reagent cartridges
- combination of 12 single-reagent cartridges and 8 dual-reagent cartridges

The Reagent Cooler maintains on-board reagent stability:

Number of quadrants	Condition	Temperature Specifications
3	Cooled	2ºC - 10ºC
1	Ambient	20ºC - 28ºC

The **Wash Cups** are used for washing the Reagent Probe, Sample Probe, and Mix Arm tip.

Component Washed	Wash Cup	Water Source
Reagent Probe	Reagent Wash Cup	Water from Water Quality Station
Sample Probe	Sample Wash Cup	Type II water from the Sample Diluent Bottle
Mix Arm tip	Mix Wash Cup	Water from Water Quality Station

The **Cuvette Change Panel** indicates the usage of cuvette segments. An audible alarm sounds in these situations:
- at the end of a run
- at cuvette change time
- if an error halts analyzer activity

The **RESET** button for this alarm is on the Cuvette Change Panel.

The **Sample Diluent Bottle** rests on a platform that monitors the weight (as an indicator of volume) of the Type II water that it contains. The SAMPLE DILUENT LOW message appears when the volume is not sufficient. During daily maintenance, the bottle is emptied, rinsed, and refilled with Type II water to prevent bacterial growth and to prevent unplanned interruption of analyzer operation.

NORMAL OPERATIONS

Process overview

This section of the chapter describes:
- processing modes
- assay processes
- theory of analyzer operation

The two assay processes are:
- Optically-read assays
- Electrolyte assays

The four process modes are:
- Flexible batch mode
- Batch mode
- Random mode
- Tandem mode

Descriptions for these modes are on **page 1 - 24**.

NOTE: All STAT requests are run in Random mode.

Optical system measurements

The analyzer uses absorbance to quantitate analyte concentrations.

By performing simultaneous multiple wavelength measurements, the interferences in the actual reaction mixture can be subtracted. Time-invariant interferences (such as hemoglobin, bilirubin, and lipemia) can be quantitated at wavelengths different from that of the chromophore. The contribution of these interferences to the chromophoric absorbance is then subtracted without performing a separate sample blank determination for each test. During polychromatic analysis, samples that contain unacceptably high values of an interfering substance may be flagged for alternative handling.

The measurements are selected to give one of these readings:
- monochromatic
- bichromatic
- polychromatic (when measuring at several different wavelengths)

A log-ratio amplifier converts transmitted intensity readings to absorbance readings.

The absorbance readings are blank-corrected (as specified for each test), then converted to concentration units.

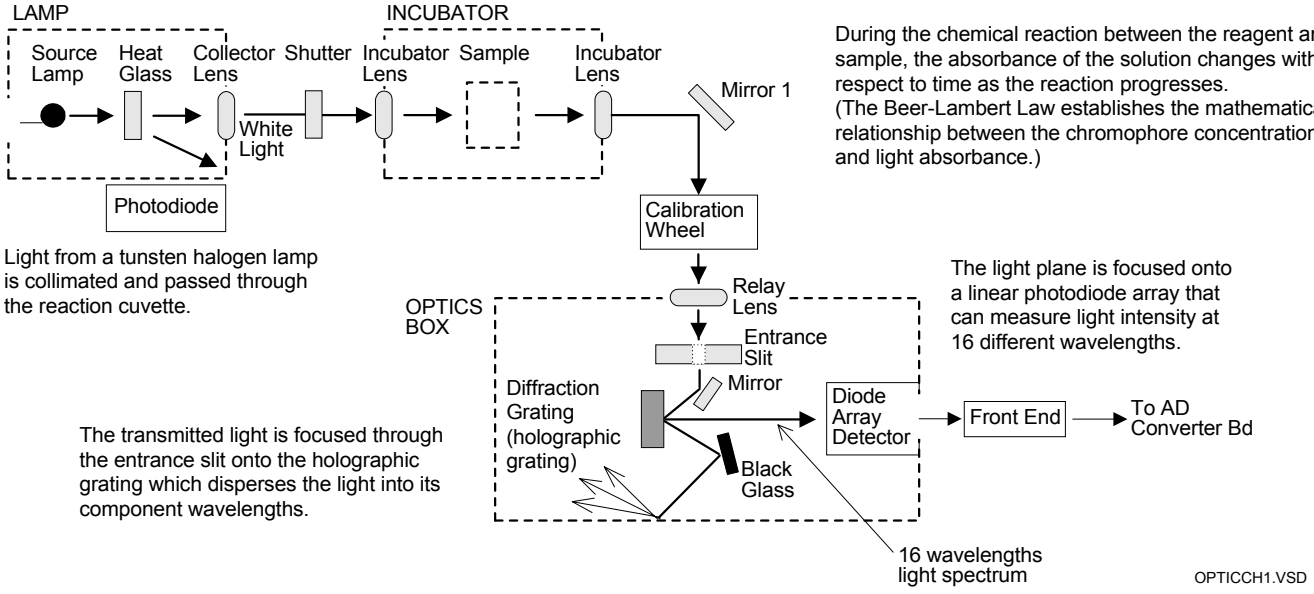


Figure 1 - 2: Optical System

Assay Process: Optically-read Assays

1. **Reagent Probe dispenses reagent**
   When testing begins, the Reagent Probe dispenses the necessary amount of reagent into an empty cuvette cell. The probe moves to the wash cup and is rinsed between reagents.

