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Introduction

This section of the Operation Manual contains the following:

- Discussion of System components and associated hardware
- Discussion of the theory of operation
- Installation and relocation specifications

The ABBOTT SPECTRUM® SERIES II™ System (Figure 1-1) is a multiple access clinical chemistry analyzer, capable of quantifying selected analytes in biological fluids.

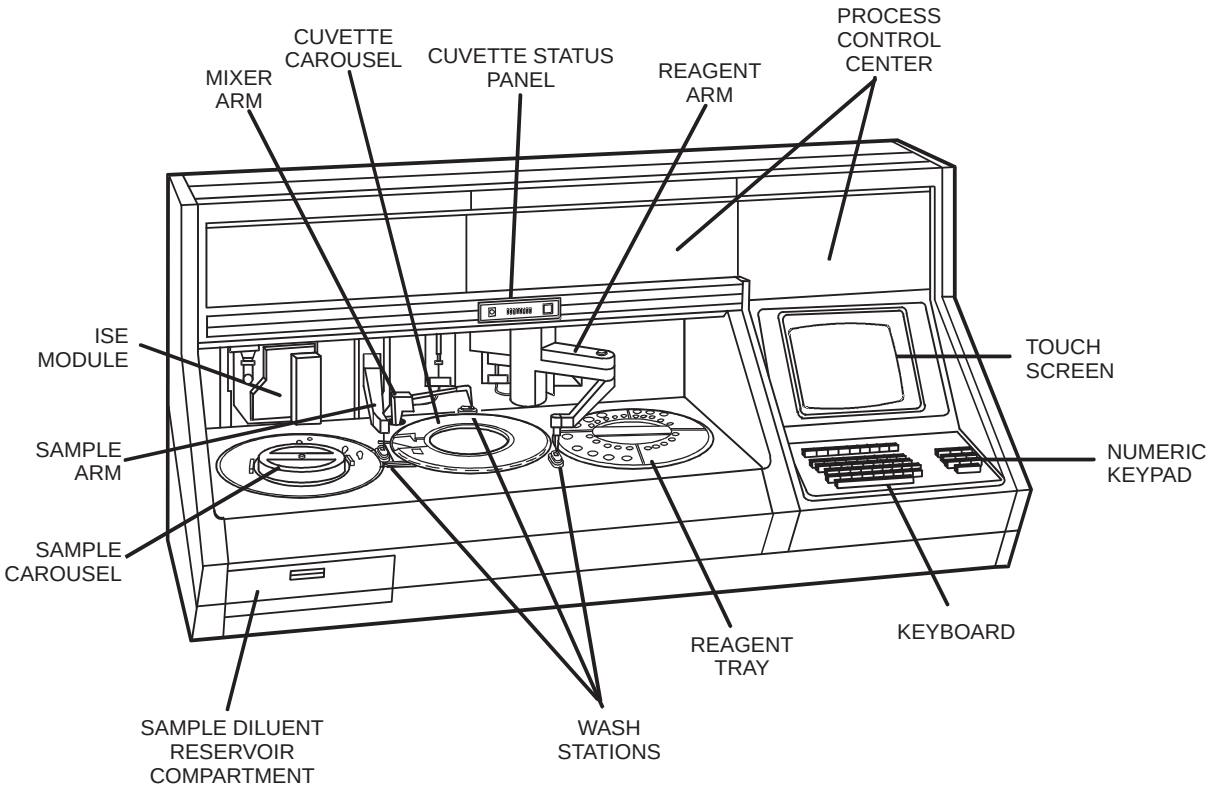

Figure 1-1 ABBOTT SPECTRUM® SERIES II™ System

System Components

Process Control Center

The Process Control Center constantly monitors and controls operation of the System. (Refer to Figure 1-2.) The Center consists of two processing units, the System Control Processor, and the Real Time Processor.

System Control Processor

The System Control Processor performs the following functions:

- Coordinates data entry and test requests from the operator
- Schedules optimized test runs based on 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

The Real Time Processor coordinates all robotic, electromechanical, and optical processes in the System.

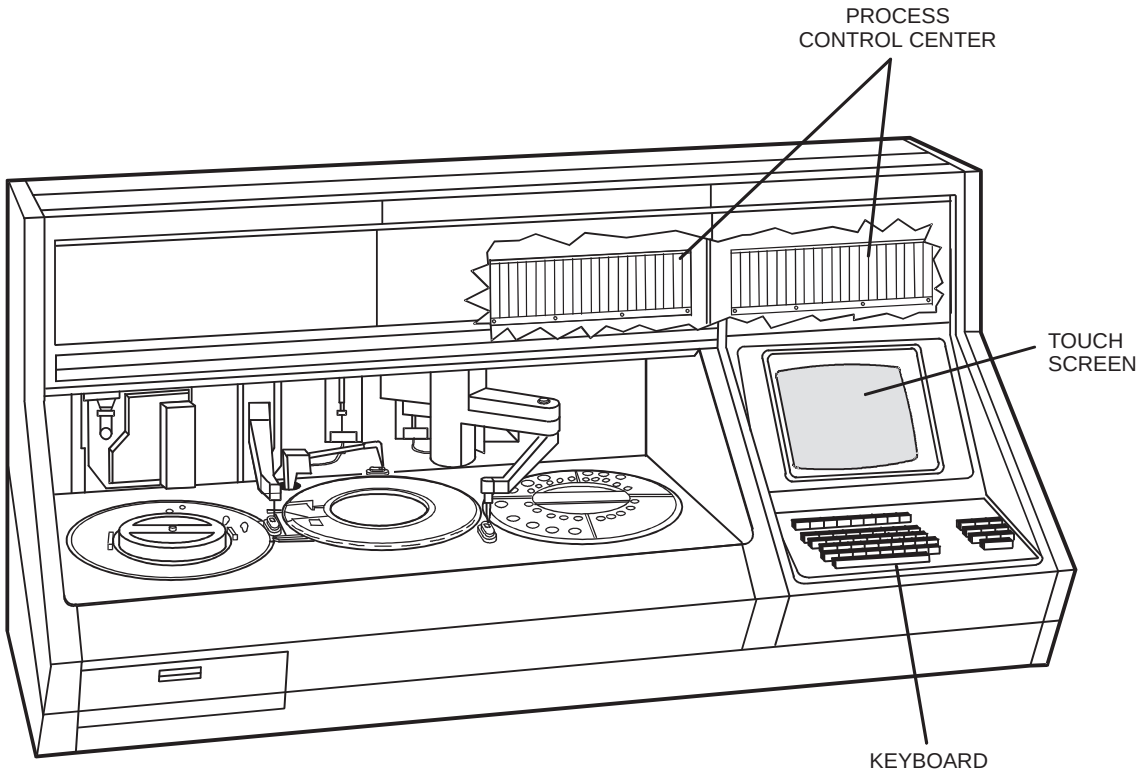

Figure 1-2 Process Control Center

Touch Screen

System operation may be controlled through the touch screen, located on the right side of the instrument, above the keyboard.

A touch is registered when a light beam in the infrared grid is interrupted by an object touching, then moving away from, the screen. Touching the appropriate field on the screen causes the field to highlight. The field remains highlighted to designate the last entered item. A selection is corrected by re-touching the appropriate field and re-entering data.

Refer to the Touch Screens section for details of each touch screen.

Keyboard

The keyboard is used to enter information required by the System and to access special functions. The cursor control (arrow) keys move the cursor to the appropriate field. Information is input by alphanumeric keys, and stored by pressing the ENTER key.

For a detailed discussion of the keyboard, refer to the Touch Screens section.

Process Area

The process area, located to the left of the touch screen, is the central workstation for handling samples and reagents. The process area includes the following:

- Sample carousel
- ISE module
- Cuvette carousel
- Reagent tray
- Robotic arms for fluid transport
- Optical system
- Wash stations

Sample Carousel

The sample carousel is located on the left side of the process area and consists of removable outer and inner rings. The outer ring is reserved for patient and quality control samples. The inner ring is reserved for the placement of calibrators, standards, and STAT samples.

Sample Arm

The sample arm is located between the sample and cuvette carousels. It aspirates and transfers aliquots of sample from a cup (or tube, if so equipped) to individual cells in the cuvette carousel.

ISE Module

The ISE module is located behind, and to the left, of the sample carousel. This component draws samples directly from the carousel to perform sodium, potassium, and chloride measurements using ion selective electrode (ISE) technology.

System Components

Mixer Arm

The mixer arm is located behind, and to the left, of the cuvette carousel. As part of the analysis, the mixer arm tip agitates the sample and reagent dispensed in the cuvette cell to assure homogeneity.

Cuvette Carousel

The cuvette carousel is located in the center of the process area. This carousel contains the cuvettes, where optical testing is accomplished. The carousel is housed in a temperature-controlled incubator.

Cuvette Status Panel

The cuvette status panel is located above the reagent arm on the center electronic access door. The panel indicates usage of cuvette segments. An audible alarm sounds at the end of a run, at cuvette change time, or when the System experiences an error which aborts System activity. The RESET button for the alarm is located on the cuvette status panel.

Reagent Arm

The reagent arm, located between the reagent tray and the cuvette carousel, transfers reagent from the appropriate cartridge to individual cuvette cells.

Reagent Tray

The reagent tray, located on the right side of the process area, accommodates a maximum of 20 single reagent cartridges or a combination of 12 single reagent cartridges and 8 dual reagent cartridges.

Wash Stations

The reagent probe, sample probe, and mixer arm tip are rinsed in the respective wash station. Refer to Figure 1-3.

The reagent probe and the mixer arm tip are rinsed with water from the water quality station. The sample probe is rinsed with water from the sample diluent reservoir.

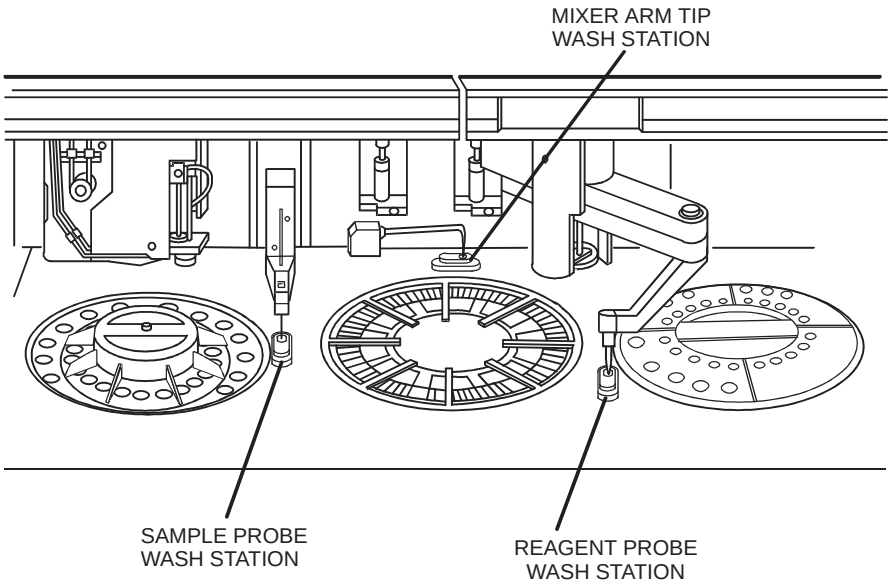

Figure 1-3 Wash Stations

Sample Diluent Reservoir

The sample diluent reservoir is located behind the sample diluent reservoir access door. Refer to Figure 1-4.

During daily maintenance, the reservoir is emptied, rinsed, and refilled with Type II water to prevent bacterial growth and untimely interruption of operation. The reservoir rests on a platform that monitors the weight of the water. The message DILUENT LEVEL LOW displays when reservoir volume is inadequate.

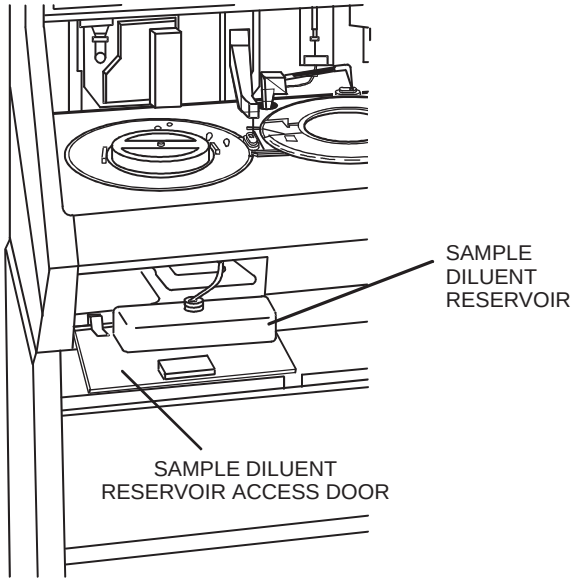

Figure 1-4 Sample Diluent Reservoir

Mainframe Interface

The ABBOTT SPECTRUM SERIES II System can interface directly with a mainframe computer. Bi- and uni-directional communication allows patient information and test results to be sent to the mainframe. Interface specifications are available from Abbott Laboratories.

For additional information, refer to Specific Procedures, Interface.

Printer

A printer and a five-foot (1.5m) interface cable are included with each System. Refer to the printer manual for additional information.

System Components

Line Conditioners

The ONEAC® line conditioners, illustrated in Figure 1-5, provide voltage regulation and noise attenuation.

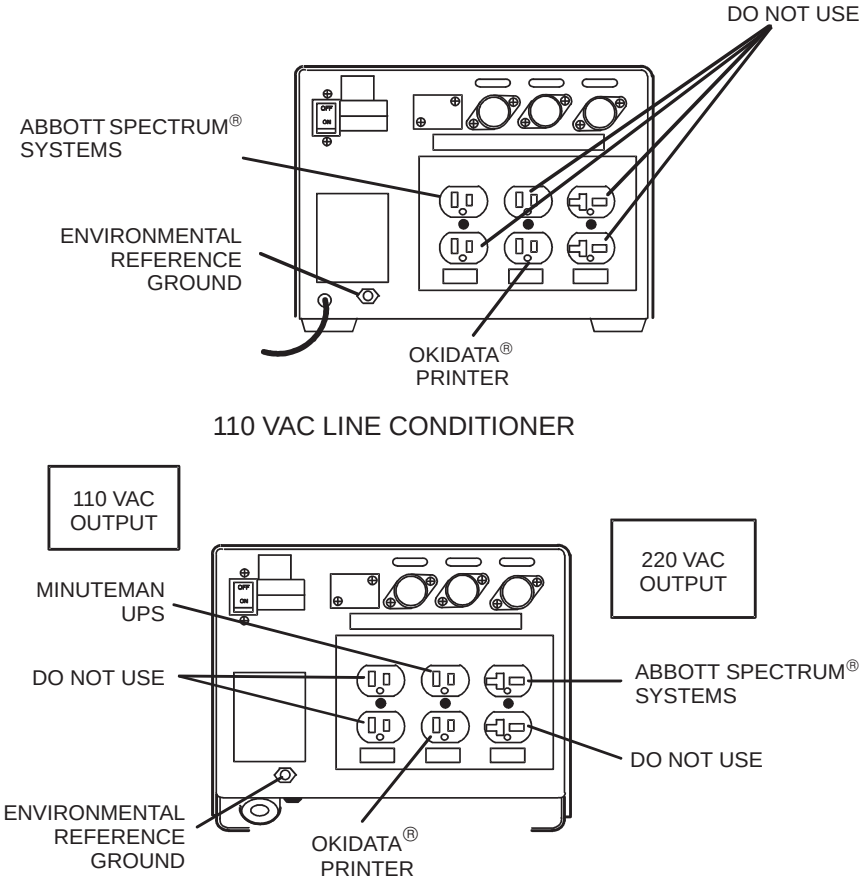

Figure 1-5 ONEAC® Line Conditioners

Support Module

The System rests on a base designed to enhance the instrument's use. The base, mounted on casters, allows the System to be moved.

Three pull-out work surfaces are accessible in the front of the base. An additional surface, on the right side, may be used to support the printer.

The lockable door can be pulled up and recessed under the work surfaces to allow access to the storage areas. Pull-out bins allow storage of maintenance and consumable items.

OKIDATA is a registered trademark of Okidata Corporation.
ONEAC is a registered trademark of Oneac Corporation.

Sample System

Sample Dispense Mechanism

The sample dispense mechanism consists of a probe, mounted on a robotic arm, and a syringe. The syringe is driven by a digitally controlled linear stepper motor. The probe aspirates sample and dispenses it into cuvette cells.

The robotic arm contains a fluid level sensing probe and fluid level sensing electronics. The probe minimizes sample carryover and assures error-free sample aspiration. An LED on the sample arm indicates current fluid sense status. The mechanism is capable of aspirating from 1.25µL to 25µL, from cups containing a minimum of 50µL of sample.

Refer to Figure 1-6 for an illustration of the sample dispense mechanism.

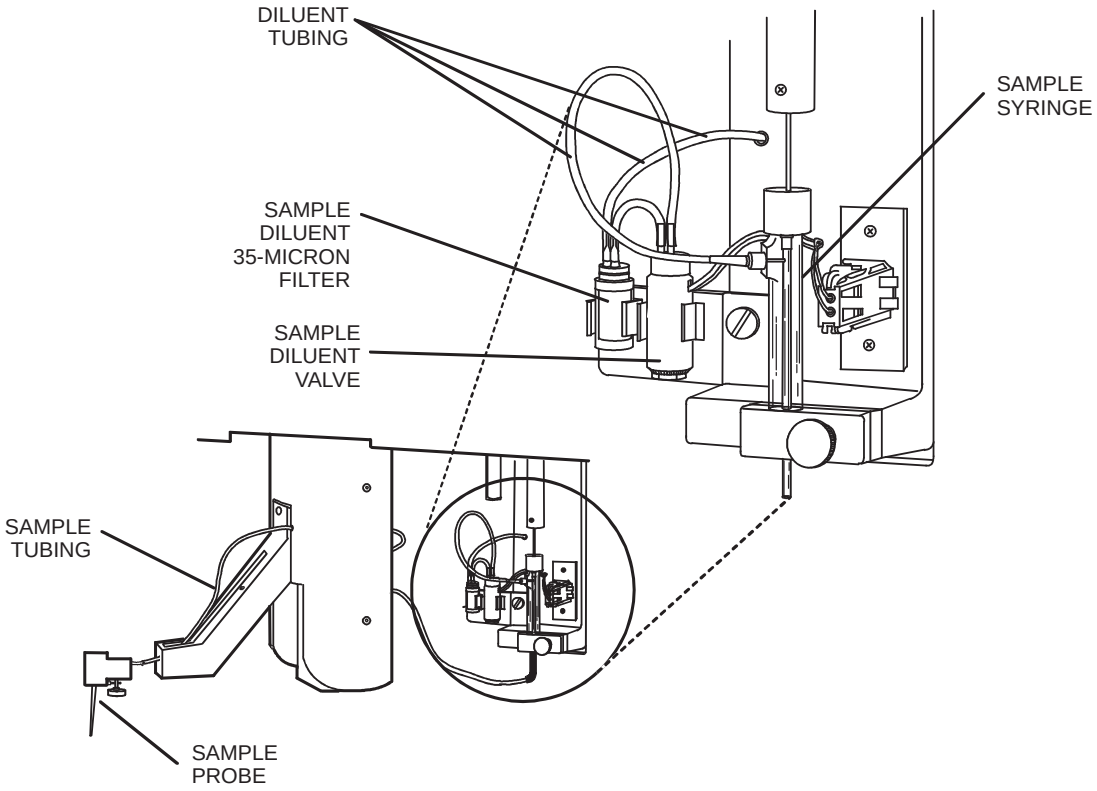

Figure 1-6 Sample Dispense Mechanism

Sample System (continued)

Sample Carousel

The sample carousel, located on the left side of the process area, is designed to accept cups. The carousel may be enhanced with a primary tube carousel. The sample carousel consists of removable outer and inner rings. The outer ring accommodates 48 patient and quality control samples. The inner ring accommodates 24 sample cups, and is reserved for the placement of calibrators, standards, and STAT samples. The System can recognize and store information on a maximum of six encoded sample carousels.

Refer to Figure 1-7 for illustrations of the sample carousel and sample carousel cover.

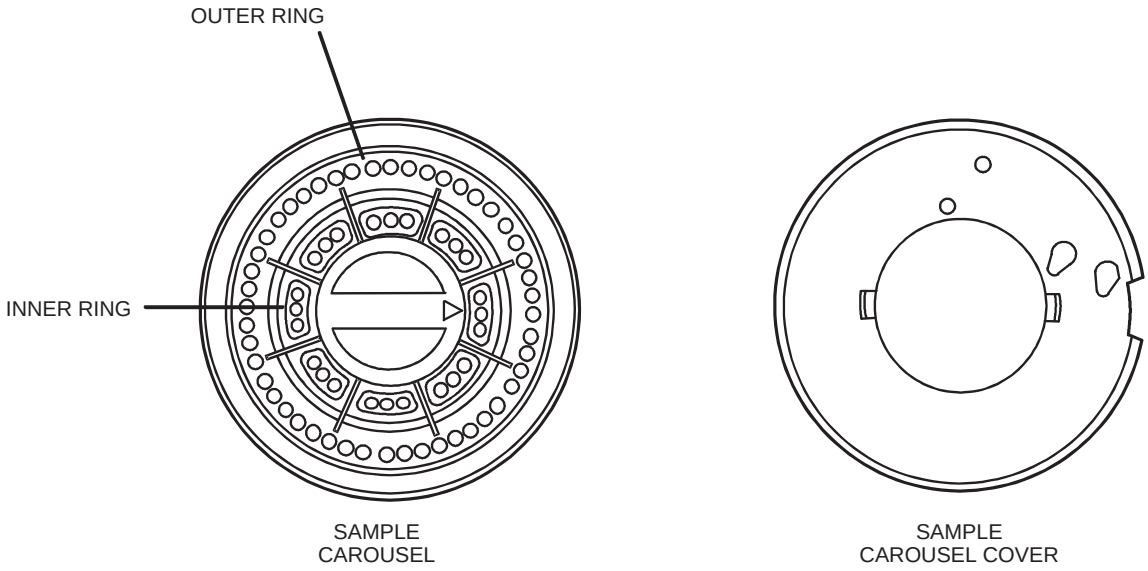

Figure 1-7 Sample Carousel and Cover

Sample Carousel Cover

The sample carousel cover should be used during operation to maintain evaporation at less than 3% per hour. Refer to Figure 1-7, above.

Sample System (continued)

Sample Volume

Sample cups are designed to contain up to 2mL of fluid. Refer to Figure 1-8 for an illustration of a sample cup. Sample volume may vary from 1.25µL to 25µL, in increments of 0.25µL. A typical sample volume (excluding sodium, potassium, and chloride) is 5µL per assay. Sodium, potassium, and chloride require 142µL of sample. The dead space, or residual cup volume, is 25µL. However, a minimum sample cup volume of 50µL is required for proper fluid sense by the sample probe. Beginning with a 50µL cup volume, the System samples fluid to a level of 25µL.

For conditions affecting sample volumes for non-Abbott applications, refer to the Reagent Manual, Supplemental Chemistry Procedures.

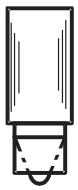

Figure 1-8 Sample Cup

Sample Carousel ID Kit

The sample carousel ID kit provides binary labels to encode the sample carousel. Labels are affixed with the lines of the barcode horizontal and the number on the top.

Sample Probe Wash

After aspirating and dispensing sample, the sample probe moves to the sample probe wash station. The System uses water from the sample diluent reservoir to rinse the inside and outside of the probe.

System Features

Sample System (continued)

Cuvette Status Panel

The cuvette status panel, illustrated in Figure 1-9, is located on the center electronic access door. An LED illuminates when the sample arm dispenses into the first cell of a cuvette segment.

Audible Alarm

An audible alarm is located on the cuvette status panel. The alarm emits a tone at the end of a run, at cuvette change time, or when the System experiences an error which aborts System activity. The tone is silenced by pressing the RESET button. The alarm does not sound for informational messages, such as linear high or low, calibration errors, or initial absorbance errors.

Cuvette Change/End of Run

At cuvette change time or at the end of a run, the alarm sounds intermittently for five seconds. The RESET button flashes until pressed.

System Abort

The audible alarm sounds when the System experiences an error which halts the assay in process. The alarm emits a continuous tone for 20 seconds after the abort. The RESET button glows amber for 20 seconds and flashes until pressed.

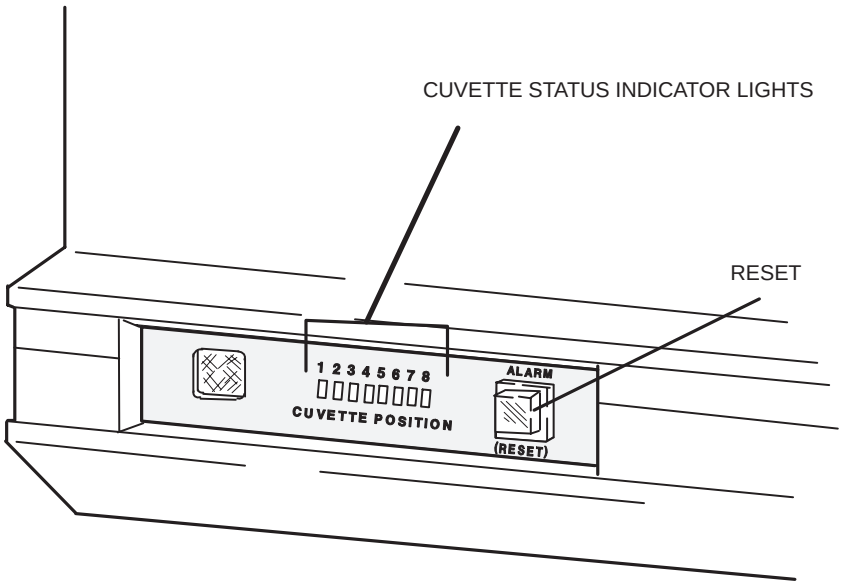

Figure 1-9 Cuvette Status Panel

Sample Diluent System

The sample diluent system consists of the following components:

- Sample probe
- Sample syringe
- Sample diluent valve
- Sample diluent 35-micron filter
- Sample tubing
- Sample diluent reservoir
- Sample diluent 70-micron filter
- Sample wash station

Fifteen microliters of water flush the sample into the cuvette cell to ensure complete delivery of the sample. Water is pumped by the sample diluent pump through the low- and high-pressure sensors, the filter, and the valve. From the valve, water flows through the sample system tubing and syringe, then into the sample probe. Waste is drained from the sample wash station through the System drain.

Mix System

Mix Mechanism

As part of the analysis, the mixer arm, illustrated in Figure 1-10, moves to the cuvette cell. To assure homogeneity, the mixer arm tip agitates the sample and the reagent dispensed in the cuvette cell. The mixer arm then moves to the mixer arm tip wash station.

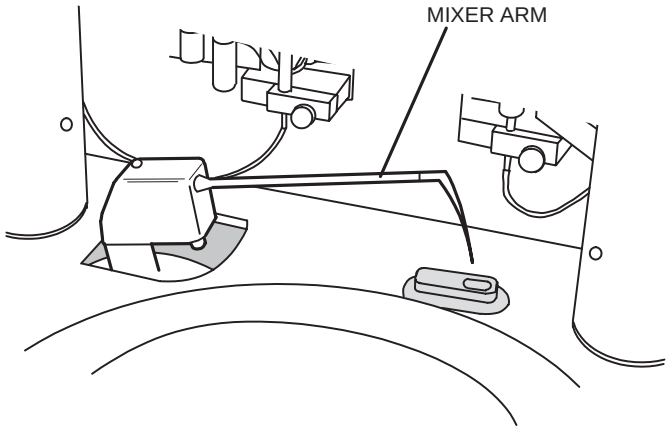

Figure 1-10 Mixer Arm

Mix System (continued)

Cuvette Carousel

The cuvette carousel accommodates eight cuvette segments, each containing 12 cells for incubation of reagent and sample. The cuvette carousel is housed in the incubator. Figure 1-11 illustrates the cuvette carousel.

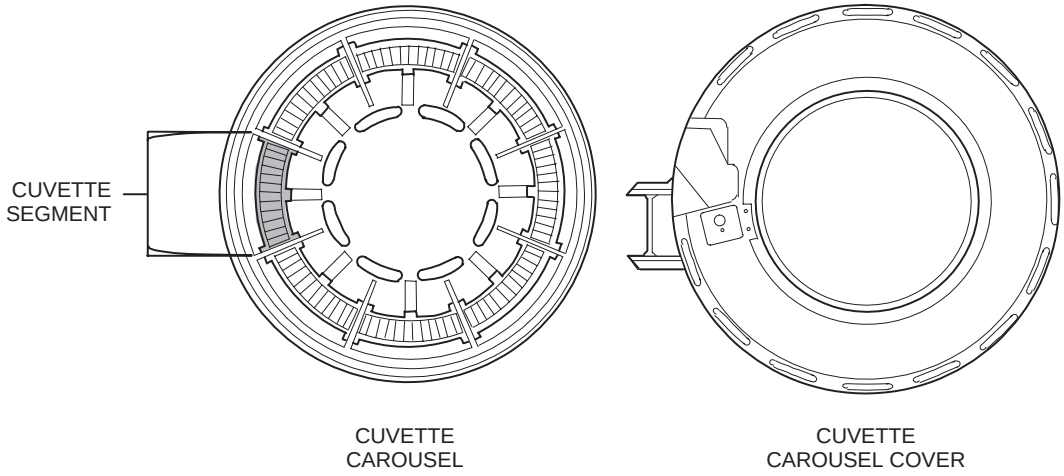

Figure 1-11 Cuvette Carousel and Cover

Cuvette Carousel Cover

The cuvette carousel cover (Figure 1-11, above) is placed over the cuvette carousel while tests are being processed. The cover is designed to protect the cuvette segments from the surrounding environment and to maintain the incubation temperature.

Cuvette Segments

Each cuvette segment (Figure 1-12) is partially immersed in the incubator to maintain a constant temperature in the cuvette cell.

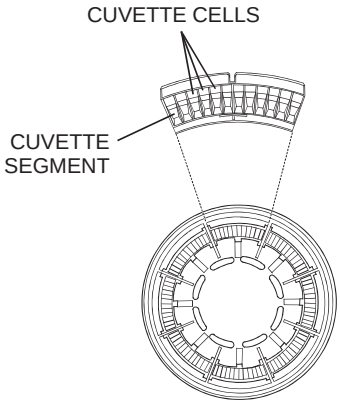

Figure 1-12 Cuvette Segment

Mix System (continued)

Incubator

The incubator is supplied with water from the water quality station. When moisture is detected, the incubator water level sensor indicates to the System that no additional water is to be supplied to the incubator. The incubator is designed with an overflow drain.

The software has the capacity to incorporate temperatures of 25°C, 30°C, and 37°C for the incubator. All ABBOTT SPECTRUM® chemistries are 37°C assays (U.S.A.).

Refer to Figure 1-13 for an illustration of the incubator.

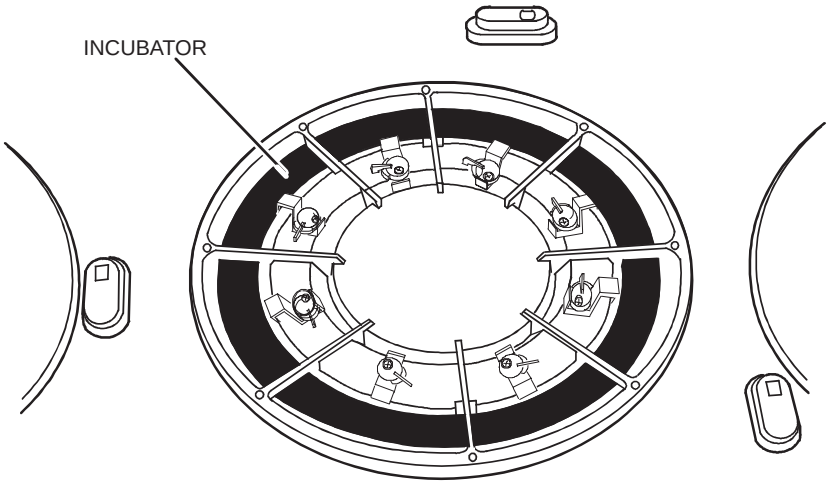

Figure 1-13 Incubator

Mixer Arm Tip Wash

After mixing reagent and sample, the mixer arm tip moves to the mixer arm tip wash station. The System uses water from the water quality station to rinse the tip.

Reagent System

Reagent Dispense Mechanism

The reagent dispense mechanism consists of a probe, mounted on a robotic arm, and a syringe. The syringe is driven by a stepper motor. The probe aspirates reagent from reagent cartridges, and dispenses it into cuvette cells. Reagent for each cell is dispensed in consecutive order, independent of the assay.

The robotic arm contains a fluid level sensing probe and fluid level sensing electronics. The conductive polypropylene probe minimizes carryover and verifies proper pipetting. An LED on the reagent arm indicates current fluid sense status. The mechanism is capable of dispensing from 25µL to 486µL of reagent.

Refer to Figure 1-14 for an illustration of the reagent dispense mechanism.

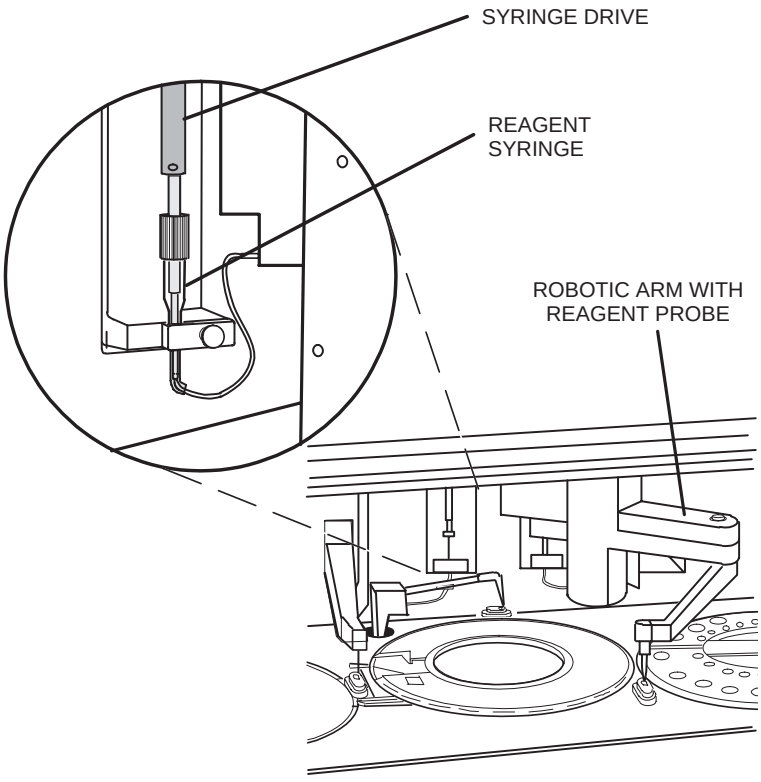

Figure 1-14 Reagent Dispense Mechanism

Reagent System (continued)

Reagent Tray

The reagent tray (Figure 1-15) consists of four independent quadrants, each accommodating five reagent cartridges. A ridge on the outer surface holds the cartridges in position. All quadrants are removable for easy storage and facilitation of special test grouping or paneling.

Two reagent quadrants are designed to hold single-component reagent cartridges (Core Positions 1-20) or dual reagent cartridges (Perimeter Positionsq P1-8).q Theq remainingq quadrantsq accommodateq only single-component cartridges.

To provide proper conditions for maximum on-board reagent stability, three quadrants of the reagent tray are maintained in the 2-10°C range. One quadrant is maintained in the 20-28°C range.

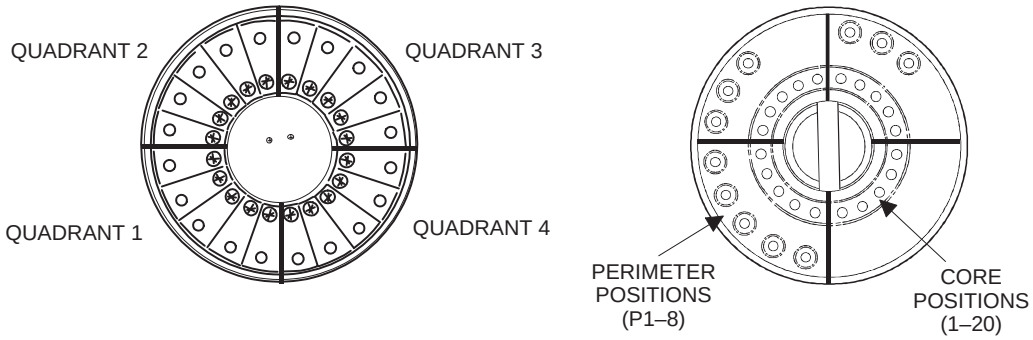

Figure 1-15 Reagent Tray and Cover

Reagent Tray Cover

The reagent tray cover (Figure 1-15, above) should be used during operation to maintain a constant temperature.

System Features

Reagent System (continued)

Reagent Cartridge Barcode Labels

A barcode label on the central surface of each reagent cartridge identifies the reagent type, master lot number, and cartridge size and type. The barcode reader scans the labels and displays a message if a reagent is placed in the incorrect temperature quadrant.

Refer to Figure 1-16 for an illustration of correct placement of the reagent cartridge in the reagent tray.

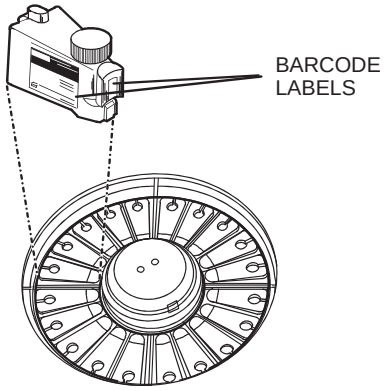

Figure 1-16 Reagent Cartridge Placement

Reagent Information

Refer to the reagent package insert and the Reagent Manual for information regarding the chemical principle, precautions, preparation, stability, and storage of reagents.

Reagent Volume

Typical reagent volume is 236µL. Volumes may vary from 25µL to 486µL, in increments of 1.92µL. The value displayed on the screen is rounded to three digits.

Reagent Probe Wash

After the final dispense of each reagent, the reagent probe moves to the reagent probe wash station. The System uses water from the water quality station to rinse the reagent probe. The source of the water must be 1 megohm resistivity or greater. The water pressure must be regulated to 5-7 psi as it enters the System to achieve the proper “fountain” effect required to rinse the outside of the probe.

Ion Selective Electrode (ISE) System

ISE Module

The Ion Selective Electrode (ISE) module is an integrated subsystem for the determination of sodium, potassium, and chloride in serum samples. Ion-selective electrodes are based on unique properties of ion specific membranes, which develop an electrical potential according to the Nernst Equation for species in solution. The self-calibrating module uses solutions and calibrators contained in the ISE reagent cartridge pack.

Refer to Figure 1-17 for an illustration of the ISE module.

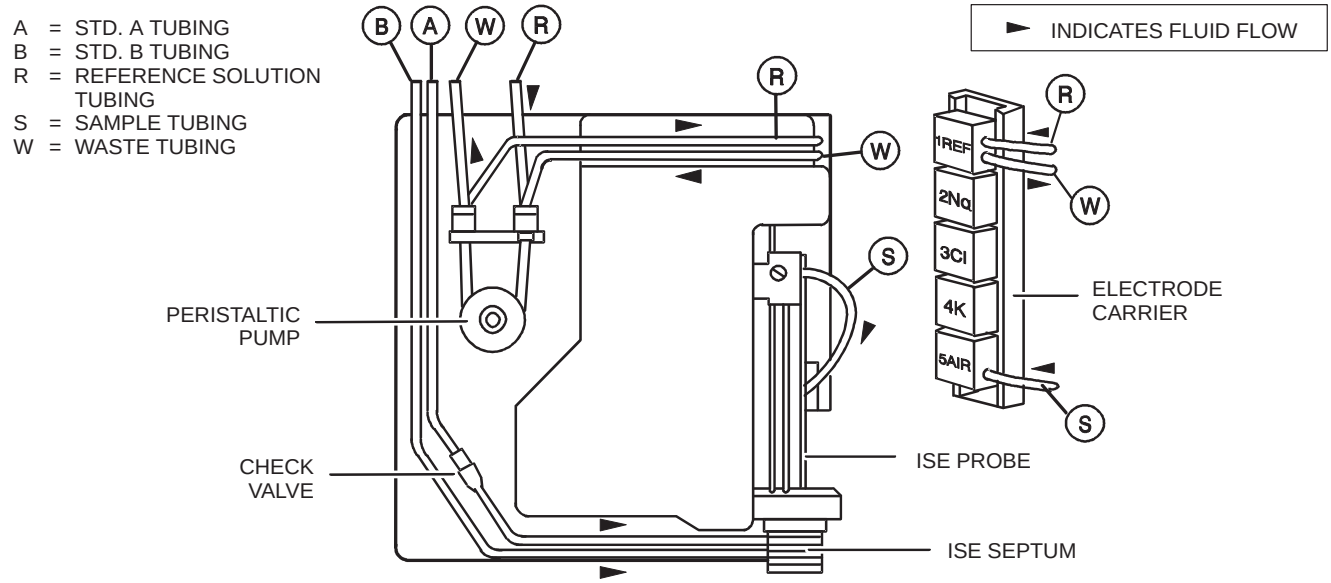

Figure 1-17 ISE Module

Ion Selective Electrode (ISE) System (continued)

Electrolyte Measurement

An electrode-measuring circuit resembles a small chemical battery. Ion-selective electrodes develop electrical potentials proportional to different concentrations of the ion being measured. The higher the sample concentration, the greater the potential developed. The reference electrode is required to quantitate the developed potential. An ion-selective electrode generates an electrical potential when placed in a solution containing the analyte it is designed to measure. The electrode membrane adds the restriction of selectivity for the ion being measured. The membrane must have permeability and selectivity to allow only one specific species of ion to permeate the membrane, even though other ions are present. The result is a change separation which results in a potential difference proportional to the concentration of the species being measured. Refer to Figure 1-18 for an illustration of the principle of electrochemical measurement.

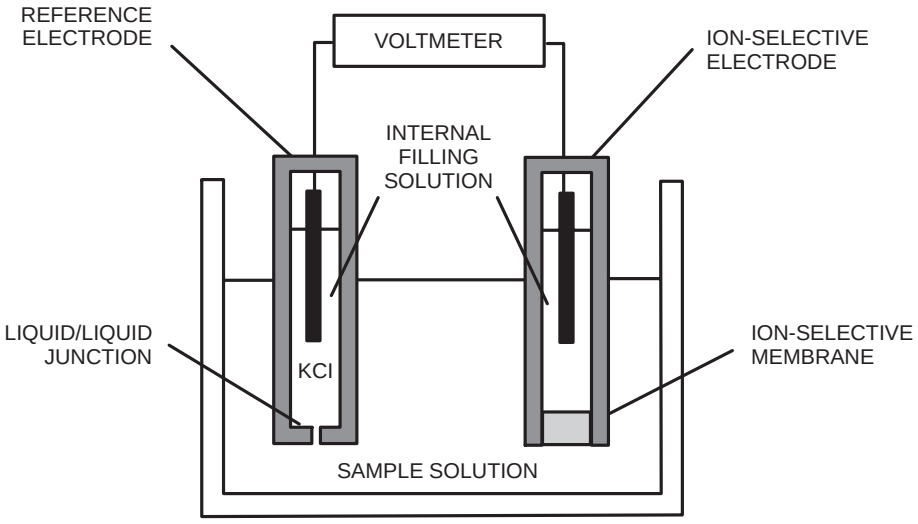

Figure 1-18 Principle of Electrochemical Measurement

The reference electrode is the electrode against which the signal of the ion-selective electrode is compared. It is actually a silver/silver chloride electrode. A 2M potassium chloride reference solution is used as the reference electrode "filling solution."

The potential developed by the ISE is logarithmically proportional to concentration, according to the Nernst Equation for species in solution. This potential difference is detected, amplified, digitized, and presented to the microcomputer, where the results are calculated.

Ion Selective Electrode (ISE) System (continued)

ISE Performance Characteristics

Historically, indirect electrolyte measurements which dilute the sample have been recognized as causing certain inherent problems during analysis. These problems include falsely lowered results due to sample dilution and plasma displacement by abnormally high lipid levels.

The ABBOTT SPECTRUM SERIES II System measures sodium, potassium, and chloride by direct ion-selective electrodes, which greatly minimize or eliminate these traditionally inherent measurement problems. As a result, ABBOTT SPECTRUM SERIES II System values for assayed controls and serum and plasma samples are approximately 2% higher for sodium and potassium than those obtained by flame photometer methods. Chloride measurements are typically 4.5% higher than ranges given for titration methods.

CAUTION

REFERENCE OR QUALITY CONTROL MATERIAL CONTAINING THE FOLLOWING PRESERVATIVES MUST BE AVOIDED FOR ELECTROLYTE ASSAYS:

- ETHYLENE GLYCOL DESTROYS ALL ELECTRODES.
- CHLORPHENOL IS TOXIC TO THE CHLORIDE ELECTRODE.
- AMMONIUM BICARBONATE CAUSES HIGH SODIUM RESULTS AND LOW POTASSIUM RESULTS.
- AZIDES CAUSE CHLORIDE TO DRIFT HIGH.

ISE Volume

The ISE module requires a minimum sample volume of 142µL. The dead space, or residual cup volume, is 25µL.

ISE Module Fluid Flow

The ISE reagent cartridge pack contains the Reference (R) solution, and Internal Standards A and B. The R solution is drawn through the R tubing, as needed, into the reference electrode. Standards A and B are pumped through the A and B tubing to the upper and lower septum chambers, respectively.

The ISE sample probe alternately draws sample and Standard A or B, as needed. Air is aspirated at the beginning and end of each sample, and is used by the air detector to verify flow rates. The ISE sample probe and the ISE electrodes are linked by the S tubing to the air detector. As each millivolt reading is measured, the sample, standard, and air aliquot are drawn sequentially through the air detector, potassium electrode, chloride electrode, sodium electrode, and reference electrode. Upon completion, all fluids are pumped through the W tubing into the waste (W) container of the ISE reagent cartridge pack.

Water System

The water system is illustrated in Figure 1-19. The water quality station is designed to regulate and filter water from the source deionizer tanks into the System. For additional information, refer to Installation and Relocation in this section.

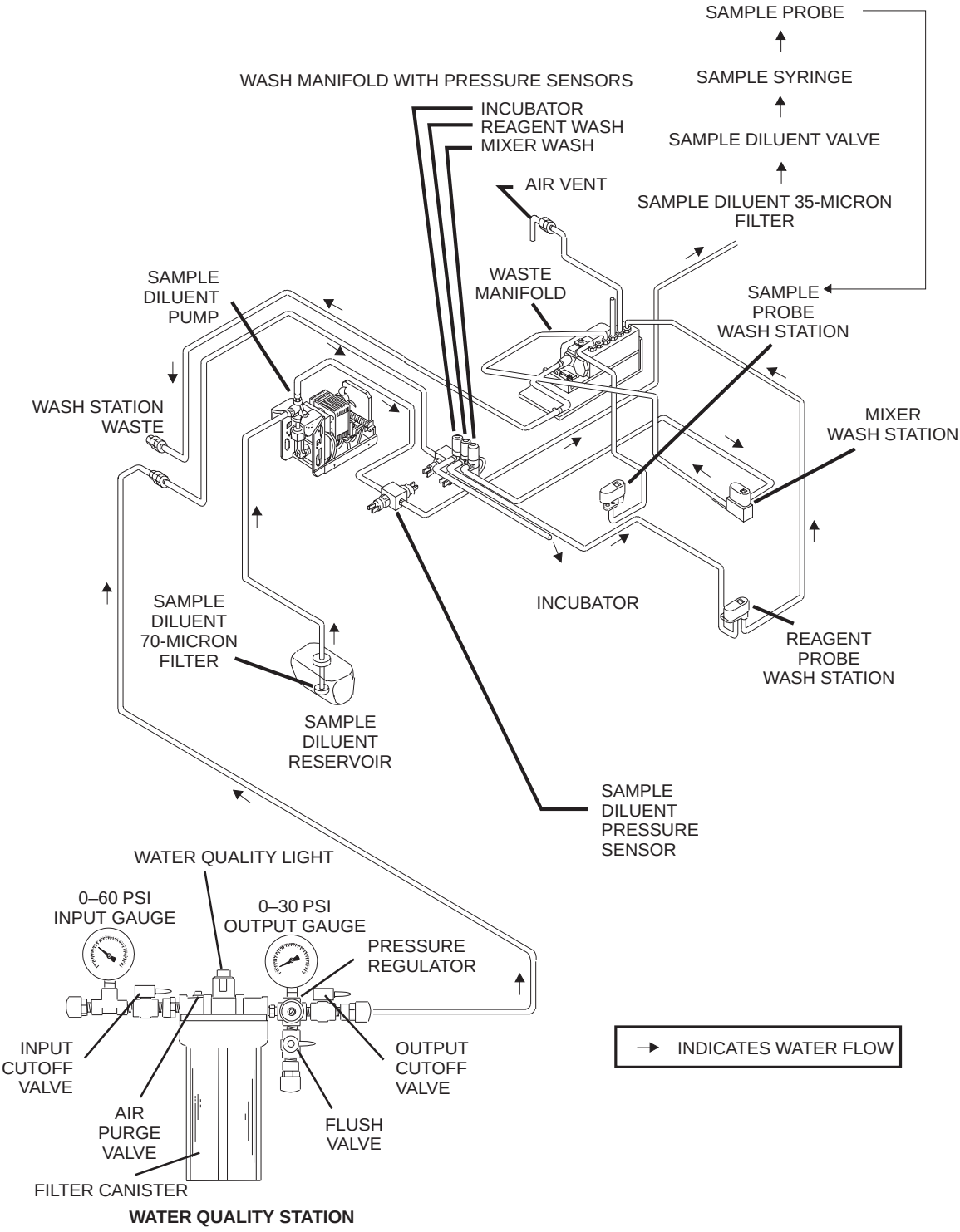

Figure 1-19 Water System

Optical System Measurements

The ABBOTT SPECTRUM SERIES II System uses absorbance to quantitate analyte concentrations. Light from a tungsten halogen lamp is collimated and passed through the cuvette. During the chemical reaction between the reagent and the sample, the absorbance of the solution changes with respect to time as the reaction progresses. (The Beer-Lambert Law establishes the mathematical relationship between the chromophore concentration and light absorbance.) The transmitted light is focused through the entrance slit of the polychrometer onto the holographic grating, which disperses the light into its component wavelengths. The dispersed light is focused onto a linear photodiode array that measures light intensity at 16 different wavelengths.

The measurements are selected to give either monochromatic, bichromatic, or, when measuring at several different wavelengths, polychromatic readings. Transmitted intensity readings are converted to absorbance readings by means of a log-ratio amplifier. The absorbance readings are blank corrected (as specified for each test), then converted to concentration units.

Refer to Figure 1-20 for an illustration of the optical system.

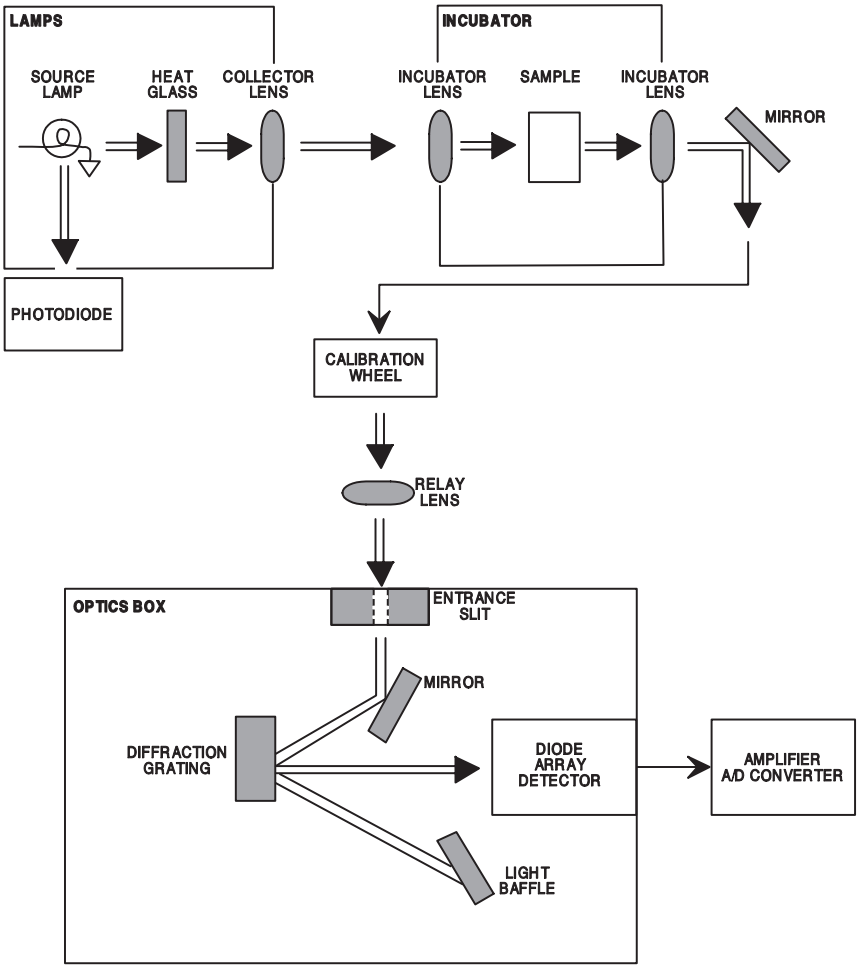

Figure 1-20 Optical System

Theory of Operation

Optical System Measurements (continued)

Bichromatic Reads	When a sample is mixed with an appropriate reagent, the chromophore (color carrier) in the reagent is developed as the result of the chemical reaction between the reagent and a component in the sample. In bichromatic (dual-wavelength) photometry, two wavelengths of light are used to measure this reaction.
Absorbance Difference (A_d)	Generally, the optical system measures each reaction at two wavelengths, i.e., bichromatically. One wavelength is selected close to the absorbance peak of the chromophore being measured (the wavelength of minimum light transmittance). The other wavelength is to the side of this peak, where more light is transmitted, i.e., the absorbance is lower. The differential in absorbance at the two wavelengths is measured, giving an absorbance difference (A_d) reading.
Blanking	Final result reads are blanked by one of the methods described below.
No Blank	No blank subtraction.
Reagent Blank	Reagent blanks are used to correct for reagent absorbance. The reagent blank assay subtracts the reagent blank read from the final read.
Serum Blank	Serum blanks are used in some end point reactions to correct for sample absorbance. The serum blank assay subtracts the serum blank read from the final read.
Reagent 1 Blank	The last read taken on Reagent 1 is subtracted from the final read and volume corrected.
Reagent 2 Blank	The last read taken on Reagent 2 is subtracted from the final read.
Aux Serum Blank	The read taken immediately after addition and mixture of the last auxiliary reagent is subtracted from the final read.
Aux Reagent Blank	The read taken immediately before addition of the final reagent is subtracted from the final read.
Kinetic Blank	A kinetic blank calculation is determined to correct intrinsic activity that may exist in the reagent in the absence of analyte. The blank value is obtained by using water as a calibration sample. This value is stored in memory and subtracted from each sample absorbance. Kinetic blanks are checked for optical integrity flags before the System accepts the calibration. If flags are present, the System automatically fails calibration.
Volume of Correction Blank	The blank readings for all assays are volume corrected before they are subtracted. Refer to Equation 1-1.

$$\text{Volume Corrected Blank} = (\text{Blank Reading} - \text{DP}) \frac{\text{Volume at Time Blank Reading Taken}}{\text{Final Assay Volume}}$$

$$\text{Final Assay Volume} = \text{Sample Volume} + \text{Reagent Volume} + \text{Flush Volume}$$

(Equation 1-1)

Chemistry Overview

End Point Reaction

Many analyses of clinical interest are measured by one or more chemical reactions catalyzed by enzymes. For example, a glucose end point assay may use a series of coupled reactions. Refer to Equation 1-2.

$$\text{Glucose + ATP} \xrightarrow{\text{Hexokinase}} \text{ADP + G-6-P}$$

$$\text{G-6-P + NAD + } H_2O \xrightarrow{\text{G-6-PDH}} \text{6-Phosphogluconate + NADH + } H^+$$

(Equation 1-2)

The enzymes, hexokinase and G-6-PDH (glucose 6-phosphate dehydrogenase), catalyze the above reactions. For each optical assay, an increase or decrease in the absorbance of a chromophore is measured. In this example, the chromophore is NADH. NAD has negligible absorbance above 300nm, while the reduced form, NADH, absorbs intensely at 340nm. Therefore, the amount of glucose present in solution is directly proportional to the amount of NADH formed. The progress of this reaction, as a function of time, is illustrated in Figure 1-21.

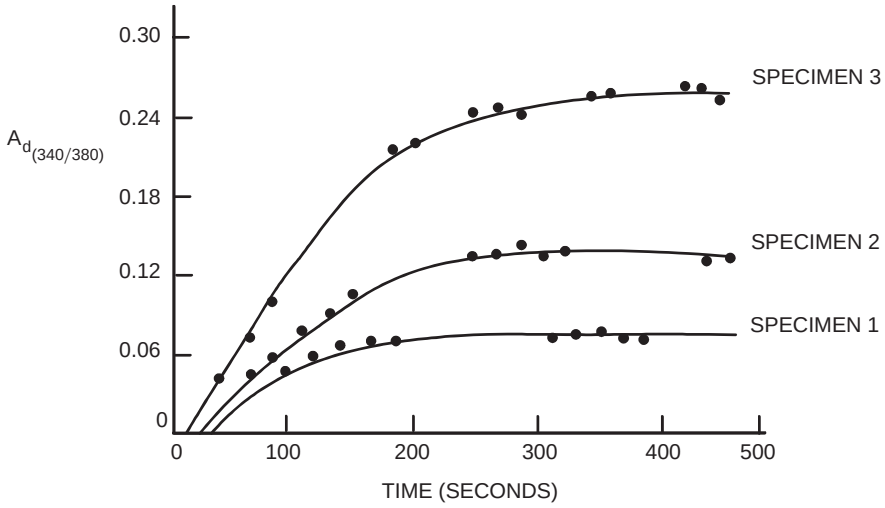

Figure 1-21 Glucose Assay Reaction

Chemistry Overview (continued)

End Point Reaction (continued)

The reaction reaches equilibrium in approximately five minutes. The amount of glucose present is proportional to the absorbance change calculated by subtracting the absorbance at time zero from the absorbance value at a time point in the plateau region. This type of analysis is called an end point assay. In order to calculate an actual concentration of glucose, a calibration curve must be derived. Standards with known glucose concentrations are processed using the absorbance difference (A_d) values at 340/380, and a calibration curve is calculated.

End point assays are checked for optical integrity before the System accepts calibration. Refer to Math Models in this section for a discussion of the calculations involved for end point chemistries.

Rate Reaction

The functional enzyme activity is determined and expressed as the amount of product (μmoles) formed per minute, per liter (International Units/Liter) catalyzed by the enzyme.

Under appropriate reaction conditions, the rate of product formation is proportional to the enzyme concentration. A typical progress curve for LDH is shown in Figure 1-22.

In the assay design, all absorbance readings are taken in the linear region of the progress curve. Refer to Math Models in this section for a discussion of the calculations involved for rate chemistries.

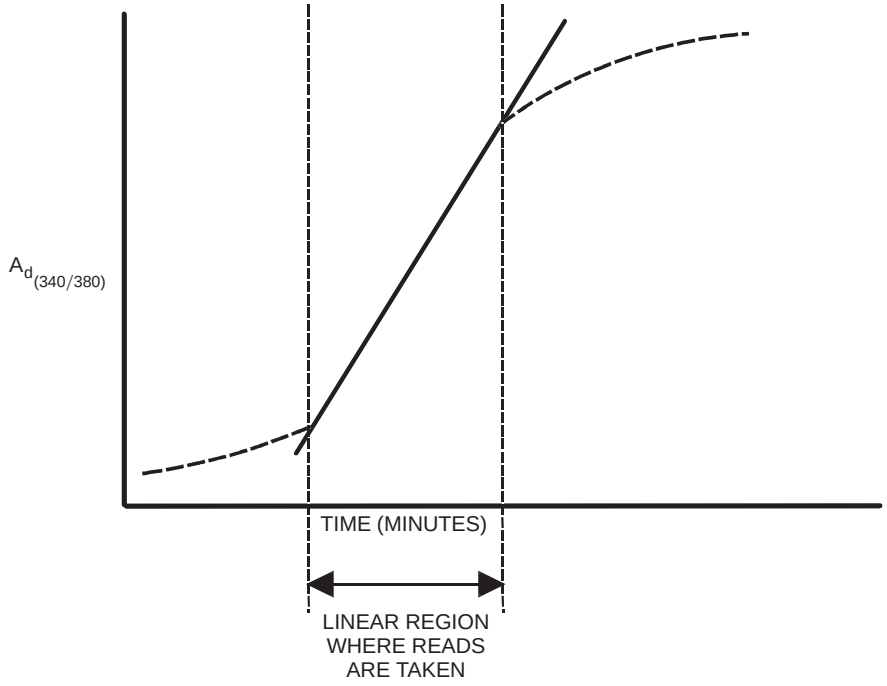

Figure 1-22 LDH Progress Curve

Chemistry Overview (continued)

Extinction Factor

The extinction factor (E.F.) expresses the bichromatic absorbance change per unit concentration change of chromophore. This value is normally expressed as the A_d change when 1 mmole/L of chromophore is measured in a 1.0 cm pathlength cuvette.

Because of the unique system optics, E.F. values must be determined for each individual photometer. The E.F. is entered into the individual Test Parameter Files. The E.F. values may vary slightly from system to system, but are specific for the chromophore and solution conditions being measured at a specified wavelength pair. Enzyme concentration is normally expressed as International Units/Liter (IU/L). One IU/L is defined as the amount of enzyme required to catalyze the formation or consumption of 1 µmole of substrate per minute, per liter. Alternative units are nanokatals/L (nKat/L). Refer to Math Models in this section for the conversion factor.

Dilution Protocol

If a dilution protocol is defined in the Test Parameter File prior to initial testing, assay results which do not fall within the reagent linear range are rescheduled for automatic dilution or concentration. RUN, in the Review & Run screen, is touched to initiate a dilution protocol. Refer to Specific Procedures, Dilution Protocol, for additional information.

Ratios

Pre-defined and user-defined ratio calculations are entered in the Test Parameter Files and may be requested in the same manner as routine assays. Ratios may be defined as a panel for ease of use. Refer to Specific Procedures, Assays – Ratios, for additional information.

Auxiliary Dispense

Auxiliary (aux) dispense assays are performed with the addition of two or three reagents to the reaction. Scheduling, recalling, rerunning, QC files, and printouts for aux dispense assays are the same as for routine nonaux assays. Autodilution and autoconcentration are performed as on routine assays. The software ensures the cuvette volume is not exceeded. Aux assays may be scheduled with routine assays. However, aux assays with different dispense or read times are run at different times on the System. The System completely dispenses an aux assay in process before dispensing an aux assay with different dispense or read times. Refer to Specific Procedures, Assays – Auxiliary Dispense, for additional information.

Theory of Operation

Test Types

Test type is defined in the TEST TYPE field of the Test Definition screen. The following test types are available on the System and have been validated for use.

- Calibrated
- Noncalibrated
- Ratio
- Offline
- Auxiliary
- Simultaneous
- Auxiliary Noncalibrated
- Simultaneous Noncalibrated
- Electrolyte

Refer to Touch Screens, Test Parameter File: Test Definition, for additional information.

Scheduling Modes

The following modes of operation are available on the System, and are defined in the Instrument Options screen.

- Flexible Batch (Flex-B)
- Batch
- Random
- Tandem

Refer to Touch Screens, Instrument Options, for additional information.

Math Models

The term “Math Model” defines a mathematical procedure used to analyze given data. Math models are defined in the Test Parameter File: Test Definition screen.

Math Model Types

The System mathematical models are:

- Linear Regression Rate
- Linear Regression Rate Kinetic Blank
- Linear Regression End Point
- User Linear Regression
- No Conversion End Point
- Calibrated Linear Rate
- No Conversion Rate
- No Conversion Rate Kinetic Blank
- 2 Point Calibration Factor End Point
- 1 Point Calibration Factor End Point
- Delta Rate
- Delta Rate Kinetic Blank

Math Models (continued)

LIN REG RATE and LIN REG RATE KIN BLNK

LIN REG RATE is the abbreviation for Linear Regression Rate. It can be requested with or without a separate kinetic blank. Linear regression rate math models are used to measure enzyme activity, using Equation 1-3.

$$\text{Enzyme Activity} = \frac{\Delta A_d}{\Delta t} \times \text{D.R.} \times \frac{1000}{\text{E.F.}} \qquad \text{(Equation 1-3)}$$

Where: D.R. = dilution ratio
E.F. = extinction factor

The dilution ratio is demonstrated in Equation 1-4.

$$\text{D.R.} = \frac{\text{Total Volume}}{\text{Sample Volume}} = \frac{\text{Sample Volume} + \text{Reagent Volume} + \text{Flush Volume}}{\text{Sample Volume}}$$

(Equation 1-4)

E.F. is the extinction factor or extinction coefficient. It is an intrinsic property, unique to every chromophore and optical system. The E.F. is experimentally determined from the Beer's Law Equation for each chromophore, and is then used as a constant. Refer to Equation 1-5.

$$A_d = \text{E.F.} \times C \times L \qquad \text{(Equation 1-5)}$$

Where: C = concentration of chromophore
L = pathlength of cuvette
A_d = absorbance difference

A_d is measured; C and L are known. E.F. is calculated from them.

Extinction factors are determined for each System and are recorded on a label on the shelf inside the upper central electronic access door.

Two conventions are used for enzyme activity units:

- International Units/Liter (IU/L)
- Nanokatels/Liter (nKat/L)

Equation 1-3 determines enzyme activity in IU/L. To convert to nKat/L, a conversion factor of 16.7 must be used, as demonstrated in Equation 1-6.

$$\text{Activity in nKat/L} = \text{Activity in IU/L} \times \frac{16.7\text{nKat/L}}{\text{IU/L}} \qquad \text{(Equation 1-6)}$$

Linear regression rates are calculated as follows:

A_d reads and their respective times are accumulated as specified in the Test Parameter File. Corrected A_ds are used for error check purposes, e.g., Max A_d flag check. Refer to Equation 1-7.

$$A_{d_{\text{corrected}}} = A_{d_n} - A_{d_{\text{specified blank}}} \qquad \text{(Equation 1-7)}$$

Where: n = 1, 2, 3, . . . (read number)

Math Models (continued)

LIN REG RATE and LIN REG RATE KIN BLNK (continued)

A table (Table 1-1) containing the following data is established.

Table 1-1 Linear Regression Rate A_d Reads and Times

A_d Values	Times
A_{d_1} A_{d_2} A_{d_3} A_{d_4}	t_1 t_2 t_3 t_4

The relative A_ds (Ad′) and times (t′) are calculated and placed in a table (Table 1-2).

Table 1-2 Linear Regression Rate Relative A_d Reads and Times

A_{d_9} Values	t_9 Values
$A_{d'_1} = A_{d_1} - A_{d_1}$ $A_{d'_2} = A_{d_2} - A_{d_1}$ $A_{d'_3} = A_{d_3} - A_{d_1}$ $A_{d'_4} = A_{d_4} - A_{d_1}$	$t'_1 = t_1 - t_1$ $t'_2 = t_2 - t_1$ $t'_3 = t_3 - t_1$ $t'_4 = t_4 - t_1$

This information is sent to a linear regression analysis routine, which determines the slope of the line ($\Delta A_d/\Delta t$). The slope value is used in Equation 1-3.

Linear regression analysis is a more accurate method of determining slope than the conventional subtraction of two points when three or more reads are available. Refer to Figure 1-23.

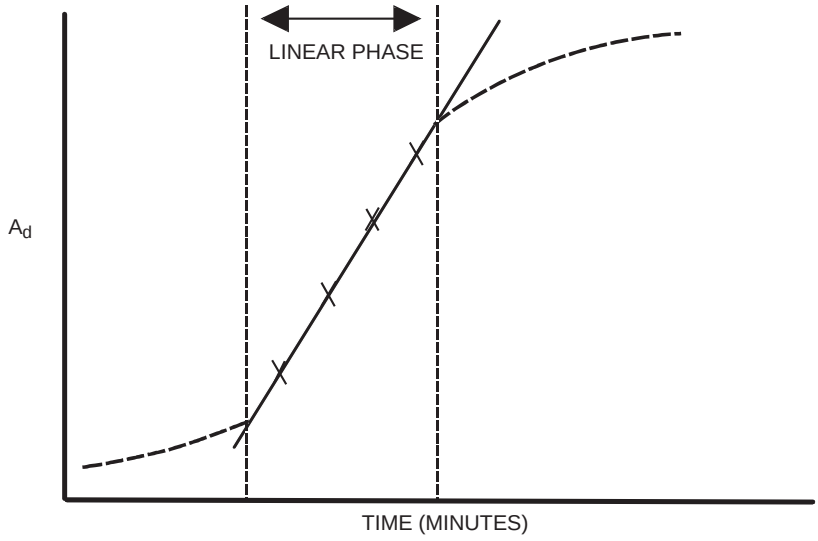

Figure 1-23 Linear Regression Rate

The dashed line indicates A_d versus Time for an enzyme assay. The Xs exemplify data points taken on the System during the linear portion of the curve. A linear regression analysis is performed on the data points to determine the best line fit (solid line). The slope ($\Delta A_d/\Delta t$) of the fitted line is calculated and used to determine enzyme activity in Equation 1-3.

Math Models (continued)

LIN REG RATE and LIN REG RATE KIN BLNK (continued)

Kinetic Blank

The System requires a kinetic blank at intervals defined in the Test Parameter Files for each enzyme or rate assay for which a kinetic blank is specified. The blank is performed separately as a calibration, using water for a calibrator. The kinetic blank corrects for background activity or optical changes the reagent may undergo during the reaction time. Refer to Equation 1-8.

$$\text{Corrected } \Delta A_d/\Delta t = \text{Sample } (\Delta A_d/\Delta t) - \text{Kinetic Blank } (\Delta A_d/\Delta t)$$

(Equation 1-8)

LIN REG END PT

LIN REG END PT is the abbreviation for Linear Regression End Point. This math model is used for substrate chemistries that come to equilibrium and have A_ds that are linear with concentration.

Before serum concentration can be calculated, a calibration curve must be run. A minimum of three, and a maximum of six, calibrators must be defined in the Test Parameter File. A_d reads are taken and blank corrected as specified in the Test Parameter File. A table is established, displaying the concentration and corrected A_d values for the respective calibrator levels. Refer to Table 1-3.

Table 1-3 Linear Regression End Point Concentrations and Corrected A_ds

Calibrator Concentrations	Corrected A_d Values
C_1	A_{d_1}
C_2	A_{d_2}
C_3	A_{d_3}
C_4	A_{d_4}

Math Models (continued)

LIN REG END PT (continued)

This information is sent to a linear regression analysis routine. The best line fit to the data is determined and the slope and intercept are calculated. Figure 1-24 displays a graphic representation of this method.

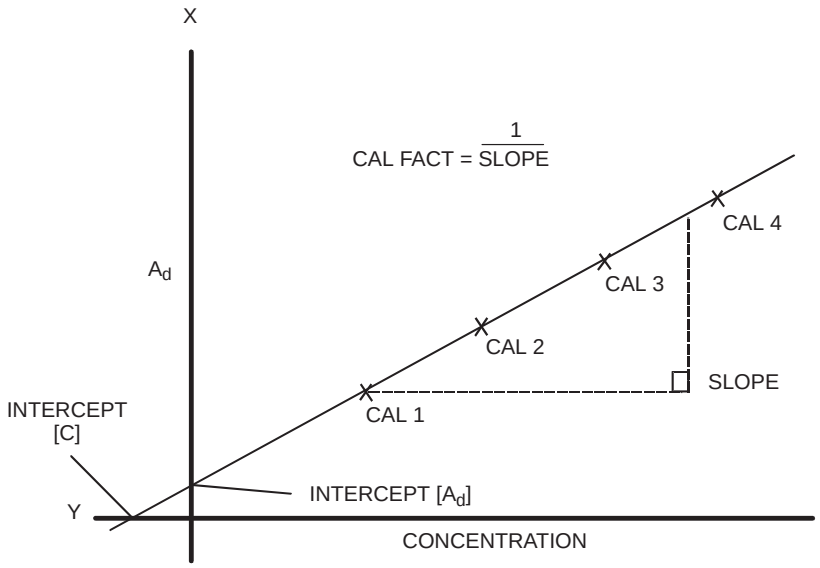

Figure 1-24 Linear Regression End Point

A_d versus concentration is plotted for four calibrator levels. The solid line represents the best line fit to the data. The slope and intercept values are used in Equation 1-13 to determine analyte concentrations in serum samples.

NOTE

THE INTERCEPT DOES NOT NECESSARILY EQUAL ZERO.

From the standard curve, all unknown sample concentrations can be determined by using the equation of a line (Equation 1-9).

$$y = mx + b \qquad \text{(Equation 1-9)}$$

Where: y = A_d (corrected for specified blank)
m = slope of calibration curve
x = concentration of analyte in serum
b = intercept of calibration curve

Rearranging Equation 1-9, concentration of the unknown sample is determined. Refer to Equations 1-10 and 1-11.

$$x = \frac{y - b}{m} \qquad \text{(Equation 1-10)}$$

or . . .

$$\text{Concentration} = \frac{A_{d_{corrected}}\ (\text{Unknown Sample}) - (A_d\ \text{Intercept of Cal Curve})}{(\text{Slope of Cal Curve})} \qquad \text{(Equation 1-11)}$$

Math Models (continued)

LIN REG END PT (continued)

The A_d for the unknown sample is measured by the polychromatic spectrophotometer. Typically, Cal Factors are reported instead of the Slope of the Cal Curve. Refer to Equation 1-12.

$$\text{Cal Factor} = \frac{1}{\text{Slope of Cal Curve}} \qquad \text{(Equation 1-12)}$$

Since the Cal Factor is the inverse of the Cal Curve Slope, Equation 1-11 becomes Equation 1-13.

$$\text{Concentration} = \text{Cal Factor} \times (A_d - \text{Intercept of Cal Curve}) \qquad \text{(Equation 1-13)}$$

The units for end point chemistries may be reported as µg/mL, mg/dL, and g/L, or µmoles/mL, mmoles/dL, and moles/L. To interchange the two methods of reporting units, a user-definable conversion factor is required in the Test Parameter File.

USER LIN REG

USER LIN REG is the abbreviation for User Linear Regression. A Cal Factor and Intercept are entered into the Test Parameter File without running a calibration curve. These two parameters are used in Equation 1-13 to determine unknown sample concentrations.

NO CONVERSION END PT

NO CONVERSION END PT is the abbreviation for No Conversion End Point. This math model is used for substrate chemistries that come to equilibrium and have A_ds that are linear with concentration.

The A_d for the unknown sample is measured using the polychromatic linear diode array. This value is reported as the result.

CAL LIN RATE

CAL LIN RATE is the abbreviation for Calibrated Linear Rate. This math model is used for substrate chemistries that reach equilibrium slowly such that there is a measurable period in which the A_ds are linear with time. A minimum of three, and a maximum of six, calibrators must be defined in the Test Parameter File.

Before serum concentrations can be calculated, a calibration curve must be run. A_d reads are taken and blank corrected as specified in the Test Parameter File. Table 1-4 displays the A_ds, Calibrator Concentrations, and Times for each calibrator level prepared.

Math Models (continued)

CAL LIN RATE
(continued)

Table 1-4 Calibrated Linear Rate A_d Reads, Concentrations, and Times

A_d Values	Calibrator Concentrations	Times
$A_{d_{11}}$ $A_{d_{12}}$ $A_{d_{13}}$ $A_{d_{14}}$	C_1	t_1 t_2 t_3 t_4
$A_{d_{21}}$ $A_{d_{22}}$ $A_{d_{23}}$ $A_{d_{24}}$	C_2	t_1 t_2 t_3 t_4
$A_{d_{31}}$ $A_{d_{32}}$ $A_{d_{33}}$ $A_{d_{34}}$	C_3	t_1 t_2 t_3 t_4

Where: $A_{d_{xy}}$ = A_d for calibrator X at time point Y

The A_d and Time values are sent to a linear regression analysis routine and the slope ($\Delta A_d/\Delta t$) is calculated for each calibrator. Refer to Figure 1-25.

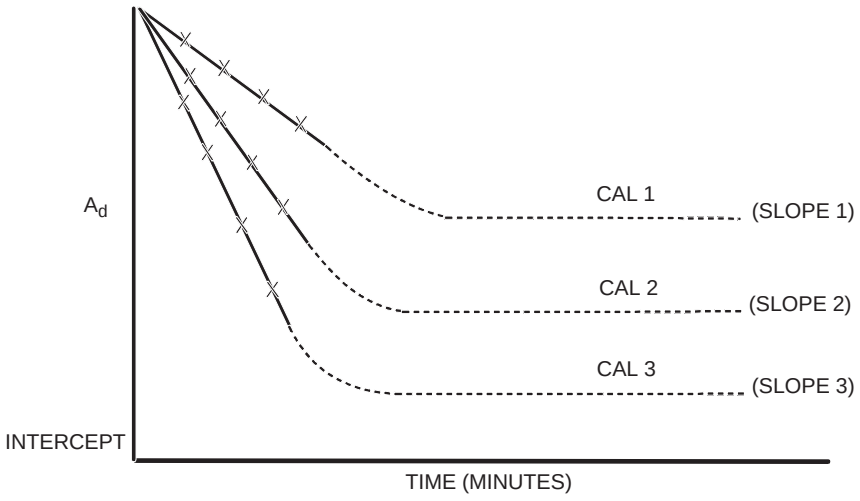

Figure 1-25 Calibrated Linear Rates (Individual Calibrations)

The dashed line represents A_d versus Time at three calibrator levels for a substrate which reaches equilibrium slowly. During the initial phase of the reaction, the A_d changes linearly with time. Rather than wait for equilibrium, the initial linear phase can be assessed. The Xs represent data points taken on the System during the linear portion of the curve. To determine the best line fit (solid line), a linear regression analysis is performed on the data points. The slope ($\Delta A_d/\Delta t$) is plotted versus calibrator concentration to construct the standard curve.

Math Models (continued)

CAL LIN RATE (continued)

Table 1-5, of concentrations and slope values, is prepared from the above calculations.

Table 1-5 Calibrated Linear Rate Concentrations and Slope Values

Calibrator Concentrations	Slope ($\Delta A_d/\Delta t$)
C_1	$\Delta A_{d_1}/\Delta t$
C_2	$\Delta A_{d_2}/\Delta t$
C_3	$\Delta A_{d_3}/\Delta t$

This information is sent again to a linear regression routine, where the Cal Curve Slope and Intercept are calculated. Refer to Figure 1-26.

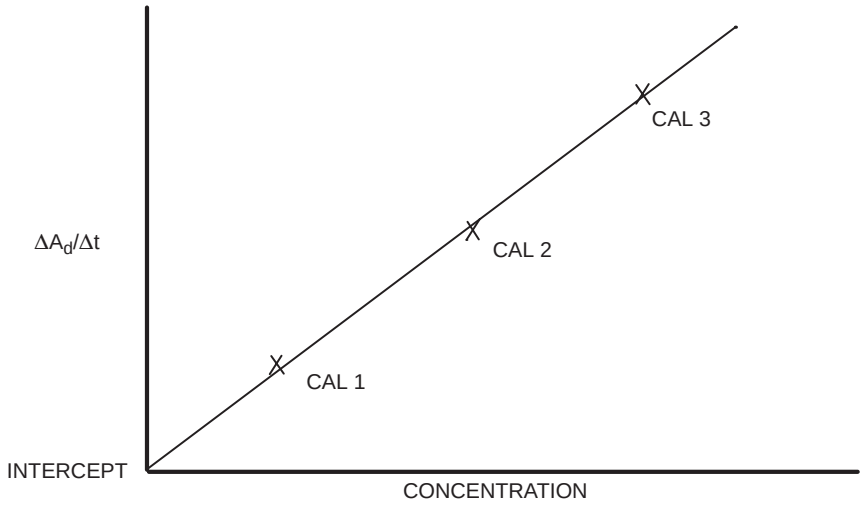

Figure 1-26 Calibrated Linear Rate (Cal Curve)

A slope ($\Delta A_d/\Delta t$) has been determined for each calibrator, then plotted versus concentration.

Serum analyte concentrations are determined using the same method as the linear regression end point math model. However, slope ($\Delta A_d/\Delta t$) is substituted for A_d. Refer to Equation 1-14.

$$\text{Concentration} = \frac{\Delta A_d/\Delta t - (\text{Intercept of Cal Curve})}{(\text{Slope of Cal Curve})}$$

(Equation 1-14)

Using the Cal Factor notation, the following calculation is made. Refer to Equation 1-15.

$$\text{Concentration} = \text{Cal Factor} \times (\Delta A_d/\Delta t - \text{Intercept of Cal Curve})$$

(Equation 1-15)

The units for calibrated linear rates are identical to linear regression end points.

Math Models (continued)

NO CONVERSION RATE and NO CONVERSION RATE KB

The No Conversion Rate math model can be requested with or without a separate kinetic blank. No conversion rates are calculated as follows:

A_d reads and their respective times are accumulated as specified in the Test Parameter File. All A_ds are blank corrected, if specified for error flag checking (Equation 1-16).

$$A_{d_{corrected}} = A_{d_n} - A_{d_{specified\ blank}} \qquad \text{(Equation 1-16)}$$

Where: n = 1, 2, 3,... (read number)

Table 1-6, containing this data, is prepared.

Table 1-6 No Conversion Rate A_d Reads and Times

A_d Values	Time
A_{d1}	t_1
A_{d2}	t_2
A_{d3}	t_3
A_{d4}	t_4

The relative A_ds (A_d') and times (t′) are calculated and placed in Table 1-7, as shown.

Table 1-7 No Conversion Rate Relative A_d Reads and Times

A_d' Values	t′ Values
$A_{d1}' = A_{d1} - A_{d1}$	$t_1' = t_1 - t_1$
$A_{d2}' = A_{d2} - A_{d1}$	$t_2' = t_2 - t_1$
$A_{d3}' = A_{d3} - A_{d1}$	$t_3' = t_3 - t_1$
$A_{d4}' = A_{d4} - A_{d1}$	$t_4' = t_4 - t_1$

This information is sent to a linear regression analysis routine which determines the slope of the line ($\Delta A_d/\Delta t$) and reports the result.

No Conversion Rate with Kinetic Blank (NO CONVERSION RATE KB) has the kinetic blank value subtracted from the slope before it is reported (Equation 1-17).

$$\text{Corrected } \Delta A_d/\Delta t = \text{Sample } (\Delta A_d/\Delta t) - \text{Kinetic Blank } (\Delta A_d/\Delta t) \qquad \text{(Equation 1-17)}$$

2 PT CAL FACT END PT

2 PT CAL FACT END PT is the abbreviation for Two Point Calibration Factor End Point. This math model is used for substrate chemistries that come to equilibrium and have A_ds that are linear with concentration.

Before serum concentration can be calculated, a calibration curve must be run. Two calibrators must be defined in the Test Parameter File. A_d reads are taken and blank corrected as specified in the Test Parameter File.

Math Models (continued)

2 PT CAL FACT
END PT (continued)

The Test Parameter File value for each calibrator is divided by the respective measured A_d values. These results are averaged (Equation 1-18) to determine the Cal Factor used in Equation 1-19 to calculate concentration.

$$C_1 = \frac{\text{Value Calibrator 1}}{A_{d_{corrected}}\ \text{Calibrator 1}}$$

$$C_2 = \frac{\text{Value Calibrator 2}}{A_{d_{corrected}}\ \text{Calibrator 2}}$$

$$\text{Cal Factor} = \frac{(C_1 + C_2)}{2} \qquad \text{(Equation 1-18)}$$

$$\text{Concentration} = \text{Cal Factor} \times (A_{d_{corrected}} - \text{Intercept}) \qquad \text{(Equation 1-19)}$$

Where: intercept = 0

The Cal Factor (the reciprocal of the slope) ($\Delta A_d/C$) of the fitted line is calculated and reported (Figure 1-27).

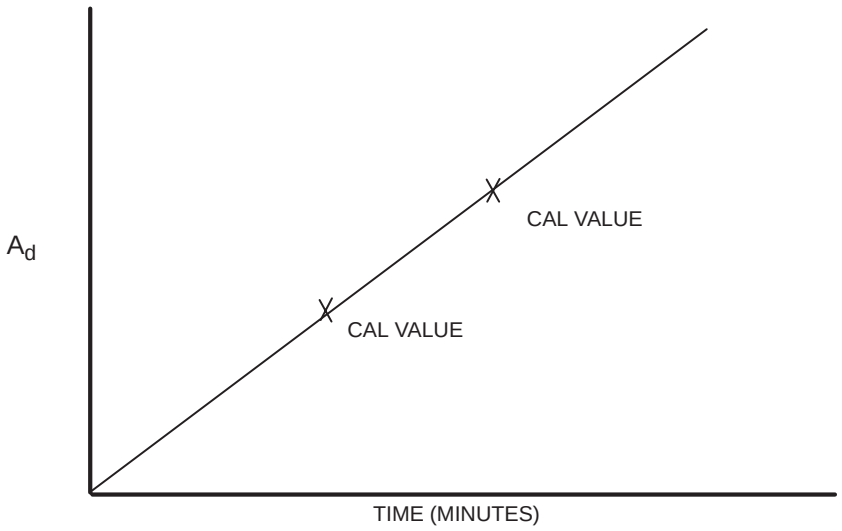

Figure 1-27 Two Point Calibration Factor End Point (Cal Curve)

This graph indicates A_d versus Concentration for the end point assay.

Math Models (continued)

1 PT CAL FACT END PT

One Point Calibration Factor End Point (1 PT CAL FACT END PT) is used for substrate chemistries that come to equilibrium and have A_ds that are linear in concentration.

A calibration curve is run before serum concentration can be calculated. Only one calibrator may be defined in the Test Parameter File. A_d reads are taken and blanked as specified in the Test Parameter File.

The calibrator value defined in the Test Parameter File is divided by the measured A_d value.

$$\text{Cal Factor} = \frac{\text{Calibrator value}}{A_{d_{\text{corrected}}}\ \text{Calibrator}} \qquad \text{(Equation 1-20)}$$

The resulting number is the Cal Factor which is used in Equation 1-21 to calculate concentration:

$$\text{Concentration} = \text{Cal Factor} \times (A_{d_{\text{corrected}}} - \text{Intercept}) \qquad \text{(Equation 1-21)}$$

Where: intercept = 0

The slope ($\Delta A_d/\Delta t$) of the fitted line is calculated and reported (Figure 1-28).

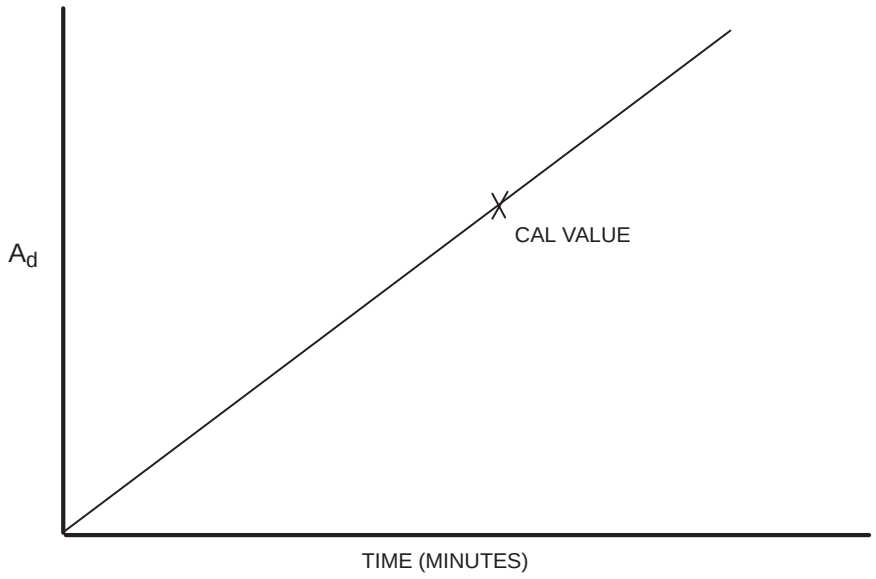

Figure 1-28 One Point Calibration Factor End Point (Cal Curve)

This graph indicates A_d versus Time for the end point assay.

Math Models (continued)

DELTA RATE and DELTA RATE KB

The Delta Rate math model is used to subtract the activity of one rate reaction from the activity of another rate reaction. It can be requested with or without a separate kinetic blank. Delta rates are calculated in the following manner.

Blank corrected A_ds and their respective times are accumulated as specified in the Test Parameter File for the first reagent analyzed (Rate A).

Table 1-8, containing the data for Rate A, is prepared:

Table 1-8 Delta Rate A A_d Reads and Times

A_{dA} Values	Time
A_{d1A}	t_{1A}
A_{d2A}	t_{2A}
A_{d3A}	t_{3A}
A_{d4A}	t_{4A}

The relative A_ds (Ad'_A) and times (t'_A) are calculated for Rate A and placed in Table 1-9.

Table 1-9 Delta Rate A Relative A_d Reads and Times

$A_d'_A$ Values	t'_A Values
$A_{d1}'_A = A_{d1A} - A_{d1A}$	$t_1'_A = t_{1A} - t_{1A}$
$A_{d2}'_A = A_{d2A} - A_{d1A}$	$t_2'_A = t_{2A} - t_{1A}$
$A_{d3}'_A = A_{d3A} - A_{d1A}$	$t_3'_A = t_{3A} - t_{1A}$
$A_{d4}'_A = A_{d4A} - A_{d1A}$	$t_4'_A = t_{4A} - t_{1A}$

This information is sent to a linear regression routine. A linear regression analysis is performed on the data points to determine the best line fit. The slope ($\Delta A/\Delta t$) of the fitted line is calculated for Rate A.

Blank corrected A_ds and their respective times are accumulated as specified in the Test Parameter File for the second reagent analyzed (Rate B).

Table 1-10, containing the data for Rate B, is prepared:

Table 1-10 Delta Rate B A_d Reads and Times

A_{dB} Values	Time
A_{d1B}	t_{1B}
A_{d2B}	t_{2B}
A_{d3B}	t_{3B}
A_{d4B}	t_{4B}

Math Models (continued)

DELTA RATE and DELTA RATE KB (continued)

The relative A_ds ($A_d'_B$) and times (t'_B) are calculated for Rate B and placed in a table (Table 1-11).

Table 1-11 Delta Rate B Relative A_d Reads and Times

$A_d'_B$ Values	t'_B Values
$A_{d1}'_B = A_{d1B} - A_{d1B}$ $A_{d2}'_B = A_{d2B} - A_{d1B}$ $A_{d3}'_B = A_{d3B} - A_{d1B}$ $A_{d4}'_B = A_{d4B} - A_{d1B}$	$t_1'_B = t_{1B} - t_{1B}$ $t_2'_B = t_{2B} - t_{1B}$ $t_3'_B = t_{3B} - t_{1B}$ $t_4'_B = t_{4B} - t_{1B}$

This information is sent to a linear regression routine. A linear regression analysis is performed on the data points to determine the best line fit. The slope ($\Delta A/\Delta t$) of the fitted line is calculated for Rate B.

For delta rate, the slope of Rate A is subtracted from the slope of Rate B to give the difference in rates of reaction in Rate A and Rate B.

Kinetic blank is a separate test using water as the sample. It corrects for background activity in the case of Delta Rate Kinetic Blank (DELTA RATE KB). The kinetic blank is calculated for Rate B only. Equation 1-22 is used for calculating delta rate with kinetic blank.

$$\Delta\text{Rate (Reaction)} = (\text{Rate B} - \text{KB Rate B}) - \text{Rate A} \qquad \text{(Equation 1-22)}$$

Once the rate (reaction) is determined, the activity is calculated using Equation 1-23:

$$\text{Activity} = \Delta\text{Rate (Reaction)} \times \text{D.R.} \times \frac{1000}{\text{E.F.}} \qquad \text{(Equation 1-23)}$$

Where: D.R. = dilution ratio
E.F. = extinction factor

The dilution ratio is demonstrated in Equation 1-24.

$$\text{D.R.} = \frac{\text{Total Volume}}{\text{Sample Volume}} = \frac{\text{Sample Volume} + \text{Reagent Volume} + \text{Flush Volume}}{\text{Sample Volume}} \qquad \text{(Equation 1-24)}$$

E.F. is the extinction factor or extinction coefficient. It is an intrinsic property, unique to every chromophore and optical system. The E.F. is experimentally determined from the Beer's Law Equation for each chromophore, and is then used as a constant. Refer to Equation 1-25.

$$A_d = \text{E.F.} \times C \times L \qquad \text{(Equation 1-25)}$$

Where: C = concentration of chromophore
L = pathlength of cuvette
A_d = absorbance difference

A_d is measured; C and L are known. E.F. is calculated from them.

Extinction factors are determined for each System and are recorded on a label on the shelf inside the upper central electronic access door.

Math Models (continued)

DELTA RATE and DELTA RATE KB (continued)

Delta rate or delta rate KB may be run with as many as three reagents. Rate A will be determined on the next to last reagent added and Rate B will be determined on the last reagent added. Refer to Figure 1-29.

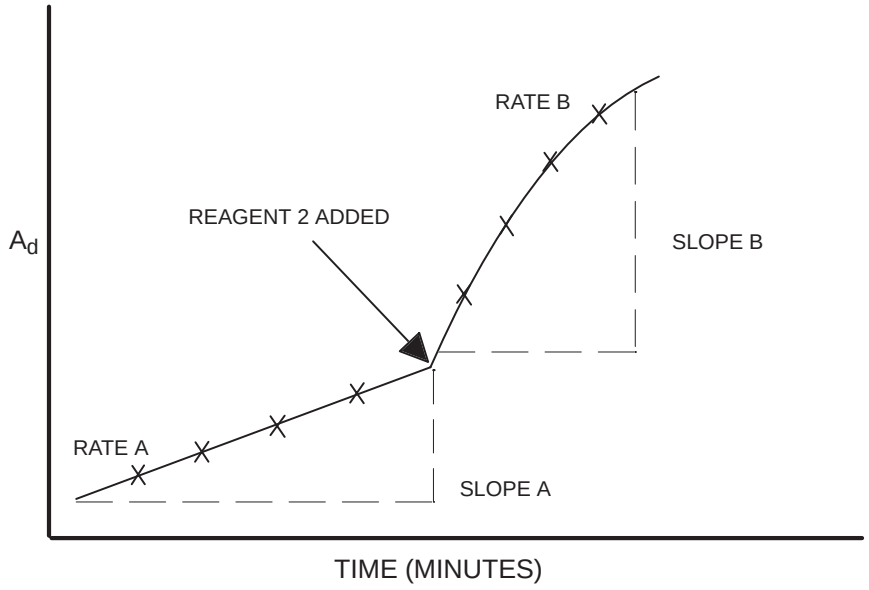

Figure 1-29 Delta Rate Reaction

Optical Method of Operation

Assay Process for Optical Assays

Optical assays are processed in the following sequence. Refer to Specific Procedures, Samples – Process, for additional information.

1. The reagent probe dispenses the appropriate amount of reagent into the next available cuvette cell. After the final dispense of each reagent, the probe moves to the reagent probe wash station and is rinsed, inside and outside.
2. The System reads the initial absorbance of the reagent to verify reagent integrity and to determine the reagent blank reading. The reading is used in calculations specified in the individual Test Parameter Files.
3. The sample probe aspirates the appropriate amount of sample from the sample cup and dispenses it into the cuvette cell containing the reagent. The sample is followed by 15µL of Type II water to ensure complete sample delivery into the cuvette cell and to prevent carryover between samples. The sample probe moves to the sample probe wash station and is rinsed, inside and outside.
4. The mixer arm moves to the cuvette cell and agitates the sample and the reagent, then moves to the mixer arm tip wash station and is rinsed.
5. A serum blank reading is determined when the mix is complete. The reading is used for calculations specified in the individual Test Parameter Files.
6. The reaction mixture in the cuvette is incubated in the water bath for the time specified in the individual Test Parameter File.
7. Absorbance readings are taken for each reaction, as specified in the individual Test Parameter Files.
8. The blanks and absorbance readings are used to compute the concentration units.
9. The results are transferred to the sample result storage area in the System Control Processor.
10. A report may be printed when all assays for a sample have been completed.

Optical Method of Operation (continued)

Assay Process for Auxiliary Dispense Assays

Auxiliary (aux) assays are processed in the following sequence. Refer to Specific Procedures, Assays - Auxiliary Dispense, for additional information.

1. The reagent probe dispenses the appropriate amount of reagent into the next available cuvette cell. After the final dispense of each reagent, the probe moves to the reagent probe wash station and is rinsed, inside and outside.
2. The System reads the initial absorbance of the reagent to verify reagent integrity and to determine the reagent blank reading. The reading is used in calculations specified in the individual Test Parameter Files.
3. The sample probe aspirates the appropriate amount of sample from the sample cup and dispenses it into the cuvette cell containing the reagent. The sample is followed by 15µL of Type II water to ensure complete sample delivery into the cuvette cell and to prevent carryover between samples. The sample probe moves to the sample probe wash station and is rinsed, inside and outside.
4. The mixer arm moves to the cuvette cell and agitates the sample and the reagent, then moves to the mixer arm tip wash station and is rinsed.
5. A serum blank reading is determined as soon as the mix is complete. The reading is used for calculations specified in the individual Test Parameter File.
6. The reaction mixture in the cuvette is incubated in the water bath for the time specified in the individual Test Parameter File.
7. Absorbance readings are taken for each reaction, as specified in the individual Test Parameter File.
8. The reagent probe dispenses the appropriate amount of the auxiliary reagent (if specified in the individual Test Parameter File) into the reaction mixture. After the final dispense of each auxiliary reagent, the probe moves to the reagent probe wash station and is rinsed, inside and outside.
9. The reaction mixture in the cuvette is incubated in the water bath for the time specified in the individual Test Parameter File.
10. Absorbance readings are taken for each reaction as specified in the individual Test Parameter File.
11. The results are transferred to the sample result storage area in the System Control Processor.
12. A report may be printed when all assays for a sample have been completed.

Optical Method of Operation (continued)

Calibration for Optical Assays

Optical assays are calibrated in the following sequence. Refer to Specific Procedures, Calibration - Optical Assays, for additional information.

1. For rate assays, a kinetic blank is measured to determine baseline activity of the reagent.
2. Assays are calibrated at defined intervals. The Cal On Command interval is defined in individual Test Parameter Files. The Master Cal interval is defined in the Instrument Options screen.
3. The calibration mode is defined in individual Test Parameter Files. The Cal On Command mode allows the calibration of each assay to be run independently of all other assays. This mode is intended for use on infrequently run assays, or assays that have very long or short calibration intervals. The Master Cal mode allows multiple assays with the same calibration interval to be calibrated as a group.

4.g Calibration options of Auto Accept and Override are defined in the Instrument Options screen.

Auto Accept allows the System to automatically interpret calibration and kinetic blank data. Calibration curves are accepted or rejected based on the tolerances defined in the individual Test Parameter Files.

Override allows the System to automatically use previously accepted calibration data when a new calibration or kinetic blank fails.

ISE Method of Operation

Assay Process for ISE Assays

ISE samples are processed in the following sequence.