2. **Initial absorbance readings**
   The analyzer reads the initial absorbance of the reagent:
   - to verify reagent integrity, and
   - to determine the blank reading

3. **Aspirate and dispense sample**
   The Sample Probe aspirates the appropriate amount of sample from the cup and dispenses this into the cuvette cell that contains the reagent. The sample is followed with 15µL of Type II water:
   - to ensure complete sample delivery into the cuvette cell, and
   - to prevent carryover between samples

4. **Wash Sample Probe**
   The probe moves to the wash cup and is rinsed inside and outside with Type II water.

5. **Mix**
   The Mix Arm moves to the cuvette and mixes the sample with the reagent. The Mix Arm then moves to the wash cup.

6. **Serum blank reading**
   A serum blank reading is taken and used for calculation when specified in the Test Parameter File.

7. **Incubation**
   The reaction mixture in the cuvette is incubated in the water bath for the required time.

8. **Electrolyte measurements**
   When electrolyte measurements are requested:
   a. The Sample Carousel turns so that the cup is under the ISE Module.
   b. The module rotates out.
   c. The probe drops into the cup and aspirates sample into the electrode train where ion concentrations are measured.

   See ISE Service Manual for additional information.

9. **Absorbance readings**
   Absorbance readings are taken when required for each reaction.

10. **Compute concentration units**
    The analyzer uses the blanks and absorbance readings to compute the concentration units.

11. **Print report**
    After all assays for a sample have been completed, a report is printed (when AUTO PRINT function is ON, no ALERT flags).

Modes of operation

The four possible modes of operation are:
- Flexible batch mode
- Batch mode
- Random mode
- Tandem mode
- STAT mode (All STAT requests are run in Random mode.)

These modes are selected in the Instrument Options file.

Flexible Batch Mode (Flex-B)

This is an efficiency processing mode. The analyzer schedules the assays so that they are run in decreasing incubation time within a run. The analyzer will run assays with the longest incubation time followed by progressively shorter assays within the run.

Batch Mode

In this mode, the analyzer assays all "same type" assays on each of the samples. Reagent for the first assay is dispensed for all samples. This sequence is repeated for each assay requested.

Priorities are:
- processing order
- test number
- temperature

Random Mode

In this mode, all assays are initiated on one sample before proceeding to the next sample. Sample sequence is based upon carousel position number.

All assays for each sample are prioritized according to their number in the processing order of the Test Parameter File. Electrolytes are the exception. Optical assays are dispensed, then electrolyte assays are aspirated on each sample.

Tandem Mode

This mode accelerates reporting. Samples are processed to yield the maximum number of completed reports in the least amount of time.

This is done by prioritizing samples processing based upon the number of assays ordered for each sample. Samples with one test are processed first, followed by those with two tests, etc.

STAT Mode

STAT requests are processed in the Random mode, regardless of the mode currently in use. When a STAT is requested, the analyzer determines the appropriate time window and begins the STAT test as soon as possible without jeopardizing assays in progress. When all assays are dispensed for the STAT, the mode of operation defaults to the previously defined mode of operation.

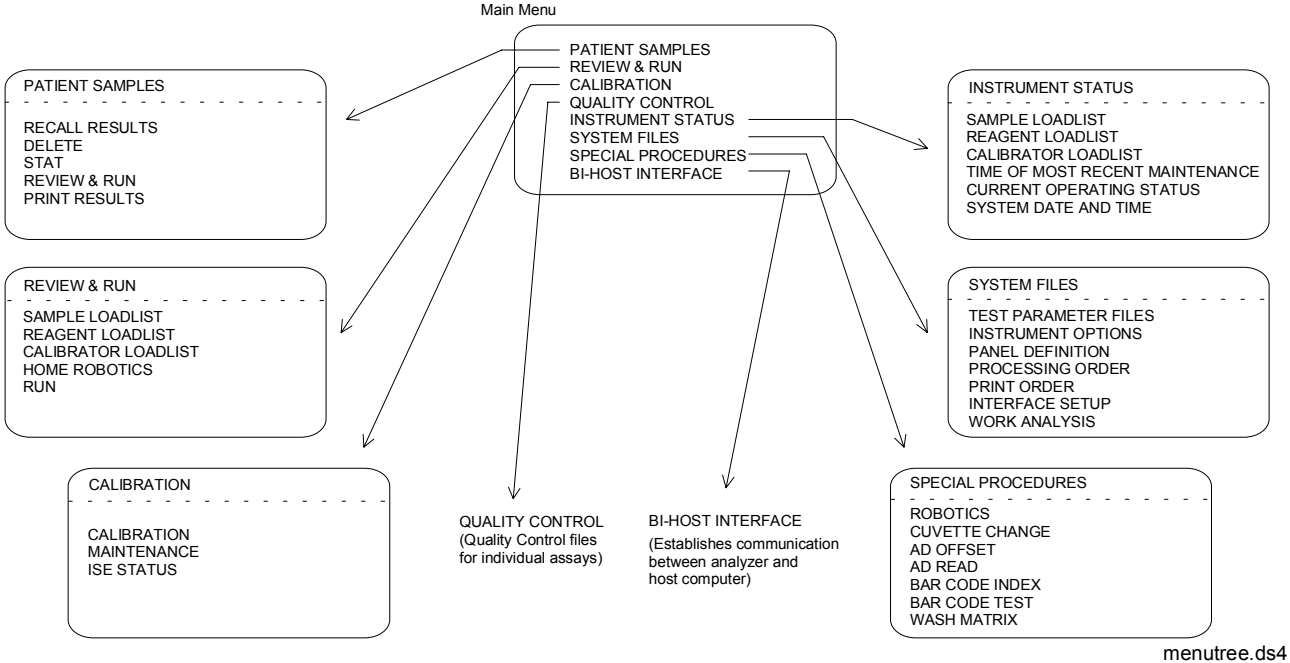


Figure 1 - 3: First and Second Level Menus

Calibration overview

An assay must be calibrated before the analyzer can process samples. Calibrators or standards are required to run an assay calibration. These calibrators/standards contain known concentrations of the analyte(s) to be determined. If assay calibration is acceptable, the calibration curve is stored by the analyzer.

Calibration is required in these situations:
- During the installation of the analyzer
- When a new assay is added to the system
- When the calibration interval has elapsed
- If the Test Parameter File for an assay has been edited
- When the reagent lot number has changed

Calibration may be required in these situations:
- When control values are out of range
- When service has been performed

Assays are calibrated at recommended intervals as defined in the Test Parameter Files; however, calibration may be performed whenever it is necessary.

These options are available for determining how and when calibrations are performed:
- calibration modes (defined in Test Parameter Files)
  - MASTER CAL
  - CAL ON COMMAND
- calibration interval

Calibration Modes

MASTER CAL

MASTER CAL allows all assigned end-point assays that have the same calibration interval to be calibrated as a group.

This option is intended to be used with high volume routine assays that must be calibrated at all times. When MASTER CAL is selected in the Test File, that assay, and other assays in the MASTER CAL mode, are calibrated at the frequency specified by the MASTER CAL INTERVAL. MASTER CAL intervals are defined in the Instrument Options file.

CAL ON COMMAND

CAL ON COMMAND allows the assigned assay(s) to be calibrated independently of all other assays.

This option is intended for use on assays that are run infrequently, or assays that have very long or very short calibration stabilities. In this mode, an assay is calibrated when that test is requested. The calibration is then stored for the length of time specified by CAL INTERVAL. Calibration intervals for this mode are defined in each Test Parameter File.

Calibration options

Calibration options are defined in the Instrument Options file.

Auto Accept

Auto Accept calibration allows the analyzer to interpret calibration data and to automatically accept or reject calibration curves.

Override

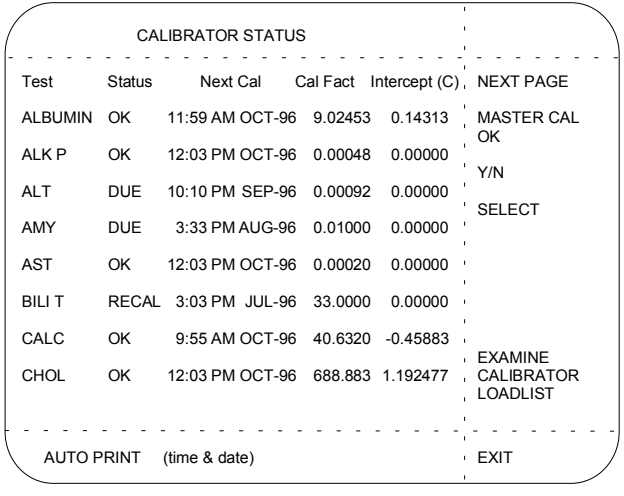
This option allows the analyzer to use previously-accepted calibration data when a new calibration attempt fails.

Combination	Status	Result
Auto Accept ON Override OFF	OK FAIL	Samples run using the new calibration data. Samples re-entered into memory. Information displays as status code.
Auto Accept OFF Override OFF	FAIL	Samples do not run until calibration data is manually accepted and **RUN** is touched.
Auto Accept ON Override ON	OK FAIL	Samples run using the new calibration data. Samples run using the previous calibration data.
Auto Accept OFF Override ON	FAIL	Samples run using the previous calibration data.