1. The ISE module moves to the appropriate sample carousel position.
2. The ISE sample probe moves to the sample cup as the air detector is monitored. The probe alternately aspirates air and fluid.
3. The probe moves to the upper (Standard A) septum position.
4. The sample, standard, and air aliquot move sequentially through the air detector, potassium electrode, chloride electrode, sodium electrode, and reference electrode, where the voltages are measured.
5. The pump moves the used sample and solutions to waste, while the result concentrations are calculated by the ISE electronics.
6. The results are transferred to the sample result storage area in the System Control Processor.
7. When all assays for a sample have been completed, a report may be printed.

Calibration for ISE Assays

The electrolyte module requires an internal two-point calibration for sodium, potassium, and chloride, at two-hour intervals or with each net 2°C change in temperature. When the calibration interval expires, the instrument recalibrates automatically as electrolyte assays are requested. An internal single-point calibration, using Standard A, is automatically performed with each electrolyte sample assay.

Installation and Relocation

Introduction

The following requirements must be met prior to installation or relocation of the instrument.

Pre-installation Checklist

Environmental Requirements

Room Temperature	20–28°C
Humidity	10% to 90% relative humidity (non-condensing)

Avoid drafts and sunlight directly on the System.

Instrument Dimensions

	Without Base		With Base	
Height	32.50 inches	82.55cm	63.00 inches	160.02cm
Length	68.00 inches	172.72cm	68.00 inches	172.72cm
Width	32.25 inches	81.92cm	32.25 inches	81.92cm
Weight	500 lbs.	273 kg	800 lbs.	364 kg

Clearance Requirements

Right Side	18 inches	45.72cm	Rear	10 inches	25.40cm
Left Side	18 inches	45.72cm	Top	12 inches	30.48cm

Entryway Requirements

Minimum Doorway Width	33 inches	83.82cm
Minimum Hallway Width	77 inches	195.58cm
Minimum Turning Radius	77 inches	195.58cm

ATTENTION

AVOID DAMAGE TO THE INSTRUMENT. DO NOT TILT IT AT GREATER THAN A 45° ANGLE OR PLACE IT ON END TO NEGOTIATE AN ENTRY.

Installation/Relocation

It is recommended that adequate resources be utilized when relocating the instrument. The instrument may be rolled from one location to another on the base.

Robotic alignment must be verified after relocation.

Power Requirements

220 SYSTEMS	110 SYSTEMS
220 Volts AC (VAC) ±10	110 Volts AC (VAC) ±10
1800 Volt Amps	1800 Volt Amps
60 Hz ±1%	60 Hz ±1%
50 Hz ±1% International	50 Hz ±1% International
20-Amp dedicated line	20-Amp dedicated line

Power Outlets

Two different circuits are required: (1) a dedicated 220 VAC circuit for the ABBOTT SPECTRUM SERIES II System, and (2) a circuit with four 110 VAC outlets for peripheral equipment.* The outlets must be checked with a test plug for proper configuration.

	220 SYSTEMS Expected	Measurement
Line to Ground	110 Volts ±10%	_____
Line to Neutral	220 Volts ±10%	_____
Ground to Neutral	110 Volts ±10%	_____
Ground to Conduit	≤ 0.5 VAC	_____

*For Systems operating on 110 VAC, refer to the power requirements for 110 Systems.

Pre-installation Checklist (continued)

Power Outlets
(continued)

110 SYSTEMS

	Expected	Measurement
Line to GroundY	110 Volts ±10%Y	_____
Line to NeutralY	110 Volts ±10%Y	_____
Ground to NeutralY	≤ 0.5 VACY	_____
Ground to ConduitY	≤ 0.5 VACY	_____

CIRCUIT BREAKER MEASUREMENTS (WITH BREAKER OPEN)

	Expected	Measurement
Line to GroundY	≤ 0.5 VACY	_____
Line to NeutralY	≤ 0.5 VACY	_____
Ground to NeutralY	≤ 0.5 VACY	_____

Power On/Off

Refer to the Specific Procedures section for procedures for powering on and off the System and the ISE module.

Water Supply to System

Water QualityY	1MΩ resistivity or greater
FiltrationY	Solids filter with deionizer system
Flow rateY	700mL per minute
PressureY	5 to 7 psi
PipingY	Inlet – $^{3}/_{8}$ inch poly Outlet – $^{1}/_{8}$ inch TYGON® (15 feet supplied with accessory kit)

Water must be free of air bubbles and gas.

Any existing system capable of delivering one megohm (1MΩ) water may be connected to the water quality station.

Type II Water
(supplied by the customer)

Fifteen microliters of Type II water are dispensed with the sample into the cuvette. Type II water is also used to wash the sample probe.

This water is supplied from the sample diluent reservoir, which must be filled by the operator during daily maintenance. The reservoir is located behind the sample diluent reservoir access door and is monitored by a weight-sensitive platform.

NOTE

REFER TO *THE PREPARATION AND TESTING OF REAGENT WATER IN THE CLINICAL LABORATORY,* NCCLS PUBLICATION, SECOND EDITION; APPROVED GUIDELINE (1991), FOR INFORMATION REGARDING WATER TYPES AND SPECIFICATIONS.

TYGON is a registered trademark of E.I. Dupont de Nemours and Co., Inc.

Installation and Relocation

Pre-installation Checklist (continued)

1MΩ Resistivity Water (supplied by the customer)

One megohm (1MΩ) resistivity water, regulated to 20 psi ± 10%, must be supplied to the water quality station at a momentary flow rate of at least 700mL/minute, for a maximum usage of 8L/hour. This water is dispensed to the incubator, and the mixer and reagent wash stations.

If 1MΩ resistivity water is not available before instrument installation, the laboratory may contract a local supplier of water purification systems to install the appropriate water purification system.

Water Quality Station (supplied and installed by Abbott Laboratories)

The 1MΩ water must be further filtered and pressure regulated at 5 to 7 psi. To fulfill this requirement, a water quality station is supplied as an accessory. The component consists of the following:

- 0-60 psi input gauge
- Input cutoff valve
- Air purge valve
- Water quality light
- Filter
- 0-30 psi output gauge
- Pressure regulator
- Flush valve
- Output cutoff valve

The water quality station will be installed by a Field Service Representative.

NOTE

FAILURE TO MAINTAIN PRESSURE BETWEEN 5 AND 7 PSI CAUSES THE AUDIBLE ALARM TO SOUND FOR 20 SECONDS.

Drainage

A drain must be available within 15 feet of the instrument, at or below the base of the instrument (not higher than 30 inches from the floor). The design of the drain must have venting mechanisms to prevent buildup of back pressure. The drain must accommodate a maximum momentary flow rate of 800mL/minute.

Table 1-12 System Specifications Summary

General Characteristics

Instrument Type	Discrete, Multiple access
Tests On-Line	31
Programmable Test Capacity	127
Test Parameters	66
Modes Of Operation	Flex-B, Batch, Random, Tandem, STAT (dispensed in Random mode)
Water Quality	Type II or 1 MΩ resistivity deionized gas-free Momentary flow rate: 700mL/min. for a maximum usage of 8L/hour Minimum support equipment: 0–60 psi input gauge, input cutoff valve, air purge valve, water quality light, filter, 0–30 psi output gauge, pressure regulator, flush valve, output cutoff valve Inlet Pressure: 20 psi ± 10%

	Volume	Accuracy	Precision
Sample Volume	1.25µL	98.0%	98.5%
	2.50µL	98.5%	99.0%
	5.0µL–25µL	99.0%	99.5%
Reagent Volume	25µL–486µL	99.5%	99.5%
Sample Carryover	≤ 0.5%		

Optical Characteristics

Light Source	Tungsten-halogen
Light Path	1.000 ± 0.006cm
Detector	Linear diode array
Analytical Modes	Polychromatic, bichromatic, monochromatic
Spectral Range	340nm–660nm
Wavelengths Available	340, 364, 380, 404, 412, 452, 484, 500, 516, 548, 564, 572, 604, 636, 652, 660nm
Wavelength Resolution	± 4nm
Linearity	0–2.5A ± 2% at all wavelengths
Noise	Less than ± 0.0003A @ 1.2A
Long Term Drift	0.0004A
Resolution	Better than 0.0001A

Electrical Characteristics

Input	220 VAC ± 10%* 20-Amp dedicated line required 50 or 60 Hz ± 1%
Power Consumption	1800 Volt Amps

*For Systems operating on 110 VAC, refer to power requirements for 110 Systems.

Environmental Requirements

Room Temp	20–28°C
Storage	–20–80°C
Humidity	10%–90% relative humidity (non-condensing) Avoid drafts and sunlight directly on the System
Shipping	10g vibration
Drainage	Proximity: Maximum 15 feet (4.57 m.) Height: Not higher than 30 inches
Continuous Flow Rate	800mL/min.
BTU Output	5982 BTU/hr. (approximately)

Reaction Temperatures

25.0 ± 0.1°C
30.0 ± 0.1°C
37.0 ± 0.1°C

Physical Dimensions

	Without Base		With Base	
Height	32.50 inches	82.55cm	63.00 inches	160.02cm
Length	68.00 inches	172.72cm	68.00 inches	172.72cm
Width	32.25 inches	81.92cm	32.25 inches	81.92cm
Weight	500 lbs.	273kg	800 lbs.	364kg

Clearance Requirements

Right Side	18 inches	45.72cm	Rear	10 inches	25.40cm
Left Side	18 inches	45.72cm	Top	12 inches	30.48cm

Entryway Requirements

Minimum Doorway Width	33 inches	83.82cm
Minimum Hallway Width	77 inches	195.58cm
Minimum Turning Radius	77 inches	195.58cm

Computer Characteristics

Processor Type	Distributive with 17 CPUs (including RMX-86™ processor)
Programming	Multi-tasking
Interface	Uni-directional and Bi-directional
Volatile Memory	560K Bytes
Non-Volatile Memory	934K Bytes
Baud Rate	Programmable

Printer

Refer to the specifications in the Printer Operations Manual.

RMX-86 is a trademark of Intel Corporation.

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Introduction

The Specific Procedures section provides step-by-step procedures for performing System functions.

All procedures assume daily maintenance has been performed. Refer to Daily Maintenance in the Maintenance & Troubleshooting Manual.

Many procedures require use of several screens. Refer to the Touch Screens section for specific field information.

NOTE

SCREENS IN THIS MANUAL DISPLAY EXAMPLE DATA. DATA DISPLAYED ON SCREENS DURING SYSTEM OPERATION MAY BE DIFFERENT.

Assays – Add

Introduction

Assay requests are entered through the Patient Samples screen.

Adding Assays to Existing SID

1. From the Main menu, touch PATIENT SAMPLES, SELECT. Type the appropriate SID number, and press ENTER.
2. When the currently requested panels/assays highlight, touch to highlight additional panels/assays. Touch NEXT SAMPLE.
3. Continue until all panels and/or assays have been requested.

NOTE

IF ASSAYS ARE HIGHLIGHTED UNINTENTIONALLY, TOUCH TO DE-HIGHLIGHT THE APPROPRIATE ASSAYS. TOUCH **NEXT SAMPLE**.

Introduction

Auxiliary (aux) dispense assays require more than one reagent dispense at different time intervals.

- Scheduling, recalling, and rerunning QC files and printouts for auxiliary dispense assays are performed in the same manner as routine non-auxiliary assays.
- Autodilution and autoconcentration are performed in the same manner as routine assays. The software ensures cuvette volume is not exceeded.
- Auxiliary assays may be scheduled with routine assays. However, auxiliary assays with different dispense or read times are run at different times on the System. The System completely dispenses an auxiliary assay in process before dispensing an auxiliary assay with different dispense or read times.
- IA and MA flags are active for all reagents when a cuvette volume of 236µL is reached.

Dual Reagent Cartridges

Dual reagent cartridges (Figure 2-1) may be used for assays requiring two reagents or two separate assays. These cartridges are comprised of three components: the core vial, the perimeter vial, and the frame. The frame is made of molded plastic with keyed openings to accommodate the vials. Labeled storage for the vial caps is provided in the center of the frame.

The reagent vials are available in two sizes: a 27mL perimeter vial with a maximum dispense volume of 486µL, and a 7mL core vial with a maximum dispense volume of 243µL.

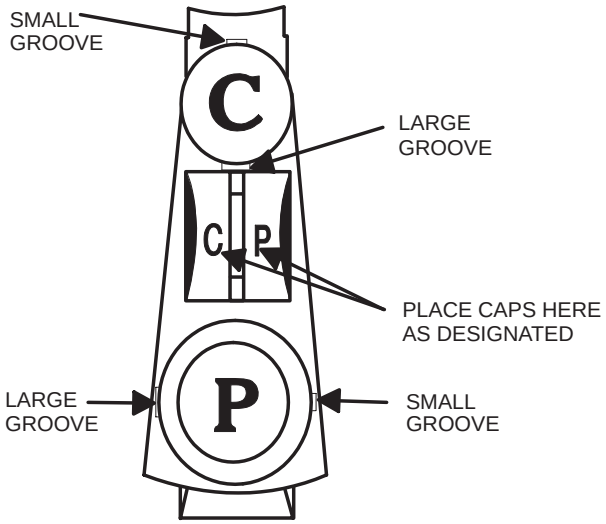


Figure 2-1 Dual Reagent Cartridge

Assays – Auxiliary Dispense

Auxiliary Dispense Assay Process	Refer to Assay Process for Auxiliary Dispense Assays in the System Overview section for additional information.
Defining an Auxiliary Assay	Specific parameters must be defined for an auxiliary assay. Refer to Test Parameter File: Reagent Definition in the Touch Screens section for specific field information.
Designating Auxiliary Reagent Washes	Refer to Wash Matrix in this section for specific procedural information.
Robotic Positioning for Dual Reagent Cartridges	The reagent probe must be positioned correctly for precise reagent dispense. Refer to Probe Positioning & Robotic Training in the Maintenance & Troubleshooting Manual for additional information.

Assays – Mixed Temperatures

Introduction

The ABBOTT SPECTRUM SERIES II System has the capability of incorporating mixed temperatures for assay processing while in the RUNNING mode. Assays operating at various temperatures run without operator intervention. Temperatures are defined for each assay in the Test Parameter Files.

The following sequence occurs when optical assays are being processed at mixed temperatures.

1. All assays at the highest running temperature are dispensed.
2. All assays at the highest running temperature are completed.
3. The banner message WAITING ON OPTICALS displays.
4. The incubator is adjusted to the next temperature and the banner message WAITING ON TEMPERATURE displays. Upon temperature stabilization, the System automatically restarts optical dispense.

Assays – Panels

Introduction

Assays may be organized into panels for ease of use when requesting patient samples.

Defining the Panel

1. From the Main menu, touch SYSTEM FILES, SELECT. Touch PANEL DEFINITION, SELECT.
2. Touch SCHEDULING NAME and type the scheduling name that will identify the panel in the Patient Samples screen.

> **NOTE**
>
> THE **PANEL NAME** FIELD IS NOT CURRENTLY ACTIVE.

3. Touch to highlight the appropriate assays. Touch DEFINITION COMPLETE.
4. Touch EXIT.

Adding Assays to Existing Panels

1. Verify that the ACTIVITY field is not highlighted.
2. From the Main menu, touch SYSTEM FILES, SELECT. Touch PANEL DEFINITION, SELECT.
3. Touch SCHEDULING NAME. Type the scheduling name, exactly as it displays in the Patient Samples screen, and press ENTER.
4. When the assigned assays highlight, touch to highlight additional assays. Touch DEFINITION COMPLETE.
5. Touch EXIT.

Deleting Panels

1. Verify that the ACTIVITY field is not highlighted.
2. From the Main menu, touch PATIENT SAMPLES, SELECT. Touch DELETE. Touch ALL. Touch PROCEED.
3. From the Main menu, touch SYSTEM FILES, SELECT. Touch PANEL DEFINITION, SELECT.
4. Touch SCHEDULING NAME. Type the scheduling name, exactly as it displays in the Patient Samples screen, and press ENTER.
5. When assigned assays highlight, touch DELETE PANEL.
6. Touch EXIT.

Deleting Assays from Panels

1. Verify that the ACTIVITY field is not highlighted.
2. From the Main menu, touch PATIENT SAMPLES, SELECT. Touch DELETE. Touch ALL. Touch PROCEED.
3. From the Main menu, touch SYSTEM FILES, SELECT. Touch PANEL DEFINITION, SELECT.
4. Touch SCHEDULING NAME. Type the scheduling name, exactly as it displays in the Patient Samples screen, and press ENTER.
5. When the assigned assays highlight, touch to de-highlight appropriate assays.
6. Touch DEFINITION COMPLETE.
7. Touch EXIT.

Assays – Precipitation

Introduction

HDL and TIBC assays are run on supernatants and eluents, respectively, of the sample. HDL supernatants are prepared by precipitating samples with the HDL precipitating reagent. TIBC assays are run on samples that have been processed through the TIBC saturating columns. (Refer to the HDL and TIBC package inserts and the Reagent Manual for specific information on these assays.) Because the assay is run on a treated sample, all other assays for the sample must be completed before requesting or running the HDL or the TIBC assay.

Requesting HDL

1. When the initial assays are requested, do not request HDL.
2. After all requested assays for the sample have been completed, request HDL and associated ratios for the sample.
3. Place the supernatant in the sample cup position indicated by the sample loadlist.
4. Touch RUN. The System assays the HDL sample, calculates the associated ratios, and prints a report with the results (if AUTO PRINT is on).

Requesting TIBC

1. When the initial assays are requested, do not request TIBC.
2. After all requested assays for the sample have been completed, request TIBC for the sample.
3. Place the eluent in the sample cup position indicated by the sample loadlist.
4. Touch RUN. The System assays the TIBC sample and prints a report with the results (if AUTO PRINT is on).

Introduction

Both pre-defined and user-defined ratios and calculations are available in the System. Ratios are entered into the Test Parameter File and displayed in the Patient Samples screen. Significant digits are defined in the Test Parameter File. Ratios are scheduled by requesting the ratio and all component tests, or by panel. Unless a ratio and component assays are defined as a panel, the System does not automatically request the component assays when only the ratio is selected. If component assays are not selected, the ratio test will remain entered and will not complete. If component assays are flagged, the ratios will be flagged.

An equation to calculate ratios has been established in the software. The equation is edited to calculate the specific ratio by the way in which ratio test names and ratio factors are set. Each test is entered into the calculation, and the appropriate constant is entered to provide the mathematics. Up to six tests and three constants can be used. The equation (Equation 2-1) and examples follow.

$$\frac{T1}{T2}(K1) + \frac{T3}{T4}(K2) + \frac{T5}{T6}(K3) \qquad \text{(Equation 2-1)}$$

The ratio is set by inserting the appropriate tests for T1–T6, and the appropriate constants for K1–K3.

For example, the Globulin ratio would be established as shown in Table 2-1, Equation 2-2, and Figure 2-2.

Table 2-1 Globulin Ratio

Ratio	Test Name	Ratio	Factor
T1	T Prot	K1	1.0
T2		*	0.0
T3	Albumn	K2	–1.0
T4		*	0.0
T5		K3	0.0
T6		*	0.0

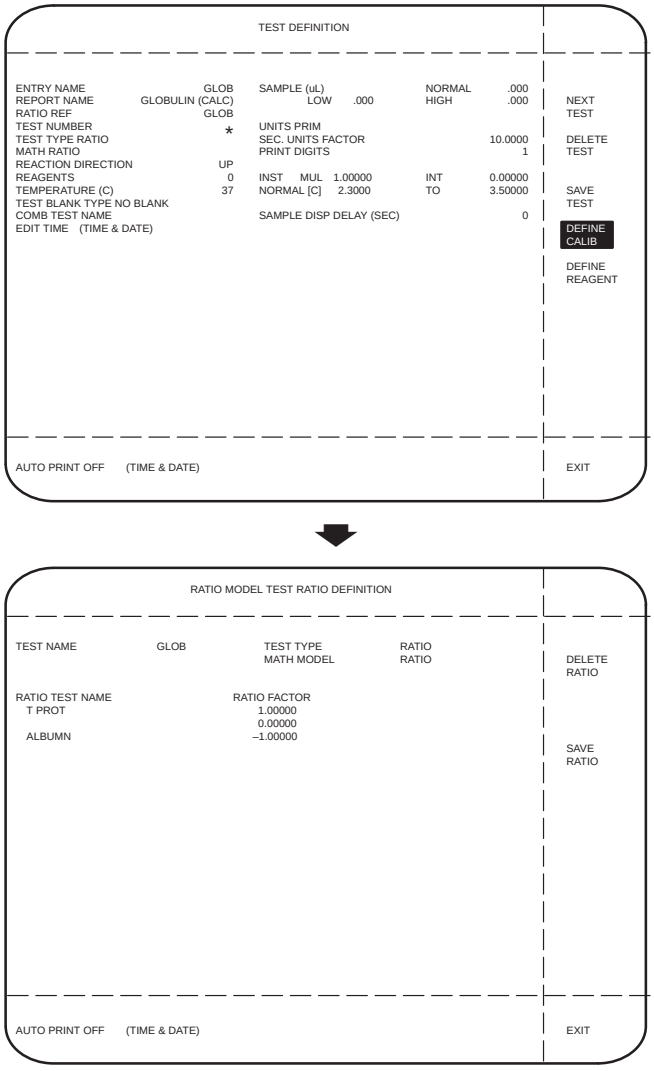
*Values must not be entered in these fields. They are assigned as 0.00 by the System.

$$\text{Globulin} = \frac{\text{T Prot (1)}}{\text{(No Entry) (0)}} + \frac{\text{Albumn (}-\text{ 1)}}{\text{(No Entry) (0)}} + \frac{\text{(No Entry) (0)}}{\text{(No Entry) (0)}}$$

(Equation 2-2)

Assays – Ratios

Introduction (continued)



*Value will vary by instrument or lot number.

Figure 2-2 Globulin Ratio Screens

Introduction (continued)

Another example of ratios is Bun/Creatinine, shown in Table 2-2.

Table 2-2 Bun/Creatinine Ratio

Ratio	Test Name	Ratio	Factor
T1	Urea	K1	1.0
T2	Crea	*	0.0
T3		K2	0.0
T4		*	0.0
T5		K3	0.0
T6		*	0.0

* Values must not be entered in these fields. They are assigned as 0.00 by the System.

The ratio for LDL Cholesterol is established as shown in Table 2-3 and Equation 2-3.

Table 2-3 LDL Cholesterol Ratio

Ratio	Test Name	Ratio	Factor
T1	Chol	K1	1.0
T2		*	0.0
T3	HDL	K2	–1.0
T4		*	0.0
T5	Trig	K3	–0.2
T6		*	0.0

* Values must not be entered in these fields. They are assigned as 0.00 by the System.

$$\text{Cholesterol} - \text{HDL} - \frac{(\text{Triglycerides})}{5} \qquad \text{(Equation 2-3)}$$

The HDL result is subtracted from Cholesterol. Triglyceride is multiplied by the K factor 0.2 (which causes Triglyceride to be divided by 5). The result is then subtracted from the remainder of the equation.

Defining a Panel

A panel may be defined, consisting of the component tests and ratio, and identified as the ratio name. Refer to Assays - Panels in this section for additional information.

Defining the Ratio Reference

Multiple assays may have the same RATIO REF name.

Assays – Ratios

Defining Ratios

1. From the Main menu, touch PATIENT SAMPLES, SELECT. Touch DELETE. Touch ALL. Touch PROCEED.
2. From the Main menu, touch SYSTEM FILES, SELECT.
3. Touch TEST PARAMETER FILES. Use the cursor control keys to access the hidden password field to the right of TEST PARAMETER FILES. Type the current password, and press ENTER. Touch SELECT.
4. Touch ENTRY NAME, and type the entry name.
5. Touch REPORT NAME, and type the report name.
6. Touch RATIO REF, and define the ratio reference. Defining this field informs the System that the ratio or test is a part of another ratio calculation. All current tests have RATIO REFERENCE fields established. For ease of use, it is recommended the RATIO REF match the ENTRY NAME.
7. Touch TEST NUMBER, and type the test number. The component assays must have a lower test number in the Test Parameter Files than the ratio itself. If not, values may not be calculated for the ratio.
8. Touch TEST TYPE, and define the test type as RATIO.
9. Touch MATH, and define the math as RATIO.
10. Ensure 37°C displays in the TEMPERATURE field.
11. Define UNITS, SEC. UNITS FACTOR, PRINT DIGITS, INST MULT, and NORMAL [C] values specific to the test.
12. Touch SAVE TEST.
13. Touch DEFINE CALIB to define the calculation.
14. Touch SAVE RATIO.
15. Touch EXIT.
16. Enter the ratio name into the Print Order. Refer to Print Order in this section for additional information.

Introduction

It may be necessary to rerun an assay to verify assay results or to correct status coded results. The status of the assay must be changed from COM (complete) to ENT (entered) before the System will rerun the assay. This is accomplished by using the RERUN function of the Recall Results screen.

Rerunning Specific SIDs

1. From the Main menu, touch PATIENT SAMPLES, SELECT.
2. Type the appropriate SID number. Touch RECALL RESULTS. Press the PRINT SCREEN key to document the current results.
3. Touch the STATUS field for the specified assay.
4. Touch RERUN. The status changes from COM to ENT and the assay result is deleted from memory.
5. Touch EXIT.
6. From the Patient Samples screen, touch REVIEW & RUN. Touch RUN.

Rerunning Selected SIDs

1. From the Main menu, touch PATIENT SAMPLES, SELECT. Touch RECALL RESULTS.
2. Touch to highlight the appropriate SIDs. Touch SELECT.
3. Touch the STATUS field for the specified assay.
4. Touch RERUN. The status changes from COM to ENT and the assay result is deleted from memory.
5. Touch NEXT SAMPLE.
6. Continue until all SIDs requiring rerun have been selected.
7. Touch EXIT.
8. From the Patient Samples screen, touch REVIEW & RUN. Touch RUN.

Rerunning by Assay (/T) for Specific SIDs

1. From the Main menu, touch PATIENT SAMPLES, SELECT.
2. Touch NAME. Type /T, followed by the appropriate assay name, exactly as it displays on the Patient Samples screen. Press ENTER.
3. Touch to highlight the appropriate SIDs. Touch RERUN SELECT. The screen automatically updates.
4. Touch EXIT.
5. From the Patient Samples screen, touch REVIEW & RUN. Touch RUN.

Assays – Rerun

Rerunning by Assay (/T) for All SIDs

1. From the Main menu, touch PATIENT SAMPLES, SELECT.
2. Touch NAME. Type /T, followed by the appropriate assay name, exactly as it displays on the Patient Samples screen. Press ENTER.
3. Touch RERUN ALL. CODE 00113 PROCEED WITH RERUN? Y/N displays. Type Y (Yes) and press ENTER.
4. Touch EXIT.
5. From the Patient Samples screen, touch REVIEW & RUN. Touch RUN.

Rerunning by Assay (/T) for Specific Carousel

1. From the Main menu, touch PATIENT SAMPLES, SELECT.
2. Touch CAR# and type the appropriate carousel number.
3. Touch NAME. Type /T, followed by the appropriate assay name, exactly as it displays on the Patient Samples screen. Press ENTER.
4. Select the appropriate option:

   To rerun all SIDs, touch RERUN ALL. CODE 00113 PROCEED WITH RERUN? Y/N displays. Type Y (Yes) and press ENTER.

   To rerun specific SIDs, touch to highlight the appropriate SIDs. Touch RERUN SELECT.
5. Touch EXIT.
6. From the Patient Samples screen, touch REVIEW & RUN. Touch RUN.

Introduction

Simultaneous assays allow multiple assay results to be obtained from a single sample dispense in a single cuvette.

- Component assays of a simultaneous assay display as separate assay selections on the Patient Samples screen. Either simultaneous or individual assays may be selected.
- When a component assay is scheduled to be rerun, all component assays may be rerun, but only values for the requested test are reported.
- When an autodilution or autoconcentration is required for component assays of a simultaneous assay, only the component assays flagged LL or LH are autodiluted or autoconcentrated. Component assays that are not flagged remain complete, with their original results. An autodilution and autoconcentration cannot be run simultaneously.
- Appropriate flags are reported for individual component assays. For example, if a component assay receives an LE flag, all component assays are flagged.
- Calibrations of all component assays are performed together.
- All component assays are run when the first assay displays in the processing order.
- Each component assay is counted as a single assay when processing in the Tandem mode.
- Each component assay possesses its own Test Parameter File. Shared parameters must be identical in the Test Parameter Files for all component assays (e.g., sample volume and reagent volume). When a shared parameter for one component assay is edited, the System automatically edits the other component Test Parameter Files and displays the message SHARED PARAMETER EDITED.
- When the Test Parameter File of a component assay is deleted, the Test Parameter Files of other component assays remain intact.
- The component assays may possess different math models. The test types must be defined as simultaneous or simultaneous noncalibrated.
- Each component assay possesses a separate Quality Control File.
- Each component assay prints separately. Each assay displays separately in the Print Order screen and may be selected separately.
- Each component assay displays separately in the Panel Definition screen and may be selected separately.

Defining a Simultaneous Assay

Specific parameters must be defined in the Test Parameter Files for component assays of simultaneous assays. Refer to Test Parameter File: Test Definition in the Touch Screens section.

Assays – Delete

Introduction

After samples have run, delete appropriate assays.

NOTE

IF THE SID HAS ONLY ONE ASSAY REQUESTED, THE SID MUST BE DELETED.

Deleting Assays from Existing SID

1. From the Main menu, touch PATIENT SAMPLES, SELECT. Type the appropriate SID number, and press ENTER.
2. The currently requested assays are highlighted. Touch to de-highlight the appropriate assays. Touch NEXT SAMPLE.
3. Touch EXIT.

Audible Alarm

Introduction

The ABBOTT SPECTRUM SERIES II System is equipped with an audible alarm system, located on the cuvette status panel. The alarm notifies the operator of System functions and robotic errors. The alarm will not sound for informational messages such as result flags or calibration errors.

A RESET button (also located on the cuvette status panel) glows amber, and then flashes until it is pressed. Pressing the RESET button while the alarm is sounding stops the tone.

System Abort

The alarm sounds when the System experiences an error with robotics, or errors that halt the assay process. The alarm emits a continuous tone for 20 seconds after an abort. The RESET button glows amber and flashes until pressed.

Cuvette Change/End of Run

The alarm sounds intermittently for 5 seconds at cuvette change time or at the end of a run. The RESET button flashes until pressed.

Adjusting the Alarm Volume

1. Raise the center upper access door.
2. Directly behind the cuvette status panel is the printed circuit board. Locate the blue volume adjustment knob, labeled R3 VOL. ADJ.
3. Identify the alarm test point, labeled TP1 VOL. TEST, located at the right edge of the printed circuit board.
4. Activate the alarm by shorting the two prongs with a metal object, such as a coin.
5. Turn the adjustment knob clockwise to decrease the volume or counterclockwise to increase the volume.
6. Lower the center upper access door.

Testing the Alarm

1. Raise the center upper access door.
2. Directly behind the cuvette status panel is the printed circuit board. Identify the alarm test point, labeled TP1 VOL. TEST, located at the right edge of the printed circuit board.
3. Activate the alarm by shorting the two prongs with a metal object, such as a coin.
4. Lower the center upper access door.

Barcode Index

Introduction

The Barcode Index File allows the System to identify a barcode label and link it to a specific reagent.

Activating the Barcode Index

1. From the Main menu, touch SPECIAL PROCEDURES, SELECT. Touch BARCODE INDEX, SELECT.
2. Touch REAGENT INDEX, and type the number specific to the new reagent. If the number is not within range, CODE 00213 ILLEGAL REAGENT INDEX – MUST BE 1–200 ONLY displays.
3. Touch CARTRIDGE TYPE. Press the CYCLE key to display the appropriate option (EMPTY, SINGLE, or DOUBLE).
4. Touch CORE REAG NAME. Type the appropriate name. The reagent name used in the barcode index must be identical to the reagent name in the previously defined Test Parameter File: Reagent Definition.
5. Touch PERIM REAG NAME. Type the appropriate name. The reagent name used in the barcode index must be identical to the reagent name in the previously defined Test Parameter File: Reagent Definition.
6. Touch SAVE FILE. CODE 00166 FILE SAVED displays.
7. Touch EXIT.

Barcode Reader

Introduction

The reagent barcode reader allows the System to identify and display the status of reagent cartridges on the System.

The reagent barcode reader uses infrared light to scan reagent cartridge barcode labels three times when the Review & Run screen is entered and/or READ REAGENT TRAY is touched in the Reagent Loadlist screen.

When the barcode reader is on, it identifies the following:

- Type of reagent, e.g., Glucose, Calcium
- Master lot number (a one- or two-digit, alphanumeric code)
- Cartridge size and type

Upon completion of the scan, the barcode reader updates the reagent loadlist STATUS field. For additional information, refer to Reagent Loadlist later in this section and in the Touch Screens section.

If the barcode reader is not functioning properly, it should be de-activated (refer to De-activating the Barcode Reader) and the Customer Support Center notified of the malfunction.

When the barcode reader is off, reagents are not scanned when the Review & Run screen is entered. The reagent lot number is not recognized and automatic recalibration does not occur when the reagent lot number changes.

Activating the Barcode Reader

1. From the Main menu, touch SYSTEM FILES, SELECT. Touch INSTRUMENT OPTIONS, SELECT.
2. Touch USE BARCODE READER to display ON.
3. Touch STORE RESULTS. CODE 00166 FILE SAVED displays.

De-activating the Barcode Reader

1. From the Main menu, touch SYSTEM FILES, SELECT. Touch INSTRUMENT OPTIONS, SELECT.
2. Touch USE BARCODE READER to display OFF.
3. Touch STORE RESULTS.
4. Manually enter the reagent name in the loadlist. Refer to Reagent Loadlist, Assigning a Reagent, in this section.

Scanning the Reagent Tray with the Barcode Reader Off

1. From the Main menu, touch REVIEW & RUN, SELECT.
2. Touch REVIEW adjacent to REAGENT LOADLIST.
3. From the Reagent Loadlist screen, touch READ REAGENT TRAY.

Calibration – Optical Assays

Introduction

Assays are calibrated at intervals defined in the Test Parameter Files. However, a calibration may be performed when necessary.

The ABBOTT SPECTRUM SERIES II System provides options for determining how and when optical calibrations are performed. The options are defined in the assay Test Parameter Files, and include calibration mode, calibration interval, and calibration data acceptance criteria.

Calibration Modes

The calibration mode specifies how and when optical calibrations are performed. The mode is defined in the assay Test Parameter File as Cal On Command or Master Cal.

The following information applies when calibration mode is edited.

- The Test Parameter Files cannot be edited while patient samples are stored in the System's memory. All patient samples must be deleted before editing.
- All loadlists are deleted when Test Parameter Files are edited and SAVE FILE is touched.
- When Test Parameter Files are edited, the Quality Control File for the edited assay is also deleted. However, the defined values for the low and high ranges are not affected. The Quality Control screen should be printed, if required for documentation.

Cal On Command

When the Cal On Command mode is selected, the calibration for a specific assay is run independently of all other assays. Sample assays are required to initiate Cal On Command.

Cal On Command assays are calibrated under the following conditions:

- The calibration interval has expired.
- RE CALIBRATE or KINETIC BLANK was touched.
- The Test Parameter File was edited.
- Assays requiring calibration have been requested in the Patient Samples screen.
- RUN was touched in the Review & Run screen.

Calibration Modes
(continued)

Master Cal

The Master Cal mode allows multiple assays with the same calibration interval to be calibrated as a group. Sample assays are not required to initiate Master Cal.

Master Cal assays are calibrated under the following conditions:

- The calibration interval has expired.
- Master Cal has been requested.
- RUN was touched in the Review & Run screen.

If a Master Cal assay fails calibration, it displays an individual calibration status of FAIL. The assay is processed as Cal On Command until an acceptable calibration has been achieved. The Master Calibration interval for that specific assay is not affected. When the next Master Cal interval has expired, the assay will be recalibrated with other Master Cal assays.

Defining the Calibration Mode

1. From the Main menu, touch PATIENT SAMPLES, SELECT. Touch DELETE. Touch ALL. Touch PROCEED.
2. From the Main menu, touch QUALITY CONTROL, SELECT. Touch the assay name, and SELECT. Press the PRINT SCREEN key to document the Quality Control File. Retain for laboratory documentation records. Touch EXIT.
3. From the Main menu, touch SYSTEM FILES, SELECT.
4. Touch TEST PARAMETER FILES. Use the cursor control keys to access the hidden password field to the right of TEST PARAMETER FILES. Type the current password, and press ENTER. Touch SELECT.
5. Touch ENTRY NAME. Type the assay name, exactly as it displays on the Patient Samples screen, and press ENTER.
6. Touch DEFINE CALIB.
7. Touch CAL MODE. Press the CYCLE key until the appropriate mode is displayed. (All assays are factory defined as Cal On Command.)
8. Touch SAVE CALIB. CODE 00166 FILE SAVED displays.
9. Touch EXIT.

Calibration – Optical Assays

Calibration Intervals

The calibration interval for Cal On Command assays is defined in individual Test Parameter Files. This interval determines when a calibration or kinetic blank is scheduled. Calibration intervals are specified for the individual assay in the reagent package insert and the Reagent Manual.

The Master Cal interval, established in one-hour increments, is defined in the Instrument Options screen. The Master Cal interval is not changed by the System. The time of next calibration may shift, based on the actual time calibration was initiated. To adjust the time of next Master Cal, refer to Defining the Master Cal Interval. Initiate the procedure at the appropriate time. The time of next calibration will reset.

The following information applies when calibration interval is edited.

- The Test Parameter Files cannot be edited while patient samples are stored in the System's memory. All patient samples must be deleted before editing.
- All loadlists are deleted when Test Parameter Files are edited and SAVE FILE is touched.
- The Quality Control File for the edited assay is also deleted when Test Parameter Files are edited. However, the defined values for the low and high ranges are not affected. The Quality Control screen should be printed, if required for documentation.

Defining the Cal On Command Interval

1. From the Main menu, touch PATIENT SAMPLES, SELECT. Touch DELETE. Touch ALL. Touch PROCEED.
2. From the Main menu, touch QUALITY CONTROL, SELECT. Touch the assay name, and SELECT. Press the PRINT SCREEN key to document the Quality Control File. Retain for laboratory documentation records. Touch EXIT.
3. From the Main menu, touch SYSTEM FILES, SELECT.
4. Touch TEST PARAMETER FILES. Use the cursor control keys to access the hidden password field to the right of TEST PARAMETER FILES. Type the current password, and press ENTER. Touch SELECT.
5. Touch ENTRY NAME. Type the assay name, exactly as it displays in the Patient Samples screen, and press ENTER.
6. Touch DEFINE CALIB.
7. Touch CAL INTERVAL (HR), and type the appropriate interval.
8. Touch SAVE CALIB. CODE 00166 FILE SAVED displays.
9. Touch EXIT.

Calibration Intervals
(continued)

Defining the Master Cal Interval

1. Verify that the ACTIVITY field is not highlighted.
2. From the Main menu, touch SYSTEM FILES, SELECT. Touch INSTRUMENT OPTIONS, SELECT.
3. Touch MASTER CALIBRATION INTERVAL, and type the appropriate interval.
4. Touch STORE RESULTS. CODE 00166 FILE SAVED displays.
5. Touch EXIT.

Calibration Options

Auto Accept Calibrations

The Auto Accept Calibrations option allows the System to interpret calibration data, and automatically accept or reject calibration data and kinetic blank values. The data is accepted or rejected based on criteria for calibration factors, calibrator concentrations, intercept [C] values, percentage tolerances, and kinetic blank tolerance ranges. These criteria are defined in the Test Parameter File for each assay.

Auto Accept On

When AUTO ACCEPT CALIBRATIONS: ON displays in the Instrument Options screen and the new calibration data/kinetic blank passes the criteria defined in the Test Parameter File, the calibration curve is stored automatically. The data in the Calibrator Status subscreen and the LAST BLANK and LAST CAL times update. The information in the ACCEPTED and the NEW fields is identical and the CAL STATUS or BLANK STATUS field displays OK.

When the calibration data/kinetic blank is rejected, based on the criteria in the Test Parameter File, the ACCEPTED field displays the previously accepted data. The NEW field displays the failed data and the CAL STATUS or BLANK STATUS field displays FAIL. Refer to Calibration Data Interpretation for additional information.

Auto Accept Off

When AUTO ACCEPT CALIBRATIONS: OFF displays, the System displays the previously accepted calibration data/kinetic blanks and the new calibration data/kinetic blanks, but does not store the information. Samples are not run until the calibration data/kinetic blank is manually accepted and RUN is touched in the Review & Run screen.

Calibration – Optical Assays

Calibration Options (continued)

Override Calibrations

The Override Calibrations function allows the System to use previously accepted calibration data or kinetic blanks when new data is unavailable.

Refer to Table 2-4 for additional information on using OVERRIDE CAL in combination with AUTO ACCEPT.

Table 2-4 Calibration Combinations

Combination	Calibration Status/ Blank Status	Result
AUTO ACCEPT ON/ OVERRIDE OFF	**OK**	Samples run using the new calibration data/kinetic blank.
	FAIL	Samples re-entered into memory. Information displays as status code.
AUTO ACCEPT OFF/ OVERRIDE OFF	**FAIL**	Samples do not run until calibration data/kinetic blank is manually accepted and RUN is touched in Review & Run.
AUTO ACCEPT ON/ OVERRIDE ON	**OK**	Samples run using the new calibration data/kinetic blank.
	FAIL	Samples run using the previous calibration data/kinetic blank.
AUTO ACCEPT OFF/ OVERRIDE ON	**FAIL**	Samples run using the previous calibration data/kinetic blank.

Defining Calibration Options

1. Verify that the ACTIVITY field is not highlighted.
2. From the Main menu, touch SYSTEM FILES, SELECT. Touch INSTRUMENT OPTIONS, SELECT.
3. Touch AUTO ACCEPT CALIBRATIONS. Press the CYCLE key to display ON or OFF.
4. Touch OVERRIDE CALIBRATIONS. Press the CYCLE key to display ON or OFF.
5. Touch STORE RESULTS. CODE 00166 FILE SAVED displays.
6. Touch EXIT.

Calibrator Loadlist

The calibrator loadlist is created automatically when the Review & Run screen is entered and the carousel number is verified. The System recognizese discrepanciese betweene the calibratore loadliste and calibrators/standards on board. CALIBRATOR LOADLIST highlights to indicate calibrators/standards need to be placed on board. Refer to Samples - Process in this section for additional information.

NOTE

THE CALIBRATOR LOADLIST IS DELETED WHEN TEST PARAMETER FILES ARE EDITED OR SYSTEM POWER IS CYCLED.

Calibrators may be typed into the calibrator loadlist. Refer to Typing a Permanent Calibrator Loadlist Entry.

Automatic Calibrator Loadlist

1. From the Main menu, touch REVIEW & RUN, SELECT or INSTRUMENT STATUS, SELECT.
2. Verify the carousel number.
3. Touch REVIEW adjacent to CALIBRATOR LOADLIST.

WARNING

BEFORE ADDING OR REMOVING CALIBRATORS/STANDARDS TO OR FROM THE SAMPLE CAROUSEL, ENSURE INSTRUMENT ROBOTICS ARE PAUSED OR HALTED, AND **NO ACTIVITY** OTHER THAN **READING** IS DISPLAYED IN THE ACTIVITY FIELD.

4. Ase directed by the calibrator loadlist, place appropriate calibrators/standards on the sample carousel. As calibrators/standards are in place, touch LOAD NOW to display ON BOARD.

NOTE

ONE HOUR AFTER THE STATUS FIELD CHANGES TO **ON BOARD**, THE STATUS REVERTS TO **LOAD NOW** AS A REMINDER TO REPLACE THE CALIBRATORS, IF APPROPRIATE.

5. Touch NEXT PAGE to verify the status of additional calibrators/standards.
6. Touch EXIT.

Typing a Permanent Calibrator Loadlist Entry

1. From the Main menu, touch REVIEW & RUN, SELECT or INSTRUMENT STATUS, SELECT.
2. Verify the carousel number.
3. Touch REVIEW adjacent to CALIBRATOR LOADLIST.
4. Touch the NAME field in the desired position.
5. Type the calibrator/standard name, exactly as it displays in the previously defined Test Parameter File, and press ENTER. The status displays PERMCAL.
6. Touch EXIT.

Calibrator Loadlist
(continued)

Deleting a Calibrator Loadlist Entry

1. From the Main menu, touch REVIEW & RUN, SELECT or INSTRUMENT STATUS, SELECT.
2. Verify the carousel number.
3. Touch REVIEW adjacent to CALIBRATOR LOADLIST.
4. Touch the NAME field in the desired position.
5. Press the BACKSPACE key or the SPACE BAR.
6. Touch EXIT.

Calibration Data Acceptance Criteria

Calibration data acceptance criteria are defined in individual Test Parameter Files. Test Parameter Files cannot be edited while patient samples are stored in the System's memory. All patient samples must be deleted before editing.

Ref Cal Factor,
Intcpt Tol [C],
% Tol of Cal Factor,
% Tol of Cal

The Ref Cal Factor, Intcpt Tol [C], % Tol of Cal Factor, and % Tol of Cal are defined in the Test Parameter Files. When a calibration is performed, the following sequence occurs:

- The newly generated Cal Factor is compared to the Ref Cal Factor in the Test Definition screen. If the % Tol of Cal Factor is exceeded, the calibration fails and CODE 00002 TEST: [redacted] CALIBRATION CAL FACTOR TOLERANCE HAS FAILED displays.
- The intercept of the calibration curve, in concentration units, is compared to the intercept tolerance range. If the newly calculated value is outside the range, the calibration fails and CODE 00286 TEST: [redacted] INTERCEPT TOLERANCE RANGE CHECK HAS FAILED displays.
- The calculated calibrator concentrations are compared to the % Tol of Cal. If the % Tol of Cal is exceeded, the calibration fails and CODE 00046 TEST: [redacted] CALIBRATOR TOLERANCE HAS FAILED FOR CALIBRATOR #: [redacted] displays.

If error codes display, refer to the Status Codes section of the Maintenance & Troubleshooting Manual for appropriate corrective action.

Determining the Ref Cal Factor

It is recommended that the Ref Cal Factor of a minimum of 10 successful calibrations, using several lot numbers of reagent, be performed. However, a provisional Ref Cal Factor can be calculated by using three or four calibrations, and updating the Ref Cal Factor in the Test Parameter File. Continue to monitor the Ref Cal Factor until at least 10 successful calibrations are achieved.

1. Document the Cal Factor values from 10 successful calibrations.
2. Calculate the average Cal Factor of the 10 values obtained.

Calibration Data Acceptance Criteria (continued)

Determining the Intcpt Tol [C]

The following method is suggested for establishing the Intcpt Tol [C]:

1. Document the Intercept [C] values from 10 successful calibrations.
2. Calculate the mean and standard deviation of the 10 values obtained.
3. Multiply the standard deviation by 4.
4. Subtract this value from the calculated mean to determine the low value for the range. Add this value to the calculated mean to determine the high value for the range.

The values determined for the Intercept Tolerance may need to be re-established periodically if there is an excessive number of failures. Changes in reagent lot numbers, calibrator lot numbers, or the instrument may cause a change in the intercept range.

Defining Intcpt Tol [C], Ref Cal Factor, % Tol of Cal Factor, % Tol of Cal

1. From the Main menu, touch PATIENT SAMPLES, SELECT. Touch DELETE. Touch ALL. Touch PROCEED.
2. From the Main menu, touch QUALITY CONTROL, SELECT. Touch the assay name, and SELECT. Press the PRINT SCREEN key to document the Quality Control File. Retain for laboratory documentation records. Touch EXIT.
3. From the Main menu, touch SYSTEM FILES, SELECT.
4. Touch TEST PARAMETER FILES. Use the cursor control keys to access the hidden password field to the right of TEST PARAMETER FILES. Type the current password, and press ENTER. Touch SELECT.
5. Touch ENTRY NAME. Type the assay name, exactly as it displays in the Patient Samples screen, and press ENTER.
6. Touch DEFINE CALIB.
7. Touch INTCPT TOL [C]. Type the appropriate Intcpt Tol [C] values.
8. Touch REF CAL FACTOR. Type the appropriate Ref Cal Factor, as specified in the reagent package insert and the Reagent Manual, or determined by the operator.
9. Touch % TOL OF CAL FACTOR. Type the appropriate % Tol of Cal Factor, as specified in the reagent package insert and the Reagent Manual.
10. Touch % TOL OF CAL. Type the appropriate % Tol of Cal, as specified in the reagent package insert and the Reagent Manual.
11. Touch SAVE CALIB. CODE 00166 FILE SAVED displays.
12. Touch EXIT.

Calibration – Optical Assays

Calibration Data Acceptance Criteria (continued)

Kinetic Blank Tolerance Range

The Tolerance Range (ABS/min) is defined in the Test Parameter Files. When a kinetic blank is performed, the kinetic blank is compared to the Tolerance Range (ABS/min). If the Tolerance Range (ABS/min) is exceeded, CODE 00282 KINETIC BLANK HAS FAILED THE TOLERANCE CHECK TEST: [redacted] displays. If error codes display, refer to the Status Codes section of the Maintenance & Troubleshooting Manual for appropriate corrective action.

Determining the Kinetic Blank Tolerance Range

The following method is suggested for establishing the Tolerance Range (ABS/min).

1. Document the kinetic blank values from 10 successful kinetic blanks.
2. Calculate the mean and standard deviation of the 10 kinetic blanks obtained.
3. Multiply the standard deviation by 4.
4. Subtract this value from the calculated mean to determine the low value for the range. Add this value to the calculated mean to determine the high value for the range.