Calibration status

The Calibration Status screen (shown on **page 1 - 29**) allows the operator to determine the calibration status of all assays on the system.

Status	Interpretation	Action
OK	Calibration curve is within the time interval, has acceptable data, and can be used.	No action required.
SCHED	Calibration is in progress.	No action required.
DUE	Defined calibration interval has expired.	Depending upon the calibration mode, the assay will be calibrated either • the next time a sample is scheduled, or • the next time RUN is touched on the REVIEW & RUN screen
REBLK	• operator requested kinetic blank, or • the assay Test Parameter Files were edited	Calibrate.
RECAL	• operator requested calibration, or • the assay Test Parameter Files were edited	Calibrate.
LOT ID	Bar Code Reader detected a master lot number change. *NOTE: For the CCx™ analyzer, operator must note reagent lot changes.*	Calibrate.
FAIL	Calibration failed the tolerance limits defined in the assay Test Parameter File.	Identify cause(s) of failed calibration and recalibrate.



calstat1.ds4

Figure 1 - 4: Example Calibrator Status Screen

NOTE: The values on this example screen are for demonstration purposes only.

End Point Assay

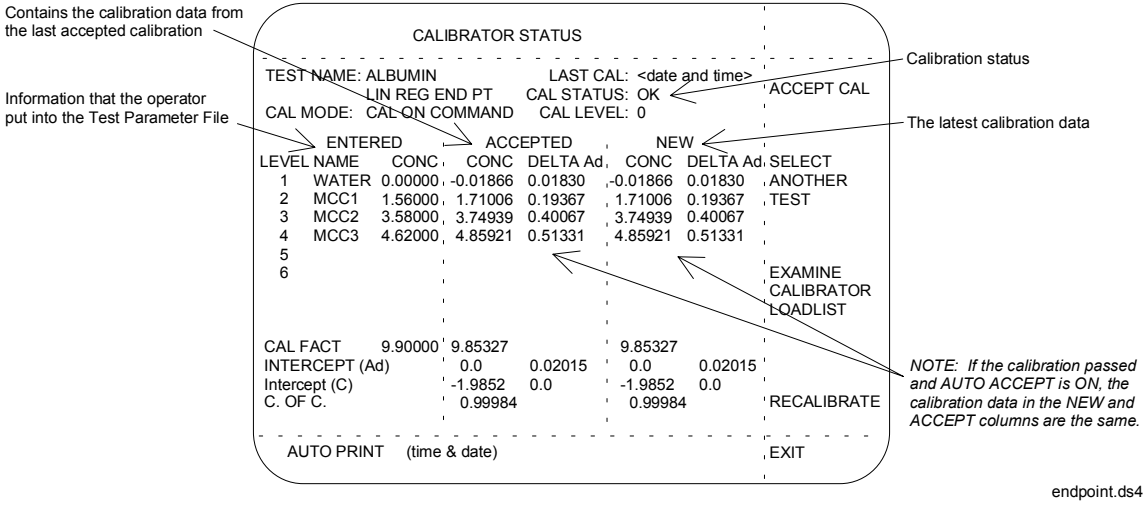


Figure 1 - 5: Example End Point Assay

Rate assays

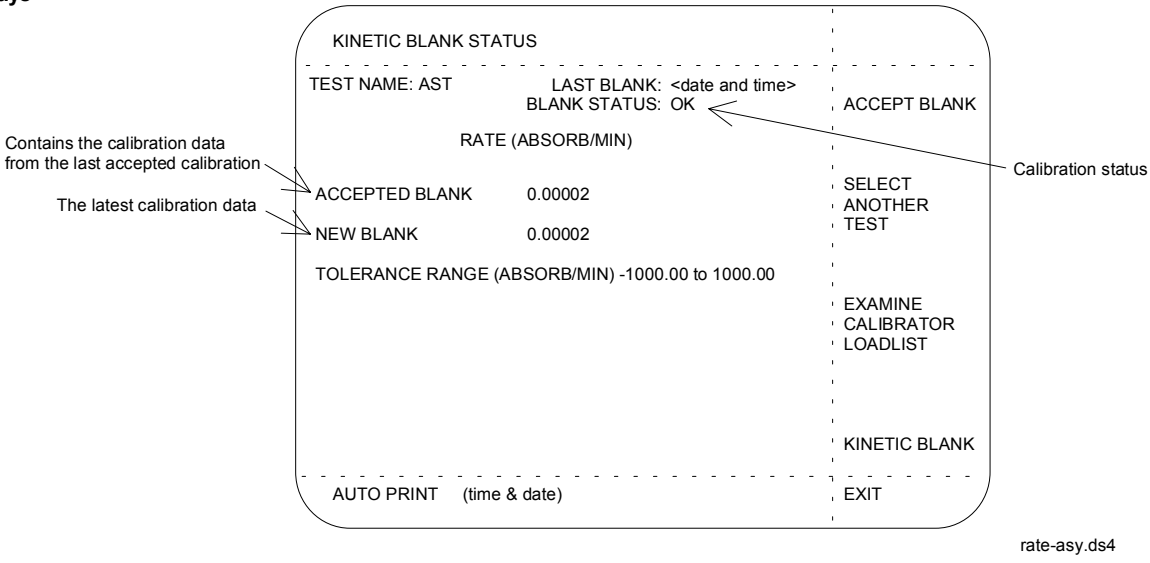


Figure 1 - 6: Example Rate Assay

Calibration Procedure: Initiate Master Cal

NOTE: Master Cal assays do not need to be requested to initiate calibration.

Procedure

1. Change cuvettes, if required.
2. From Main Menu:
   - CALIBRATION (twice)
3. Request calibration of Master Cal.
   - MASTER CAL OK

   When Y/N appears:
   - Y
   - ENTER
     (to toggle from MASTER CAL OK to MASTER CAL DUE)
   - EXIT (twice)
   - REVIEW & RUN
4. - REVIEW
     (to review loadlists)
5. Place calibrators on Sample Carousel in the position indicated.
   - LOAD NOW
     (to display ON BOARD)
6. - RUN

CALIBRATOR STATUS

Test	Status	Next Cal		Cal Fact	Intercept (C)
ALBUMIN	OK	11:59 AM	OCT-96	9.02453	0.14313
ALK P	OK	12:03 PM	OCT-96	0.00048	0.00000
ALT	DUE	10:10 PM	SEP-96	0.00092	0.00000
AMY	DUE	3:33 PM	AUG-96	0.01000	0.00000
AST	OK	12:03 PM	OCT-96	0.00020	0.00000
BILI T	RECAL	3:03 PM	JUL-96	33.0000	0.00000
CALC	OK	9:55 AM	OCT-96	40.6320	-0.45883
CHOL	OK	12:03 PM	OCT-96	688.883	1.192477

NEXT PAGE
MASTER CAL OK
Y/N
SELECT
EXAMINE CALIBRATOR LOADLIST
AUTO PRINT (time & date)
EXIT

calstat2.ds4

Figure 1 - 7: Example Calibrator Status Screen

*NOTE: If any assay fails calibration, troubleshoot according to status code(s) generated. See **Chapter 2** for additional information.*

Calibration Procedure: Cal on Command

NOTE: Cal on Command assays must be requested to initiate calibration.

Procedure

1. Change cuvettes, if required.

2. From Main Menu:
   - CALIBRATION (twice)

3. Request calibration of Cal on Command assays. (Urea example)
   - UREA
   - RECALIBRATE

   Verify that the calibration status of Urea is RECAL.

   To request calibration of Albumin:
   - SELECT ANOTHER TEST
   - ALBUMIN
   - RECALIBRATE
   - SELECT ANOTHER TEST

   Repeat the above for Calcium.

CALIBRATOR STATUS

TEST NAME: UREA NITROGEN LAST CAL: 9:20 AM 22-SEP-96
LIN REG END PT CAL STATUS: RECAL
CAL MODE: CAL ON CMD CAL LEVEL: 0

LEVEL	NAME	ENTERED CONC	ACCEPTED CONC	ACCEPTED DELTA Ad	NEW CONC	NEW DELTA Ad
1	WATER	0.00000	-2.22104	-0.01616	-0.22104	-0.01616
2	MCC1	10.0000	9.48550	-0.11478	9.48550	-0.11478
3	MCC2	29.6000	31.0811	-0.33428	31.0811	-0.33428
4	MCC3	51.9000	51.1544	-0.53832	51.1544	-0.53832
5						
6						
CAL FACT		-93.0000	-98.3867		-98.3867	
INTERCEPT (Ad)			0.0	-0.01837	0.0	-0.01837
Intercept (C)			-1.80745	0.0	-1.80745	0.0
C. OF C.			0.99903		0.99903	

ACCEPT CAL
SELECT ANOTHER TEST
EXAMINE CALIBRATOR LOADLIST
RECALIBRATE
EXIT

AUTO PRINT (time & date)

caloncom.ds4

Figure 1 - 8: Example Calibrator Status Screen

To request calibration of AST, ALT, CK, and LDH assays (assays that require a kinetic blank):

- AST
- KINETIC BLANK
- SELECT ANOTHER TEST

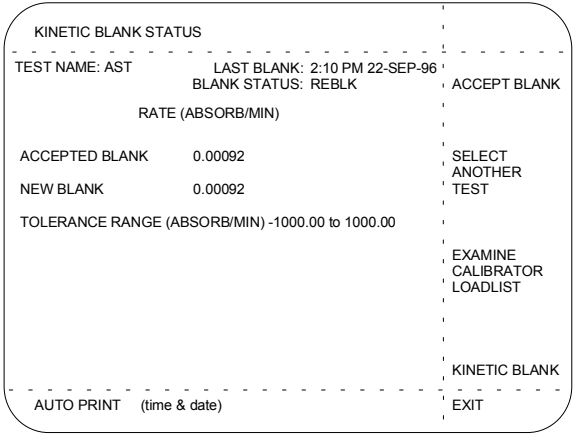


Figure 1 - 9: Example Kinetic Blank Status Screen

Repeat the above for ALT, CK, and LDH for kinetic blank.