Defining the Kinetic Blank Tolerance Range

1. From the Main menu, touch PATIENT SAMPLES, SELECT. Touch DELETE. Touch ALL. Touch PROCEED.
2. From the Main menu, touch QUALITY CONTROL, SELECT. Touch the assay name, and SELECT. Press the PRINT SCREEN key to document the Quality Control File. Retain for laboratory documentation records. Touch EXIT.
3. From the Main menu, touch SYSTEM FILES, SELECT.
4. Touch TEST PARAMETER FILES. Use the cursor control keys to access the hidden password field to the right of TEST PARAMETER FILES. Type the current password, and press ENTER. Touch SELECT.
5. Touch ENTRY NAME. Type the name of the assay, exactly as it displays in the Patient Samples screen, and press ENTER.
6. Touch DEFINE CALIB.
7. Touch TOLERANCE RANGE (ABS/MIN), and type the appropriate Tolerance Range (ABS/min). The defined range may include both positive and negative numbers.
8. Touch SAVE CALIB. CODE 00166 FILE SAVED displays.
9. Touch EXIT.

Calibrator/Standard Concentrations

Prior to using new calibrator/standard materials lot numbers, it is necessary to edit the new lot number calibrator/standard concentrations into the appropriate Test Parameter File.

Test Parameter Files cannot be edited while patient samples are stored in the System's memory. All patient samples must be deleted before editing.

Defining Calibrator/Standard Concentrations

1. From the Main menu, touch PATIENT SAMPLES, SELECT. Touch DELETE. Touch ALL. Touch PROCEED.
2. From the Main menu, touch QUALITY CONTROL, SELECT. Touch the assay name, and SELECT. Press the PRINT SCREEN key to document the Quality Control File. Retain for laboratory documentation records. Touch EXIT.
3. From the Main menu, touch SYSTEM FILES, SELECT.
4. Touch TEST PARAMETER FILES. Use the cursor control keys to access the hidden password field to the right of TEST PARAMETER FILES. Type the current password, and press ENTER. Touch SELECT.
5. Touch ENTRY NAME. Type the name of the assay, exactly as it displays in the Patient Samples screen, and press ENTER.
6. Touch DEFINE CALIB.
7. Touch the LEVEL [C] field adjacent to the calibrator/standard to be changed. Type the concentration, as defined in the calibrator/standard package insert.
8. Touch SAVE CALIB. CODE 00166 FILE SAVED displays. When an edit is made to a Test Parameter File and saved, the CAL STATUS changes to RECAL. A prompt for recalibration will be noted the next time the test is requested.
9. Touch EXIT.

Calibration/Reblank Initiation

Initiating Cal On Command/Kinetic Blank

1. From the Main menu, touch CALIBRATION, SELECT. From the Calibration screen, touch CALIBRATION, SELECT.
2. Determine whether the Test Parameter Files have been edited. When the files have been edited, RECAL displays in the STATUS field. Select the appropriate option.

   If RECAL displays, proceed to step 4.

   If RECAL does not display, proceed to step 3.
3. Touch the desired test name, and SELECT to display the Calibrator Status subscreen for the specific assay. Touch RE CALIBRATE or KINETIC BLANK. The STATUS field changes to RECAL or REBLANK.
4. Touch EXIT.
5. From the Main menu, touch PATIENT SAMPLES, SELECT. Request the assay. When the assay is requested with at least one SID, a calibration is initiated.
6. Process the sample. Refer to Samples – Process in this section.

NOTE

AT LEAST ONE SAMPLE MUST BE PROCESSED TO INITIATE CAL ON COMMAND OR A KINETIC BLANK.

Calibration/Reblank Initiation
(continued)

Initiating Master Cal

1. From the Main menu, touch CALIBRATION, SELECT. From the Calibration screen, touch CALIBRATION, SELECT.
2. Determine whether the time interval for Master Cal has expired. When the interval has expired, MASTER CAL DUE displays. Select the appropriate option.

   If MASTER CAL DUE displays, the Master Calibration time interval has expired. Touch EXIT to initiate a calibration of all assays associated with the Master Calibration time interval defined in the Instrument Options screen.

> **NOTE**
>
> IF CALIBRATION OF ALL ASSAYS IS NOT APPROPRIATE, ENSURE **MASTER CAL OK** DISPLAYS BEFORE TOUCHING **EXIT**.

   If MASTER CAL OK displays, the calibration curve of all assays associated with the Master Calibration time interval in the Instrument Options screen is within the time interval, has acceptable data, and can be used. Touch MASTER CAL OK to display MASTER CAL DUE. The status of tests defined as Master Cal in the Test Parameter File will change to DUE. Touch EXIT to initiate a master calibration.
3. Touch EXIT to display the Main menu.
4. Refer to Samples – Process in this section to complete calibration protocol. When calibration is complete, the MASTER CAL STATUS updates to OK and the TIME OF NEXT CALIBRATION field updates.

Calibration Data Interpretation

It is important to recognize acceptable and unacceptable calibration data and to understand how to perform troubleshooting. Calibration reference data, accepted data, and new data display on the Calibrator Status subscreen.

Entered Column

The ENTERED column contains reference data. The newly calculated cal factor, calibrator concentrations, and intercept tolerances are compared to those established in the Test Parameter Files and displayed in the ENTERED column.

Accepted Column

The ACCEPTED column displays the calibration data from the last accepted calibration. If the calibration passed and AUTO ACCEPT is on, data is identical in the NEW and ACCEPTED columns. The CAL STATUS or BLANK STATUS field displays OK. If the calibration failed, data in the NEW and ACCEPTED columns is different. (This data is used in troubleshooting.) The CAL STATUS or BLANK STATUS field displays FAIL.

Calibration Data Interpretation
(continued)

New Column

The NEW column displays the latest calibration data. The newly calculated cal factor, calibrator concentrations, and intercept tolerances are compared to those established in the Test Parameter Files and displayed in the ENTERED column. If the cal factor, calibrator concentrations, or intercept exceed the established tolerances, the appropriate status code displays to aid in troubleshooting.

CALIBRATOR STATUS

TEST NAME: GLUCOSE
LIN REG END PT
CAL MODE: CAL ON CMD

LAST CAL: 10:28 AM 31-MAR-95
CAL STATUS: OK
CAL LEVEL: 0

ACCEPT CAL

	ENTERED		ACCEPTED		NEW	
LEVEL	NAME	CONC	CONC	DELTA Ad	CONC	DELTA Ad
1	WATER	0.00000	−2.31282	0.00590	−2.31282	0.00590
2	MCC1	99.8000	98.6190	0.25701	98.6190	0.25701
3	MCC2	292.000	299.609	0.78070	299.609	0.78070
4	MCC3	511.300	507.185	1.32146	507.185	1.32146
5						
6						
CAL FACT		377.000	383.845		383.845	
INTERCEPT [Ad]			0.0	0.00011	0.0	0.00011
INTERCEPT[C]			−0.04162	0.0	−0.04162	0.0
C. OF C.			0.99973		0.99973	

SELECT ANOTHER TEST

EXAMINE CALIBRATOR LOADLIST

RE CALIBRATE

AUTO PRINT (time & date) EXIT

CALIBRATOR STATUS

TEST NAME: GLUCOSE
LIN REG END PT
CAL MODE: CAL ON CMD

LAST CAL: 10:28 AM 31-MAR-95
CAL STATUS: FAIL
CAL LEVEL: 0

ACCEPT CAL

	ENTERED		ACCEPTED		NEW	
LEVEL	NAME	CONC	CONC	DELTA Ad	CONC	DELTA Ad
1	WATER	0.00000	−1.67467	−0.00824	−103.145	−0.00834
2	MCC1	99.8000	100.933	0.26423	435.195	0.27248
3	MCC2	292.000	285.969	0.77217	638.090	1.41082
4	MCC3	511.300	514.523	1.39955	324.636	0.81070
5						
6						
CAL FACT		377.000	364.298		532.306	
INTERCEPT [Ad]			0.0	−0.01283	0.0	0.18914
INTERCEPT[C]			4.67465	0.0	−98.7909	0.0
C. OF C.			0.99983		0.68965	

SELECT ANOTHER TEST

EXAMINE CALIBRATOR LOADLIST

RE CALIBRATE

AUTO PRINT (time & date) EXIT

Figure 2-3 Calibration Status Screens

Calibration – Optical Assays

Calibration Data Interpretation
(continued)

Acceptable Data

Calibration is acceptable when no status codes are generated and quality control values are within the established range.

Unacceptable Data

Unacceptable calibration data may be identified by status codes and/or by Quality Control values outside the established range. The most frequently displayed calibration status codes are:

CODE 00002a	TEST: [redacted] CALIBRATION CAL FACTOR TOLERANCE HAS FAILED
CODE 00046a	TEST: [redacted] CALIBRATOR TOLERANCE HAS FAILED FOR CALIBRATOR #: [redacted]

For a complete listing of status codes, refer to the Maintenance & Troubleshooting Manual.

Troubleshooting Calibration Failures

1. Refer to the appropriate status code in the Maintenance & Troubleshooting Manual for probable cause and corrective action.
2. Resolve the concern.
3. Repeat the calibration, ensuring proper reconstitution and stability of reagents and calibrators.
4. Rerun quality control and patient samples that have been processed.
5. If the second calibration fails, contact the Customer Support Center.

Introduction

The electrolyte module requires an internal two-point calibration for sodium, potassium, and chloride, at two-hour intervals or with each net 2° C change in temperature.

When the calibration interval expires, the instrument calibrates automatically as electrolyte assays are requested. An internal single-point calibration, using Standard A, is automatically performed with each electrolyte sample assay.

Carousel - Changing While System is Reading

Introduction

To expedite processing, operation may begin on an additional carousel when READING is displayed in the ACTIVITY field.

Changing Carousels While the System is Reading

CAUTION

PROCEED ONLY IF **READING** IS DISPLAYED IN THE ACTIVITY FIELD.

1. When sample information has been requested, verify READING is displayed in the ACTIVITY field.
2. Mount the new carousel.
3. Proceed to Samples - Process in this section.

Introduction

The cuvette status panel indicates the usage status of cuvette segments. As cuvette segments are used, the corresponding LED illuminates on the panel. The System tracks cell usage during runs and uses each cell. When all cells have been used, CODE 00234 UNABLE TO SCHEDULE ALL OPTICAL TESTS is generated, indicating no cuvettes are available. When the assays have been completed, CODE 00003 ALL CUVETTES USED – CHANGE TO CONTINUE displays.

An alarm sounds intermittently when a cuvette change is required. The light on the RESET button flashes after the five-second tone has completed. The flashing light is reset by pressing the RESET button.

NOTE

WHEN INSTRUMENT POWER IS CYCLED DURING SYSTEM OPERATION, USED CUVETTES MUST BE CHANGED.

Changing Cuvettes

CAUTION

DO NOT PROCEED IF THE ACTIVITY FIELD IS HIGHLIGHTED.

1. Verify that the ACTIVITY field is not highlighted.
2. From the Main menu, touch STATUS. Press the PRINT SCREEN key to print appropriate status codes, if desired for documentation. Touch CANCEL ALL.
3. Replace the used cuvettes with new cuvettes. To maintain incubator temperature stability, remove and replace used cuvettes, two at a time, from the back of the carousel to the front. Dispose of the used cuvettes in accordance with local, state, and federal regulations governing the treatment of regulated medical waste.

CAUTION

DROPLETS OF WATER NORMALLY ADHERE TO THE EXTERIOR OF CUVETTE SEGMENTS WHEN THEY ARE REMOVED FROM THE CAROUSEL INCUBATOR. WHEN REMOVING USED SEGMENTS, DO NOT ALLOW WATER DROPLETS TO CONTAMINATE UNUSED SEGMENTS.

4. Simultaneously press the SHIFT key and the CUVETTE CHANGE key. The LEDs on the cuvette status panel go out and CUVETTES CHANGED displays on the screen.
5. Continue normal operation. The System begins operation with cuvette cell 1.

Dilution Protocol

Introduction

Assay results which exceed the reagent linear range are automatically rescheduled for dilution or concentration, if a dilution protocol is defined in the SAMPLE and REAGENT VOL fields in the Test Parameter Files prior to initial testing.

Defining the Dilution Protocol

For ABBOTT SPECTRUM SERIES II System chemistries, refer to the package insert or Reagent Manual for normal, low, and high sample and reagent volume settings. Refer to Test Parameter Files in this section and the Touch Screens section for additional information.

When CODE 00013 LINEAR HIGH OR LOW CHECK FAILURE. TEST: [redacted] is generated, the following activities occur.

- The assay is re-entered into memory, if the dilution protocol has been previously defined in the LOW and HIGH field under SAMPLE (uL) and REAGENT VOL (uL).
- The assay result is flagged LH or LL, based on the LINEARITY [C] field defined in the assay Test Parameter File.
- The assay result is flagged DP.

Scheduling the Dilution Protocol

1. From the Main menu, touch PATIENT SAMPLES, SELECT.
2. Touch RECALL RESULTS. Touch ALL. Touch NEXT SAMPLE to scroll through patient reports. Identify patient samples flagged DP for the assay(s) indicated in Code 00013. Touch PRINT SCREEN for each sample flagged DP and retain for laboratory documentation records.
3. Touch EXIT.
4. From the Main menu, touch REVIEW & RUN, SELECT.
5. Touch RUN.

If the System is in the Flex-B or Batch mode, it proceeds in the Batch mode with dilutions performed within assay type as the first assay of its type. If it is in the Random or Tandem mode, the dilution is the first assay performed after RUN is touched, provided all other assays are complete and no new samples have been requested. If other assays are at an ENT (entered) status, the dilution is performed after the other assays are processed, e.g., when stopping for a cuvette change.

If the sample exceeds the linearity [C] after the dilution protocol, the System will not attempt an additional dilution protocol. The operator must make a manual dilution, request a rerun of the assay, calculate the result, and edit the result. When the report is printed, a # flag accompanies the edited result and is footnoted, # User Entered Result.

If the sample is flagged IA (Initial Absorbance) or LE (Low Energy), no automatic dilution or concentration is performed. Protocols on samples flagged MA (Maximum Absorbance) are performed unless the sample was identified as /C at the beginning of the run.

Halt

Introduction

The Halt function is used as an emergency stop for the System. Activation of Halt aborts System activities immediately. Halt also may be used to abort a diagnostic routine. The Halt may take up to three minutes, depending on System activities. The keyboard does not respond until the Halt process is complete. When the process is complete, the HALT key is no longer illuminated. No printouts are generated for a halted routine.

When Halt is initiated, the HALT key illuminates, and the following activities occur.

- The robotics abort activity in process.
- The ISE module completes the sample in process, sends the results to the System, and moves to the home position.
- All incomplete assays return to ENT status.
- If calibrating, the Patient Samples screen displays the status as SCH.
- SYSTEM HALTED displays.

Activating Halt

1. Simultaneously press the SHIFT key and the HALT key.
2. SYSTEM HALTED displays and all robotic activity stops. The message displays until Halt is de-activated.
3. Resolve the concern for which the System was halted.

De-activating Halt

1. Allow RUNNING to disappear from the ACTIVITY field.
2. Simultaneously press the SHIFT key and the HALT key.
3. To process assays re-entered into the memory, from the Main menu, touch REVIEW & RUN, SELECT. Verify the carousel number.
4. Touch HOME ROBOTICS.
5. Touch RUN.

Activating Halt During Automated Daily Maintenance

1. Simultaneously press the SHIFT key and the HALT key.
2. SYSTEM HALTED displays and all robotic activity stops. The System automatically prints a report indicating that automated daily maintenance was aborted.

Re-activating Automated Daily Maintenance

1. De-activate Halt by simultaneously pressing the SHIFT key and the HALT key.
2. Re-activate automated daily maintenance by simultaneously pressing the SHIFT key and the DAILY MAINT. key once to initiate home robotics. After robotics are complete, simultaneously press the SHIFT key and the DAILY MAINT. key again to re-activate automated daily maintenance. CODE 00318 DAILY MAINTENANCE STARTED displays.

Interface (Bi-Directional)

Introduction

The bi-directional feature allows the System to interface bi-directionally with a host computer. This provides the ability to download sample requests to the System from a host computer which has been programmed to meet specifications set by Abbott Laboratories. (Specifications are available from Abbott Laboratories.) In addition, the System has the ability to report patient results to the host computer.

Transmission from the host computer to the System occurs only when the System is in the Bi-Host Interface screen. Entry into the screen is not allowed if RUNNING displays in the ACTIVITY field, or data is being transmitted to the host.

Downloading Patient Loadlists

1. From the Main menu, touch BI-HOST INTERFACE, SELECT.
2. From the Bi-Host Interface screen, the download of patient loadlists is automatic and no further action is required.
3. When the transmission of information is complete, the Main menu automatically displays.

NOTE

IF A COMMUNICATION FAILURE OCCURS ON THE HOST COMPUTER OR THE ABBOTT SPECTRUM SERIES II SYSTEM, A BREAK (ABORT) OPTION IS AVAILABLE IN THE BI-HOST INTERFACE SCREEN. SELECTION OF BREAK TERMINATES THE COMMUNICATION IN PROGRESS AND DISPLAYS THE MAIN MENU. **BREAK SHOULD NOT BE SELECTED FOR ROUTINE DOWNLOADS**. THE BREAK FEATURE IS PROVIDED TO ALLOW OPERATION TO CONTINUE IF THE EXTERNAL HOST FAILS. FOR ADDITIONAL INFORMATION, REFER TO THE MAINTENANCE & TROUBLESHOOTING MANUAL, OBSERVED CONCERNS, COMMUNICATION FAILURE OCCURRED BETWEEN THE ANALYZER AND THE HOST COMPUTER.

Downloading Patients to Another Carousel Number

NOTE

THE HOST COMPUTER MAY BE PROGRAMMED TO DEFAULT TO A SPECIFIC CAROUSEL.

1. Patients can be downloaded to multiple sample carousels. To change carousel numbers, from the Main menu, touch PATIENT SAMPLES, SELECT.
2. Touch CAR#, and type the desired carousel number. Press ENTER.
3. Touch EXIT. On the next download, the samples display on the sample loadlist for the new carousel number.

Transmitting Patient Reports Automatically

Auto-Send is a mode in which completed samples are automatically transmitted to the host computer. The AUTO-SEND OFF/ON field displays in the Bi-Host Interface screen. The System default setting at power-on is AUTO-SEND OFF. This is not a selectable field; the field displays the status of AUTO-SEND set by the host computer.

If AUTO-SEND ON displays, reports are buffered until the host computer is available to receive them. If AUTO-SEND OFF displays, reports are buffered for transmission to the host until AUTO-SEND is on or the reports are deleted.

Reports selected for transmission cannot be deleted until they have been sent to the host computer or CANCEL BI-HOST is selected. If deletion of a report buffered for AUTO-SEND is attempted, the on-screen message CANNOT DELETE PATIENT WITH REPORT PENDING displays.

Editing Interface Parameters

1. From the Main menu, touch SYSTEM FILES, SELECT. Touch INTERFACE SETUP, SELECT.
2. Touch NEXT until the Bi-Directional Host screen displays.
3. Touch the field adjacent to the parameter to be edited. Press the CYCLE key to display the selection for each parameter.
4. Touch SAVE. New parameters will be used by the System after power has been cycled.
5. Touch EXIT.

Deleting Patient Reports Buffered for Auto-Send

1. From the Main menu, touch PATIENT SAMPLES, SELECT.
2. Touch DELETE.
3. Touch CANCEL BI-HOST.
4. Select the samples to delete.
5. Touch PROCEED.

Interface (Uni-Directional)

Introduction

The uni-directional feature allows the System to transmit data to a host computer which has been programmed to meet specifications set by Abbottd Laboratories.d (Specificationsd ared availabled fromd Abbott Laboratories.) The transmission may be accomplished through the Auto Send mode or samples may be transmitted manually.

When the System is turned on, it automatically verifies the electronic circuits used for data transmission. If CODE 00018 HOST INTERFACE TIMEOUT displays, the System has sensed a malfunction that would eliminate data transmission. Refer to the Maintenance & Troubleshooting Manual for status code resolution.

When sending a large group of samples, the touch screen is inactive for a few seconds while the data package is being formatted. When the data package has been formatted, touch screen operation returns to normal during the transmission. When transmission is in progress, CODE 00145 REPORT IN PROGRESS displays.

Transmitting Samples Automatically

1. Each sample is automatically transmitted to the host computer when all assays for the sample are complete.
2. The System does not receive acknowledgement from the host computer that a sample has been received. At the host computer terminal, verify all samples have been received before deleting them from the System.
3. If a sample or group of samples was not received by the host, re-transmit manually.

Transmitting Samples Manually

1. From the Main menu, touch PATIENT SAMPLES, SELECT. Touch RECALL RESULTS.
2. Select the appropriate option:

   To transmit all samples, touch SEND UNI HOST.

   To transmit specific samples, touch to highlight the appropriate SIDs. Touch SELECT. Touch SEND UNI HOST.

   If more than one sample was selected, touch NEXT SAMPLE, SEND UNI HOST.
3. Repeat until selected samples have been transmitted.
4. Verify all samples were received.

Editing Interface Parameters

1. From the Main menu, touch SYSTEM FILES, SELECT. Touch INTERFACE SETUP, SELECT.
2. Touch NEXT until the Uni-Directional Host screen displays.
3. Touch the field adjacent to each parameter to be edited. Press the CYCLE key to display the selection for each parameter.
4. Touch SAVE. New parameters will be used by the System after power has been cycled.
5. Touch EXIT.

Password

Introduction

Use of a password protects the Test Parameter Files, Workload Analysis Files, and Sample Distribution Files from unauthorized access. A password must be entered to access the files for creating or editing parameters or resetting counters. However, files may be displayed and printed without entering a password.

NOTE

ALL NEW INSTRUMENTS ARE SHIPPED WITH THE PASSWORD **ABBOTT** DEFINED IN INSTRUMENT OPTIONS.

Lost Password

If the password is lost, forgotten, or misplaced, contact the Customer Support Center.

Defining the Password

1. Verify that the ACTIVITY field is not highlighted.
2. From the Main menu, touch SYSTEM FILES, SELECT. Touch INSTRUMENT OPTIONS, SELECT.
3. Touch OLD PASSWORD. Type the current password, and press ENTER.
4. The cursor automatically moves to the NEW PASSWORD field. Type the new password, and press ENTER.
5. The cursor automatically moves to the CONFIRM field. Type the new password, and press ENTER.
6. Touch STORE RESULTS. CODE 00166 FILE SAVED displays.
7. Touch EXIT.
8. Record the new password in an appropriate location.

Pause

Introduction

The PAUSE key is used to temporarily stop System dispense. Assays in process when Pause is activated continue to be processed.

Activating Pause

1. Simultaneously press the SHIFT key and the PAUSE key.
2. CODE 00301 SYSTEM PAUSED displays.
3. After a few dispenses, dispensing stops, but the System continues to take reads on assays in process and aspirate sample for ISE measurement.

De-activating Pause

1. Simultaneously press the SHIFT key and the PAUSE key.
2. To process assays re-entered into the System memory, from the Main menu, touch REVIEW & RUN, SELECT. Verify the carousel number.
3. Touch RUN.

Introduction

The ABBOTT SPECTRUM SERIES II System is designed for 24-hour use. It is recommended that, upon installation, the System power remain on continuously, unless instructed to power down by the Customer Support Center or Field Service.

There are two power switches on the System. The Main power switch, located on the right rear panel of the instrument, turns all power on and off. The Maintenance power switch, located on the right side of the instrument inside the access door, turns power on and off for the computer, robotics, and optical areas of the System. When Maintenance power is off, power remains on for the ISE module electronics.

WARNING

HIGH VOLTAGE EXISTS IN THE SYSTEM WHEN THE MAINTENANCE POWER IS **OFF** AND THE MAIN POWER IS **ON**. VISUALLY LOCATE THE POWER SWITCHES BEFORE TOUCHING THEM.

Powering On

1. Visually locate the Main power switch and turn it to the ON position. Wait 10 seconds.
2. Visually locate the Maintenance power switch and turn it to the ON position.
3. The System Power On screen displays. If an error occurs during the Power On procedure, ERROR displays in the right column. If ERROR displays, contact the Customer Support Center for assistance. Refer to System Power On in the Touch Screens section for additional information.
4. Verify adequate volume in the sample diluent reservoir.
5. Verify adequate volume in the ISE reagent cartridge pack.
6. Verify adequate capacity in the waste reservoir (if a floor drain is not used).
7. Verify probes are not damaged and are correctly positioned.
8. Verify all cuvette segments are clean. When power is cycled (Main or Maintenance), the System begins operation with cuvette cell 1.
9. The cursor will be positioned in the DATE field. Type the date.
10. Use the cursor control keys to highlight MONTH. Press the CYCLE key to display the current month.
11. Use the cursor control keys to highlight YEAR. Type the last two digits of the calendar year.
12. Use the cursor control keys to highlight TIME. Type the current time (non-military). Use the cursor control keys to highlight AM/PM. Press the CYCLE key to display the correct option.
13. Verify that the time and date are correct. Calibration intervals for both Cal On Command and Master Cal utilize this internal clock.
14. When all entries are verified and OK displays for each System-controlled diagnostic check, touch PROCEED.
15. If using an ABBOTT SPECTRUM SERIES II System interfaced with a host computer, re-enter the Bi-Host Interface screen to re-establish proper communication between the System and the host computer. Wait for the Main menu to display.
16. Continue normal operation.

Power On/Off

Powering Off

1. Visually locate the Maintenance power switch and turn it to the OFF position. Wait 10 seconds.
2. Visually locate the Main power switch and turn it to the OFF position.

Intermittent Power Interruptions

During intermittent power interruption, e.g., electrical storms, it is recommended to turn both the Maintenance and Main power switches to the OFF position. To avoid possible electronic damage when power is interrupted, wait 30 seconds before resupplying power.

Anticipated Power Interruption

If a power interruption is anticipated, the following procedures must be followed prior to loss of power.

1. To avoid compromising on-board stability, remove reagents from the cooled quadrants of the reagent tray. Cap and refrigerate the reagents.
2. Select the appropriate option:

   If power will be interrupted for 5 to 15 minutes, proceed to step 11.

   If power will be interrupted for 15 minutes or more, proceed to step 3.
3. Place absorbent toweling under the ISE module.
4. To prevent dripping, place the ISE reagent cartridge pack on the top deck.
5. Carefully disconnect the A, B, and R tubing from the ISE reagent cartridge pack, in a motion away from the operator to avoid aerosol spray.
6. To prevent contamination, wipe the tubing individually with a clean, lint-free tissue.
7. Place the A, B, and R tubing on a clean, lint-free tissue. From the Main menu, touch CALIBRATION, SELECT. Touch ISE STATUS, SELECT. Touch PURGE to draw air through the tubing and allow the cycle to complete.
8. Place the tubing in Type II water. Touch PURGE to draw water through the tubing and allow the cycle to complete.
9. Remove the tubing from the water and place it on a clean, lint-free tissue. Touch PURGE to draw air through the tubing and allow the cycle to complete.
10. Disconnect the R and W tubing from the electrode train, and release the tubing from the peristaltic pump.
11. Visually locate the Maintenance power switch and turn it to the OFF position. Wait 10 seconds.
12. Visually locate the Main power switch and turn it to the OFF position.
13. When power is restored, follow the Powering On procedure.

(continued)

Anticipated Power Interruption (continued)

14. Reconnect the tubing, if appropriate.
    a. Position the R tubing around the right side of the peristaltic pump rollers and connect it to the left side of the mounting bracket.
    b. Position the W tubing around the left side of the peristaltic pump rollers and connect it to the right side of the mounting bracket.

ATTENTION

DO NOT TWIST THE R AND W TUBING WHEN MOUNTING IT AROUND THE PERISTALTIC PUMP ROLLERS.

    c. Connect the R and W tubing to the appropriate ports on the reference electrode. Verify the S tubing is connected.
    d. Insert the A, B, and R tubing into the ISE reagent cartridge pack.
    e. Replace the ISE reagent cartridge pack on the ISE reagent shelf.
    f.b From the ISE Status screen, touch PURGE, and allow the cycle to complete. Touch PURGE again, and allow the cycle to complete. Touch CALIBRATE, and allow the cycle to complete. Record the slope. Touch CALIBRATE again; allow the cycle to complete, and record the slope. Verify slope performance against acceptance criteria.

Emergency Power Loss

If emergency power is not available, use the following procedure.

ATTENTION

FAILURE TO OBSERVE THIS PROCEDURE MAY RESULT IN PERMANENT ELECTRODE DAMAGE.

1. Visually locate the Maintenance switch and turn it to the OFF position. Wait 10 seconds.
2. Visually locate the Main power switch and turn it to the OFF position.
3. To avoid compromising on-board stability, remove reagents from the cooled quadrants of the reagent tray. Cap and refrigerate the reagents.
4. Select the appropriate option:

   If power will be interrupted for 5 to 15 minutes, proceed to step 10.

   If power will be interrupted for 15 minutes or more, proceed to step 5.
5. To prevent dripping, place the ISE reagent cartridge pack on the top deck.
6. Remove the electrode carrier from the ISE module.
7. Disengage the electrode latch and slide the electrodes out.
8. Flush each electrode individually with warm Type II water. Refer to ISE Electrode Flushing in the Weekly Maintenance section of the Maintenance & Troubleshooting Manual.
9. Reassemble the electrode train and engage the electrode latch.

(continued)

Power On/Off

Emergency Power Loss (continued)

10. Reinstall the electrode carrier.
11. When power is restored, follow the Powering On procedure.
12. Replace the ISE reagent cartridge pack on the ISE reagent shelf.

NOTE

IF USING A SYSTEM INTERFACED WITH A HOST COMPUTER AND A SUDDEN POWER LOSS OCCURS, CONTACT THE HOST REPRESENTATIVE TO ENSURE INTEGRITY OF DATA BEING TRANSMITTED.

Cycling Power

When "Cycle the power" is indicated as corrective action, use the following procedure.

1. Visually locate the Maintenance power switch and turn it to the OFF position.
2. Visually locate the Main power switch and turn it to the OFF position.
3. Wait 60 seconds.
4. Visually locate the Main power switch and turn it to the ON position.
5. Visually locate the Maintenance power switch and turn it to the ON position.
6. Replace used cuvettes.
7. Enter time and date.
8. Verify AUTO PRINT status is satisfactory.
9. Continue normal operation.

Print Order

Introduction

The Print Order function is used to establish the order in which assays are printed on the sample report.

NOTE

THE PRINT ORDER IS NOT STORED IN MEMORY UNTIL **SAVE** IS TOUCHED. IF **EXIT** IS TOUCHED BEFORE **SAVE**, EDITS WILL BE LOST.

Assigning Print Order

1. From the Main menu, touch SYSTEM FILES, SELECT. Touch PRINT ORDER, SELECT. Touch INSERT.
2. Use the cursor control keys to move the cursor to position 1 under PRINT ORDER, and press ENTER. The position 1 field highlights.
3. Use the cursor control keys to move the cursor to the appropriate assay in the TEST MENU, and press ENTER. The assay displays in position 1.
4. Repeat until all assays are arranged, changing position numbers as appropriate.
5. Touch SAVE. CODE 00166 FILE SAVED displays.
6. Touch EXIT.

Inserting Assays into Existing Print Order

1. From the Main menu, touch SYSTEM FILES, SELECT. Touch PRINT ORDER, SELECT. Touch INSERT.
2. Use the cursor control keys to move the cursor to the position under PRINT ORDER where the assay is to be inserted, and press ENTER. The position number highlights.
3. Use the cursor control keys to move the cursor to the appropriate assay in the TEST MENU, and press ENTER. The assay displays in the selected position under PRINT ORDER.
4. Repeat until all assays have been inserted.
5. Touch SAVE. CODE 00166 FILE SAVED displays.
6. Touch EXIT.

Deleting Assays from Print Order

1. From the Main menu, touch SYSTEM FILES, SELECT. Touch PRINT ORDER, SELECT. Touch DELETE.
2. Use the cursor control keys to move to the appropriate assay position under PRINT ORDER, and press ENTER. The assay displays in the TEST MENU. The assays below the deleted assay move into the vacant position.
3. Repeat until appropriate assays are deleted.
4. Touch SAVE. CODE 00166 FILE SAVED displays.
5. Touch EXIT.

Processing Order

Introduction

The Processing Order function is used to establish the order in which assays are processed.

NOTE

THE PROCESSING ORDER IS NOT STORED IN MEMORY UNTIL **SAVE** IS TOUCHED. IF **EXIT** IS TOUCHED BEFORE **SAVE**, EDITS WILL BE LOST.

Assigning Processing Order

1. From the Main menu, touch SYSTEM FILES, SELECT. Touch PROCESSING ORDER, SELECT. Touch INSERT.
2. Use the cursor control keys to move the cursor to position 1 under PROCESSING ORDER, and press ENTER. The position 1 field highlights.
3. Use the cursor control keys to move the cursor to the appropriate assay in the TEST MENU, and press ENTER. The assay displays in position 1.
4. Repeat until all assays are arranged, changing position numbers as appropriate.
5. Touch SAVE. CODE 00166 FILE SAVED displays.
6. Touch EXIT.

Inserting Assays into Existing Processing Order

1. From the Main menu, touch SYSTEM FILES, SELECT. Touch PROCESSING ORDER, SELECT. Touch INSERT.
2. Use the cursor control keys to move the cursor to the position under PROCESSING ORDER where the assay is to be inserted, and press ENTER. The position number highlights.
3. Use the cursor control keys to move the cursor to the appropriate assay in the TEST MENU, and press ENTER. The assay displays in the selected position under PROCESSING ORDER.
4. Repeat until all assays have been inserted.
5. Touch SAVE. CODE 00166 FILE SAVED displays.
6. Touch EXIT.

Deleting Assays from Processing Order

1. From the Main menu, touch SYSTEM FILES, SELECT. Touch PROCESSING ORDER, SELECT. Touch DELETE.
2. Use the cursor control keys to move to the desired assay position under PROCESSING ORDER, and press ENTER. The assay displays in the TEST MENU. The assays below the deleted assay move into the vacant position.
3. Repeat until appropriate assays are deleted.
4. Touch SAVE. CODE 00166 FILE SAVED displays.
5. Touch EXIT.

Quality Control – Define

Introduction

The mean, standard deviation (S.D.), percentage coefficient of variation (% C.V.), number of entries and ranges for each assay, and status of each level are defined, displayed, and printed using the Quality Control screens. Refer to Quality Control Status screen and Quality Control Status Sub-screen in the Touch Screens section.

- When a Test Parameter File is edited, all quality control data for that assay is deleted, except the low and high ranges.
- Quality control must be ordered as /C 1, /C 2, or /C 3 in the Patient Samples screen in order for quality control information to be generated in the Quality Control screen.
- Only controls entered as /C 1, /C 2, or /C 3 before running are evaluated against the established quality control ranges. Controls manually designated will not be evaluated against the established quality control ranges.
- If low and high value fields are left at zero (0), no check is made and all unflagged results are entered into the file.

Defining Quality Control Ranges

1. From the Main menu, touch QUALITY CONTROL, SELECT.
2. Touch the assay name, and SELECT.
3. Touch LOW VALUE. Type the appropriate value from the quality control package insert or the operator-determined value.
4. Touch HIGH VALUE. Type the appropriate value from the quality control package insert or the operator-determined value for the selected control level.
5. Repeat steps 2 through 4 for each control level.
6. Touch SAVE FILE. CODE 00166 FILE SAVED displays.
7. If desired, touch SELECT ANOTHER TEST.
8. Repeat steps 2 through 6 for each assay desired.
9. Touch EXIT.

Quality Control – Define

QC Screening

QC Screening is defined in the Instrument Options screen.

QC Screen On

When QC SCREEN: ON displays, controls are run in the Random mode at the beginning of the run. A status for each control level is displayed and maintained in the QC file. If less than three levels are run, the unused level is manually accepted. If the value for a QC sample falls outside the defined low or high range, CODE 00312 CONTROL FAILED OR MISSING FOR TEST: [redacted], PLEASE REVIEW QUALITY CONTROL STATUS is generated. Samples may be dispensed; however, the System does not report results for an assay for any patient sample until QC status is OK.

QC Screen Off

When QC SCREEN: OFF displays, and the value for a QC sample falls outside the defined low or high range, CODE 00285 TEST: [redacted] CONTROL OUT OF RANGE FOR CONTROL LEVEL: [redacted] ON SAMPLE ID: [redacted] is generated. The System does not use the value in the calculation of QC. However, samples run regardless of quality control results.

NOTE

WHEN PROCESSING QUALITY CONTROL WITH EACH CAROUSEL, IT IS RECOMMENDED THAT THE QC SCREEN BE DEFINED AS **OFF**.

Activating QC Screening

1. From the Main menu, touch SYSTEM FILES, SELECT. Touch INSTRUMENT OPTIONS, SELECT.
2. Touch QC SCREEN: OFF to display ON.
3. Touch STORE RESULTS. CODE 00166 FILE SAVED displays.
4. Touch EXIT.

De-activating QC Screening

1. From the Main menu, touch SYSTEM FILES, SELECT. Touch INSTRUMENT OPTIONS, SELECT.
2. Touch QC SCREEN: ON to display OFF.
3. Touch STORE RESULTS. CODE 00166 FILE SAVED displays.
4. Touch EXIT.

Quality Control – Process

Introduction

Quality control samples should be run in accordance with Good Laboratory Practice procedures. Two options are available for processing quality control samples: automatic and manual.

Processing Quality Control Automatically

Quality control values designated as /C in the NAME field of the Patient Samples screen are evaluated against the established quality control ranges. When a value falls within the low or high range defined in the Quality Control screen, the value is automatically stored. When a value falls outside the range, CODE 00285 TEST: [redacted] CONTROL OUT OF RANGE FOR CONTROL LEVEL: [redacted] ON SAMPLE ID: [redacted] displays. LOW or HIGH displays in the STATUS field of the Quality Control File, and the value is not entered or used in the calculation of the quality control mean, S.D., or % C.V.

NOTES

- SAMPLES WILL RUN REGARDLESS OF QUALITY CONTROL RESULTS.
- FLAGGED RESULTS WILL NOT BE ENTERED INTO QUALITY CONTROL CALCULATIONS.
- VALUES RESULTING FROM RATIO CALCULATIONS OF /C DESIGNATED SAMPLES ARE NOT EVALUATED AGAINST THE ESTABLISHED QUALITY CONTROL RANGES.

Processing Quality Control Manually

Quality control values not designated as /C 1, /C 2, or /C 3 in the NAME field of the Patient Samples screen may be manually sent to the Quality Control File when assays are complete.

1. From the Main menu, touch PATIENT SAMPLES, SELECT. Touch RECALL RESULTS.
2. Touch to highlight desired quality control samples. Touch SELECT.
3. Review values in the Recall Results screen and determine if acceptable. Touch CONTROLS. Touch the desired control level and allow the screen to update automatically.

NOTES

- FLAGGED RESULTS WILL BE ENTERED INTO QUALITY CONTROL CALCULATIONS.
- SAMPLE VALUES REVIEWED AND DESIGNATED AS CONTROLS AFTER THE RUN IS COMPLETE WILL NOT BE EVALUATED AGAINST ESTABLISHED QUALITY CONTROL RANGES BEFORE ENTRY INTO THE QUALITY CONTROL FILE.
- MANUAL QUALITY CONTROL ENTRIES WILL NOT BE COUNTED IN THE WORKLOAD ANALYSIS FILES.

Quality Control – Process

Quality Control Status

Quality control status is displayed in the STATUS field of the Quality Control screen.

HIGH	QC value for the level was above the set range.
LOW	QC value for the level was below the set range.
NEW	QC value for this level has never been run.
OK	QC value for the level was acceptable or has been manually accepted by the user.
RERUN	If results are not within range and QC SCREEN: ON displays in the Instrument Options screen, the operator is offered the option of accepting the level and storing the results, or rerunning the assay.
SCHED	QC value for this level is being run.

Changing QC Status

QC status may be manually edited from LOW or HIGH to OK.

1. From the Main menu, touch QUALITY CONTROL, SELECT.
2. Touch the assay name, SELECT.
3. Touch the desired LEVEL field. Touch ACCEPT.
4. Touch SAVE FILE. CODE 00166 FILE SAVED displays.
5. Touch EXIT.

Quality Control – Delete

Introduction

The Quality Control Delete function enables management of the Quality Control File.

The entire level must be deleted under the following circumstances:

- *** displays, indicating a value deleted from the file is moderately different from the mean (an approximate factor of two)
- 0000 displays in the MEAN, S.D., % C.V., and ENTRIES fields, indicating a value deleted from the file is significantly different from the mean (an approximate factor of five)

Deleting Quality Control

1. From the Main menu, touch QUALITY CONTROL, SELECT. Touch the desired assay name, and SELECT. Touch DELETE.
2. Select the appropriate option.

   To delete all result entries for this assay, touch ALL. Touch PROCEED. The screen updates automatically and retains the LOW and HIGH values.

   To delete a specific result entry of a specific level, touch ENTRY. The screen displays LEVEL: 1 above the ENTRIES field (1 is the default entry). Touch this field, and type the desired level. Use the cursor control keys to highlight VALUE 0.00000 adjacent to the LEVEL field. Type the value to be deleted, exactly as it displays in the Recall Results screen. Touch PROCEED. The screen updates automatically and retains the LOW and HIGH values.

   To delete all result entries for a specific level, touch LEVEL. The screen displays LEVEL: 1 above the ENTRIES field (1 is the default entry). Touch this field, and type the desired level. Touch PROCEED. The screen updates automatically and retains the LOW and HIGH values.
3. Touch EXIT.

Reagent Loadlist

Introduction

The Reagent Loadlist screen may be entered from the Review & Run screen or the Instrument Status screen. The reagent loadlist is created for the appropriate carousel when the Review & Run screen is entered and the carousel number is verified. The System verifies the sample loadlist against the reagents available when barcodes are scanned. REAGENT LOADLIST highlights to indicate reagents need to be placed on board or moved. For additional information, refer to Samples – Process in this section.

The reagent barcode reader uses infrared light to scan reagent cartridge barcode labels thre e times when the Review & Run screen is entered or READ REAGENT TRAY is touched in the Reagent Loadlist screen.

Information identified by the barcode reader includes:

- Type of reagent, e.g., Glucose, Calcium
- Master lot number (a one- or two-digit, alphanumeric code)
- Cartridge size and type

Upon completion of the scan, the barcode reader updates the reagent loadlist STATUS field. If the reagent tray is full and an additional reagent is needed, the System deletes reagent cartridges with an UNUSED status and assigns new reagents to an available position. When the Review & Run screen is entered, REAGENT LOADLIST is highlighted.

If either the non-cooled or cooled quadrants are full and an additional like reagent is needed, the System reschedules reagents into an available position in the appropriate quadrant. When the Review & Run screen is entered, REAGENT LOADLIST is highlighted.

NOTE

THE REAGENT LOADLIST IS DELETED WHEN TEST PARAMETER FILES ARE EDITED OR SYSTEM POWER IS CYCLED.

Reagent Loadlist Status

The status of reagents is displayed in the STATUS field of the Reagent Loadlist screen.

?	Indicates the System does not recognize the reagent because an error occurred in reading or typing the reagent name.
ASSIGNED	Indicates the reagent was assigned to that position by typing the name into the reagent loadlist or by touching the status LOAD NOW or ASSIGNED. If the reagent is ASSIGNED but no assays are requested, the ASSIGNED status is highlighted.
EMPTY	Indicates no reagent is detected.
LOAD NOW	Indicates the reagent must be loaded to run the assays or the barcode reader did not identify the reagent barcode.
LOT ID	Indicates the lot number read by the barcode reader is different from the previous reagent cartridge.
LOW REAGENT	Indicates there is insufficient volume of reagent to perform the scheduled assays if SWITCH LOW REAGENT is on. The status LOW REAG must be changed to ASSIGNED for the assay to be run.
MOVE REAGENT	Indicates the reagent should be moved to the appropriate quadrant of the tray.

Reagent Loadlist Status
(continued)

ON BOARD	Indicates the reagent is available for use.
UNUSED	Indicates the reagent is available for use but currently no assays are requested.

Automatic Reagent Loadlist

1. From the Main menu, touch REVIEW & RUN, SELECT or INSTRUMENT STATUS, SELECT.
2. Verify the carousel number.
3. Touch REVIEW adjacent to REAGENT LOADLIST.

WARNING

WHEN ADDING OR REMOVING REAGENTS TO OR FROM THE REAGENT CAROUSEL, ENSURE INSTRUMENT ROBOTICS ARE PAUSED OR HALTED, AND THE ACTIVITY FIELD DOES **NOT** DISPLAY **RUNNING** OR **AUX PENDING**.

4. As directed by the reagent loadlist, place appropriate reagents on the reagent carousel. As reagents are in place, touch LOAD NOW to display ON BOARD.
5. Touch NEXT PAGE to verify the status of additional reagents.
6. Touch EXIT.

Assigning a Reagent

The keyboard may be used to enter, delete, or rearrange reagents on the loadlist.

The status remains assigned until one of the following conditions occurs:

- The barcode reader identifies a different barcode in that position.
- The reagent name is overwritten with a new reagent name.
- The reagent is manually deleted from the loadlist.
- System power is cycled.

Assigning Single Reagent Cartridges

1. From the Main menu, touch REVIEW & RUN, SELECT. Touch REVIEW adjacent to REAGENT LOADLIST.
2. Touch the desired REAG NAME field position. Type the appropriate reagent name, exactly as it displays in the REAGENT NAME field of the Test Parameter File: Reagent Definition screen. Press ENTER. The status updates to display ASSIGNED.
3. Continue until all reagents are defined.
4. Load appropriate reagents in assigned positions.
5. Touch EXIT.

Reagent Loadlist

Assigning a Reagent
(continued)

Assigning Dual Reagent Cartridges (P1-8 only)

1. From the Main menu, touch REVIEW & RUN, SELECT. Touch REVIEW adjacent to REAGENT LOADLIST.
2. Touch the desired REAG NAME field position. Type the appropriate reagent name, exactly as it displays in the REAGENT NAME field of the Test Parameter File: Reagent Definition screen.
3. Type ***/*** after the reagent name and press ENTER.
4. A highlighted field displays below the core reagent name. Type the reagent name for the perimeter reagent and press ENTER.

NOTE

ENTRY IS REQUIRED IN THE PERIMETER FIELD IF IT IS HIGHLIGHTED. THE CURSOR REMAINS IN THIS FIELD UNTIL AN ENTRY IS MADE.

5. Repeat steps 2 through 4 until all reagents are defined.

Deleting a Reagent Loadlist Entry

Deleting Single Reagent Cartridges

1. From the Main menu, touch REVIEW & RUN, SELECT. Touch REVIEW adjacent to REAGENT LOADLIST.
2. Touch the appropriate field to highlight.
3. Press the BACKSPACE key or the SPACE BAR.
4. Touch EXIT.

Deleting Dual Reagent Cartridges

1. From the Main menu, touch REVIEW & RUN, SELECT. Touch REVIEW adjacent to REAGENT LOADLIST.
2. Use the cursor control keys to highlight the appropriate core reagent field.
3. Press the BACKSPACE key or the SPACE BAR.
4. Touch EXIT.

Introduction

A report prints automatically for each patient sample under the following conditions:

- AUTO PRINT displays ON.
- Printer power is on.
- Printer SELECT light is illuminated.
- All assays have been processed for a sample and have a status of COM (complete).
- A result was entered (in the case of an offline assay) or edited, and all other assays are complete.

Reports do not print automatically under the following conditions:

- AUTO PRINT displays OFF.
- Printer power is off.
- Printer SELECT light is not illuminated.
- A result is flagged or a dilution protocol is indicated, and all flags or dilution protocol have not been satisfied.

Reports may be manually printed. Refer to the appropriate printing procedure.

If the printer SELECT light is not illuminated or printer power is turned off while the System is transmitting a report to the printer, CODE 00026 PRINTER TIMEOUT ERROR is generated. The following sequence occurs.

1. The patient report in process is reprinted when the printer is functional. However, if a SID report with a lower number is requested, the report in process must be requested from the Recall Results screen.
2. All other print requests are prioritized as follows:
   - PRINT SCREEN key or sample loadlist (whichever was requested first)
   - Requests via the PRINT field in the Recall Results screen
   - AUTO PRINT

Selecting Report Spacing

The System defaults to a single-spaced printout. A double-spaced printout may be selected.

1. From the Main menu, touch SYSTEM FILES, SELECT. Touch PRINT ORDER, SELECT.
2. Touch DOUBLE SPACE to display ON.
3. Touch SAVE. CODE 00166 FILE SAVED displays.
4. Touch EXIT.

Reports

Selecting Result Units

The System allows the selection of result units.

1. From the Main menu, touch SYSTEM FILES, SELECT. Touch PRINT ORDER, SELECT.
2. Touch PRINT UNITS. Press the CYCLE key to display the appropriate unit (PRIMARY, SECONDARY, or BOTH).
3. Touch SAVE. CODE 00166 FILE SAVED displays.
4. Touch EXIT.

Printing All SIDs

1. From the Main menu, touch PATIENT SAMPLES, SELECT. Touch RECALL RESULTS.
2. Touch PRINT. All SIDs in the System print.
3. Touch EXIT.

Printing Specific SIDs

1. From the Main menu, touch PATIENT SAMPLES, SELECT.
2. Touch SID, and type the appropriate SID number (from the sample loadlist).
3. Touch RECALL RESULTS.
4. Touch PRINT.
5. Touch EXIT.

Printing Specific SID by Name

1. From the Main menu, touch PATIENT SAMPLES, SELECT.
2. Touch NAME, and type the appropriate name (full last name, partial last name, or first letter of the last name).
3. Touch RECALL RESULTS. If more than one selection displays, select the desired patient.
4. Touch PRINT.
5. Touch EXIT.

Printing Selected SIDs

1. From the Main menu, touch PATIENT SAMPLES, SELECT. Touch RECALL RESULTS.
2. Touch to highlight the appropriate SIDs. Touch NEXT PAGE to display additional SIDs. When appropriate SIDs have been highlighted, touch SELECT.
3. Touch PRINT. The first SID prints.
4. While the report is printing, touch NEXT SAMPLE and PRINT to print each selected SID.
5. Touch EXIT.