Verify that calibration status is REBLK for AST, ALT, CK, and LDH.

4. Schedule tests for Control 1 and Control 2.

SID	Tests
Control 1	UREA ALT CALC LDH ALBUMIN CK AST
Control 2	UREA ALT CALC LDH ALBUMIN CK AST

   - REVIEW & RUN

5. Review loadlists:
   Highlight the loadlist.
   - REVIEW

6. Place calibrators on the Sample Carousel in the position indicated.
   - LOAD NOW
     (to display ON BOARD)

7. Place controls on the Sample Carousel in the positions indicated.

8. Initiate the run.
   - RUN

*NOTE: If any assay fails calibration, troubleshoot according to status code(s) generated. See **Chapter 2** for additional information.*

Defining Calibrator Values

Purpose

When calibrators change lot numbers, the appropriate Test Parameter Files must be edited.

NOTE: When making an edit, patient loadlists must be deleted and the system may not be running assays.

When an assay test parameter file is edited:

- The Reagent Loadlist is cleared.
- The Calibrator Loadlist is cleared.
- The calibration status changes to RECAL.
  A calibration will be performed the next time the test is requested.
- The Mean, SD, CV, and number of entries on the Quality Control screen are deleted.

Procedure

1. Verify that patient loadlists are deleted. From Main Menu:
   - PATIENT SAMPLES
   - DELETE
   - ALL
   - PROCEED
   - EXIT

2. Edit the calibrator values for Glucose:
   - SYSTEM FILES
   - TEST PARAMETER FILES

   Press Cursor Control key to access Password field.

   Type ABBOTT
   - ENTER
   - GLU
   - ENTER

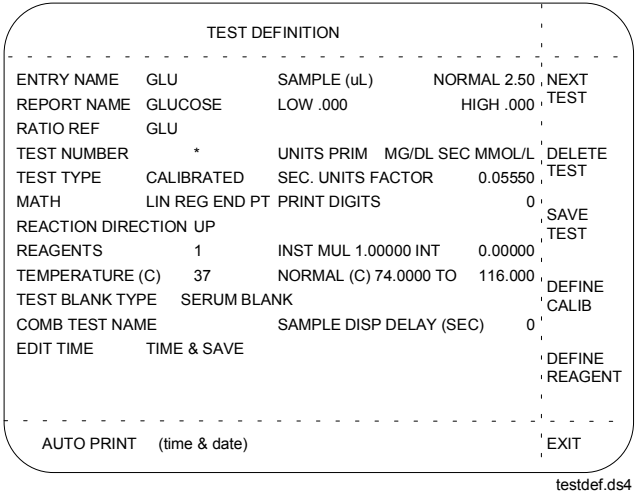


Figure 1 - 10: Example Test Definition Screen

- DEFINE CALIB

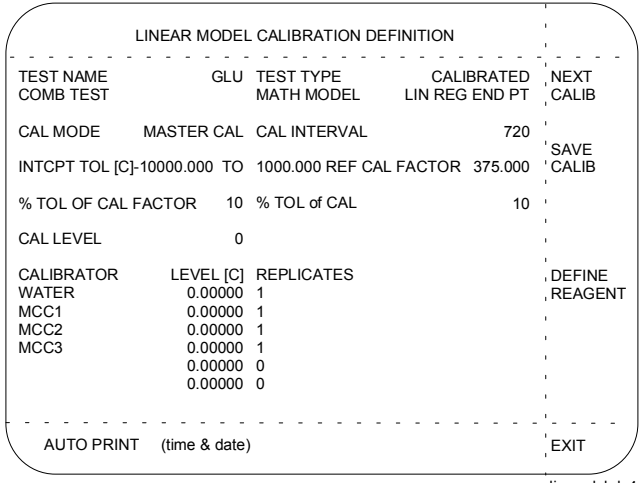


Figure 1 - 11: Example Linear Model Calibration Definition Screen

- Enter concentrations per calibrator package insert.
- SAVE CALIB
  (CODE 00166 FILE SAVED displays)
- EXIT (3 times)

Sample run

Procedure

This is an example run for 2 samples:
- Sample 1 Albumin and Phosphorus
- Sample 2 Albumin and Total Protein

Actual options selected depend upon the assays desired.

1. From Main Menu:
   - PATIENT SAMPLES
   - SELECT

2. - ALBUMIN
   - PHOS
   - NEXT SAMPLE

   - ALBUMIN
   - T PROT
   - NEXT SAMPLE

   NOTE: SID, CAR #, and POS # are automatically assigned.

3. - REVIEW & RUN

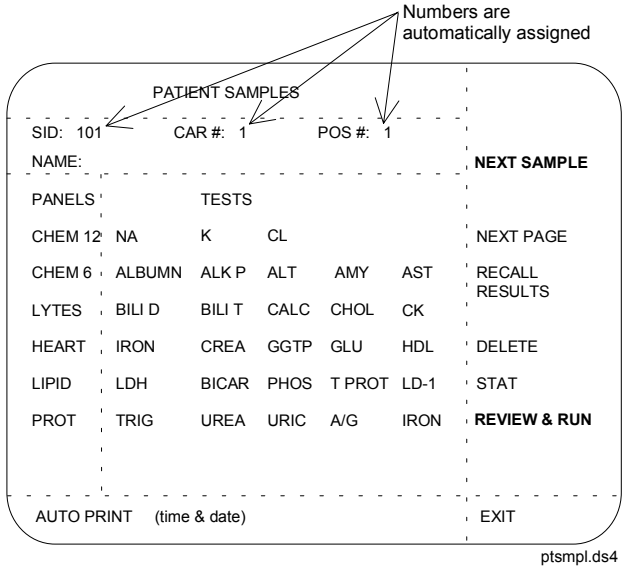


Figure 1 - 12: Patient Samples Screen (test-selection)

4. Verify that the carousel read as 1.

5. When the message PLEASE WAIT, BUILDING REAGENT AND CALIBRATOR LOADLISTS disappears, the loadlists have been built.

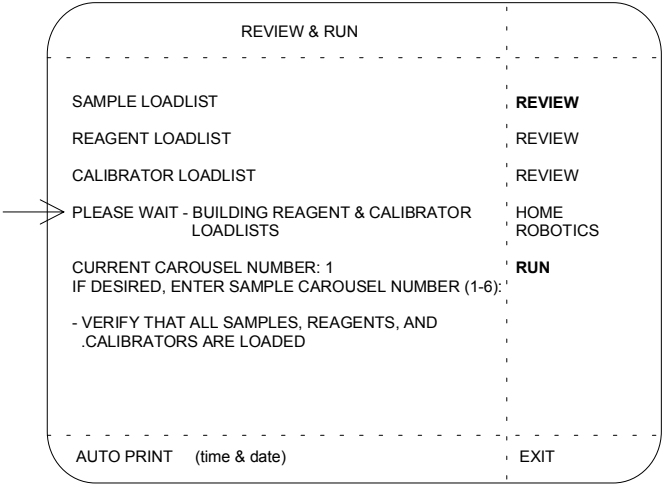


Figure 1 - 13: Review & Run Screen

- REVIEW (the REVIEW next to Sample Loadlist)

6. - PRINT LOADLIST

7. When CAROUSEL NUM ALL appears:
   - Type 1 (or appropriate carousel number)
   - ENTER

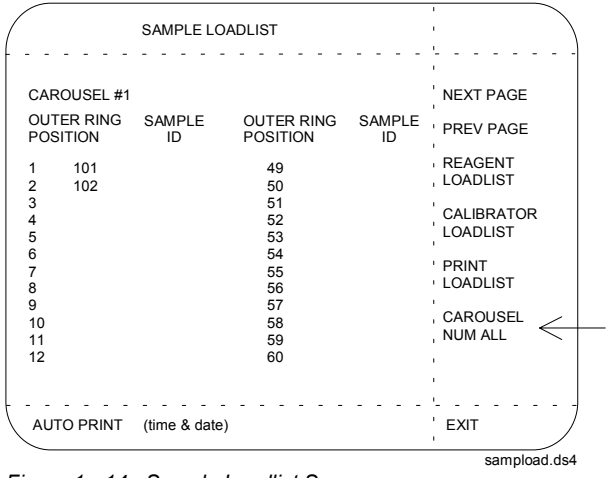


Figure 1 - 14: Sample Loadlist Screen

After the loadlist has printed:
- EXIT

8. Pipette approximately 300 µL of sample into a sample cup.

   NOTE: Use a clean, disposable pipette to dispense each sample.

9. Place sample cup(s) onto the sample carousel according to the printed loadlist.

10. Place sample cover onto sample carousel. Ensure cuvette and reagent tray covers are in place.

11. ■ RUN

    After a series of checks, the analyzer initiates the run. The Main Menu then reappears on the screen.

12. When the run is complete:
    - the results will print
    - the analyzer will beep to alert the operator

    Review the results printout for errors, control status, and patient values.

NAME: SAMPLE ID: 101

SAMPLE ENTERED <time and date>

REPORT PRINTED <time and date>

TEST NAME	RESULT	CODE	UNITS	NORMAL RANGE
ALBUMIN	4.0		G/DL	3.9 - 4.9
PHOSPHORUS	2.8		MG/DL	2.4 - 4.7

Figure 1 - 15: Example Printout

Quality control overview

NOTE: For details on reproducibility performance, refer to:
VP 51: Run: Calcium/AST
VP 52: Run: Reproducibility

Purpose

To display these:
- Mean
- Standard Deviation (SD)
- Percent Coefficient of Variation (% CV)
- Number of entries for each assay

It is generally considered good laboratory practice to include control sera with unknown samples. Values obtained using commercial sera should be within the range specified by the manufacturer as acceptable for this method.