Printing Carousel

1. From the Main menu, touch PATIENT SAMPLES, SELECT.
2. Touch CAR#, and type the desired carousel number.
3. Touch RECALL RESULTS.
4. Touch PRINT.
5. Touch EXIT.

Table 2-5 Report Summary

Sample Status	PATIENT SAMPLES SCREEN				PRINTED REPORT			
	Test Status	Result	Flag	Units	Result	Flag	Units	Auto Print
Sample and Assay	ENT	NO	NO	Pending	NO	NO	Pending	NO
Test in Process First Time	SCH	NO	NO	Pending	NO	NO	Pending	NO
Test Completed	COM	YES	NO	Units	YES	NO	Units	YES
	COM	YES	IA	Units	NO	@	Pending	YES
	COM	YES	MA	Units	NO	@	Pending	YES
	COM	YES	LE	Units	NO	@	Pending	YES
	ENT	YES	LL DP or LH DP	Pending	NO	* or @	Pending	NO
Out of Range Test Rescheduled First Time	ENT	NO	LL DP or LH DP	Pending	NO	* or @	Pending	YES
	ENT	YES	LL DP or LH DP	Pending	NO	* or @	Pending	NO
Out of Range Test in Process	SCH	YES	LL DP or LH DP	Pending	NO	* or @	Pending	NO
Test Completed Second Time (Results in Range)	COM	YES	DP	Units	YES	DP	Units	YES
Test Completed Second Time (Results Out of Range)	COM	YES	LL or LH	Units	YES	* or @	Units	YES
Test Completed (Results Edited)	COM	YES	#	Units	YES	#	Units	YES
Test Completed (No Dilution Protocol Defined)	COM	YES	LL or LH	Units	NO	@	Pending	YES

@	=	Flagged result.
#	=	User entered result.
*******	=	Indicates an attempt has been made to divide by zero. If displayed for a rate reaction, the zero may be present in the extinction factor. Refer to the instrument label for the correct extinction factor and enter the information in the appropriate Test Parameter File.
*	=	Dilution Protocol (printed).
DP	=	Dilution Protocol (screen).
IA	=	Initial Absorbance. Refer to Status Code 00011 in the Maintenance & Troubleshooting Manual.
MA	=	Maximum Absorbance. Refer to Status Codes 00012 and 00287 in the Maintenance & Troubleshooting Manual.
LE	=	Low Energy. Refer to Status Code 00027 in the Maintenance & Troubleshooting Manual.
LL	=	Linear Low. Refer to Status Code 00013 in the Maintenance & Troubleshooting Manual.
LH	=	Linear High. Refer to Status Code 00013 in the Maintenance & Troubleshooting Manual.
ENT	=	Assay has been requested and will be run next time RUN is touched in the Review & Run screen.
SCH	=	Assay is in process.
COM	=	Assay is complete.

Results – Edit

Introduction

Assay results completed by the System, or assays defined as offline, may be edited. The assay and result flags that accompanied the original result, e.g., IA, MA, LL, are deleted when the result is edited.

Editing Results

1. From the Main menu, touch PATIENT SAMPLES, SELECT. Touch RECALL RESULTS.
2. Touch to highlight the appropriate SID. Touch PRINT to document the current results. Touch NEXT PAGE if more than ten assays are requested for the SID.
3. Touch to highlight the RESULTS field to be edited. Type the appropriate result, and press ENTER.
4. When ENTER is pressed, the RERUN field displays RESTORE. Touch RESTORE. The previous result is deleted and updated with the edited result and a COM (complete) status.
5. A report prints automatically, if AUTO PRINT is on and all assays on the SID are complete. A flag accompanies the results, and is footnoted, # User Entered Result.
6. Touch NEXT SAMPLE if more than one SID was recalled.
7. Repeat steps 2 through 6 until appropriate results are edited.
8. Touch EXIT.

Results – Offline

Introduction

Assay results generated by an analyzer other than the ABBOTT SPECTRUM SERIES II System may be typed into the Recall Results screen to provide a complete patient report. Offline assay results may be entered if the assay is defined in the Test Parameter Files and has been requested in the Patient Samples screen.

Entering Offline Results

1. From the Main menu, touch PATIENT SAMPLES, SELECT. Touch RECALL RESULTS.
2. Touch to highlight appropriate SIDs. Highlight the RESULTS field to be edited. Type the appropriate result, and press ENTER.
3. When ENTER is pressed, the RERUN field displays RESTORE. Touch RESTORE. The result displays with a COM (complete) status.
4. A report prints, if AUTO PRINT is on and all assays on the SID are complete. A flag accompanies the results, and is footnoted, # User Entered Result.
5. Touch NEXT SAMPLE if more than one SID was recalled.
6. Repeat steps 2 through 5 until appropriate results are edited.
7. Touch EXIT.

Introduction

The Recall Results function is used to view the assay result status. It is also the function under which assay results are entered and edited, assays are rerun, and quality control is manually assigned.

Recalling All SIDs

1. From the Main menu, touch PATIENT SAMPLES, SELECT. Touch RECALL RESULTS.
2. Touch ALL to display the first SID number. The screen displays ten assays per page. Touch NEXT PAGE to display additional assays.
3. Touch NEXT SAMPLE to view the next SID number.
4. Touch EXIT.

Recalling Specific SIDs

1. From the Main menu, touch PATIENT SAMPLES, SELECT.
2. Touch SID, and type the appropriate SID number (from the sample loadlist). Touch RECALL RESULTS.
3. The screen displays ten assays per page. Touch NEXT PAGE to display additional assays.
4. Touch EXIT.

Recalling Specific SID by Name

1. From the Main menu, touch PATIENT SAMPLES, SELECT.
2. Touch NAME, and type the appropriate name (full last name, partial last name, or first letter of the last name).
3. Touch RECALL RESULTS. If more than one selection displays, select the desired patient.
4. The screen displays ten assays per page. Touch NEXT PAGE to display additional assays.
5. Touch EXIT.

Recalling Selected SIDs

1. From the Main menu, touch PATIENT SAMPLES, SELECT. Touch RECALL RESULTS.
2. Touch the appropriate SIDs. Touch NEXT PAGE to display additional SIDs. When appropriate SIDs have been highlighted, touch SELECT.
3. Touch NEXT SAMPLE to view selected SIDs.
4. Touch EXIT.

Recalling Carousel

1. From the Main menu, touch PATIENT SAMPLES, SELECT.
2. Touch CAR#, and type the desired carousel number. Touch RECALL RESULTS.
3. Touch the appropriate SIDs. Touch NEXT PAGE to display additional SIDs. Touch SELECT.
4. Touch NEXT SAMPLE to view selected SIDs.
5. Touch EXIT.

Sample Distribution

Introduction

The Sample Distribution function provides resettable and cumulative totals of samples run on the System. When a SID has been entered into the System, it is included in one of the following categories: STAT, ROUTINE, or CONTROL. For each category, the percentage of the active and cumulative totals is displayed. The active counters can be reset and provide a sample distribution for specific time periods, determined by the user. Cumulative counters cannot be reset by the user and are a permanent record of the number and type of samples run. A printed report containing the sample information may be generated.

NOTES

- SIDS MANUALLY DESIGNATED AS A CONTROL IN THE RECALL RESULTS SCREEN ARE NOT COUNTED AS A CONTROL IN THE SAMPLE DISTRIBUTION SCREEN.
- THE NUMBERS SHOWN ON THE DISPLAY RESET AUTOMATICALLY AT 4.2 BILLION. ALWAYS REFERENCE NUMBERS ON THE PRINTOUT WHEN THE MOST ACCURATE DATA IS REQUIRED.

Accessing and Printing Sample Distribution

1. From the Main menu, touch SYSTEM FILES, SELECT. Touch WORK ANALYSIS, SELECT.
2. When the Workload Analysis screen displays, touch SAMPLE DIST.
3. When the Sample Distribution screen displays, touch PRINT REPORT. A report is generated which contains all data displayed on the Sample Distribution screen. Ensure the printer is on and SELECT is illuminated.
4. Touch EXIT.

Resetting and Printing Sample Distribution

1. From the Main menu, touch SYSTEM FILES, SELECT. Touch WORK ANALYSIS. Use the cursor control keys to access the hidden password field to the right of WORK ANALYSIS. Type the appropriate password and press ENTER. Touch SELECT.
2. When the Workload Analysis screen displays, touch SAMPLE DIST.
3. When the Sample Distribution screen displays, touch RESET AND PRINT REPORT. A Y/N prompt and CODE 00507 PROCEED WITH RESET? display.
4. Select the appropriate option:

   To reset the counters, type Y (Yes). The screen updates, the RESET DATE field displays the current date, and a report is generated (if the printer is on and SELECT is illuminated).

   To avoid resetting the counters, type N (No).
5. Touch EXIT.

Sample Loadlist

Introduction

The Sample Loadlist screen may be entered from the Review & Run screen or the Instrument Status screen. The sample loadlist is created for the appropriate carousel when the Review & Run screen is entered and the carousel number is verified.

While in the Sample Loadlist screen, a printout may be requested. The printout documents the position number of all samples currently in memory, the assays requested on each patient, the SID number, patient name (if entered at the time the sample loadlist is printed), and location of available positions in the sample carousel. When a loadlist is printed, the unused positions are labeled UNUSED. An unused carousel is identified by UNUSED CAROUSEL.

As new samples are requested in the Patient Samples screen, they are placed in the next available carousel position. The samples remain on the loadlist at the completion of operation and are removed by following the appropriate sample deletion procedure. Refer to Samples - Delete in this section.

Printing the Sample Loadlist

1. From the Main menu, touch REVIEW & RUN, SELECT or INSTRUMENT STATUS, SELECT.
2. Touch REVIEW adjacent to SAMPLE LOADLIST.
3. Verify the printer is on and SELECT is illuminated.
4. Touch PRINT LOADLIST. The message CAROUSEL NUM: ALL displays. (The default is ALL.)

   To print one copy of all carousel loadlists in the System memory, press ENTER.

   To print a specific carousel, type the carousel number (valid entries are 1-6), and press ENTER.
5. Touch EXIT.

Samples – Delete

Introduction

Patient SIDs, test requests, and results are held in the System's non-volatile memory. The Delete Function is used to remove all record of the sample, and respective assays, from the System memory.

Deleting All SIDs

1. Verify that the ACTIVITY field is not highlighted.
2. From the Main menu, touch PATIENT SAMPLES, SELECT. Touch DELETE.
3. When the Delete screen displays, touch ALL.
4. Touch PROCEED. The deletion process may be observed in the highlighted field above the AUTO PRINT field. When all SIDs have been deleted, the Patient Samples screen displays automatically.

Deleting Specific SIDs

1. Verify that the ACTIVITY field is not highlighted.
2. From the Main menu, touch PATIENT SAMPLES, SELECT.
3. Type the appropriate SID (from the sample loadlist), and press ENTER.
4. When the SID displays, touch DELETE.
5. Touch PROCEED. When the SID has been deleted, the Patient Samples screen displays automatically.

Deleting Selected SIDs

1. Verify that the ACTIVITY field is not highlighted.
2. From the Main menu, touch PATIENT SAMPLES, SELECT. Touch DELETE.
3. When the Delete screen displays, a list of SID numbers displays. Touch to highlight the appropriate SID numbers. If the desired SID is not displayed, touch NEXT PAGE until the appropriate SID displays. Select all SIDs to be deleted before proceeding.
4. Touch PROCEED. When the SIDs have been deleted, the Patient Samples screen displays automatically.

Deleting Patient Name

1. Verify that the ACTIVITY field is not highlighted.
2. From the Main menu, touch PATIENT SAMPLES, SELECT.
3. Touch NAME, and type the appropriate patient name.
4. Touch DELETE.
5. Touch PROCEED. When the patient name has been deleted, the Patient Samples screen displays automatically.

Deleting Carousel Number and/or Position Number

1. Verify that the ACTIVITY field is not highlighted.
2. From the Main menu, touch PATIENT SAMPLES, SELECT.
3. Touch CAR#, and type the appropriate carousel number.
4. Touch POS #, and type the appropriate position number.
5. Touch DELETE.
6. Touch PROCEED. When the carousel number and/or position number has been deleted, the Patient Samples screen displays automatically.

Samples – Routine Requests

Introduction

Follow the appropriate procedure to request samples.

WARNING

BEFORE ADDING OR REMOVING PATIENT SAMPLES TO OR FROM THE SAMPLE CAROUSEL, ENSURE INSTRUMENT ROBOTICS ARE PAUSED OR HALTED, AND **NO ACTIVITY** OTHER THAN **READING** IS DISPLAYED IN THE ACTIVITY FIELD. THIS WILL PREVENT POSSIBLE INTERFERENCE WITH ROBOTICS.

CAUTION

FAILURE TO FOLLOW THE SAMPLE ENTRY PROCEDURE PRECISELY MAY CREATE AN UNEXPECTED SAMPLE LOADLIST. SAMPLE LOADLIST MUST BE VERIFIED PRIOR TO TOUCHING RUN.

NOTE

WHEN MANUALLY ASSIGNING SID NUMBERS, THE SYSTEM MAY RECOGNIZE THREE-DIGIT NUMBERS AS SPECIFIC CAROUSEL AND POSITION.

Requesting Samples by System-Assigned SID, CAR#, and POS #

1. From the Main menu, touch PATIENT SAMPLES, SELECT.
2. Touch the appropriate assays and/or panels. The SID, CAR#, and POS # are automatically assigned.
3. Touch NAME, and type the appropriate name. Touch NEXT SAMPLE.
4. Continue entering sample information until all samples have been requested. Touch NEXT SAMPLE after each sample request.

Requesting Samples by Specific SID with System-Assigned CAR# and POS #

1. From the Main menu, touch PATIENT SAMPLES, SELECT.
2. Type the appropriate SID number. The CAR# and POS # are automatically assigned.
3. Touch NAME, and type the appropriate name.
4. Touch the appropriate assays and/or panels. Touch NEXT SAMPLE.
5. Continue entering sample information until all samples have been requested. Touch NEXT SAMPLE after each sample request.

Requesting Samples by Manually Assigned SID, CAR#, and POS #

1. From the Main menu, touch PATIENT SAMPLES, SELECT.
2. Type the appropriate SID number.
3. Touch CAR#, and type the appropriate carousel number.
4. Touch POS #, and type the appropriate position number (valid entries are 1–48).
5. Touch NAME, and type the appropriate name.
6. Touch the appropriate assays and/or panels. Touch NEXT SAMPLE.
7. Continue entering sample information until all samples have been requested. Touch NEXT SAMPLE after each sample request.

Requesting Samples by Specific POS #

1. From the Main menu, touch PATIENT SAMPLES, SELECT.
2. The SID and CAR# may be automatically assigned, or typed.
3. Touch POS #. Type /R and the specific positions desired, e.g., /R16-23.
4. Touch the appropriate assays or panels. Touch NEXT SAMPLE.
5. Observe the assignment of SIDs above the AUTO PRINT field.
6. Continue entering sample information until all samples have been requested. Touch NEXT SAMPLE after each sample request.

Requesting Multiple Samples with Same Type Assays or Panels

1. From the Main menu, touch PATIENT SAMPLES, SELECT.
2. Touch POS #. Type **/** and the specific position desired, e.g., /10.
3. Touch the appropriate assays and/or panels. Touch NEXT SAMPLE.
4. Observe the assignment of SIDs above the AUTO PRINT field.
5. Continue entering sample information until all samples have been requested. Touch NEXT SAMPLE after each sample request.

Samples – STAT Requests

Introduction

The ABBOTT SPECTRUM SERIES II System is designed to allow STAT assay requests. If a STAT assay is requested after a run is in progress, the System determines the appropriate time window, and begins the STAT test as soon as possible without jeopardizing assays in progress. When processing of the STAT begins, all tests for that STAT are dispensed before the regularly scheduled tests resume. A report prints automatically when all STAT assays are complete (if AUTO PRINT is on and a dilution protocol is not required).

NOTE

WHEN MANUALLY ASSIGNING SID NUMBERS, THE SYSTEM MAY RECOGNIZE THREE-DIGIT NUMBERS AS SPECIFIC CAROUSEL AND POSITION.

Requesting STAT Samples

1. From the Main menu, touch PATIENT SAMPLES, SELECT.
2. Touch SID. The SID number may be automatically assigned, or typed.
3. Touch CAR#. The carousel number may be automatically assigned, or typed.
4. Touch STAT. The POS # is automatically assigned by the System.
5. Touch the appropriate assays or panels. Touch NEXT SAMPLE to display the STAT Sample screen.
6. Touch NEXT STAT.
7. Repeat steps 2 through 6 until all STATs are requested.
8. Touch PROCEED. The System automatically displays the Review & Run screen.

WARNING

BEFORE ADDING OR REMOVING PATIENT SAMPLES TO OR FROM THE SAMPLE CAROUSEL, ENSURE INSTRUMENT ROBOTICS ARE PAUSED OR HALTED, AND **NO ACTIVITY** OTHER THAN **READING** IS DISPLAYED IN THE ACTIVITY FIELD. THIS WILL PREVENT POSSIBLE INTERFERENCE WITH ROBOTICS.

Introduction

After samples have been requested, complete the following procedure to process samples.

Processing Samples

1. Display the Review & Run screen. If entering from the Patient Samples screen, touch REVIEW & RUN. If entering from the Main menu, touch REVIEW & RUN, SELECT.
2. When the sample carousel ID reader identifies the carousel, CAROUSEL NUMBER READ WAS: # IF DESIRED, ENTER SAMPLE CAROUSEL NUMBER (1–6): displays. Verify the carousel number.
3. Select the appropriate option:

   If the carousel number is correct, press ENTER to continue.

   If the sample carousel ID reader identifies a different carousel, SAMPLE CAR. ID DIFFERS FROM PREVIOUS – CONTINUE: Y/N displays.

   If the identified carousel is appropriate, type Y (Yes) and press ENTER to continue. CODE 00200 SAMPLE CAROUSEL # CHANGED displays momentarily.

   If the identified carousel is inappropriate, type N (No) and press ENTER. Mount the correct carousel, type the carousel number, and press ENTER.
4. The System recognizes discrepancies between the reagent loadlist and the reagents on board, and between the calibrator loadlist and calibrators/standards on board.

   If REAGENT LOADLIST is highlighted, proceed to step 5.

   If CALIBRATOR LOADLIST is highlighted, proceed to step 9.

   If neither loadlist is highlighted, proceed to step 11.
5. When the message PLEASE WAIT, BUILDING REAGENT & CALIBRATOR LOADLISTS disappears, touch REVIEW adjacent to REAGENT LOADLIST.
6. Verify the status of each reagent. Touch NEXT PAGE to verify the status of additional reagents.
7. Reconstitute required reagents and place in appropriate quadrant positions.

Processing Samples
(continued)

8. Select the appropriate option.

   Option 1

   Touch READ REAGENT TRAY. The barcode activates and updates the status to display ON BOARD. This status indicates the cartridge has been properly identified and assays have been requested requiring use of the reagent.

   Option 2

   Touch LOAD NOW. The status updates to display ASSIGNED. This status indicates the reagent name was typed into the reagent loadlist, or ON BOARD or LOAD NOW was touched. The status remains ASSIGNED until one of the following conditions occurs:

   - The barcode reader identifies a different barcode in that position.
   - The reagent name is overwritten with a new reagent name.
   - The reagent is manually deleted from the loadlist.
   - The System power is cycled.

   Reagents with an ASSIGNED status, which are not required for the requested samples, will have a highlighted STATUS field.

9. If CALIBRATOR LOADLIST was highlighted in the Review & Run screen, touch CALIBRATOR LOADLIST and proceed to step 10. If CALIBRATOR LOADLIST was not highlighted, proceed to step 11.

10. As directed by the calibrator loadlist, place the appropriate calibrators/standards in the designated location. Touch LOAD NOW to display ON BOARD. Touch NEXT PAGE to verify the status of additional calibrators/standards.

CAUTION

FAILURE TO FOLLOW SAMPLE ENTRY PROCEDURE PRECISELY MAY CREATE AN UNEXPECTED SAMPLE LOADLIST. SAMPLE LOADLIST MUST BE VERIFIED PRIOR TO TOUCHING **RUN**.

11. Touch SAMPLE LOADLIST. (If proceeding from step 4, touch REVIEW adjacent to SAMPLE LOADLIST.) Verify the sample loadlist.

12. Verify the printer is on and SELECT is illuminated.

13. Touch PRINT LOADLIST. The message CAROUSEL NUM: ALL displays. (The default is ALL.)

    To print one copy of all carousel loadlists in the System memory, press ENTER.

    To print a specific carousel, type the carousel number (valid entries are 1–6), and press ENTER.

Processing Samples
(continued)

14. Touch EXIT.

WARNING

BEFORE ADDING OR REMOVING PATIENT SAMPLES TO OR FROM THE SAMPLE CAROUSEL, ENSURE INSTRUMENT ROBOTICS ARE PAUSED OR HALTED, AND **NO ACTIVITY** OTHER THAN **READING** IS DISPLAYED IN THE ACTIVITY FIELD. THIS WILL PREVENT POSSIBLE INTERFERENCE WITH ROBOTICS.

15. Verify the ACTIVITY field is not highlighted or displays READING.
16. Utilizing the printed loadlist, place sample cups with the appropriate patient sample on the sample carousel.
17. When samples, reagents, and calibrators/standards are on board and all covers are in place, touch RUN. The System verifies robotics with homing sequence, electronics, and optics.
18. **Do not touch EXIT**. Allow the System to display the Main menu automatically.

NOTE

IF EXIT IS TOUCHED PRIOR TO OR AFTER TOUCHING RUN, THE MESSAGE **TO RESUME DISPENSING, TOUCH RUN** DISPLAYS. THE SYSTEM COMPLETES THE REVIEW PROCESS OF THE LOADLISTS OR A HOME ROBOTICS SEQUENCE (IF INITIATED) AND PAUSES. NO STATUS CODE DISPLAYS DURING THE PAUSE. TOUCH **RUN** TO CONTINUE OPERATION.

IF EXIT IS TOUCHED A SECOND TIME, THE MESSAGE **SYSTEM PAUSED** DISPLAYS. SCHEDULED OPTICAL ASSAYS CONTINUE, BUT FURTHER DISPENSE ACTION STOPS. THE SYSTEM DISREGARDS THE COMMAND TO RUN AND AUTOMATICALLY DISPLAYS THE MAIN MENU. TOUCH **RUN** TO CONTINUE OPERATION.

Spectral Correction

Introduction

The Spectral Correction function allows the operator to adjust the test parameter calculation.

WARNING

INCORRECT IMPLEMENTATION OF THE SPECTRAL CORRECTION FUNCTION MAY PRODUCE ERRONEOUS RESULTS AND FLAGS.

FOR PRE-PROGRAMMED ASSAYS, SPECTRAL CORRECTION SHOULD NOT BE ACTIVATED OR EDITED UNLESS SPECIFICALLY INDICATED IN THE REAGENT PACKAGE INSERT PROVIDED BY ABBOTT LABORATORIES.

FOR NON-ABBOTT APPLICATIONS, THE USER MUST VERIFY THE CORRECT IMPLEMENTATION OF THE SPECTRAL CORRECTION FUNCTION.

Spectral correction fields for individual tests are located in the wavelength designation areas of the Reagent Definition screen in the Test Parameter Files.

Defining Spectral Correction

Spectral correction is defined in the following columns and fields:

PRIM/SEC

Designates the wavelength pair at which readings are taken.

USE IN

Designates use of the wavelength pair in the spectral correction equation. Valid entries are:

A	Primary wavelength is used in the spectral correction equation.
B-E	Define where the readings are used in the spectral calculation.
LE	Monochromatic wavelength is used for a low energy check.
NO	Wavelength pair is not used in calculations.

CONST

Designates what is multiplied by the reading taken at the wavelengths defined in that row.

E.F.

Designates the extinction factor for the assay (entered only in the first row).

SPECTRAL CORRECTION LOW/HIGH

Designates the range on the value of the reading multiplied by the constant. The value in the low/high range is reagent blank corrected. If the A_d value is outside this range, the sample is flagged LE and CODE 00288 TEST: [redacted] POLYCHROMATIC RANGE CHECK FAILED FOR SAMPLE ID: [redacted] or CODE 00289 TEST: [redacted] POLYCHROMATIC RANGE CHECK FAILED FOR CALIBRATOR: [redacted] displays.

CONSTANT INTERCEPT

The constant (K), expressed in A_d from the spectral correction equation.

CORRECTION LIMIT

The limit at which the spectral correction contribution is corrected, using the spectral correction equation.

Activating Spectral Correction

Spectral correction is activated by entering a selection other than A in the USE IN column. If no other selection is entered in the USE IN column, the readings taken at the primary wavelength (A) are multiplied by the constant for A before calculations are made.

If B is entered in the USE IN column, the equation is calculated as shown in Equation 2-4:

$$\text{Adjusted} - AD = (A_{d_A} \times \text{Constant A}) - (A_{d_B} \times \text{Constant B})$$

(Equation 2-4)

If C, D, or E is entered in the USE IN column, or a value is entered in the CONSTANT INTERCEPT field, the spectral correction is considered in the calculation. Refer to Equation 2-5.

$$\text{Spectral Correction} = (A_{d_C} \times \text{Constant C}) - (A_{d_D} \times \text{Constant D}) - (A_{d_E} \times \text{Constant E}) + \text{Constant Intercept}$$

(Equation 2-5)

If the CORRECTION LIMIT defined in the Test Parameter File is less than or equal to the calculated spectral correction, as defined in Equation 2-5, then calculated spectral correction is determined by Equation 2-6.

$$\text{Adjusted } A_d = (A_{d_A} \times \text{Constant A}) - (A_{d_B} \times \text{Constant B}) - (A_{d_C} \times \text{Constant C}) - (A_{d_D} \times \text{Constant D}) - (A_{d_E} \times \text{Constant E}) + \text{Constant Intercept}$$

(Equation 2-6)

NOTE

THE SPECTRAL CORRECTION LIMIT AND THE CONSTANT INTERCEPT, DEFINED IN THE TEST PARAMETER FILE, WILL BE VOLUME CORRECTED FOR DILUTION PROTOCOL.

If the CORRECTION LIMIT defined in the Test Parameter File is greater than the calculated spectral correction (as defined in Equation 2-5), then the adjusted A_d is determined by Equation 2-7.

$$\text{Adjusted } A_d = (A_{d_A} \times \text{Constant A}) - (A_{d_B} \times \text{Constant B})$$

(Equation 2-7)

NOTE

IF NO ENTRY EXISTS FOR A GIVEN USE IN B, C, D, OR E, THE RESULTANT ENTRY IN EQUATIONS 2-4 AND 2-5 WILL BE ZERO.

Spectral Correction

De-activating Spectral Correction for Routine Assays

The spectral correction fields are located in the wavelength designation of the Reagent Definition screen.

1. Enter the primary wavelength in each of the six PRIM fields.
2. Enter the secondary wavelength in each of the first five SEC fields. Enter the MA designation in the sixth SEC field.
3. Enter A in the first five USE IN fields. Enter LE in the sixth USE IN field.
4. Enter 1.00 in each of the six CONST fields.
5. Enter the extinction factor, if necessary, in the first E.F. field.
6. Enter 0.00 in each of the six SPECTRAL CORRECTION LOW fields.
7. Enter 0.00 in each of the six SPECTRAL CORRECTION HIGH fields.
8. Enter 0.00 in each of the six CONSTANT INTERCEPT fields.
9. Enter 0.00 in each of the six CORRECTION LIMIT fields.

Switch Low Reagent

Introduction

The Switch Low Reagent function is used in conjunction with cartridge transfer (an automatic, software-controlled feature). When two or more cartridges of the same reagent are available on the System, the System automatically switches to the next lowest position number of like reagent when the cartridge status is EMPTY or LOW REAG:

- EMPTY Indicates the cartridge is void of reagent.
- LOW REAG Indicates reagent volume is low, but 3–5 dispenses remain (in small cartridges).

Status codes are generated to indicate the transfer. Refer to Status Codes in the Maintenance & Troubleshooting Manual.

Activating Switch Low Reagent

1. From the Main menu, touch SYSTEM FILES, SELECT.
2. Touch INSTRUMENT OPTIONS, SELECT.
3. Touch SWITCH LOW REAG: OFF to display ON.
4. Touch STORE RESULTS. CODE 00166 FILE SAVED displays.
5. Touch EXIT.

De-activating Switch Low Reagent

1. From the Main menu, touch SYSTEM FILES, SELECT.
2. Touch INSTRUMENT OPTIONS, SELECT.
3. Touch SWITCH LOW REAG: ON to display OFF.
4. Touch STORE RESULTS. CODE 00166 FILE SAVED displays.
5. Touch EXIT.
6. Due to the transfer time and the mechanism of scheduling samples, some samples may be re-entered into System memory. If this occurs, from the Main menu, touch REVIEW & RUN, SELECT. Touch RUN.

Test Parameter Files

Introduction

Test Parameter Files consist of a Test Definition screen, a Calibration Definition screen and a Reagent Definition screen for each assay, ratio, or offline assay. A maximum of 127 assays may be entered. The information in the Test Parameter Files is used by the System for operation, report formatting, and reagent limits designation.

ABBOTT SPECTRUM® reagents are accompanied by a package insert containing information required to define each assay.

The Test Parameter Files may be viewed and printed without a password. However, the current password must be entered to define, edit, or delete files. All patients must be deleted from memory before defining, editing, or deleting a Test Parameter File.

Each field in the Test Parameter File, except ENTRY NAME, REAGENT NAME, TEST TYPE, and MATH may be edited without deleting the file. Test Parameter Files are edited for the following reasons:

- Calibrator/standard concentration values changed with a lot number change.
- Recommendation from a reagent package insert or a notification from Abbott Laboratories.
- A new reference/normal range is established by the operator or the range is changed due to a recommendation from a reagent package insert.

Defining Test Parameter Files

1. From the Main menu, touch PATIENT SAMPLES, SELECT. Touch DELETE. Touch ALL. Touch PROCEED.
2. From the Main menu, touch QUALITY CONTROL, SELECT. Touch the appropriate assay name, and SELECT. Press the PRINT SCREEN key to document the Quality Control File. Retain for laboratory documentation records. Touch EXIT.
3. From the Main menu, touch SYSTEM FILES, SELECT.
4. Touch TEST PARAMETER FILES. Use the cursor control keys to access the hidden password field to the right of TEST PARAMETER FILES. Type the appropriate password, and press ENTER. Touch SELECT.
5. Touch ENTRY NAME. Type the name that will identify the new assay, and press ENTER. CODE 00165 CREATING TEST FILE displays.
6. Highlight each field and enter the appropriate information. Refer to Test Parameter File: Test Definition in the Touch Screens section for specific field information.
7. When entries are complete, touch SAVE TEST. CODE 00166 FILE SAVED displays.
8. Touch DEFINE CALIB to display the Calibration Definition screen. Highlight each field and enter the appropriate information. Refer to Test Parameter File: Calibration Definition in the Touch Screens section for specific field information.
9. When all entries have been made, touch SAVE CALIB. CODE 00166 FILE SAVED displays.

Defining Test Parameter Files (continued)

10. Touch DEFINE REAGENT to display the Reagent Definition screen. Highlight each field and type the appropriate information. Refer to Test Parameter File: Reagent Definition in the Touch Screens section for specific field information.
11. When entries are complete, touch SAVE/NEXT REAGENT. The System automatically displays the Test Definition screen.
12. When new assays are entered, the wash matrix must be edited. Refer to Wash Matrix in this section and the Touch Screens section for additional information.

Defining Offline Test Parameter Files

1. From the Main menu, touch PATIENT SAMPLES, SELECT. Touch DELETE. Touch ALL. Touch PROCEED.
2. From the Main menu, touch QUALITY CONTROL, SELECT. Touch the appropriate assay name, and SELECT. Press the PRINT SCREEN key to document the Quality Control File. Retain for laboratory documentation records. Touch EXIT.
3. From the Main menu, touch SYSTEM FILES, SELECT.
4. Touch TEST PARAMETER FILES. Use the cursor control keys to access the hidden password field to the right of TEST PARAMETER FILES. Type the appropriate password, and press ENTER. Touch SELECT.
5. Touch ENTRY NAME. Type the name that will identify the new assay, and press ENTER. CODE 00165 CREATING TEST FILE displays.
6. Touch TEST TYPE, and press the CYCLE key to display OFFLINE. Press ENTER.
7. Enter the appropriate information in the REPORT NAME, UNITS, PRINT DIGITS, and NORMAL [C] fields.
8. Touch SAVE TEST. CODE 00166 FILE SAVED displays.
9. Touch EXIT.

Test Parameter Files

Editing Test Parameter Files

1. From the Main menu, touch PATIENT SAMPLES, SELECT. Touch DELETE. Touch ALL. Touch PROCEED.
2. From the Main menu, touch QUALITY CONTROL, SELECT. Touch the appropriate assay name, and SELECT. Press the PRINT SCREEN key to document the Quality Control File. Retain for laboratory documentation records. Touch EXIT.
3. From the Main menu, touch SYSTEM FILES, SELECT.
4. Touch TEST PARAMETER FILES. Use the cursor control keys to access the hidden password field to the right of TEST PARAMETER FILES. Type the appropriate password, and press ENTER. Touch SELECT.
5. Touch ENTRY NAME, and type the appropriate assay name. Press ENTER.
6. When the Test Parameter File displays, highlight the fields to be edited and type the information. When edits are complete, touch SAVE TEST. CODE 00166 FILE SAVED displays.
7. If appropriate, touch DEFINE CALIB to display the Calibration Definition screen. Enter the appropriate information. When entries are complete, touch SAVE CALIB. CODE 00166 FILE SAVED displays.
8. If appropriate, touch DEFINE REAGENT to display the Reagent Definition screen. Enter the appropriate information. When entries are complete, touch SAVE/NEXT REAGENT. The System automatically displays the Test Definition screen.
9. Touch EXIT.

Deleting Test Parameter Files

1. From the Main menu, touch PATIENT SAMPLES, SELECT. Touch DELETE. Touch ALL. Touch PROCEED.
2. From the Main menu, touch QUALITY CONTROL, SELECT. Touch the appropriate assay name, and SELECT. Press the PRINT SCREEN key to document the Quality Control File. Retain for laboratory documentation records. Touch EXIT.
3. From the Main menu, touch SYSTEM FILES, SELECT.
4. Touch TEST PARAMETER FILES. Use the cursor control keys to access the hidden password field to the right of TEST PARAMETER FILES. Type the current password, and press ENTER. Touch SELECT.
5. Touch ENTRY NAME, and type the appropriate assay name. Press ENTER.
6. When the Test Parameter File displays, touch DELETE TEST.
7. CODE 00257 PROCEED WITH DELETE? Y/N displays. Type Y (Yes) to delete the assay, and press ENTER. CODE 00164 FILE DELETED displays.
8. Touch EXIT.

Time and Date

Introduction

The System time and/or date may be edited from the Instrument Status screen.

Editing System Time and Date

1. From the Main menu, touch INSTRUMENT STATUS, SELECT.
2. Touch CHANGE DATE, and type the appropriate date.
3. Use the cursor control keys to highlight MONTH. Press the CYCLE key to display the current month.
4. Use the cursor control keys to highlight YEAR. Type the last two digits of the calendar year.
5. Use the cursor control keys to highlight TIME. Type the current time (non-military). Use the cursor control keys to highlight AM/PM. Press the CYCLE key to display the correct option.
6. Verify the time and date are correct. Calibration intervals for both Cal On Command and Master Cal utilize this internal clock.
7. When entries are verified, touch EXIT. The System automatically updates.

Wash Matrix

Introduction

The Wash Matrix is designed to prevent reagent carryover between dispenses. The number of wash cycles between different reagents may be edited from the Reagent Probe Wash Cycles screen when changes are indicated, e.g., new reagents are available from Abbott Laboratories or the reagent package insert indicates an edit is required.

When AFTER REAGENT is highlighted, the numbers displayed indicate the number of cycles required after the highlighted assay. When BEFORE REAGENT is highlighted, the numbers displayed indicate the number of cycles required before proceeding to the highlighted assay.

Refer to Wash Matrix in the Touch Screens section for additional field information.

Editing Values in the Wash Matrix

1. From the Main menu, touch SPECIAL PROCEDURES, SELECT. Touch WASH MATRIX, SELECT.
2. Highlight the assay name, and press ENTER.
3. Touch BEFORE REAGENT or AFTER REAGENT.
4. Touch the number field adjacent to the assay name that is to be entered or edited, and type the appropriate value.
5. Complete both the BEFORE REAGENTS and AFTER REAGENTS tables for appropriate assays.
6. Touch SAVE FILE. CODE 00166 FILE SAVED displays.
7. Touch EXIT.

Editing Values in the Wash Matrix for Auxiliary Reagents

The operator may designate the number of washes to be performed between the same auxiliary reagent subsequent to sample dispense (i.e., second or third auxiliary reagent).

1. From the Main menu, touch SPECIAL PROCEDURES, SELECT. Touch WASH MATRIX, SELECT.
2. Touch the reagent name, then touch AFTER REAGENT.
3. Adjacent to the reagent name, type the number of washes to be performed between dispenses of that reagent. Valid values are 1–16.
4. Touch SAVE FILE. CODE 00166 FILE SAVED displays.
5. Touch EXIT.

Introduction

Workload Analysis is a password-protected function which provides cumulative totals and resettable totals of assays run on the System. The Workload Analysis Files may be displayed and printed without entering the password. However, the password must be entered to access the files for resetting counters.

The System tabulates the cumulative totals and active totals for each assay defined in the Test Parameter Files. The cumulative total is the number of each assay run since the DATE INITIATED field was activated. These counters cannot be reset by the user and are a permanent record of assays run.

Active counters can be reset and provide assay totals for specific time periods, determined by the user. A further breakdown of the assays tabulated by the active counters can be viewed on the Workload Distribution screen.

A sample that is to be counted as a control must be designated as a control before a run is started. If designated as a control after the run has started, any assays that have completed are not entered in the Control category.

Edited results on optical tests and assays flagged IA are not counted in any category. Assays flagged DP, LL, LH, MA, and LE are counted as completed assays. Ratios and offline tests are counted and included in the active test totals and in the Workload Distribution categories, but are not included in the cumulative test totals or the system-to-date total.

A report, containing information in the Workload Analysis and Workload Distribution screens, may be printed.

NOTE

THE NUMBERS SHOWN ON THE DISPLAY RESET AUTOMATICALLY AT 4.2 BILLION. ALWAYS REFERENCE NUMBERS ON THE PRINTOUT WHEN THE MOST ACCURATE DATA IS REQUIRED.

Accessing and Printing Workload Analysis Files

1. From the Main menu, touch SYSTEM FILES, SELECT. Touch WORK ANALYSIS, SELECT.
2. Ensure the printer is on and SELECT is illuminated.

NOTE

IF THE PASSWORD WAS NOT ENTERED OR THE SYSTEM IS RUNNING, **CODE 00508 NO PASSWORD GIVEN. CANNOT RESET COUNTERS** OR **CODE 00154 SYSTEM IS RUNNING** WILL BE DISPLAYED WHEN THE WORKLOAD ANALYSIS SCREEN IS ENTERED.

3. When the Workload Analysis screen displays, touch PRINT REPORT. A report is generated which contains all data displayed on both the Workload Analysis screen and the Workload Distribution screen.
4. Touch EXIT.

Workload Analysis

Resetting and Printing Workload Analysis Files

1. From the Main menu, touch SYSTEM FILES, SELECT. Touch WORK ANALYSIS, SELECT. Use the cursor control keys to access the hidden password field to the right of WORK ANALYSIS. Type the appropriate password and press ENTER. Touch SELECT.
2. When the Workload Analysis screen displays, touch RESET AND PRINT REPORT. A Y/N prompt and CODE 00507 PROCEED WITH RESET? display.
3. Select the appropriate option:

   To reset the counters and print the report, type Y (Yes). The screen updates, the RESET DATE field displays the current date, and a report is generated. Ensure the printer is on and SELECT is illuminated.

   To avoid resetting the counters, type N (No) and proceed to step 4.
4. Touch EXIT.

Workload Distribution

Introduction

The Workload Distribution screen displays each assay defined in the Test Parameter Files in one of the following categories: STAT, ROUTINE, CONTROL, or CALIB. A total of all assays completed is displayed for each of the four categories.

A report, containing information in the Workload Analysis and Workload Distribution screens, may be printed.

NOTE

THE NUMBERS SHOWN ON THE DISPLAY RESET AUTOMATICALLY AT 4.2 BILLION. ALWAYS REFERENCE NUMBERS ON THE PRINTOUT WHEN THE MOST ACCURATE DATA IS REQUIRED.

Accessing and Printing Workload Distribution Files

1. From the Main menu, touch SYSTEM FILES, SELECT. Touch WORK ANALYSIS, SELECT.
2. When the Workload Analysis screen displays, touch WORKLOAD DIST.
3. When the Workload Distribution screen displays, press the PRINT SCREEN key to print a copy of the currently displayed screen. (Ensure the printer is on and SELECT is illuminated.)
4. Touch NEXT PAGE and, if an additional page exists, the screen automatically displays. Press the PRINT SCREEN key. Repeat as required.
5. Touch EXIT.

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Touch Screens

Introduction

This section of the Operation Manual contains a discussion of each ABBOTT SPECTRUM SERIES II System screen, in the order in which it is accessed from the Main menu.

Touch screens are used for the following purposes:

- Enter sample, patient, and reagent information
- Specify operation criteria
- Generate reports
- Display messages
- Perform maintenance and diagnostic procedures

NOTE

ILLUSTRATIONS OF SCREENS DISPLAY EXAMPLE DATA. DATA DISPLAYED ON SCREENS DURING SYSTEM OPERATION MAY BE DIFFERENT.

Touch Screens

The surface of the screen is touch sensitive. A touch is registered when a light beam in the infrared grid is interrupted by an object touching, then moving away from, the screen. Most functions are selected by touching the corresponding field on the screen, causing it to highlight. Procedures in this manual assume use of the touch screen.

Keyboard

Operation of the System is also possible from the keyboard, illustrated in Figure 3-1.

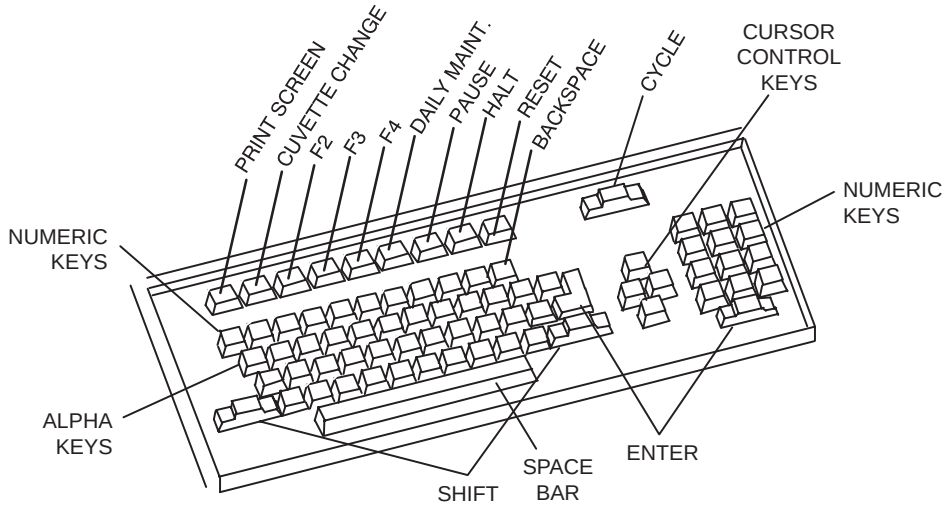


Figure 3-1 Keyboard

PRINT SCREEN

The PRINT SCREEN key is pressed to print a copy of the currently displayed screen.

CUVETTE CHANGE

The cuvette change function may be performed when the ACTIVITY field is not highlighted. The CUVETTE CHANGE key is pressed simultaneously with the SHIFT key to update the cuvette status panel.

Touch Screens

Keyboard (continued)

F2–F4	Not currently active.
DAILY MAINT.	The automated daily maintenance function may be performed when the ACTIVITY field is not highlighted. The DAILY MAINT. key is pressed simultaneously with the SHIFT key to initiate automated daily maintenance.
PAUSE	The PAUSE key is pressed simultaneously with the SHIFT key to interrupt System operation. The System stops dispensing, but assays in process at the time Pause is activated are completed. Refer to Specific Procedures, Pause, for additional information.
HALT	The Halt function is used as an emergency stop for the System. Activation of Halt aborts System activities immediately. Halt also may be used to abort a diagnostic routine. Halt is initiated by pressing the HALT key simultaneously with the SHIFT key. Refer to Specific Procedures, Halt, for additional information.
RESET	Not currently active.
CYCLE	The CYCLE key scrolls, or cycles, multiple options within a field.
BACKSPACE	The BACKSPACE key is used to delete information within a field.
ALPHANUMERIC KEYS	Alphanumeric keys are used to enter data required by the System. Both numeric key selections are operable. To enter data, the appropriate field on the screen is highlighted, data is entered, and ENTER is pressed.
CURSOR CONTROL KEYS	The cursor control (arrow) keys are used to move the cursor up, down, left, and right.
ENTER	The ENTER key is used to store data.
SHIFT	The SHIFT key is pressed simultaneously with function keys to activate and de-activate System functions, e.g., SHIFT and HALT are pressed simultaneously to initiate a Halt.
SPACE BAR	The space bar is used in data entry. It may be used to delete information within a field.

System Fields

The following System fields display, as appropriate (Figure 3-2).

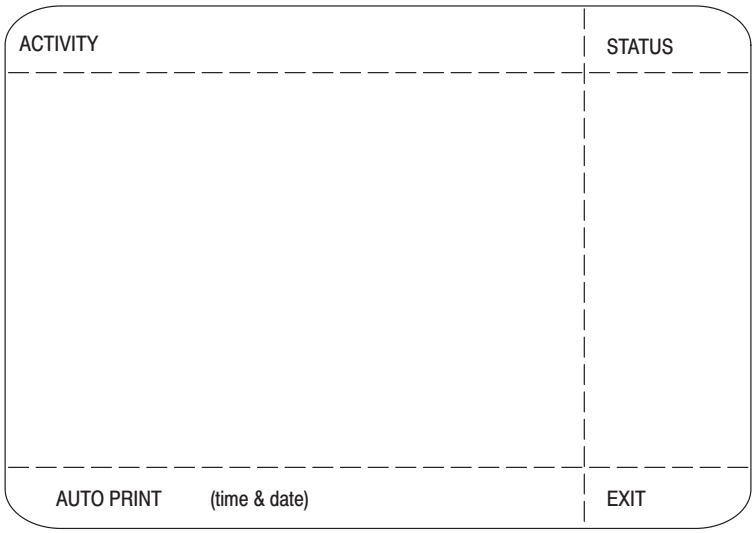


Figure 3-2 System Fields

ACTIVITY

System activity displays in the upper left corner of the screen in the ACTIVITY field. Five activities may display in this field.

- AUX PENDING — Displays when the System is waiting for the second or third reagent to be dispensed.
- ISE RUNNING — Displays when opticals are no longer in process, but electrolytes are in progress.
- MAINTENANCE — Displays when a maintenance routine is being performed.
- READING — Displays after the sample and reagent carousels have been accessed and are no longer required for processing.
- RUNNING — Displays when the sample, reagent, and/or mix arms are in operation.

STATUS

Displays in the upper right field when the System sends a message to the operator. From the Main menu, STATUS is touched to display the message. Refer to the ISE Status Codes & Diagnostics and Status Codes sections in the Maintenance & Troubleshooting Manual for specific information.

AUTO PRINT

Displays in the lower left field as OFF or ON. When OFF is touched, ON displays. When AUTO PRINT ON displays, a patient report prints automatically after all assays for the sample are complete. Adjacent to AUTO PRINT is the current System time and date.

EXIT

Displays in the lower right field. When touched, the preceding screen displays.

System Power On

Introduction

The System Power On screen (Figure 3-3) displays when instrument power is turned on. Display of the screen during operation indicates the System has experienced a power interruption or the System power was manually cycled. Refer to Specific Procedures, Power On/Off, for additional information.

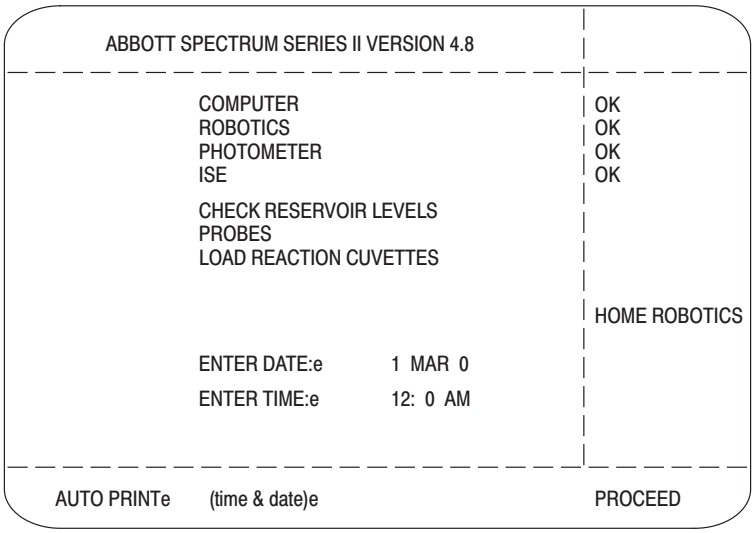


Figure 3-3 System Power On Screen

Data Entry Fields

ENTER DATE — A field used to enter the appropriate date for use by the instrument. When the Power On Check is completed, the cursor automatically displays in the ENTER DATE field. However, if a diagnostic check has been repeated, the cursor must be moved to the appropriate field for data entry.

ENTER TIME — A field used to enter the appropriate time for use by the instrument.

Touch Screen Fields

COMPUTER, ROBOTICS, PHOTOMETER, ISE — System-controlled diagnostic checks. No operator action is required.

As each system passes its diagnostic check, OK displays adjacent to the diagnostic check. If the system does not pass, ERROR displays. If ERROR displays, contact the Customer Support Center.

COMPUTER — Verifies the master processor and related electronics.

ROBOTICS — Verifies the ability of the following components to find the flag limits and home positions:

- Sample arm
- Reagent arm
- Mixer arm
- Sample carousel
- Cuvette carousel
- Barcode reader

Touch Screen Fields (continued)

PHOTOMETER	Verifies the photodiode array and optical electronics.
ISE	Verifies establishment of communications between the ISE module and the System.
CHECK RESERVOIR LEVELS, PROBES, LOAD REACTION CUVETTES	Serves as a reminder to: • Verify adequate volume in the sample diluent reservoir • Verify adequate volume in the reagent cartridges • Verify probes are undamaged • Verify cuvette segments are unused • Empty the waste (if necessary)
PROCEED	Displays the Main menu. (Wait for the message PLEASE WAIT FOR SYSTEM TO COMPLETE CHECK to disappear.)

System Power On

On Screen Messages

WAIT	Indicates a diagnostic check is in progress.
OK	Indicates the diagnostic check passed.
ERROR	Indicates an error occurred during a diagnostic check.
POWER ON CHECK PASSED–PLEASE WAIT	Displays for a few seconds, approximately one minute after power on. During this period, the screen is inoperative.
PRESS ANY KEY FOR INTERVENTION WITHIN 5 SECONDS	Displays during power up before a robotic diagnostic check. It is intended for use during troubleshooting or initial installation. If a key is pressed, the robotics homing sequence is not initiated and the System proceeds to the Main menu after PROCEED is touched.
ISE INIT	Displays when an error occurs during a diagnostic check and the ISE check was not initiated. Touch ISE INIT to initiate the ISE check.

Introduction

The Main menu (Figure 3-4) displays when PROCEED is touched from the System Power On screen.

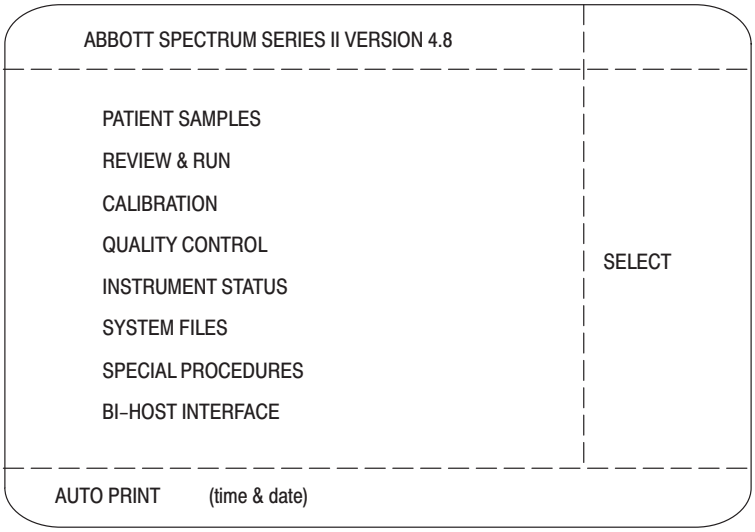


Figure 3-4 Main Menu

Main Menu

Introduction (continued)

A partial listing of options available from the Main menu is presented in Figure 3-5.

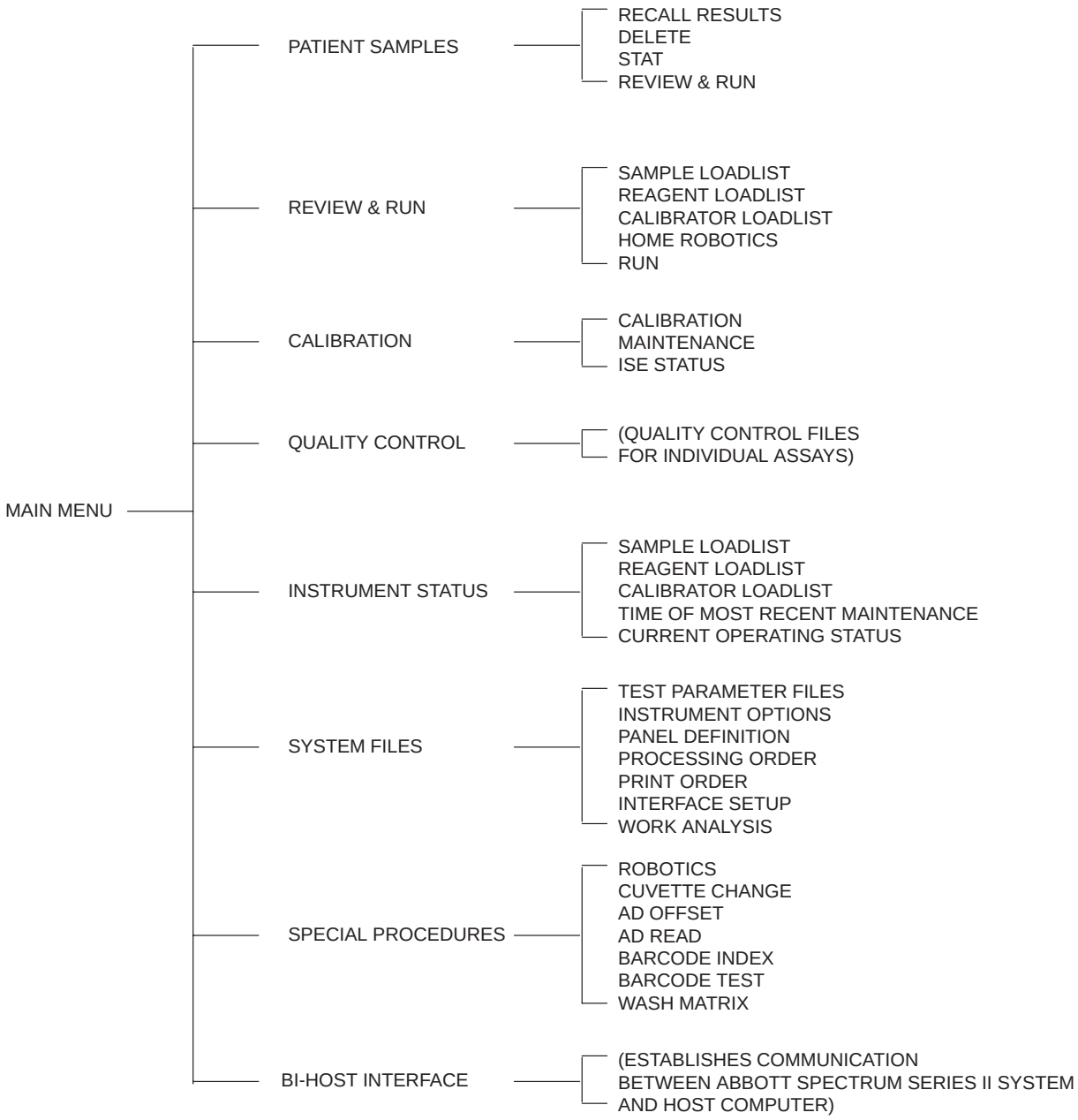


Figure 3-5 System Options

Touch Screen Fields

PATIENT SAMPLES	Touch this field and SELECT to display the Patient Samples screen, which allows entry, review, print, and deletion of samples and assays.
REVIEW & RUN	Touch this field and SELECT to display the Review & Run screen, which allows addition of new samples, reagents, and calibrators to the System loadlists. RUN is initiated from the Review & Run screen.
CALIBRATION	Touch this field and SELECT to display the Calibration screen, which allows review, acceptance, initiation, or rejection of end point and kinetic blank calibration, and access to System maintenance and ISE status screens.
QUALITY CONTROL	Touch this field and SELECT to display the Quality Control screen, which allows review of the status of each level, quality control mean, standard deviation, percentage coefficient of variation, and entry and edit of quality control ranges for each assay.
INSTRUMENT STATUS	Touch this field and SELECT to display the Instrument Status screen, which displays time of most recent maintenance, carousel number, incubator temperature, processing mode, number of tests scheduled, number of tests completed, number of unused segments, and System time and date. Current loadlists may be displayed from the Instrument Status screen.
SYSTEM FILES	Touch this field and SELECT to display the System Files screen, which allows entry, review, and edit of assay parameters, panel definitions, processing order, print order, and interface parameters. Workload analysis screens may be accessed from the System Files screen.
SPECIAL PROCEDURES	Touch this field and SELECT to display the Special Procedures screen, which allows access to Robotics, Cuvette Change, Ad Offset, Ad Read, Barcode Index, Barcode Test, and Wash Matrix screens.
BI-HOST INTERFACE	Touch this field and SELECT to display the Bi-Host Interface screen, which allows bi-directional communications between the ABBOTT SPECTRUM SERIES II System and a host computer.
SELECT	Used in conjunction with a screen name to display the screen.

Patient Samples

Introduction

The Patient Samples screen displays when PATIENT SAMPLES is selected from the Main menu. Refer to Figure 3-6 for the Patient Samples Screen Flow Map.

This screen is used to assign and edit sample identification (SID) numbers, patient names, patient identification (PIDs), carousel numbers, position numbers, assay requests, and panel requests. The panel and assay names that display are the names defined in System Files. The Test Result/SID File has a capacity of 239 SID numbers, or 2,399 assays.

CAUTION

FAILURE TO FOLLOW SAMPLE ENTRY PROCEDURE PRECISELY MAY CREATE AN UNEXPECTED SAMPLE LOADLIST. VERIFY SAMPLE LOADLIST PRIOR TO TOUCHING **RUN**.

Data Entry Fields

SID

A 20-character, alphanumeric field used to assign a sample identification number unique to each individual sample. The SID number may be auto assigned by the System or manually entered.

NOTES

- THE SYSTEM WILL NOT ACCEPT THE SLASH (/) OR COMMA (,) CHARACTER IN THE DATA ENTRY FIELDS OF THE PATIENT SAMPLES SCREEN.
- WHEN MANUALLY ASSIGNING SID NUMBERS, THE SYSTEM MAY RECOGNIZE THREE-DIGIT NUMBERS AS SPECIFIC CAROUSEL AND POSITION.

NAME

A 20-character, alphanumeric field used to enter a patient name.

CAR#

A 1-character, numeric field used to assign a carousel number. The CAR# may be manually entered or auto assigned by the System. When the 48 outer ring positions are filled and a sample is requested, the carousel number must change or the sample must be requested as a STAT. Touch CAR# and type the new carousel number. The sample carousel can be encoded with a binary code representing the carousel number read when the Review & Run screen is entered. If information is manually entered in the PID field, it will not print in a System-generated report.

Data Entry Fields (continued)

PID	A 20-character, alphanumeric field used to assign a patient identification number unique to each sample. The PID number may be auto assigned by the System or manually entered. If auto-assigned, information in this field is sent to or received from a host computer via the interface. If manually entered, information in this field does not print in the patient report.
POS #	A field used to identify the position of the sample (1-48) in the outer ring of the sample carousel. The position number may be auto assigned by the System or manually entered. If auto-assigned, information in this field is sent to or received from a host computer via the interface. If manually entered, information in this field does not print in the patient report.

NOTE

IF THE POS # FIELD IS TOUCHED FIRST ON A NEW SCREEN, IT IS NECESSARY TO ENTER AN UNUSED VALID POSITION NUMBER, E.G., 1–48. REVIEW THE SAMPLE LOADLIST OR RECALL RESULTS TO DETERMINE THE APPROPRIATE UNUSED POSITION NUMBER.

Touch Screen Fields

NEXT SAMPLE	Stores the entry and allows sample entry to continue.
NEXT PAGE	Displays additional panels and assays that may be requested.
RECALL RESULTS	Allows review of patient assays, results, and assay status.
DELETE	Deletes sample identification (SID) numbers and assay results.
STAT	Requests STAT processing mode for a sample.
REVIEW & RUN	Allows addition of new samples, reagents, and calibrators to the System loadlists. RUN is initiated from the Review & Run screen.
EXIT	Displays the Main menu.

NOTE

THE CURRENT SAMPLE ENTRY IS NOT STORED WHEN EXIT IS TOUCHED. TOUCH **NEXT SAMPLE** TO STORE EDITS.

Patient Samples

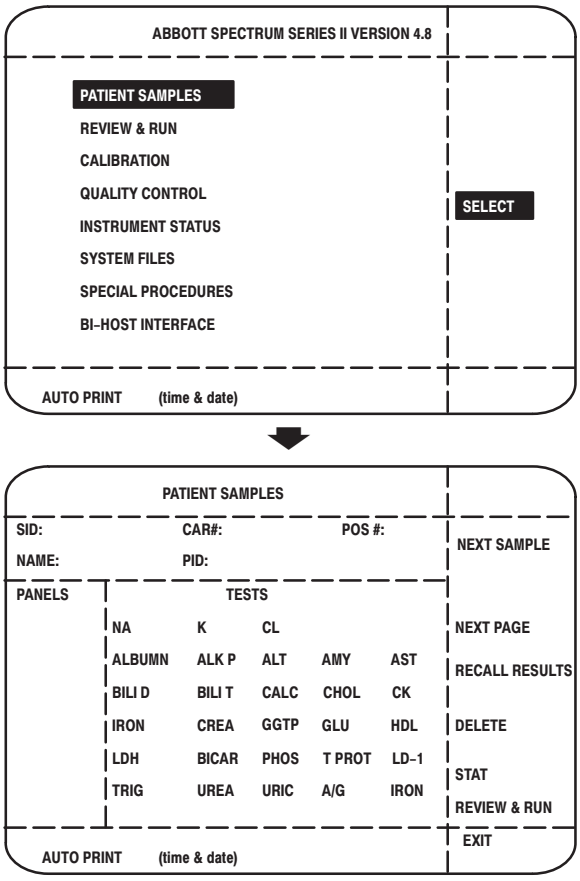


Figure 3-6 Patient Samples Screen Flow Map

Recall Results

Introduction

The Recall Results screen displays when RECALL RESULTS is selected from the Patient Samples screen. Refer to Figure 3-7 for the Recall Results Screen Flow Map.

This screen is used to view assays, results, and status of assays. Entering, editing, rerunning, and printing of assay results and manual assignment of quality control may also be accomplished in this screen.

Data Entry Field

RESULTS — A field which displays current assay results. Results may be edited, or a value may be typed for an offline assay.

Touch Screen Fields

TESTS — Identifies the assay name.

STATUS — Displays the status of the assay. Alternatives include:

- **ENT** — Indicates the assay has been entered but not currently scheduled by the System.
- **SCH** — Indicates the assay is currently in progress.
- **COM** — Indicates the assay is complete.

DISPLAYED FLAGS

- **DP** — Indicates the dilution protocol has been defined in the Test Parameter Files. DP and ENT indicate the need for a dilution protocol; DP and COM indicate completion of a dilution protocol. The result on the printed report will be flagged with an asterisk (*) and DP to indicate a dilution protocol was performed to obtain the result.
- **IA** — Indicates an Initial Absorbance reagent check failed. CODE 00011 TEST: [redacted] INITIAL ABSORBANCE "IA" CHECK FAILED FOR REAGENT: # [redacted], POSSIBLE REAGENT PROBLEM displays. The printed report will be flagged with an @.
- **LE** — Indicates one of the following conditions occurred:
  - Low Energy optical condition. CODE 00027 LOW ENERGY. CALIBRATOR # [redacted], TEST: [redacted] or CODE 00029 LOW ENERGY. TEST: [redacted] SAMPLE ID: [redacted] displays. The printed report will be flagged with an @.
  - Spectral correction condition. CODE 00337 POLYCHROMATIC RANGE CHECK FAILED FOR WAVELENGTH POSITION #: [redacted] TEST: [redacted] displays. The printed report will be flagged with an @.

Recall Results

Touch Screen Fields (continued)

LL/LH	Indicates a Linear Low or Linear High condition occurred. CODE 00013 LINEAR HIGH OR LOW CHECK FAILURE. TEST: [redacted] displays. The printed report will be flagged with an asterisk (*) and DP to indicate a dilution protocol was defined in the Test Parameter File and was performed on the specific assay.
MA	Indicates one of the following conditions occurred: • Maximum Absorbance reagent check failed. CODE 00012 TEST: [redacted] REACTION ABSORBANCE "MA" EXCEEDS LIMIT REAGENT: # [redacted] PROBABLE HIGH ANALYTE CONCENTRATION. The printed report will be flagged with an @. • Rate C. of C. failed. CODE 00287 TEST: [redacted] RATE COEFFICIENT OF CORRELATION CHECK FAILED SAMPLE ID: [redacted] TEST: [redacted] displays. The printed report will be flagged with an @.
UNITS	Displays the units of measure appropriate for the assay. When PENDING is displayed without results, the assay has not been completed. When PENDING is displayed with results, and the status is ENT or SCH, the assay is available for entering (ENT) or running (SCH) a dilution protocol.
SEND UNI HOST	Transmits data uni-directionally to a host computer.
PRINT	Prints additional patient reports. This function has a higher priority than AUTO PRINT. If a report is printed using this field, the AUTO PRINT command is canceled.
NEXT PAGE	Displays the next page of the sample report.
NEXT SAMPLE	Displays the next sample report, if all or specific SIDs were selected in the Recall Results screen.
RERUN	Allows an assay status change from COM to ENT so the assay can be repeated when RUN is touched from the Review & Run screen.

Touch Screen Fields (continued)

RESTORE	Displays when a result is edited or entered as an offline assay.
CONTROLS	Allows completed assay results to be sent to the Quality Control Files. Refer to Quality Control Status Sub-screen in this section and Specific Procedures, Quality Control – Define, for additional information.
CANCEL PRINT	Cancels a print request.
EXIT	Displays the Patient Samples screen.

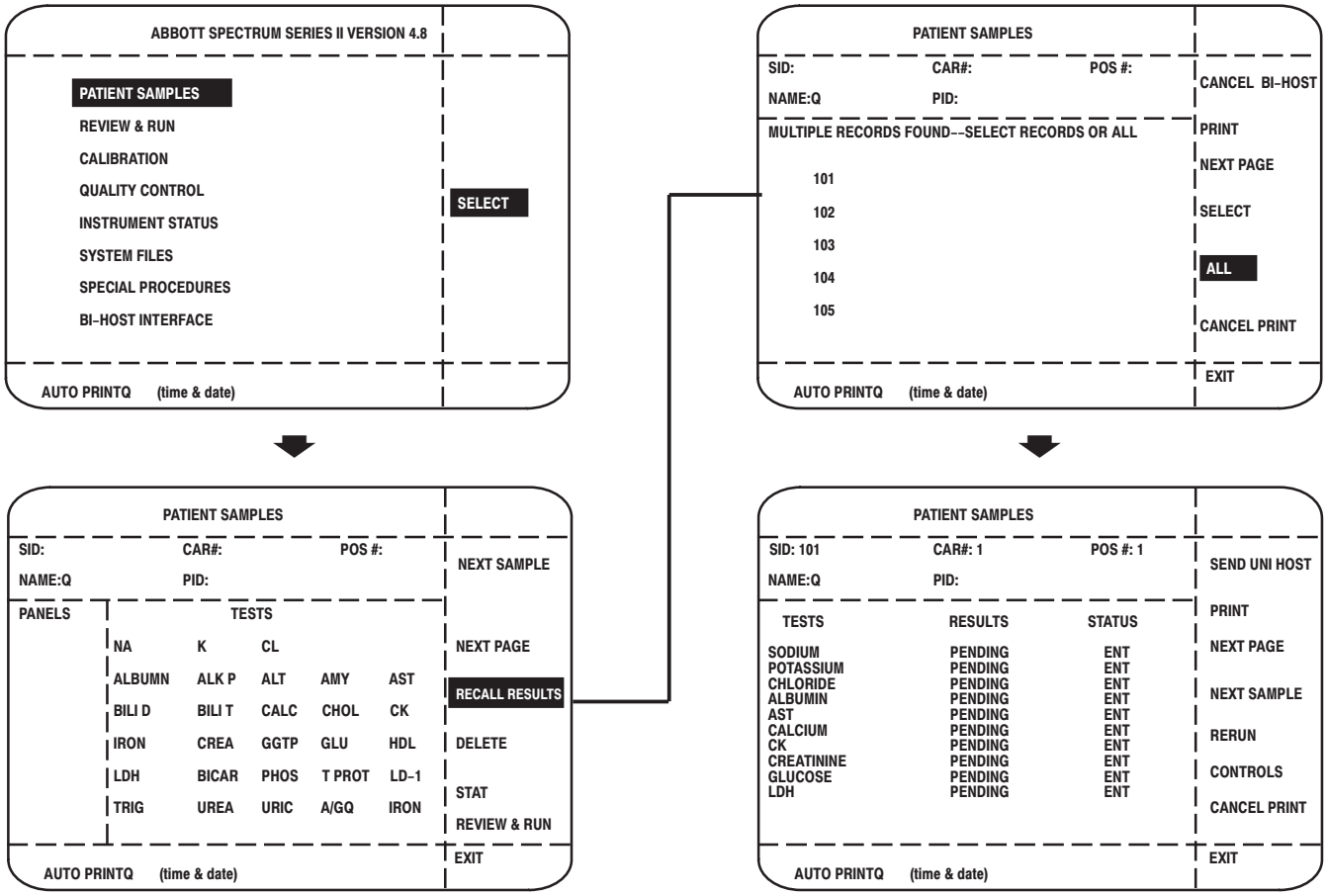


Figure 3-7 Recall Results Screen Flow Map

Delete

Introduction

The Delete screen displays when DELETE is touched from the Patient Samples screen. Refer to Figure 3-8 for the Delete Screen Flow Map.

Patient SIDs, test requests, and results are held in the System in non-volatile memory. The delete function removes all record of the sample and respective assays. Refer to Specific Procedures, Samples – Delete, for additional information.

NOTE

SAMPLES MAY NOT BE DELETED WHEN THE SYSTEM IS RUNNING.

Touch Screen Fields

PROCEED	Initiates the delete function. When delete is in process, the SIDs selected for deletion display above AUTO PRINT as they are deleted. When the deletion is complete, the Patient Samples screen displays.
CANCEL PRINT	Cancels a print report pending on a selected SID.
CANCEL BI-HOST	Cancels a Bi-Host report pending on a selected SID.
EXIT	Displays the Patient Samples screen.

NOTE

IF EXIT IS TOUCHED PRIOR TO PROCEED, THE DELETE FUNCTION IS CANCELED.

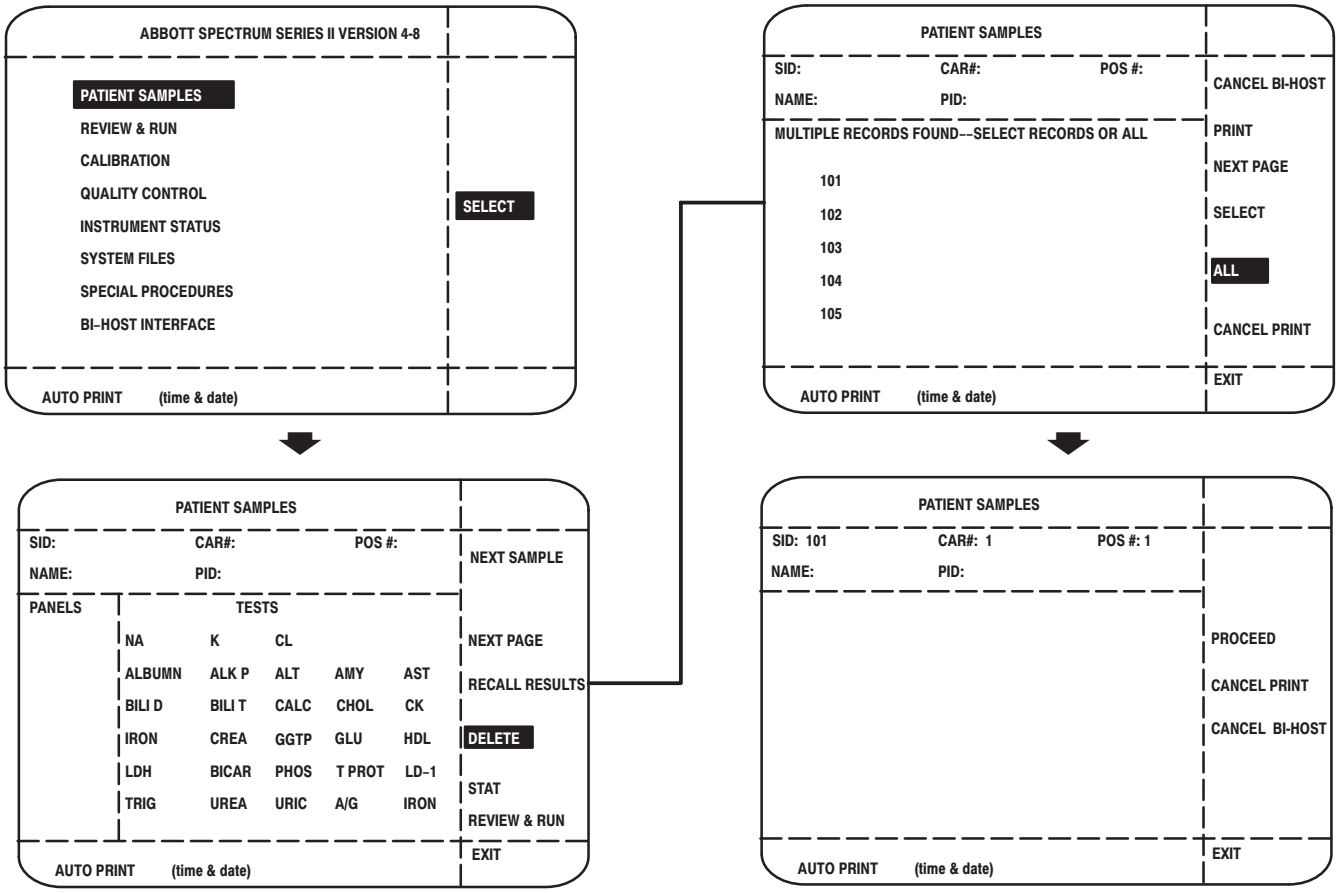


Figure 3-8 Delete Screen Flow Map

STAT Sample

Introduction

The STAT Sample screen displays when **STAT** is touched from the Patient Samples screen. Refer to Figure 3-9 for the STAT Sample Screen Flow Map. Refer to Specific Procedures, Samples – STAT Requests, for additional information.

The System assigns STAT position numbers. Eight STAT samples for each carousel can be held in memory. When a ninth STAT sample is requested, the System displays **CODE 00121 NO ROOM FOR STATS**. STAT samples may be deleted to accommodate additional STAT samples when the System is not running. Refer to Specific Procedures, Samples – Delete, for additional information on sample deletion.

Touch Screen Fields

SAMPLE ID	Displays the SID number entered or auto assigned in the Patient Samples screen.
POSITION	Displays the auto assigned position number. STAT sample position numbers are assigned by the System.
PROCEED	Displays the Review & Run screen to allow processing of the assays.
NEXT STAT	Displays the Patient Samples screen to allow addition of STAT or routine samples before processing begins on previously requested STAT samples.

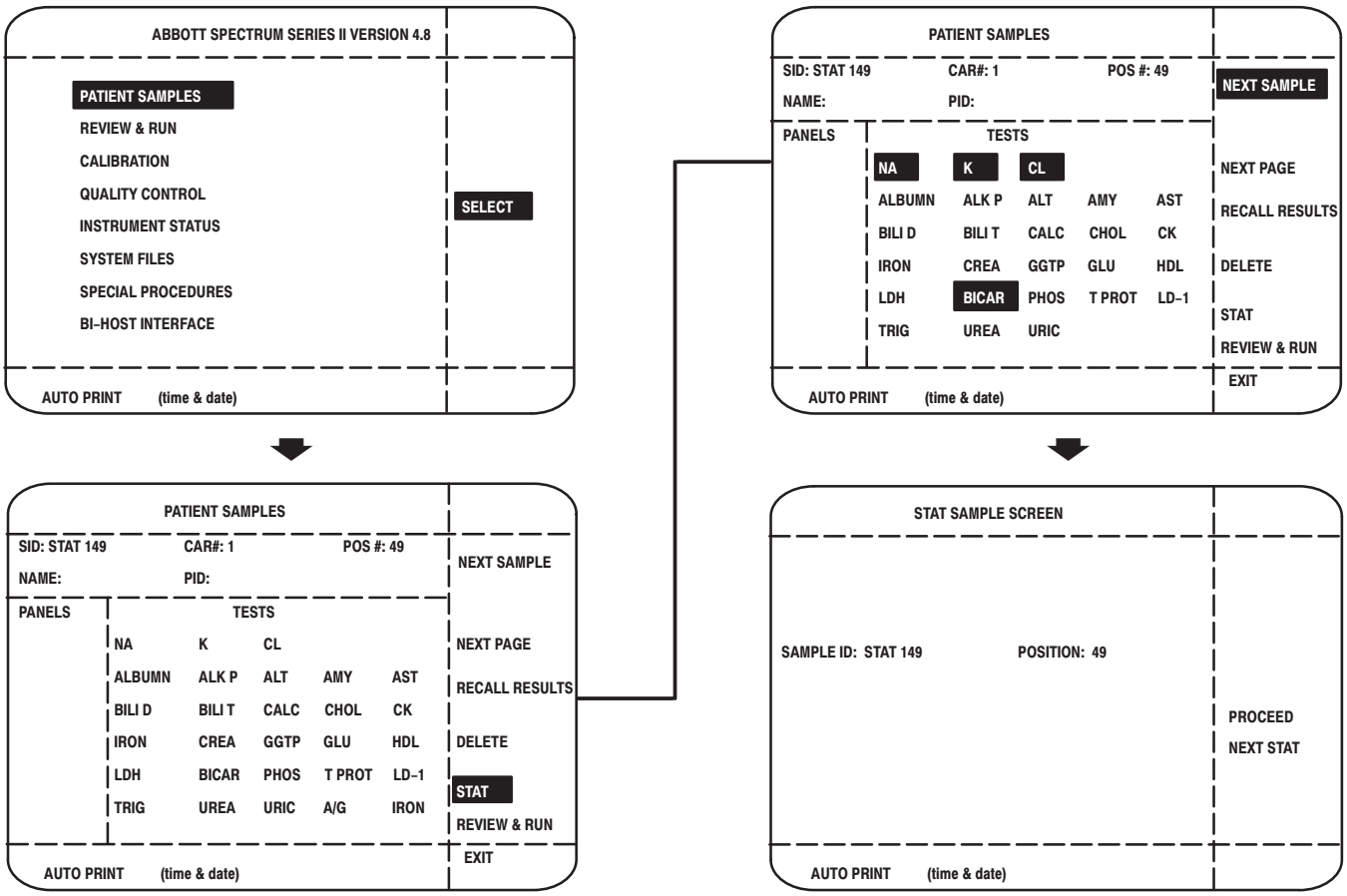


Figure 3-9 STAT Sample Screen Flow Map

Review & Run

Introduction

The Review & Run screen may be entered from the Main menu or the Patient Samples screen. Refer to Figure 3-10 for the Review & Run Screen Flow Map.

This screen allows review of the sample, reagent, and calibrator loadlists. Each time the Review & Run screen is entered, the System reviews the loadlist files. New samples, ENT- or DP-specified samples, and the necessary reagents and calibrators are added to the existing loadlists.

Data Entry Field

IF DESIRED, ENTER SAMPLE CAROUSEL NUMBER	A field used to enter the appropriate carousel number.

Touch Screen Fields

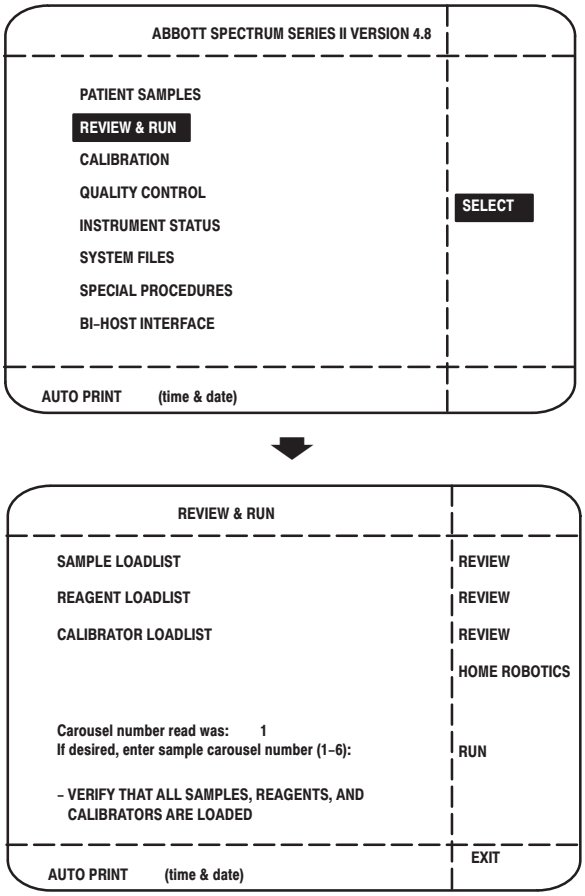
REVIEW	Displays the sample, reagent, or calibrator loadlist.
HOME ROBOTICS	Returns robotics to the home position.
RUN	Touch RUN when all samples, reagents, and calibrators are loaded. The System homes robotics and stabilizes the source lamp, optics electronics, and incubator temperature. When all conditions have been met, the Main menu displays, the reagent probe descends into the wash station, and RUNNING displays in the ACTIVITY field. When RUN is touched immediately upon entering the Review & Run screen, the System automatically runs all assays for which samples, reagents, and calibrators are currently on board.
EXIT	When EXIT is touched once, the message TO RESUME DISPENSING, TOUCH "RUN" displays. The System completes the review process of the loadlists or, if initiated, a home robotics sequence, and pauses. (No status code displays during the pause.) Touch RUN to continue operation. When EXIT is touched a second time, the messages SYSTEM IS PAUSED and EXIT SELECTED – WILL EXIT WHEN OPERATION IS COMPLETE display. The System disregards the command to RUN and exits automatically to the Main menu.

On Screen Messages

PLEASE WAIT – INITIALIZING ISE	Displays when electrolytes are requested and the ISE is calibrating. No action by the operator is required.
PLEASE WAIT – BUILDING CALIBRATOR & REAGENT LOADLISTS	Displays if REVIEW or EXIT is touched before the System has completed the loadlists. No action by the operator is required.
ERROR OCCURRED WHILE READING SAMPLE CAROUSEL ID	Displays when the sample carousel is not encoded or the System did not recognize the code. Verify coding on the sample carousel and home robotics.
CAROUSEL NUMBER READ WAS: # IF DESIRED, ENTER CAROUSEL NUMBER (1-6)	Displays the carousel number read. Verify the appropriate carousel was read. If necessary, type the appropriate carousel number, then press ENTER.
WAITING FOR OPTICAL LAMP TO STABILIZE/Ad START UP	Displays while the instrument adjusts the source lamp and optics electronics before the run can begin. No action by the operator is required.
ROBOTICS ERROR OCCURRED – HOME ROBOTICS WHEN READY	Displays when an error occurred during the run-initiated robotics sequence. A message displays, identifying the problem. When the problem is resolved, touch HOME ROBOTICS.
ROBOTICS HOMED – TOUCH “RUN” WHEN READY TO START	Displays when the home robotics sequence was successful. Touch RUN to initiate instrument operation.
RUN SELECTED – WILL START WHEN OPERATIONS COMPLETE	Displays when RUN is selected and the System is building loadlists. No action by the operator is required.
TO RESUME DISPENSING, TOUCH “RUN”	Displays when EXIT is touched once. Touch RUN to continue operation. Touch EXIT again to display the Main menu.
EXIT SELECTED – WILL EXIT WHEN OPERATION IS COMPLETE	Displays when EXIT is touched twice and the System is building loadlists or homing robotics.
SAMPLE CAROUSEL ID DIFFERS FROM PREVIOUS–CONTINUE? Y/N	Displays if the sample carousel ID reader identifies a carousel number different from the previous sample carousel number.

Review & Run

Option 1 via Main Menu



Option 2 via Patient Samples Screen

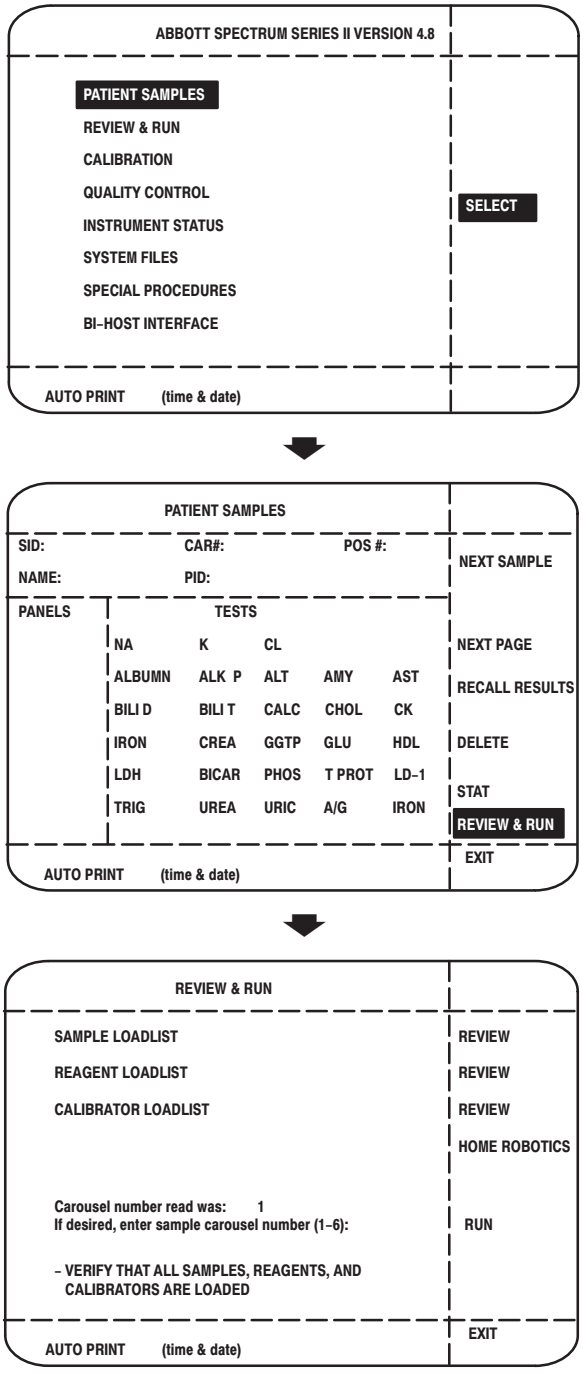


Figure 3-10 Review & Run Screen Flow Map

Sample Loadlist

Introduction

The Sample Loadlist screen may be entered from the Review & Run screen or the Instrument Status screen. Refer to Figure 3-11 for the Sample Loadlist Screen Flow Map.

The sample loadlist is created for the appropriate carousel when the Review & Run screen is entered and the carousel number is verified. Refer to Specific Procedures, Sample Loadlist, for additional information.

Data Entry Field

PRINT LOADLIST	A field used to print loadlists. Verify the printer is on and SELECT is illuminated. Touch PRINT LOADLIST. The message CAROUSEL NUM: ALL displays. (The default is ALL.) To print one copy of all carousel loadlists in the System memory, press ENTER. To print a specific carousel, type the carousel number (valid entries are 1-6) and press ENTER.

Touch Screen Fields

CAROUSEL #	Displays the desired carousel number.
OUTER RING POSITION	Displays the sample carousel position number on the outer ring of the sample carousel.
SAMPLE ID	Displays the SID (sample identification) number entered by the operator or auto assigned by the System in the Patient Samples screen.
INNER RING POSITION	Displays the sample carousel position number on the inner ring of the sample carousel.
NEXT PAGE	Displays the next page of the sample loadlist.
PREV PAGE	Displays the previous page of the sample loadlist.
REAGENT LOADLIST	Displays the reagent loadlist.
CALIBRATOR LOADLIST	Displays the calibrator loadlist.
EXIT	Displays the preceding screen.

Sample Loadlist

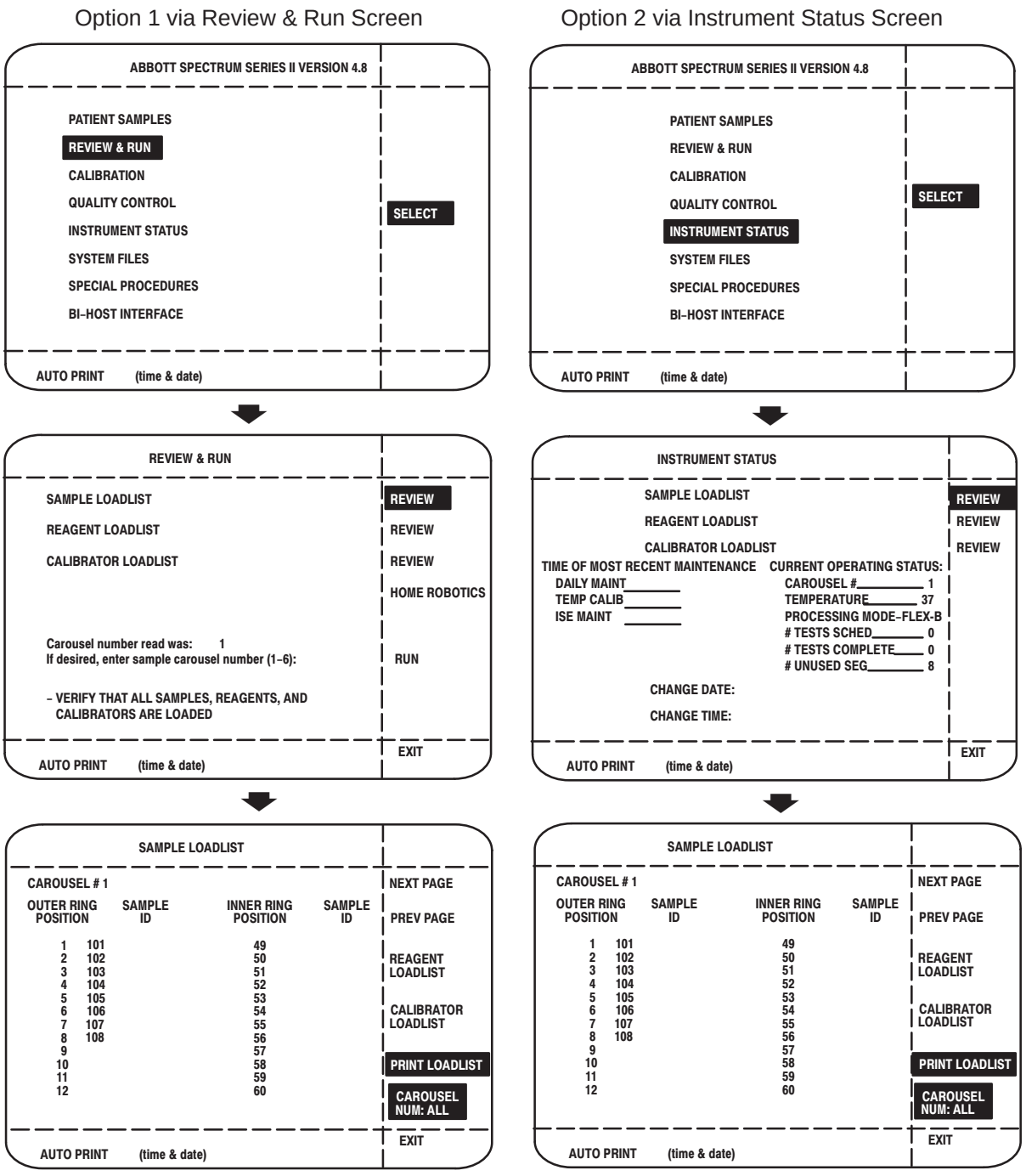


Figure 3-11 Sample Loadlist Screen Flow Map

Reagent Loadlist

Introduction

The Reagent Loadlist screen may be entered from the Review & Run screen or from the Instrument Status screen. Refer to Figure 3-12 for the Reagent Loadlist Screen Flow Map.

The reagent loadlist is created when the Review & Run screen is entered and the carousel number is verified. Refer to Specific Procedures, Reagent Loadlist, for additional information.

Data Entry Fields

REAG NAME	A field used to display the reagent name entered in the Test Parameter File: Reagent Definition.
STATUS	A field used to display the status of each reagent.
?	Indicates the System does not recognize the reagent because an error occurred in reading or typing the reagent name.
ASSIGNED	Indicates the reagent was assigned to that position by typing the name into the reagent loadlist or by touching the status LOAD NOW or ASSIGNED. If the reagent is ASSIGNED, but no assays are requested, the ASSIGNED status will be highlighted.
EMPTY	Indicates that no reagent is detected.
LOAD NOW	Indicates the reagent must be loaded to run the assays or the barcode reader did not identify the reagent barcode.
LOW REAG	Indicates reagent volume is low.
MOVE REAG	Indicates the reagent should be moved to the appropriate area of the tray.
ON BOARD	Indicates the reagent is available for use.
UNUSED	Indicates the reagent is available for use but currently no assays are requested.

Reagent Loadlist

Touch Screen Fields

POS	Displays the reagent carousel position for each reagent.
NEXT PAGE	Displays the next page of the reagent loadlist.
SAMPLE LOADLIST	Displays the sample loadlist.
CALIBRATOR LOADLIST	Displays the calibrator loadlist.
READ REAGENT TRAY	Scans the reagent barcode labels three times to update the reagent loadlist.
EXIT	Displays the preceding screen.

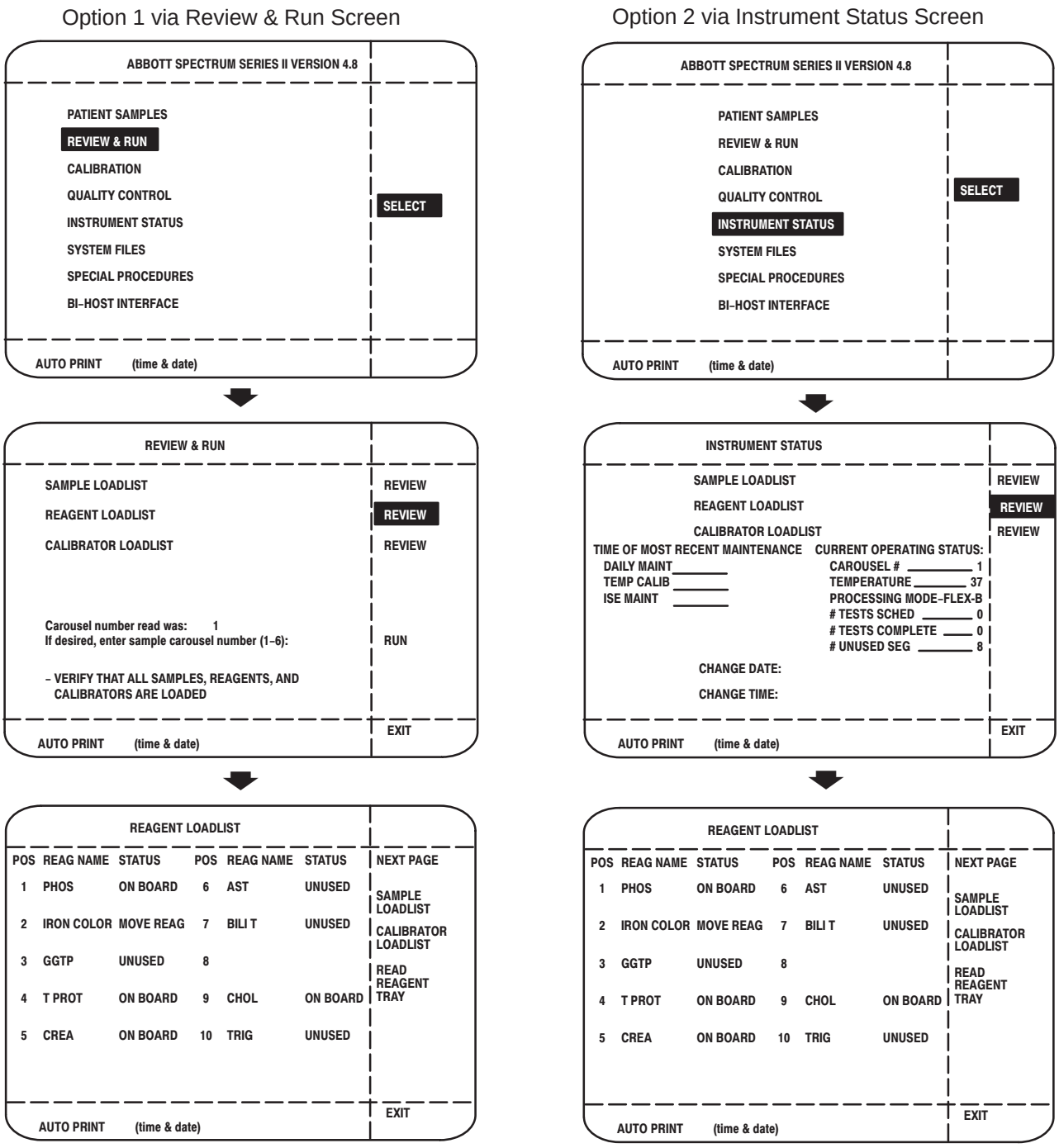


Figure 3-12 Reagent Loadlist Screen Flow Map

Calibrator Loadlist

Introduction

The Calibrator Loadlist screen may be entered from the Review & Run screen or from the Instrument Status screen. Refer to Figure 3-13 for the Calibrator Loadlist Screen Flow Map.

The calibrator loadlist is created when the Review & Run screen is entered and the carousel number is verified. The calibrator loadlist highlights to indicate calibrator/standard material needs to be placed on board. Refer to Specific Procedures, Calibration – Optical Assays, for additional information.