To access individual quality control fields:

1. From the Main Menu select QUALITY CONTROL.
   The Quality Control Status Screen appears.
2. Select the desired assay and SELECT. The Quality Control Status Sub-screen appears (example on **page 1-41**).

   This sub-screen displays the value of the quality control data and the calculation associated with each level of control.
3. Edit or review Quality Control data as appropriate.
4. Save files.
5. Exit the Quality Control Sub-status Screen or select another assay.

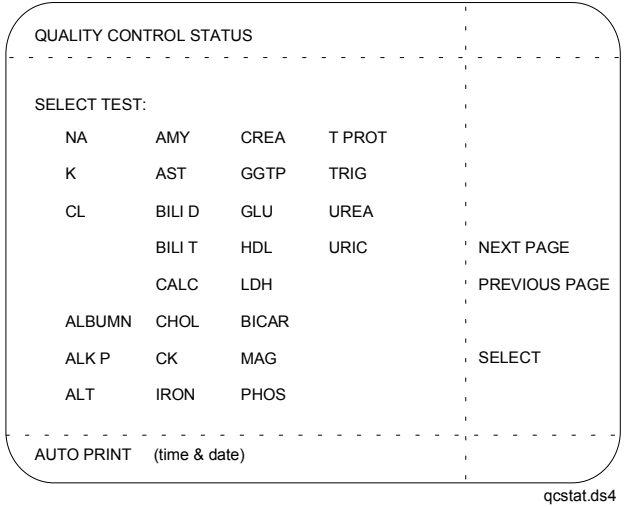


Figure 1 - 16: Quality Control Status Screen

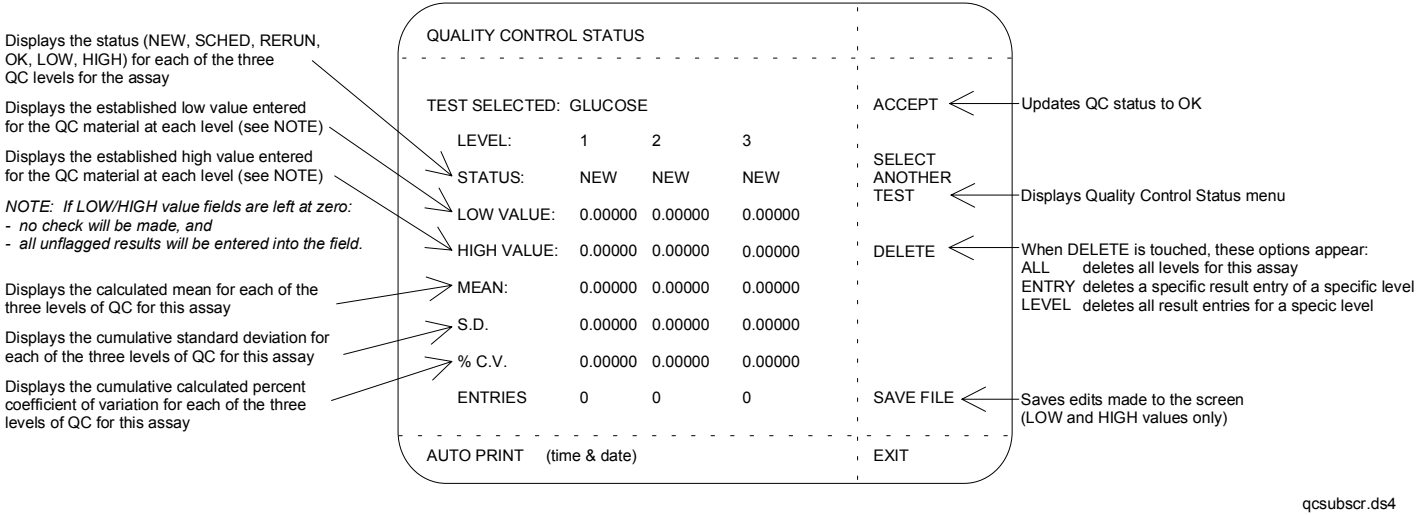


Figure 1 - 17: Example Quality Control Status Sub-screen

- When a value deleted from the file is moderately different from the mean (approx. a factor of 2), *** appears. The entire level must then be deleted.
- Any edit made in the Test Parameter File will automatically delete Quality Control data entries in the Quality Control file for the edited assay. Before editing an assay's Test Parameter File, print the Quality Control file.
- Only controls entered at /C 1, /C 2, or /C 3 before running will be evaluated against the established Quality Control ranges. Controls that are manually designated will not be evaluated against the established Quality Control ranges.