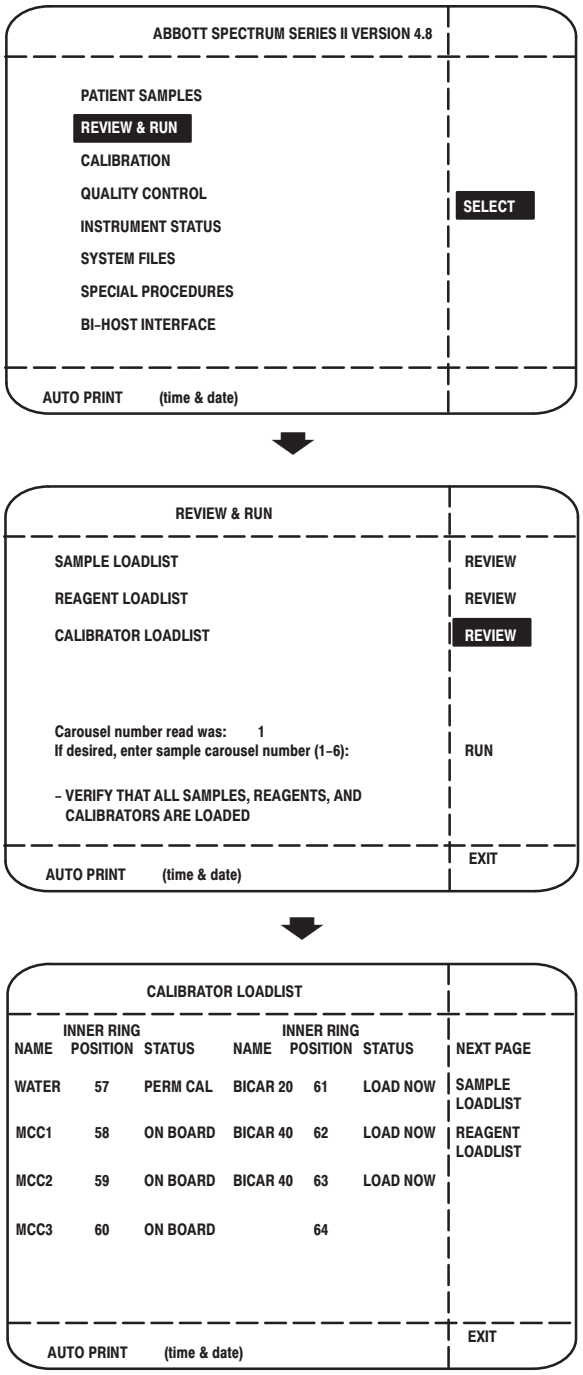
Data Entry Fields

NAME	A field used to display the name of the calibrator/standard entered in the Test Parameter File.
STATUS	A field used to display the status of each calibrator/standard.
?	Indicates the System does not recognize the calibrator/standard because an error occurred in typing the calibrator/standard name.
LOAD NOW	Indicates the calibrator/standard must be loaded to run the assays.
ON BOARD	Indicates the calibrator/standard is available for use.
PERM CAL	Indicates the calibrator/standard name was typed in the calibrator loadlist.
UNUSED	Indicates the calibrator/standard is available for use but currently no assays are requested.

Touch Screen Fields

INNER RING POSITION	Displays the sample carousel position number on the inner ring of the sample carousel.
NEXT PAGE	Displays the next page of the calibrator loadlist.
SAMPLE LOADLIST	Displays the sample loadlist.
REAGENT LOADLIST	Displays the reagent loadlist.
EXIT	Displays the preceding screen.

Option 1 via Review & Run Screen



Option 2 via Instrument Status Screen

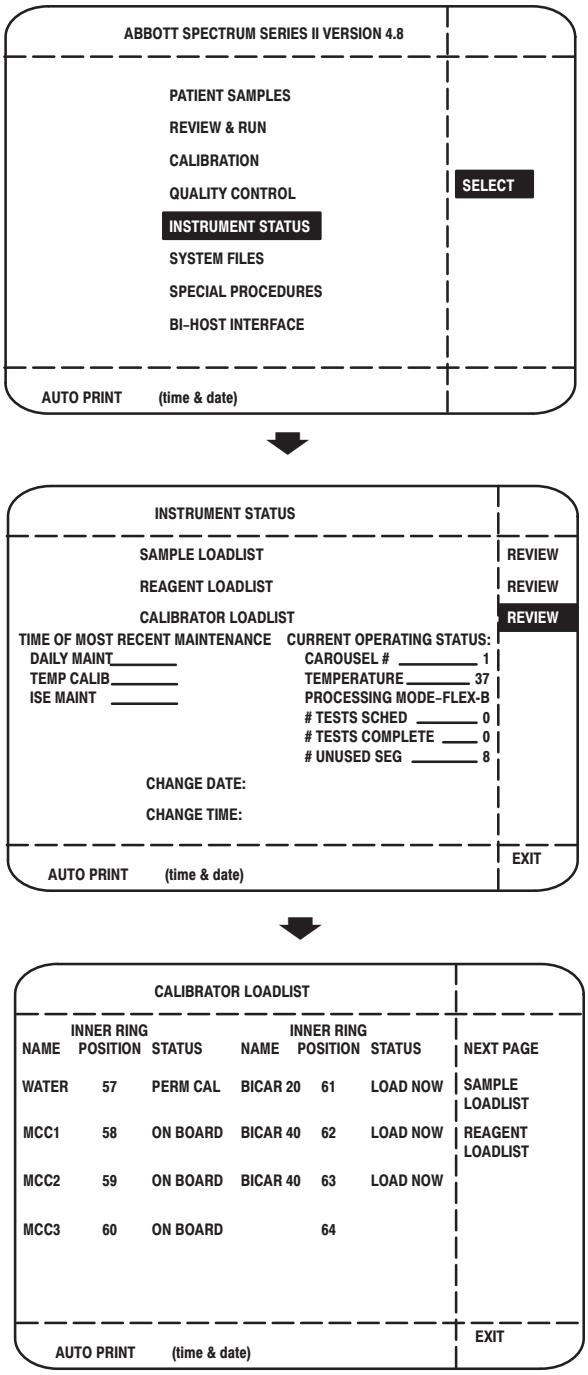


Figure 3-13 Calibrator Loadlist Screen Flow Map

Calibration

Introduction

The Calibration screen displays when CALIBRATION is selected from the Main menu. Refer to Figure 3-14 for the Calibration Screen Flow Map.

The Calibrator Status, Maintenance, and ISE Status screens are accessed from this screen.

Touch Screen Fields

CALIBRATION	Touch this field and SELECT to enter the Calibrator Status screen, which displays end point and rate assay names and the date of the next calibration.
MAINTENANCE	Touch this field and SELECT to enter the Maintenance Menu, which is used to verify and adjust incubator temperature, initiate automated daily maintenance, perform temperature calibration, perform ISE maintenance, and change the ISE reagent cartridge pack.
ISE STATUS	Touch this field and SELECT to enter the ISE Status screen, which is used for ISE maintenance and diagnostics.
SELECT	Used in conjunction with a screen name to display the screen.
EXIT	Displays the Main menu.

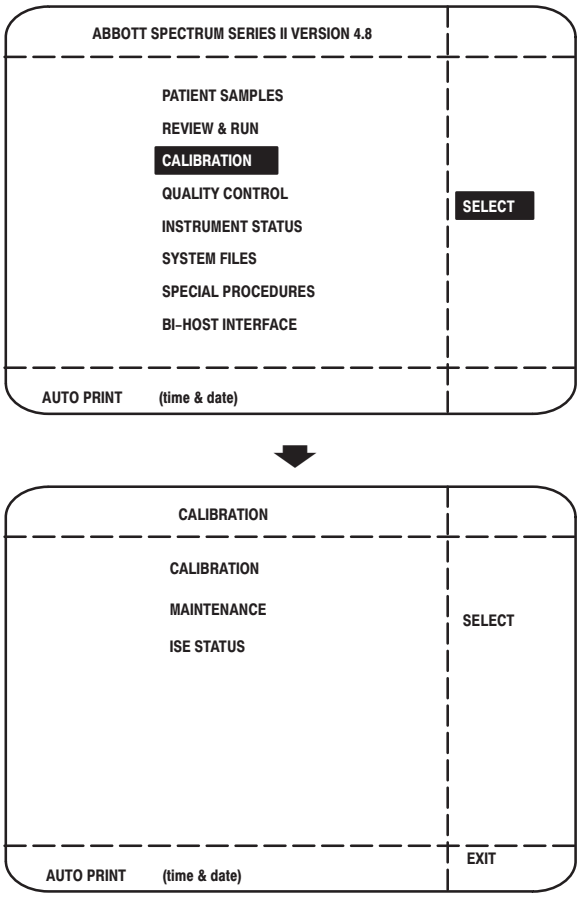


Figure 3-14 Calibration Screen Flow Map

Calibrator Status

Introduction

The Calibrator Status screen displays when CALIBRATION is selected from the Calibration screen. Refer to Figure 3-15 for the Calibrator Status Screen Flow Map.

This screen displays the status of all assays on the System.

Touch Screen Fields

TEST — Displays the name of the assay as defined in the Test Parameter Files.

STATUS — Displays the current status of the calibration data.

- DUE — Indicates the defined calibration interval has expired. Depending on the calibration mode, the assay will be calibrated the next time a sample is scheduled or RUN is touched in the Review & Run screen.
- FAIL — Indicates the calibration failed the tolerance limits defined in the assay Test Parameter Files, or AUTO ACCEPT is off. FAIL can also be an interim calibrator status when Master Cal has been initiated; the status will update to SCHED as the System prioritizes assay calibration order. When calibration completes, the status will display OK or FAIL.
- LOT ID — Indicates the barcode reader detected a master lot number change. Calibration will be performed.
- OK — Indicates the calibration curve is within the time interval, has acceptable data, and can be used.
- REBLK — Indicates a kinetic blank was requested by the operator, or the assay Test Parameter Files were edited. Calibration will be performed.
- RECAL — Indicates the operator requested calibration, or the assay Test Parameter Files were edited. Calibration was automatically requested.
- SCHED — Indicates the calibration is in progress.

Touch Screen Fields (continued)

NEXT CAL	Displays the time and date of the next calibration as defined in the Test Parameter Files or Instrument Options screen.
CAL FACT	Displays the calibration factor of the calibration curve or the kinetic blank.
INTERCEPT [C]	Displays the concentration intercept of the calibration curve.
NEXT PAGE	Displays additional assays.
MASTER CAL	Displays the status of master calibration.
DUE	Indicates the master calibration time interval has expired. The System will initiate a calibration of all assays associated with the master calibration time interval as defined in the Instrument Options screen.
OK	Indicates the calibration curve of all master cal assays is within the time interval. If MASTER CAL was OK and MASTER CAL is touched, a Y/N prompt and CODE 00259 PROCEED WITH MASTER CAL CHANGE? display. To initiate a calibration of all assays associated with the Master Calibration time interval in the Instrument Options screen, type Y (Yes) and press ENTER. If calibration of all assays is not appropriate, type N (No) and press ENTER.
SELECT	Used in conjunction with an assay name to display the Calibrator Status sub-screen for that specific assay.
EXAMINE CALIBRATOR LOADLIST	Displays the current calibrator loadlist.
EXIT	Displays the Calibration screen.

Calibrator Status

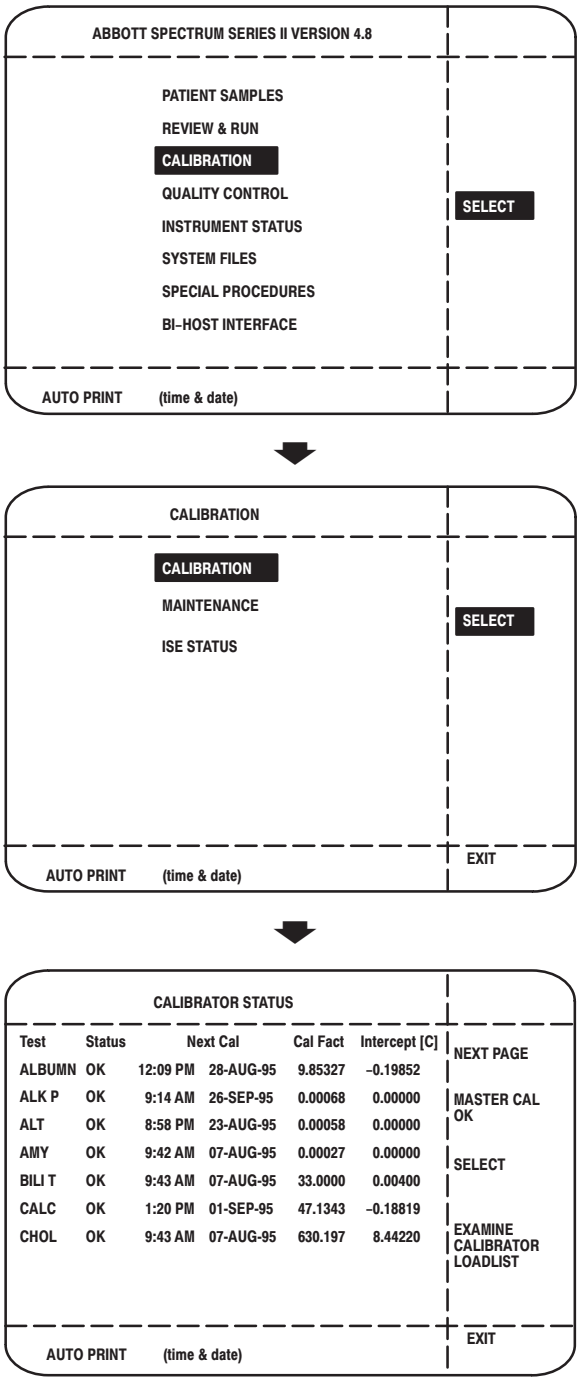


Figure 3-15 Calibrator Status Screen Flow Map

Calibrator Status Sub-screen for Calibrated Assays

Introduction

The Calibrator Status sub-screen displays when a specific end point assay is selected from the Calibrator Status screen. Refer to Figure 3-16 for the Calibrator Status Sub-screen Flow Map.

This screen displays the status of calibration data for a specific assay.

Touch Screen Fields

TEST NAME — Displays the name and math model of the assay selected from the Calibrator Status screen.

LAST CAL — Displays the time and date of the last calibration based on the calibration interval defined in the Test Parameter Files.

CAL STATUS — Displays the current status of the calibration data.

- DUE — Indicates the defined calibration interval has been exceeded and, depending on the calibration mode, will be calibrated the next time a sample assay is requested or RUN is touched in the Review & Run screen.
- FAIL — Indicates the end point assay failed the tolerance range defined in the Test Parameter Files, or AUTO ACCEPT is off.
- OK — Indicates the calibration curve is within the tolerance range defined in the Test Parameter File, has acceptable data, and can be used.
- RECAL — Indicates the operator requested calibration, or the assay Test Parameter Files were edited. The calibration was automatically requested.

CAL MODE — Displays the calibration mode as defined in the Test Parameter File.

Calibrator Status Sub-screen for Calibrated Assays

Touch Screen Fields (continued)

CAL LEVEL	Current display will be zero.
ENTERED	Displays the level number, name, and concentration of the calibrators/ standards as defined in the Test Parameter Files.
ACCEPTED	Displays the concentration and delta absorbance from the last accepted calibration.
NEW	Displays the concentration and delta absorbance from the most recent calibration. If the new calibration is accepted, the calibration data in the NEW and ACCEPTED columns is the same.
CAL FACT	Displays the calibration factor of the calibration curve.
INTERCEPT [Ad]	Displays the intercept of the calibration curve in Ad.
INTERCEPT [C]	Displays the concentration intercept of the calibration curve.
C. OF C.	Displays the coefficient of correlation for the calibration curve.
ACCEPT CAL	Allows manual acceptance of the new calibration. This field is touched when a new calibration is acceptable and AUTO ACCEPT is off, or when the System has rejected a calibration and the operator wishes to manually accept the new calibration.
SELECT ANOTHER TEST	Displays the Calibrator Status screen.
EXAMINE CALIBRATOR LOADLIST	Displays the current calibrator loadlist.
RE CALIBRATE	Performs a new calibration.
EXIT	Displays the Calibration screen.

Calibrator Status Sub-screen for Calibrated Assays

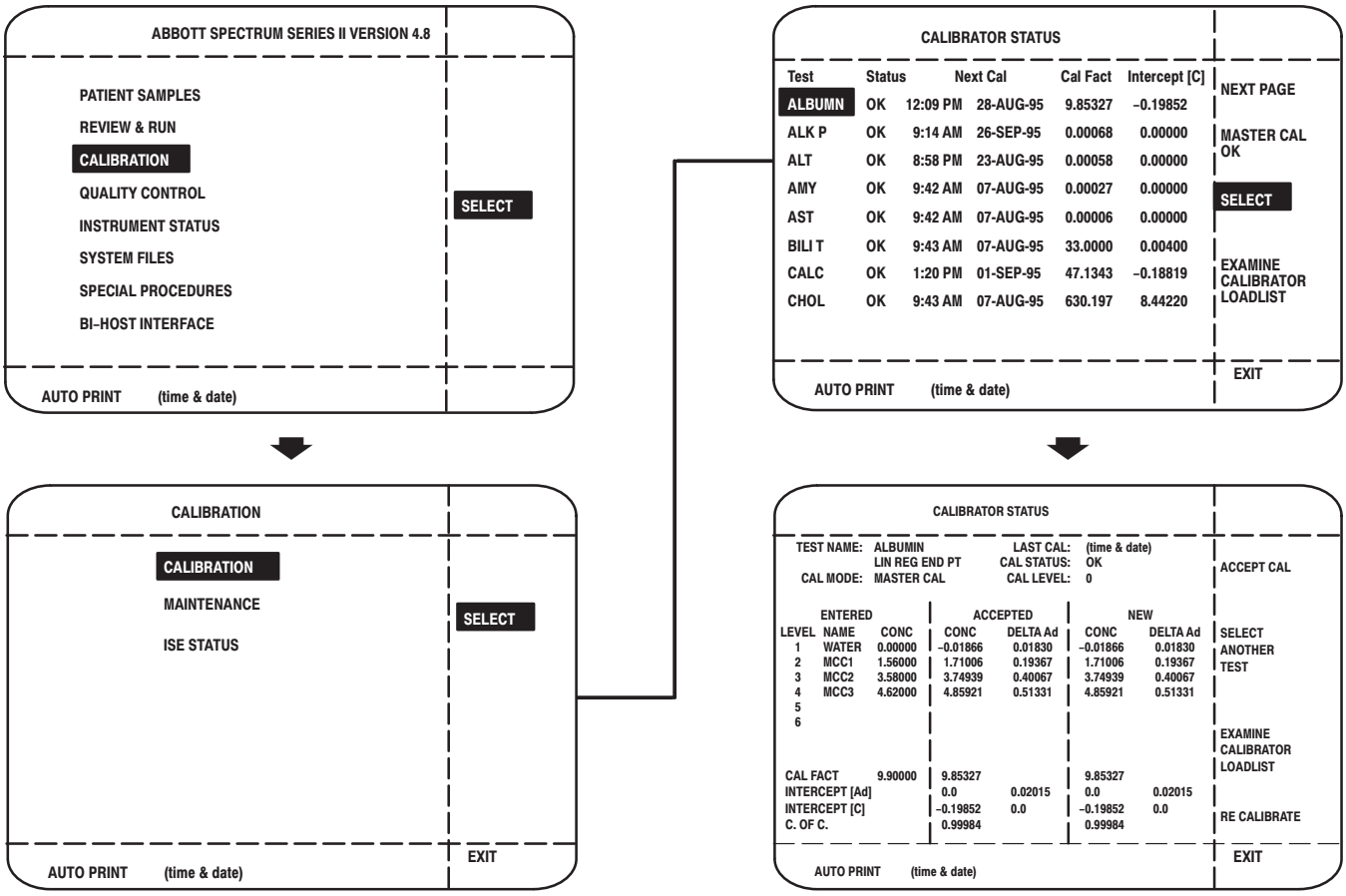


Figure 3-16 Calibrator Status Sub-screen Flow Map

Calibrator Status Sub-screen for Kinetic Blank

Introduction

The Calibrator Status sub-screen displays when a specific enzymatic assay is selected from the Calibrator Status screen. Refer to Figure 3-17 for the Calibrator Status Sub-screen Flow Map.

This screen displays the status of the kinetic blank calibration data and the time and date of the last accepted kinetic blank for the specific assay.

Touch Screen Fields

TEST NAME	Displays the name of the assay selected from the Calibrator Status screen.
LAST BLANK	Displays the time and date of the last kinetic blank based on the calibration interval defined in the Test Parameter File.
BLANK STATUS	Displays the current status of the kinetic blank.
DUE	Indicates the defined calibration interval has been exceeded and, depending on the calibration mode, will be calibrated the next time a sample assay is requested or RUN is touched in the Review & Run screen.
FAIL	Indicates the kinetic blank assay failed the tolerance range defined in the assay Test Parameter Files, or AUTO ACCEPT is off.
OK	Indicates the calibration curve is within the tolerance range defined in the Test Parameter File, has acceptable data, and can be used.
REBLK	Indicates the operator requested a kinetic blank, or the assay Test Parameter Files were edited. The kinetic blank was automatically requested.
ACCEPTED BLANK	Displays the RATE (ABSORB/MIN) from the last accepted kinetic blank.
NEW BLANK	Displays the RATE (ABSORB/MIN) from the most recent kinetic blank. If the new calibration is accepted, the calibration data in the NEW and ACCEPTED columns is the same.
TOLERANCE RANGE (ABSORB/MIN)	Displays the tolerance range for the kinetic blank as defined in the Test Parameter File. When the blank is outside this range, CODE 00282 KINETIC BLANK HAS FAILED THE TOLERANCE CHECK TEST: [redacted] is generated.
ACCEPT BLANK	Allows manual acceptance of the kinetic blank. This field is touched when AUTO ACCEPT is off or the System has rejected a kinetic blank and the operator wishes to accept the kinetic blank.

Touch Screen Fields (continued)

SELECT ANOTHER TEST	Displays the Calibrator Status screen.
EXAMINE CALIBRATOR LOADLIST	Displays the current calibrator loadlist.
KINETIC BLANK	Performs a new kinetic blank.
EXIT	Displays the Calibration screen.

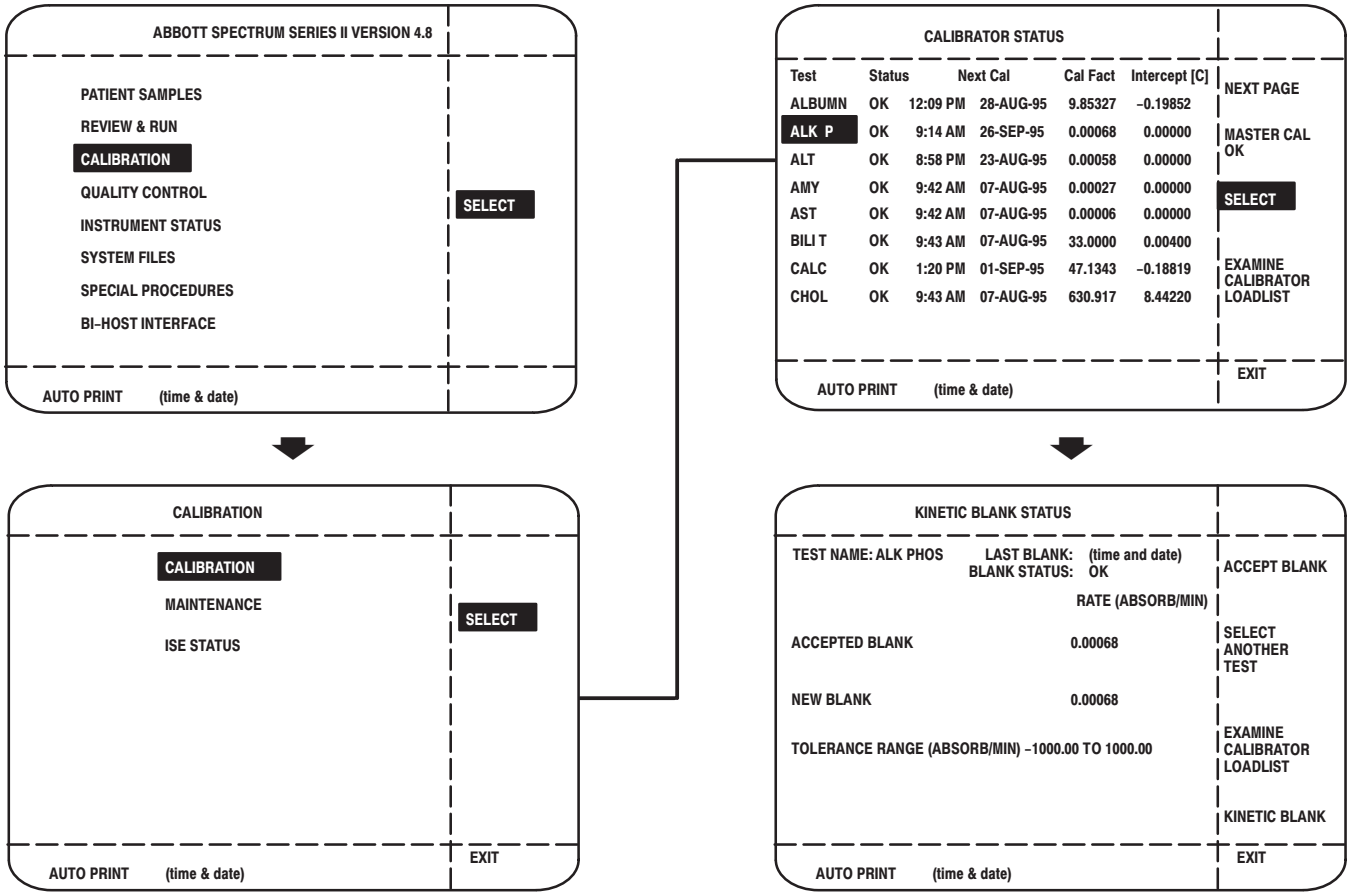


Figure 3-17 Calibrator Status Sub-screen Flow Map

Maintenance Menu

Introduction

The Maintenance Menu displays when MAINTENANCE is selected from the Calibration screen. Refer to Figure 3-18 for the Maintenance Menu Flow Map.

Automated daily maintenance, temperature calibration, ISE maintenance, and ISE pack change functions are performed from this screen.

Touch Screen Fields

DAILY MAINTENANCE	Touch this field and SELECT to initiate automated daily maintenance.
TEMPERATURE CALIBRATION	Touch this field and SELECT to display the Temperature Calibration screen, used to validate measured incubator temperature and request an incubator temperature adjustment.
ISE MAINTENANCE	Touch this field and SELECT to initiate ISE maintenance.
ISE PACK CHANGE	Touch this field and SELECT after changing the ISE reagent cartridge pack. The ISE purges twice and calibrates. A calibration report prints.
SELECT	Used in conjunction with a screen name or a function to display the screen or initiate the function.
EXIT	Displays the Calibration screen.

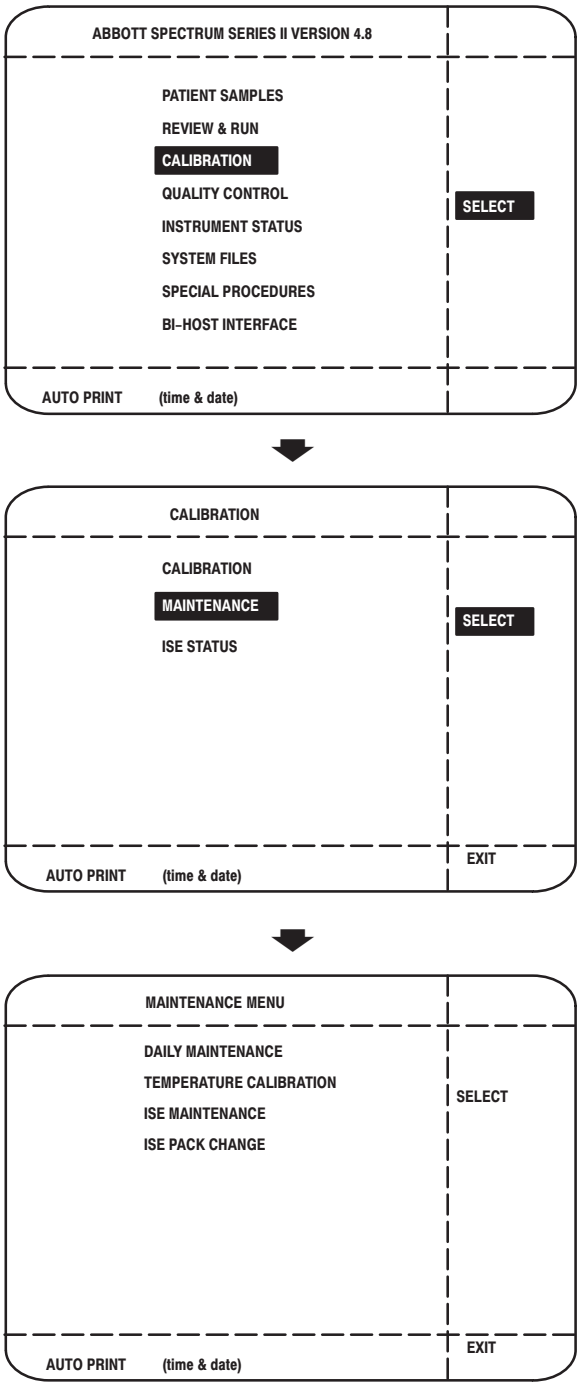


Figure 3-18 Maintenance Menu Flow Map

Temperature Calibration

Introduction

The Temperature Calibration screen displays when TEMPERATURE CALIBRATION is selected from the Maintenance Menu. Refer to Figure 3-19 for the Temperature Calibration Screen Flow Map.

This screen is used to validate measured incubator temperature and request an incubator temperature adjustment.

Data Entry Fields

DESIRED INSTRUMENT TEMPERATURE	A field used to enter desired temperature.
DESIRED CUVETTE ROTATION TIME	A field used to enter desired duration of cuvette rotation (default is 5 minutes).
ENTER MEASURED TEMPERATURE	A field used to enter temperature measured by thermistor when NO is touched in response to IS MEASURED TEMPERATURE READING WITHIN .1 OF DESIRED TEMP?

Touch Screen Fields

CURRENT INSTRUMENT TEMPERATURE	Displays the current operating temperature.
IS MEASURED TEMPERATURE READING WITHIN .1 OF DESIRED TEMP? YES/NO	Allows selection of YES to validate measured temperature, or NO to enter measured temperature for adjustment.
TEMP OFFSETS	Displays the original and current calculated offsets for each temperature.
ORIGINAL	Displays the prior offsets for temperature settings.
CURRENT	Displays the present offsets for temperature settings.
STATUS	Displays the status of the incubator temperature.
HOLDING TEMP	Indicates the desired temperature has been achieved.
SETTING TEMP	Indicates the System is equilibrating the temperature.

Touch Screen Fields (continued)

ROTATE CUVETTE	Initiates and continues cuvette rotation for the requested time period.
STOP ROTATION	Terminates cuvette rotation.
HOME ROBOTICS	Returns robotics to the home position.
EXIT	Displays the Maintenance Menu.

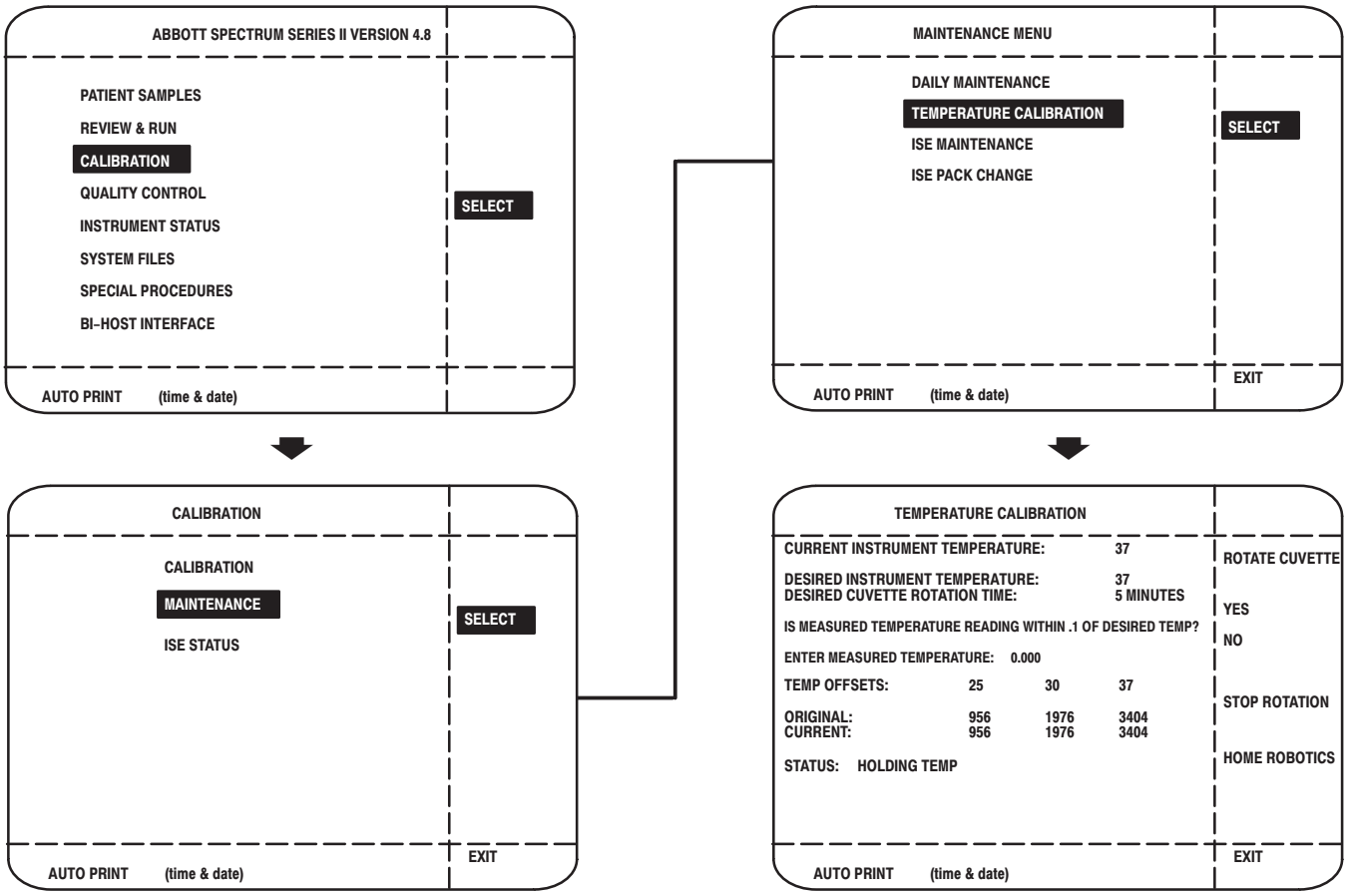


Figure 3-19 Temperature Calibration Screen Flow Map

ISE Status

Introduction

The ISE Status screen displays when ISE STATUS is selected from the Calibration screen. Refer to Figure 3-20 for the ISE Status Screen Flow Map.

This screen is used during ISE maintenance and diagnostics.

Touch Screen Fields

RADIAL MOVEMENT	Allows manual movement of the ISE module.
MOVE HOME	Moves the ISE module to the home position.
MOVE TO INNER	Moves the ISE module to the inner ring.
MOVE TO OUTER	Moves the ISE module to the outer ring.
MOVE CAROUSEL	Moves a specific sample carousel position under the ISE module.
PROBE EXTENSION	Allows movement of the ISE sample probe.
PROBE UP	Moves the ISE sample probe up.
TOP OF CUP	Moves the ISE sample probe to the top of the cup.
SET TOP	Displays the Top of Cup step position.
STEP UP	Steps the ISE sample probe up to make height adjustments to Top of Cup position.
STEP DOWN	Steps the ISE sample probe down to make height adjustments to Top of Cup position.
BOTTOM OF CUP	Moves the ISE sample probe to the bottom of the cup.

NOTE

THE SCREEN PERMITS STEPS BELOW 175 AND ABOVE 288. HOWEVER, POSITIONS OUTSIDE THE 175–288 RANGE ARE NOT STORED WHEN **SAVE POSITION** IS TOUCHED.

Touch Screen Fields (continued)

ISE CARE	Controls pump movement, analysis of samples, and calibration.
FLUSH	Circulates ISE Std A and B fluids through the System (short cycle).
PURGE	Circulates ISE Std A and B fluids through the System (long cycle).
ANALYZE SERUM	Determines the value of samples and displays results on the screen.
CALIBRATE	Initiates a 2-point calibration.
RESET	Moves the ISE sample probe up, moves the ISE module to the home position, and resets the electronics.
LOWER SCREEN	The area below the dotted line displays the following information. Electrode information displays in the left portion, including electrode name, the slope of each electrode, and whether the electrode channel is on or off. ***NC*** indicates the electrode did not calibrate or the time interval has expired. The time remaining until the current calibration is no longer valid is also displayed. ISE status information, including Aspirate Flow Time (AFT), Fill Flow Time (FFT), and status codes, displays in the center of this section. Results display in the right portion. Refer to Specific Procedures in this manual and ISE Status Codes & Diagnostics in the Maintenance & Troubleshooting Manual for additional information.
MAINTENANCE MODE	Allows entry into the ISE diagnostic maintenance screens. Refer to ISE Status Codes & Diagnostics in the Maintenance & Troubleshooting Manual for additional information.

ISE Status

Touch Screen Fields (continued)

FLOW	Displays the flow rate of samples through the ISE module. Aspirate Flow Time (AFT) and Fill Flow Time (FFT) display in the center section of the lower screen.
STATUS	Displays the ISE sample probe position (UP or DOWN) and the calibration status.
SAVE POSITION	Enters in memory the Top of Cup (set point) position.

NOTE

THE SCREEN PERMITS STEPS BELOW 175 AND ABOVE 288. HOWEVER, POSITIONS OUTSIDE THE 175–288 RANGE ARE NOT STORED WHEN **SAVE POSITION** IS TOUCHED.

HARDWARE RST	Resets all hardware related to the ISE. After hardware reset, the ISE must be calibrated.
EXIT	Displays the Calibration screen.

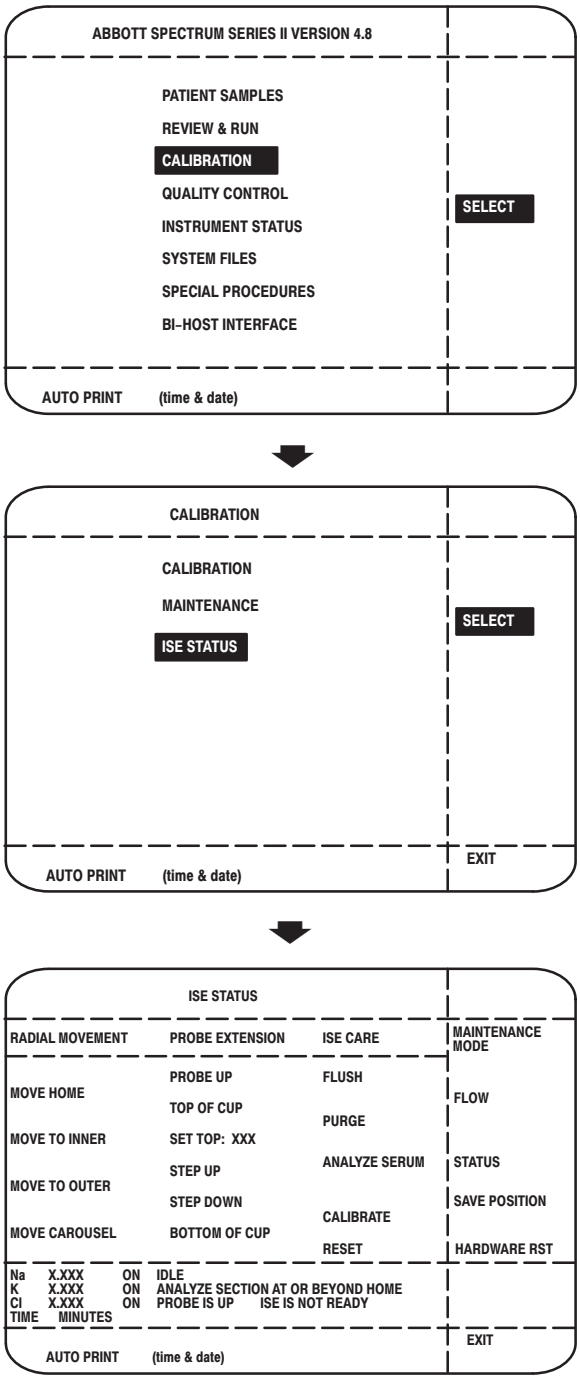


Figure 3-20 ISE Status Screen Flow Map

Quality Control Status

Introduction

The Quality Control Status screen displays when QUALITY CONTROL is selected from the Main menu. Refer to Figure 3-21 for the Quality Control Status Screen Flow Map.

The mean, standard deviation (S.D.), percentage coefficient of variation (% C.V.), and number of entries for each assay are displayed using the Quality Control screens.

NOTE

QUALITY CONTROL MUST BE ORDERED AS /C 1, /C 2, OR /C 3 IN THE PATIENT SAMPLES SCREEN FOR QUALITY CONTROL INFORMATION TO BE GENERATED IN THE QUALITY CONTROL SCREENS.

Touch Screen Fields

NEXT PAGE	Displays additional assays.
PREVIOUS PAGE	Displays the assays on the previous screen.
SELECT	Used in conjunction with an assay name to display the Quality Control Status sub-screen for that specific assay.
EXIT	Displays the Main menu.

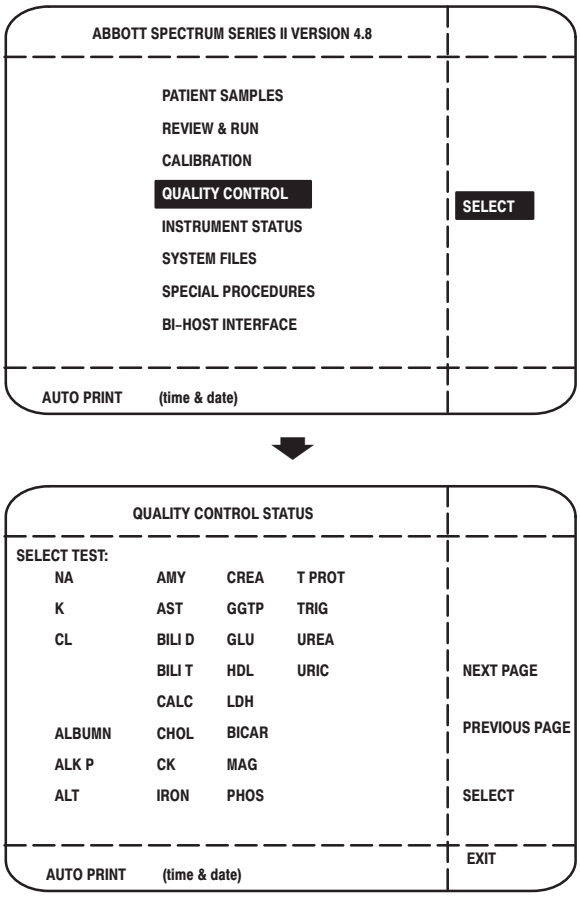


Figure 3-21 Quality Control Status Screen Flow Map

Quality Control Status Sub-screen

Introduction

The Quality Control Status sub-screen displays when a specific assay is selected from the Quality Control Status screen. Refer to Figure 3-22 for the Quality Control Status Sub-screen Flow Map.

The sub-screen displays the status of the quality control data and the calculations associated with each level of control. Only controls entered as /C 1, /C 2, or /C 3 before running are evaluated against the established quality control ranges. Controls manually assigned will not be evaluated against the established quality control ranges.

Data Entry Fields

LOW VALUE — A field used to define the established low value for the quality control material at each level.

HIGH VALUE — A field used to define the established high value for the quality control material at each level.

> **NOTE**
>
> IF LOW AND HIGH VALUE FIELDS REMAIN ZERO, NO CHECK IS MADE AND ALL UNFLAGGED RESULTS ARE ENTERED INTO THE FILE.

DELETE — A field used to delete the mean, S.D., and % C.V. values, while retaining the LOW and HIGH field values.

When DELETE is touched, the following options display:

- **ALL** — Deletes all levels for the assay.
- **ENTRY** — Deletes a specific result entry for a specific level.
- **LEVEL** — Deletes all result entries for a specific level.
- **PROCEED** — Initiates the deletion process.

> **NOTES**
>
> - WHEN A VALUE DELETED FROM THE FILE IS MODERATELY DIFFERENT FROM THE MEAN (AN APPROXIMATE FACTOR OF TWO), *** DISPLAYS. THE ENTIRE LEVEL MUST THEN BE DELETED.
> - WHEN A VALUE DELETED FROM THE FILE IS SIGNIFICANTLY DIFFERENT (AN APPROXIMATE FACTOR OF FIVE), 0000 DISPLAYS IN THE MEAN, S.D., AND % C.V. FIELDS. THE ENTIRE LEVEL MUST THEN BE DELETED.
> - EDITS MADE IN THE TEST PARAMETER FILE AUTOMATICALLY DELETE QUALITY CONTROL DATA ENTRIES IN THE QUALITY CONTROL FILE. HOWEVER, HIGH VALUE AND LOW VALUE MUST BE MANUALLY EDITED. ABBOTT LABORATORIES RECOMMENDS PRINTING THE QUALITY CONTROL FILE PRIOR TO EDITING THE ASSAY TEST PARAMETER FILE.

Touch Screen Fields

TEST SELECTED	Displays the selected assay.
LEVEL	Displays the quality control level.
STATUS	Displays the status for each of the three quality control levels for the assay.
HIGH	QC value for the level was above the set range.
LOW	QC value for the level was below the set range.
NEW	QC value for this level has never been run.
OK	QC value for the level was acceptable or has been manually accepted by the user.
RERUN	If results are not within range and QC SCREEN: ON displays in the Instrument Options screen, the operator is offered the option of accepting the level and storing the results, or rerunning the assay.
SCHED	QC value for this level is being run.
MEAN	Displays the calculated mean for each of the three levels of quality control for the specific assay.
S.D.	Displays the cumulative standard deviation for each of the three levels of quality control for the specific assay.
% C.V.	Displays the cumulative calculated percentage coefficient of variation for the specific assay.
ENTRIES	Displays the number of values for the specific assay.
SELECT ANOTHER TEST	Displays the Quality Control Status screen.
ACCEPT	Updates the quality control status to OK.
SAVE FILE	Stores edits to the LOW VALUE, HIGH VALUE, and STATUS fields.
EXIT	Displays the Main menu.

Quality Control Status Sub-screen

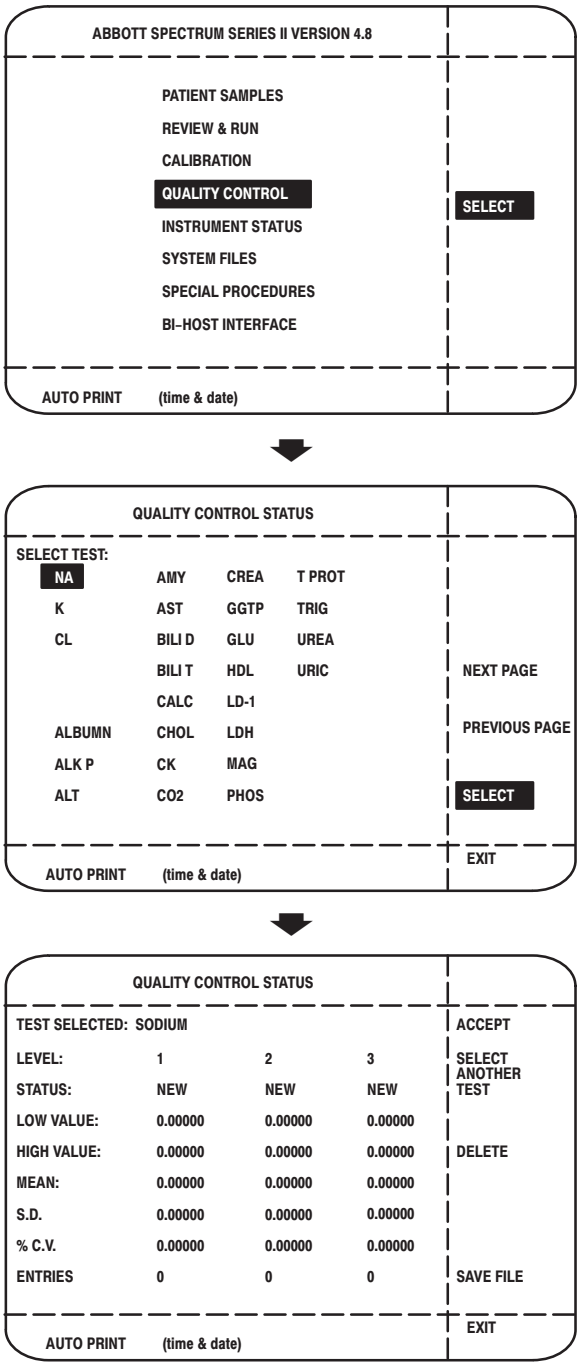


Figure 3-22 Quality Control Status Sub-screen Flow Map

Introduction

The Instrument Status screen displays when INSTRUMENT STATUS is selected from the Main menu. Refer to Figure 3-23 for the Instrument Status Screen Flow Map.

This screen allows access to current loadlists, and displays information about time of most recent maintenance, carousel number, incubator temperature, processing mode, number of tests scheduled, number of tests completed, and number of unused segments. From this screen, the System date and time may be changed.

Data Entry Fields

CHANGE DATE	A field used to change the System date.
CHANGE TIME	A field used to change the System time.

Touch Screen Fields

TIME OF MOST RECENT MAINTENANCE	Displays the time of the most recent maintenance performed on the System.
DAILY MAINT	Displays the time of the most recent automated daily maintenance routine.
TEMP CALIB	Displays the time of the most recent temperature calibration. The time is updated when YES is touched in response to IS MEASURED TEMPERATURE READING WITHIN .1 OF DESIRED TEMP? in the Temperature Calibration screen.
ISE MAINT	Displays the time of the most recent ISE maintenance routine.
CURRENT OPERATING STATUS	Displays the current operating status.
CAROUSEL #	Displays the sample carousel number currently in use.
TEMPERATURE	Displays the current incubator temperature. The displayed value should match the temperature selected for the test in progress.
PROCESSING MODE	Displays the processing mode selected from the Instrument Options screen.
# TESTS SCHED	Displays an approximate number of tests entered. The numbers are valid unless the Review & Run screen is entered while RUNNING is displayed in the ACTIVITY field.
# TESTS COMPLETE	Displays an approximate number of completed tests. The numbers are valid unless the Review & Run screen is entered while RUNNING is displayed in the ACTIVITY field.
# UNUSED SEG	Displays the number of unused cuvette segments. The value should be eight (8) at the beginning and zero (0) at the time of cuvette change.

Instrument Status

Touch Screen Fields (continued)

REVIEW	Displays the sample, reagent, or calibrator loadlist.
EXIT	Displays the Main menu.

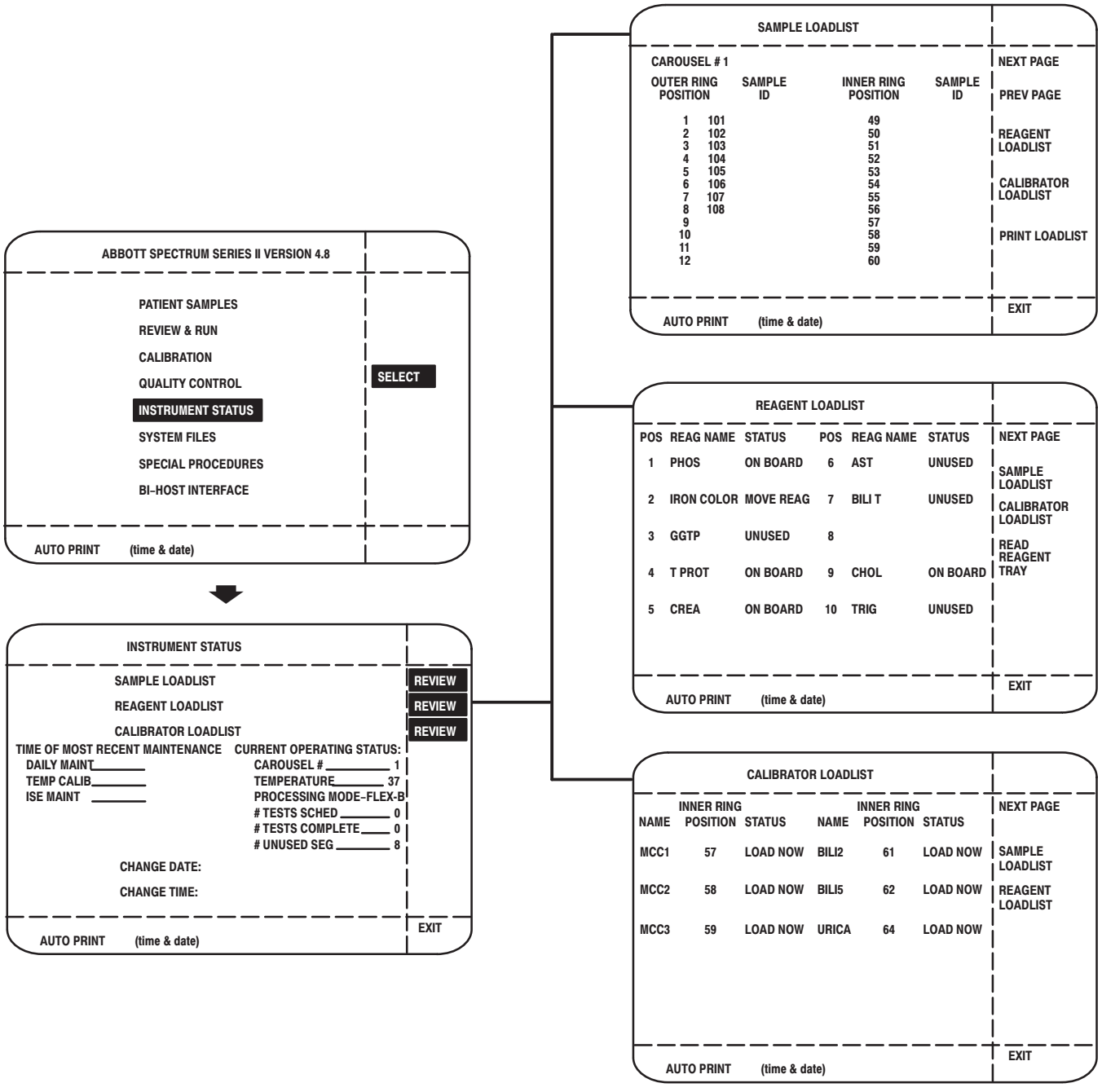


Figure 3-23 Instrument Status Screen Flow Map

Introduction

The System Files screen displays when SYSTEM FILES is selected from the Main menu. Refer to Figure 3-24 for the System Files Screen Flow Map.

This screen allows access to test assay, calibrator, and reagent parameters, instrument operating options, panel definitions, processing order, printing order, interface setup parameters, and Workload Analysis Files.

Touch Screen Fields

TEST PARAMETER FILES	Touch this field and SELECT to display the Test Parameter File screen.
INSTRUMENT OPTIONS	Touch this field and SELECT to display the Instrument Options screen.
PANEL DEFINITION	Touch this field and SELECT to display the Panel Definition screen.
PROCESSING ORDER	Touch this field and SELECT to display the Processing Order screen.
PRINT ORDER	Touch this field and SELECT to display the Print Order screen.
INTERFACE SETUP	Touch this field and SELECT to display the Interface Setup screen.
WORK ANALYSIS	Touch this field and SELECT to display the Workload Analysis screen.
SELECT	Used in conjunction with a screen name to display the screen.
EXIT	Displays the Main menu.

System Files

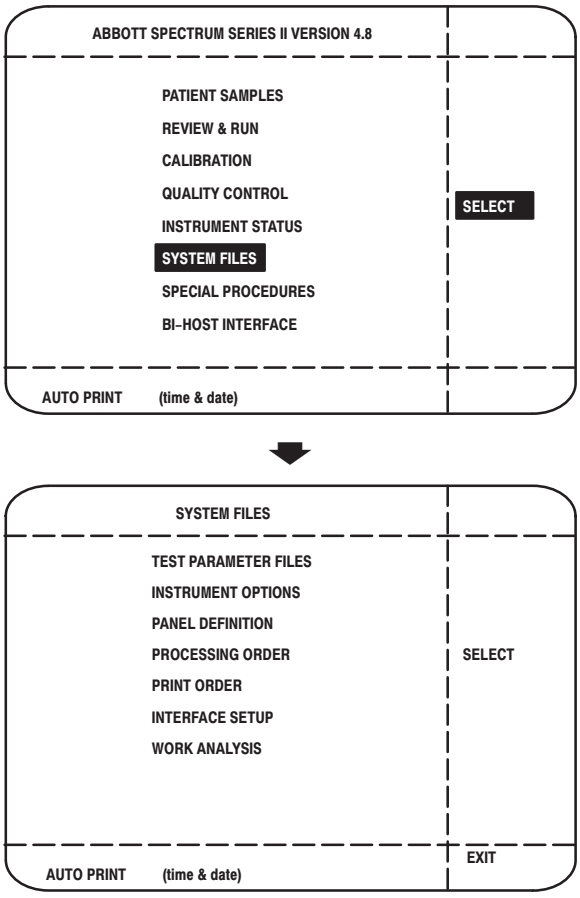


Figure 3-24 System Files Screen Flow Map

Test Parameter File: Test Definition

Introduction

The Test Parameter File: Test Definition screen displays when TEST PARAMETER FILES is selected from the System Files screen. Refer to Figure 3-25 for the Test Parameter File: Test Definition Screen Flow Map.

This file holds in memory parameters that define 127 assays. Test parameters cannot be edited while samples are in memory. CODE 00155 PATIENTS LOADED, CAN NOT EDIT PARMS displays when an edit is attempted while samples are in memory. To edit parameters, first delete all samples.

Edits to the Test Parameter File automatically delete quality control data entries in the Quality Control File for the edited assay. Abbott Laboratories recommends printing the Quality Control File prior to editing the assay Test Parameter File.

The correct password must be entered to add, edit, or delete a Test Parameter File. However, files may be displayed and printed without use of a password.

Data Entry Fields

ENTRY NAME	A 6-character, alphanumeric field used to enter the name designated by the reagent package insert and the Reagent Manual.
REPORT NAME	A 20-character, alphanumeric field used to enter a report name as it will be printed on the report.
RATIO REF	A 6-character, alphanumeric field used to enter characters for use in programmable ratios. This field typically matches the ENTRY NAME field.
TEST NUMBER	A field used to define the position of the assay in the Patient Samples screen. The component assays (or ratios of a ratio assay) must have a lower test number than the ratio itself. If not, values may not be calculated for the ratio.

Test Parameter File: Test Definition

Data Entry Fields (continued)

TEST TYPE	A field used to select the test type. The following test types are available and have been validated for use. The CYCLE key is pressed to display the appropriate option.
CALIBRATED	A single reagent, calibrated configuration.
NONCALIBRATED	A single reagent configuration without a calibration.
RATIO	A result obtained by combining results of other tests in a defined way. This test is not specifically dispensed on the System. Its value depends on the results obtained for its constituent tests. Refer to Specific Procedures, Assays – Ratios, for additional information.
OFFLINE	A test run on another analyzer. This function is included to allow the offline test results to display on printed reports. The result is manually entered in the Recall Results screen, and flagged # User Entered Result. Refer to Specific Procedures, Results – Offline, for additional information.
AUX	A multiple-reagent configuration that is calibrated.
SIMULTANEOUS	A multiple assay, single-reagent configuration.
AUX NON CALIB	A multiple-reagent configuration that is not calibrated.
SIM NON CALIB	A multiple assay, single-reagent configuration that is not calibrated.
ELECTROLYTE	A three-part test (sodium, potassium, and chloride) run on the ISE unit.

Data Entry Fields (continued)

MATH	A field used to select the preprogrammed math model. The following math models are available and have been validated for use. The CYCLE key is pressed to display the appropriate option. Refer to System Overview, Math Models, for additional information.
LIN REG RATE	Abbreviation for Linear Regression Rate, used to measure enzyme activity.
LIN REG RATE KIN BLNK	Abbreviation for Linear Regression Rate, with a separate kinetic blank.
LIN REG END PT	Abbreviation for Linear Regression End Point, used for substrate chemistries that come to equilibrium and have A_ds that are linear with concentration.
USER LIN REG	Abbreviation for User Linear Regression, used to determine unknown sample concentrations.
NO CONVERSION END PT	Abbreviation for No Conversion End Point, used for substrate chemistries that come to equilibrium and have A_ds that are linear with concentration.
CAL LIN RATE	Abbreviation for Calibrated Linear Rate, used for substrate chemistries that reach equilibrium slowly so there is a measurable period in which the A_ds are linear with time.
NO CONVERSION RATE	Used to determine the slope of the line ($\Delta A_d/\Delta t$).
NO CONVERSION RATE KB	Abbreviation for No Conversion Rate, with a separate kinetic blank.
2 PT CAL FACT END PT	Abbreviation for Two Point Calibration Factor End Point, used for substrate chemistries that come to equilibrium and have A_ds that are linear with concentration.
1 PT CAL FACT END PT	Abbreviation for One Point Calibration Factor End Point, used for substrate chemistries that come to equilibrium and have A_ds that are linear with concentration.
DELTA RATE	Used to subtract the activity of one rate reaction from the activity of another rate reaction.
DELTA RATE KB	Abbreviation for Delta Rate, with a separate kinetic blank.

Test Parameter File: Test Definition

Data Entry Fields (continued)

REACTION DIRECTION	A field used to specify allowable reaction direction. The CYCLE key is pressed to display the appropriate option (UP or DOWN).
REAGENTS	A field used to specify the number of reagents for optical assays. Valid entries are 1-3.
TEMPERATURE	A field used to enter the incubator temperature. The CYCLE key is pressed to display the appropriate option (37, 30, or 25).
TEST BLANK TYPE	A field used to enter blanking options, as stated in the reagent package insert and the Reagent Manual. The CYCLE key is pressed to display the appropriate option.
NO BLANK	No blank is used when no blank subtraction is required.
REAGENT BLANK	Reagent blank is used to correct for reagent absorbance. The reagent blank assay subtracts the reagent blank read from the final read.
SERUM BLANK	Serum blank is used for some end point reactions to correct for sample absorbance. The serum blank assay subtracts the serum blank read from the final read.
REAGENT 1 BLANK	The last read taken on Reagent 1 is subtracted from the final read and volume corrected.
REAGENT 2 BLANK	The last read taken on Reagent 2 is subtracted from the final read.
AUX SERUM BLANK	The read taken immediately after addition and mixture of the last auxiliary reagent is subtracted from the final read.
AUX REAGENT BLANK	The read taken immediately before addition of the final reagent is subtracted from the final read.

Data Entry Fields (continued)

COMB TEST NAME

A field used to link the Test Parameter Files of simultaneous assays. This parameter is not defined for the first component assay. When the file for the second component assay is created, the name of the first component is entered in the COMB TEST NAME field. If a third component test file is defined, the name of the second component assay is entered into this field. All other parameters are defined individually for the assays.

EDIT TIME

A field used to display the time and date of most recent edits to the Test Parameter File.

SAMPLE (uL)

A field used to enter the sample volume for the reaction. Valid entries are 1.25µL to 25µL, in 0.25µL increments. NORMAL defines routine assays. LOW and HIGH allow entry of sample volume to be used for Auto Concentration (LL) or Auto Dilution (LH) conditions. Values are defined in the reagent package insert and the Reagent Manual.

Both sample and reagent volume fields must be defined for each assay when defining normal, low, and high fields.

UNITS

A field used to display the units of the final result.

PRIM

Displays the concentration unit of the final result.

SEC

Displays an alternate unit for the final result.

SEC. UNITS FACTOR

A field used to enter a multiplier for converting the results in primary units to secondary units.

PRINT DIGITS

A field used to select the number of significant digits to appear to the right of the decimal for each printed assay result. Valid entries are 0-4.

Printing of an assay may be suppressed by displaying NONE in the PRINT DIGITS field.

NOTE

RESULTS DISPLAYED IN THE RECALL RESULTS SCREEN ARE NOT AFFECTED BY THE NUMBER OF PRINT DIGITS SPECIFIED.

Test Parameter File: Test Definition

Data Entry Fields (continued)

INST MUL INT	MUL allows entry of a factor to multiply the final instrument results to equal the results of another analyzer when instrument-to-instrument correlation is necessary. INT is the intercept of a linear regression performed between the ABBOTT SPECTRUM SERIES II System and another analyzer, demonstrated in Equation 3-1. New Results = ABBOTT SPECTRUM SERIES II System Results × MUL + INT (Equation 3-1)
NORMAL [C]	A field used to enter the low-to-high value of sample reference/normal range. These values should be determined for each laboratory population.
SAMPLE DISP DELAY (SEC)	Not currently active.
RATE C. OF C.	A field used to enter the acceptable minimum value for the coefficient of correlation of the line through multiple read points taken during a rate assay. The recommended value for screening is 0.90. Assay results which fail the Rate C. of C. check display MA in the Recall Results screen. CODE 00287 TEST: [redacted] RATE COEFFICIENT OF CORRELATION CHECK FAILED SAMPLE ID: [redacted] displays for each failed assay. Flagged values do not print automatically. Reports printed by command from the screen or by a host computer contain the results, with the MA flag. Refer to Status Codes in the Maintenance & Troubleshooting Manual for additional information.

Touch Screen Fields

NEXT TEST	Displays the next assay.
DELETE TEST	Deletes the assay parameters from the memory. If selected, PROCEED WITH DELETE? Y/N displays. Type Y (Yes) to delete the file or N (No) to retain the file and press ENTER.
SAVE TEST	Stores screen edits.
DEFINE CALIB	Displays the Calibration Definition screen.
DEFINE REAGENT	Displays the Reagent Definition screen. To store the assay in memory, reagents must be defined for each assay (except offline and ratios).
EXIT	Displays the System Files screen.

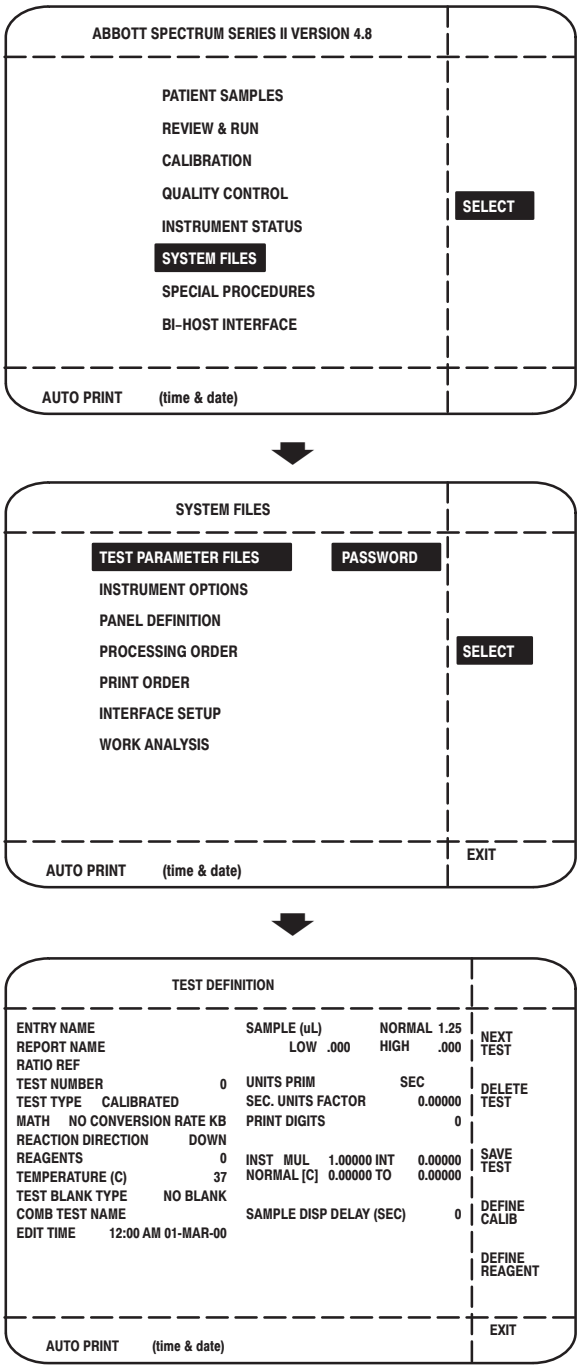


Figure 3-25 Test Parameter File: Test Definition Screen Flow Map

Test Parameter File: Calibration Definition

Introduction

The Test Parameter File: Calibration Definition screen displays when an entry name and DEFINE CALIB are selected from the Test Definition screen. Refer to Figure 3-26 for the Test Parameter File: Calibration Definition Screen Flow Map.

The Calibration Definition screen defines parameters for the calibration of assays (e.g., calibration/standard concentration values). Test parameters cannot be edited while samples are in memory. CODE 00155 PATIENTS LOADED, CAN NOT EDIT PARMS displays when an edit is attempted while samples are in memory. To edit calibration parameters, first delete all samples.

Data Entry Fields

TEST NAME	A field that displays the ENTRY NAME from the Test Definition File.
COMB TEST	A field that displays the COMB TEST NAME from the Test Definition File.
CAL MODE	A field used to select the calibration mode for end point assays. The CYCLE key is pressed to display the appropriate option (MASTER CAL or CAL ON COMMAND). Refer to Specific Procedures, Calibration - Optical Assays, for additional information.
INTCPT TOL [C]	A field used to enter the acceptable range for the concentration intercept of the calibration. When the intercept is outside this range, CODE 00286 TEST: [redacted] INTERCEPT TOLERANCE RANGE CHECK HAS FAILED displays.
% TOL OF CAL FACTOR	A field used to enter acceptable tolerance of assayed calibration factors from the reference calibration factor. When this value is exceeded, CODE 00002 TEST: [redacted] CALIBRATION CAL FACTOR TOLERANCE HAS FAILED displays.
CAL LEVEL	Not currently active.
CALIBRATOR	A field used to designate the calibrator.
LEVEL [C]	A field used to enter concentration values for each of the six calibrators/standards. A maximum of one value per level can be designated.
REPLICATES	A field used to enter averaged repetitive calibrators. Valid entry is 1.

Data Entry Fields (continued)

TEST TYPE	A field that displays the TEST TYPE from the Test Definition File.
MATH MODEL	A field that displays the MATH MODEL from the Test Definition File.
CAL INTERVAL (HR)	A field used to enter the expected calibration interval as designated by the package insert or established by the operator.
REF CAL FACTOR	A field used to enter the expected calibrator factor as designated by the package insert or established by the operator.
% TOL OF CAL	A field used to enter the acceptable tolerance of assayed calibrator values from the entered values of the calibrators. When this value is exceeded, CODE 00046 TEST: [redacted] CALIBRATOR TOLERANCE HAS FAILED FOR CALIBRATOR #: [redacted] displays.
TOLERANCE RANGE (ABS/MIN)	A field used to enter the acceptable range for the kinetic blank. When the blank is not within range, CODE 00282 KINETIC BLANK HAS FAILED THE TOLERANCE CHECK TEST: [redacted] displays.

Touch Screen Fields

DELETE CALIB	Deletes the Calibration Definition file from the memory. If selected, PROCEED WITH DELETE? Y/N displays. Type Y (Yes) to delete the file or N (No) to retain the file and press ENTER.
SAVE CALIB	Stores screen edits.
DEFINE REAGENT	Displays the Reagent Definition screen.
EXIT	Displays the Test Definition screen.

Test Parameter File: Calibration Definition

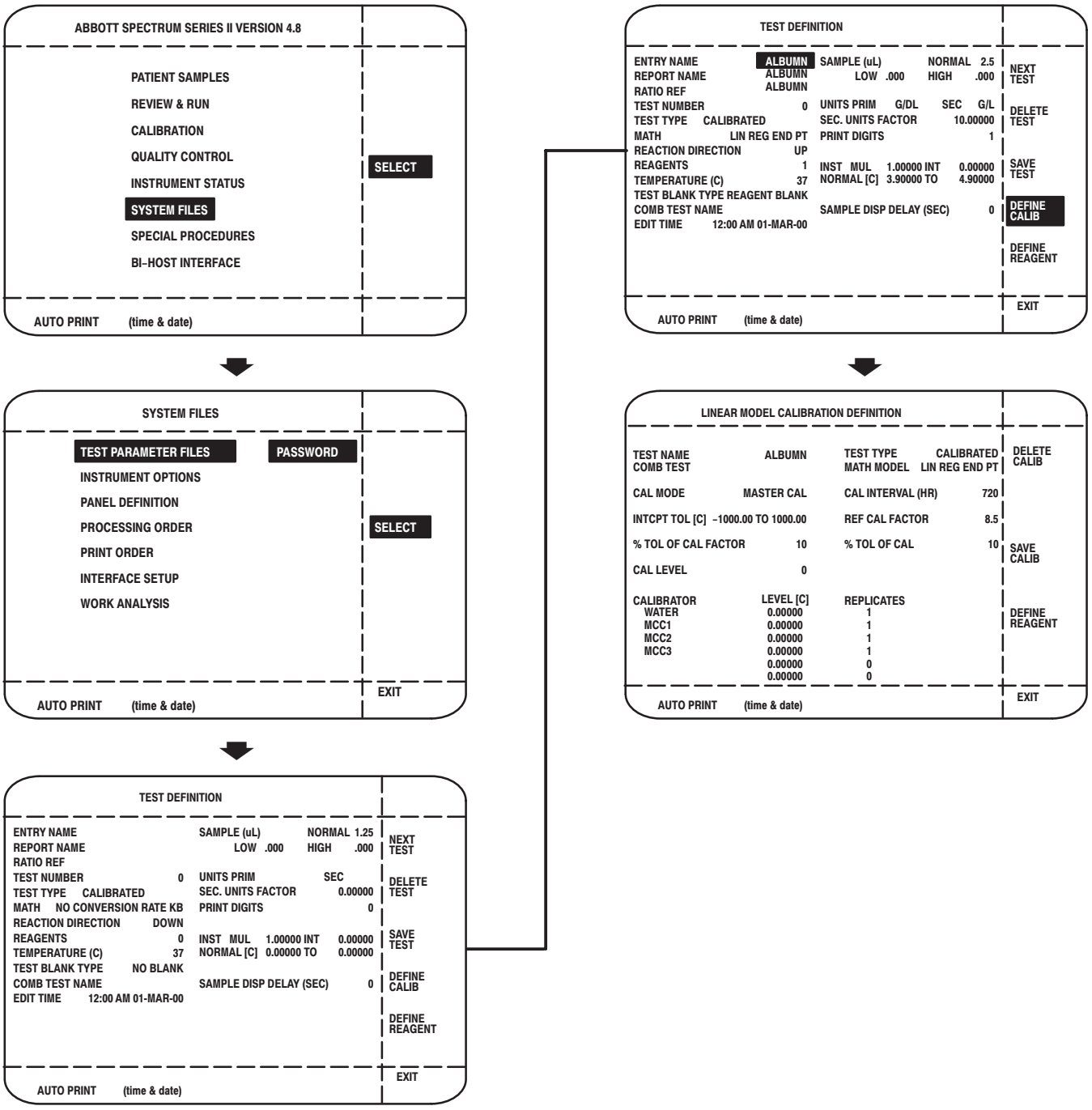


Figure 3-26 Test Parameter File: Calibration Definition Screen Flow Map

Test Parameter File: Reagent Definition

Introduction

The Test Parameter File: Reagent Definition screen displays when an entry name and DEFINE REAGENT are touched. Refer to Figure 3-27 for the Test Parameter File: Reagent Definition Screen Flow Map.

This screen is used to enter and edit test reagent parameters. Test reagent parameters cannot be edited while samples are entered. CODE 00155 PATIENTS LOADED, CAN NOT EDIT PARMS displays when edit is attempted while samples are in memory. Delete all samples before editing.

Data Entry Fields

REAGENT NUMBER FOR TEST

A field used to display the number of the reagent currently being defined.

REAGENT NAME

A 10-character, alphanumeric field used to enter a reagent name, as designated by the reagent package insert and the Reagent Manual. Edits to this field are not stored when SAVE is touched. To edit the REAGENT NAME, the assay file must be deleted and re-entered. This name displays on the reagent loadlist and the wash matrix. When a change is made to the REAGENT NAME, the corresponding reagent name will be changed in the wash matrix.

REAGENT VOL (uL)

A field used to enter the reagent volume. Valid entries are 25µL to 486µL, in increments of 1.92µL. The value displayed on the screen is rounded to three digits. CODE 00168 REAGENT VOLUME OUT OF RANGE displays when entries are not within the range. NORMAL is used for routine assays. The LOW and HIGH fields allow entry of reagent volume for Auto Concentration (LL) or Auto Dilution (LH) conditions.

Both sample and reagent volume fields must be defined for each assay when defining normal, high, and low fields.

If the sample is flagged Initial Absorbance (IA) or Low Energy (LE), no dilution or concentration protocol will be performed. However, a dilution protocol will be performed on samples flagged Maximum Absorbance (MA).

FIRST READ TIME

A field used to specify the time of the first read. Valid entries are 0–65520 seconds. First read time of zero (0) substitutes the serum blank for the first read.

LAST READ TIME

Used for linear interpolation.

NUMBER OF READS

A field used to specify the number of readings. Maximum valid entries are 14 - (2 X number of reagents) for rate assays; end point assays are restricted to 1 or 2 reads.

Test Parameter File: Reagent Definition

Data Entry Fields (continued)

READ INTERVAL (SEC)	A field used to specify the time between readings, in increments of 0.1 second. The System will use only a 60-second interval.
AUX REAG DISP (SEC)	A field used to specify the time, in seconds, of the auxiliary reagent dispense. Time is measured from the sample dispense for the first reagent and from the last reagent for subsequent reagents. The time entered must be 60 seconds greater than the final read time on the previous reagent.
RSM	A 2-digit numeric field used to enter the reagent step modifier (RSM). Valid entries are -2–10, with a default value of zero (0). The use of this feature is documented in the reagent package insert.
USE IN	A field used to specify spectral correction for simultaneous assays. For all routine assays, the first five rows of the column should be set at A; the last row should be set at LE. Parameters for simultaneous assays are provided in the reagent package insert.
PRIM/SEC	A field used to specify the wavelength pair selections. Valid entries are 340, 364, 380, 404, 412, 452, 484, 500, 516, 548, 564, 572, 604, 636, 652, 660, UA (Microamp), MA (Milliamp). MA is used as the secondary wavelength selection when monochromatic readings are desired. The first five wavelength pair selections must be the same for routine assays. The last wavelength pair must be the primary wavelength of the first five pairs and the MA as a low energy check. The wavelength pairs may be different for simultaneous assays. The use of this feature is documented in the reagent package insert.
CONST	A field used to specify spectral correction parameters for simultaneous assays. For routine assays, all six rows should be set at 1.0. Parameters for simultaneous assays are provided in the reagent package insert.
E.F.	A field used to specify the extinction coefficient for the chromophore measured at the specific wavelength. Each instrument has specific extinction factors (E.F.s) established for the wavelengths. When an E.F. is required for a reagent, use the value number set for your instrument for those specific wavelengths.
SPECTRAL CORRECTION LOW/HIGH	A field used to specify flagging ranges for spectral correction. For routine assays, all fields for low/high should be set at 0.0. Parameters for simultaneous assays are provided in the reagent package insert.
LINEARITY [C]	A field used to enter high and low linear limits necessary for assay performance. Values above the high limit display (LH) and values below the low limit display (LL), and CODE 00013 LINEAR HIGH OR LOW CHECK FAILURE. TEST: [redacted] is generated.

Data Entry Fields (continued)

INITIAL Ad	A field used to specify the limit of initial reagent acceptability. The displayed value must be greater than 0 and less than or equal to 3.0. When this value is exceeded, CODE 00011 TEST: [redacted] INITIAL ABSORBANCE "IA" CHECK FAILED FOR REAGENT: # [redacted], POSSIBLE REAGENT PROBLEM displays. Values greater than 2.4 may be present in some recommended Test Parameter Files for Initial A_d and ABS LIMIT. Do not use values greater than 2.4 unless specifically indicated by Abbott Laboratories.
ABS LIMIT (Ad)	A field used to specify the absorbance limit set for the reagent. Absorbance values beyond this limit indicate that the reagent's analytical capacity is near exhaustion (i.e., substrate depletion). Further change in absorbance may not be proportional to the analyte concentration. The value is a maximum absorbance (in A_d) for UP reactions and a minimum absorbance (in A_d) for DOWN reactions. The displayed value must be greater than 0 and less than or equal to 3.0. When this value is exceeded, CODE 00012 TEST: [redacted] REACTION ABSORBANCE "MA" EXCEEDS LIMIT. REAGENT: # [redacted] PROBABLE HIGH ANALYTE CONCENTRATION displays.
BEFORE WASH CYCLES	A field used to specify the number of reagent probe washes before the assay (valid entries are 1–18). The System defaults to 18. This field is active only when more than 60 reagents are entered in the Test Parameter File. Refer to Specific Procedures, Wash Matrix, for additional information.
AFTER WASH CYCLES	A field used to specify the number of reagent probe washes after the assay (valid entries are 1–18). The System defaults to 18. This field is active only when more than 60 reagents are entered in the Test Parameter File. Refer to Specific Procedures, Wash Matrix, for additional information.
MIX TIME	A field used to specify the stir time, up to 5.0 seconds. The reagent package insert and the Reagent Manual designate the appropriate mix time.
COOLING	A field used to specify the requirement for reagent cooling. When reagents are placed in an inappropriate temperature, MOVE REAG displays on the reagent loadlist.
CONSTANT INTERCEPT	A field used to specify the intercept value used in the spectral correction calculation. For routine assays, this parameter should be set at 0.0. Parameters for simultaneous assays are provided in the reagent package insert.

Test Parameter File: Reagent Definition

Data Entry Fields (continued)

CORRECTION LIMIT	A field used to specify the value at which spectral correction with C, D, E and constant intercept wavelengths is initiated. For routine assays, this parameter should be set at 0.0. Parameters for simultaneous assays are provided in the reagent package insert.

Touch Screen Fields

LOT ID	Defines the reagent lot number read by the barcode reader.
CANCEL	Disregards screen edits and displays the Test Parameter File screen.
SAVE/NEXT REAGENT	Stores screen edits and displays the reagent's Test Definition screen.

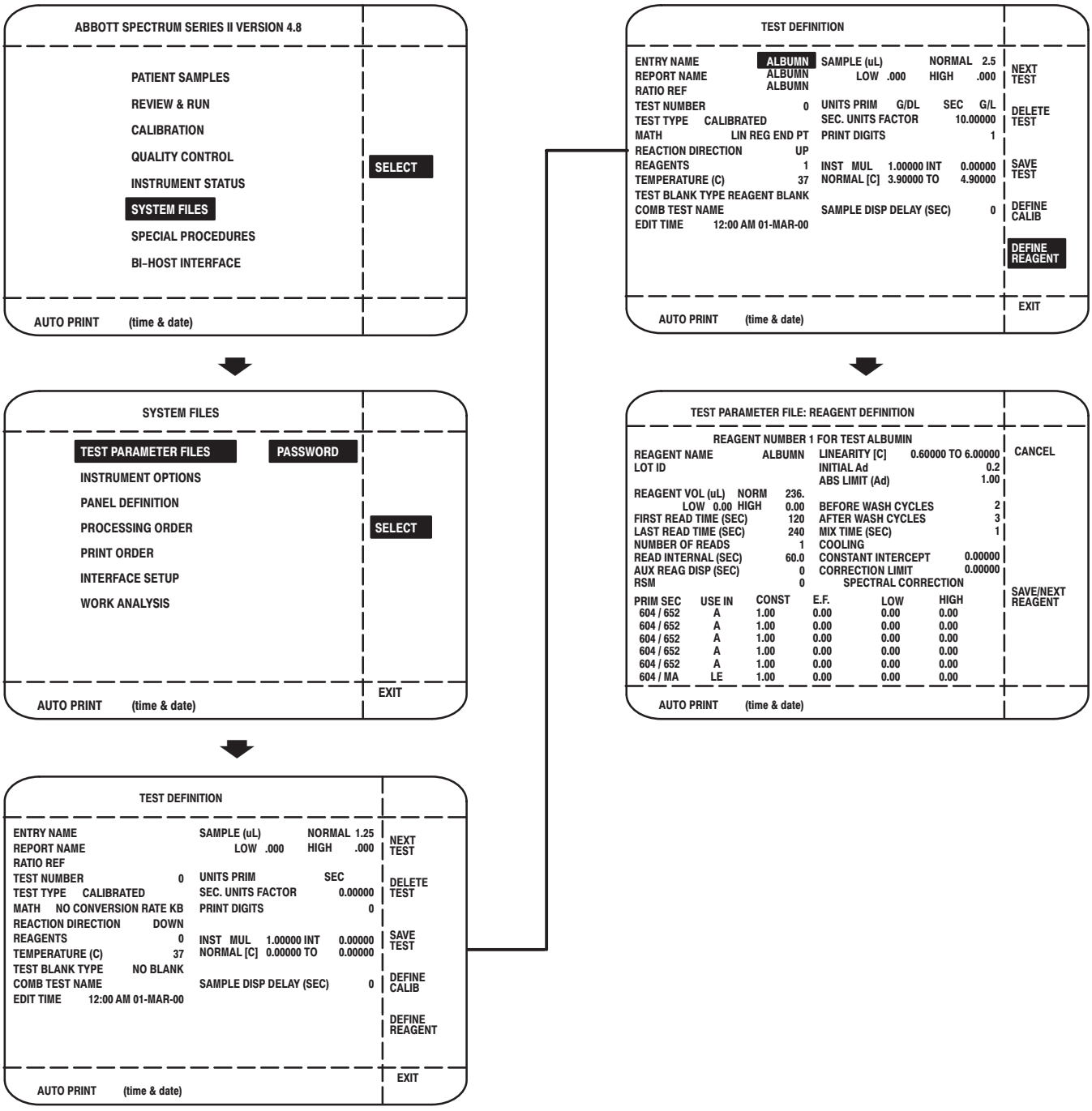


Figure 3-27 Test Parameter File: Reagent Definition Screen Flow Map

Instrument Options

Introduction

The Instrument Options screen displays when INSTRUMENT OPTIONS is selected from the System Files screen. Refer to Figure 3-28 for the Instrument Options Screen Flow Map.

Several unique features of the System are available through this screen. The System may be customized to maximize processing and efficiency when the ACTIVITY field is not highlighted.

Data Entry Fields

REPORT HEADER

A field used to enter the report header (1-5 lines of 60 characters). This information prints at the top of the patient report. Touch this field, then type the appropriate information.

CHANGE PASSWORD

A field used to limit access to the Test Parameter Files, Workload Analysis Files, and Sample Distribution Files for creating, editing, or deleting. The OLD PASSWORD must be entered to establish a NEW PASSWORD, which must be re-entered to CONFIRM.

SCHEDULING MODE

A field used to select the scheduling mode. The CYCLE key is pressed to display the appropriate option (FLEX-B, BATCH, RANDOM, or TANDEM).

FLEX-B (Flexible Batch)

Flexible Batch, or Flex-B, is an efficiency processing mode. The System schedules assays to run in decreasing incubation time within a run. This decreases the time interval needed between end of dispense and end of run. When operating in the Flex-B mode, the System runs assays in a different order from run to run, depending on the mix of tests requested. Each time RUN is touched, the System runs assays with the longest incubation time, followed by progressively shorter assays within the run.

BATCH

In the Batch mode, the System runs 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. The priorities for same-type assays are:

- Processing Order (if defined)
- Test Number (if assay is not defined in Processing Order)
- Temperature (defined in individual Test Parameter Files)

RANDOM

In the Random mode, all assays are initiated on one sample before proceeding to the next. Sample sequence is based on carousel postion number. All assays for each sample are prioritized according to their number in the Processing Order or the Test File, with the exception of electrolytes. Optical assays are dispensed; then electrolyte assays are aspirated on each sample. Assays with the same temperature, or samples with the same assays ordered, are positioned in an optimized order on consecutive samples. The ISE aspirates samples while a temperature change is in progress.

Data Entry Fields (continued)

STAT Samples	STAT requests are processed in the Random mode, regardless of the mode currently in use. When a STAT is requested, the System 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.
TANDEM	The Tandem mode accelerates reporting by prioritizing sample processing based on the number of assays ordered for each sample. Samples are processed to yield the maximum number of completed reports in the least amount of time. Thus, samples with one assay precede those with two, which precede those with three, etc. (Electrolytes are considered a single assay.) When both optical and electrolyte assays are requested, opticals are dispensed, then electrolyte assays are aspirated on each sample. Assays within each sample are prioritized by number in the Processing Order or the Test File.
PARTIAL ISE	A field used to select partial ISE. The CYCLE key is pressed to display the appropriate option (ON or OFF). When PARTIAL ISE: ON displays, the instrument analyzes electrolytes when one or two electrodes fail to calibrate. Only the results of the successfully calibrated electrodes are reported. When PARTIAL ISE: OFF displays, the instrument does not analyze samples for electrolytes if any one of the electrode channels is not calibrated.
SWITCH LOW REAG	A field used to select switch low reagent. This function is used in conjunction with cartridge transfer. The CYCLE key is pressed to display the appropriate option (ON or OFF). When SWITCH LOW REAG: ON displays, and two or more cartridges of the same reagent are available on the System, the System automatically switches to the next lowest position number of like reagent when the System senses reagent volume is low. When SWITCH LOW REAG: OFF displays, cartridge transfer occurs automatically when no reagent is detected in the first cartridge.
QC SCREEN	A field used to select quality control screening. The CYCLE key is pressed to display the appropriate option (ON or OFF). When QC SCREEN: ON displays, the System does not report values for assays for which quality control sample has failed. When QC SCREEN: OFF displays, the System generates reports for assays for which QC failed. Refer to Specific Procedures, Quality Control - Define, for additional information.

Instrument Options

Data Entry Fields (continued)

OVERRIDE CALIBRATIONS	A field used to select override calibrations. The CYCLE key is pressed to display the appropriate option (ON or OFF). When OVERRIDE CALIBRATIONS: ON displays, the System uses the established calibration curve information if the new calibration fails.
AUTO ACCEPT CALIBRATIONS	A field used to select auto accept calibrations. The CYCLE key is pressed to display the appropriate option (ON or OFF). When AUTO ACCEPT CALIBRATIONS: ON displays, the System uses the criteria in the Test Definition Files to automatically accept or reject calibration information without intervention from the operator. When the calibration is outside the established range, status codes display.
MASTER CALIBRATION INTERVAL	A field used to specify the time (in hours) between master calibrations. Valid entries are 1-65535.
USE PROCESSING ORDER	A field used to select use processing order. The CYCLE key is pressed to display the appropriate option (ON or OFF). When USE PROCESSING ORDER: ON displays, the System processes samples according to the defined Processing Order. When USE PROCESSING ORDER: OFF displays, the System processes samples according to Test File Order (except when utilizing Flex-B mode of operation).
TEMPERATURE OFFSETS	A field used to display the electronic number used by the System software to set the temperature.
ISE TOP OF CUP	A field used to display the electronic number used by the System software to step the ISE probe to the top of the sample cup.
USE BARCODE READER	A field used to select the barcode reader. The CYCLE key is pressed to display the appropriate option (ON or OFF). When USE BARCODE READER: OFF displays, the barcode reader does not read automatically upon entry into the Review & Run screen. The reader must be turned on each time a new reagent cartridge is placed on the System, allowing the barcode reader to recognize reagent lot identification and request calibration when the reagent lot changes.

Touch Screen Fields

TIME OF NEXT MASTER CALIBRATION	Displays the time and date of the next scheduled master calibration. This parameter may not be edited.
TEMPERATURES	Displays the incubator temperatures.

Touch Screen Fields (continued)

STORE RESULTS	Stores screen edits.
EXIT	Displays the System Files screen.

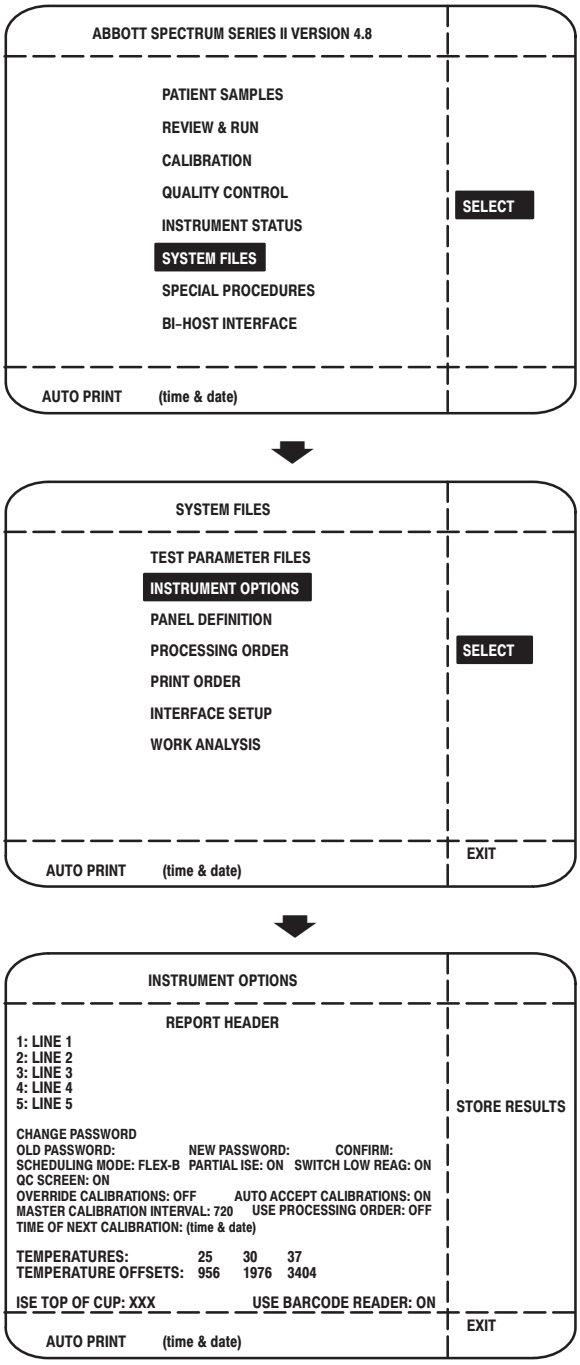


Figure 3-28 Instrument Options Screen Flow Map

Panel Definition

Introduction

The Panel Definition screen displays when PANEL DEFINITION is selected from the System Files screen. Refer to Figure 3-29 for the Panel Definition Screen Flow Map.

To simplify assay requests, individual tests may be assigned to panels. This is an active file, and the number of panels which may be input to the file depends on the number of assays in each panel. CODE 00137 NO MORE ROOM FOR PANELS displays when the file is full.

Data Entry Fields

PANEL NAME	Not currently active.
SCHEDULING NAME	A 6-character, alphanumeric field used to enter a scheduling name.

Touch Screen Fields

DEFINITION COMPLETE	Touched when appropriate assays have been selected and the panel is complete.
DELETE PANEL	Allows removal of associated assays from memory. After delete, the panel name no longer displays on the Patient Samples screen. A panel cannot be deleted when patient samples are completed or scheduled. Delete samples before deleting a panel.
NEXT PAGE	Displays the next page of assays.
EXIT	Displays the System Files screen.

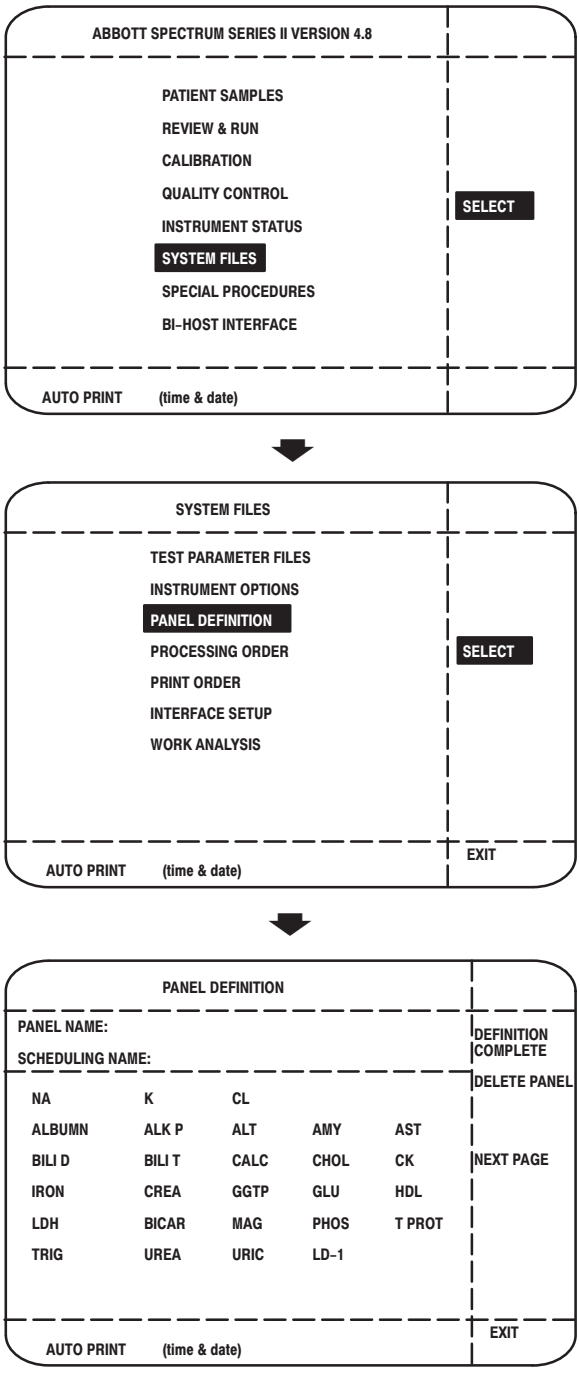


Figure 3-29 Panel Definition Screen Flow Map

Processing Order

Introduction

The Processing Order screen displays when PROCESSING ORDER is selected from the System Files screen. Refer to Figure 3-30 for the Processing Order Screen Flow Map.

This screen is used to establish the order in which assays are processed. If a Processing Order is not specified, or USE PROCESSING ORDER: OFF displays in the Instrument Options screen, the System uses the Test File Order, except for ISEs.

With a partial Processing Order assigned, the tests follow the Processing Order first, then follow Test File Order to complete the remaining tests.

When scheduling in Flexible Batch (Flex-B) mode, the System determines the Processing Order if no Processing Order is specified or USE PROCESSING ORDER: OFF displays in the Instrument Options screen. If the Processing Order is on and defined, the System follows the Processing Order in the Batch mode until it is complete. Remaining assays are processed in an order determined by the System.

Master Calibration and Cal On Command follow the Processing Order, when Processing Order is on.

When positioning samples for Batch processing, System activity is delayed for each assay temperature change.

Touch Screen Fields

PROCESSING ORDER	Used to establish and display the Processing Order.
TEST MENU	Displays the assays (in the Test File Order) when no Processing Order is established.
PAGE ORDER	Displays the next page of the Processing Order.
PAGE MENU	Displays the next page of the Test Menu.
INSERT	Allows an assay from the Test Menu to be inserted in the Processing Order.
DELETE	Allows deletion of an assay from the Processing Order.
SAVE	Stores the Processing Order.
EXIT	Displays the System Files screen.

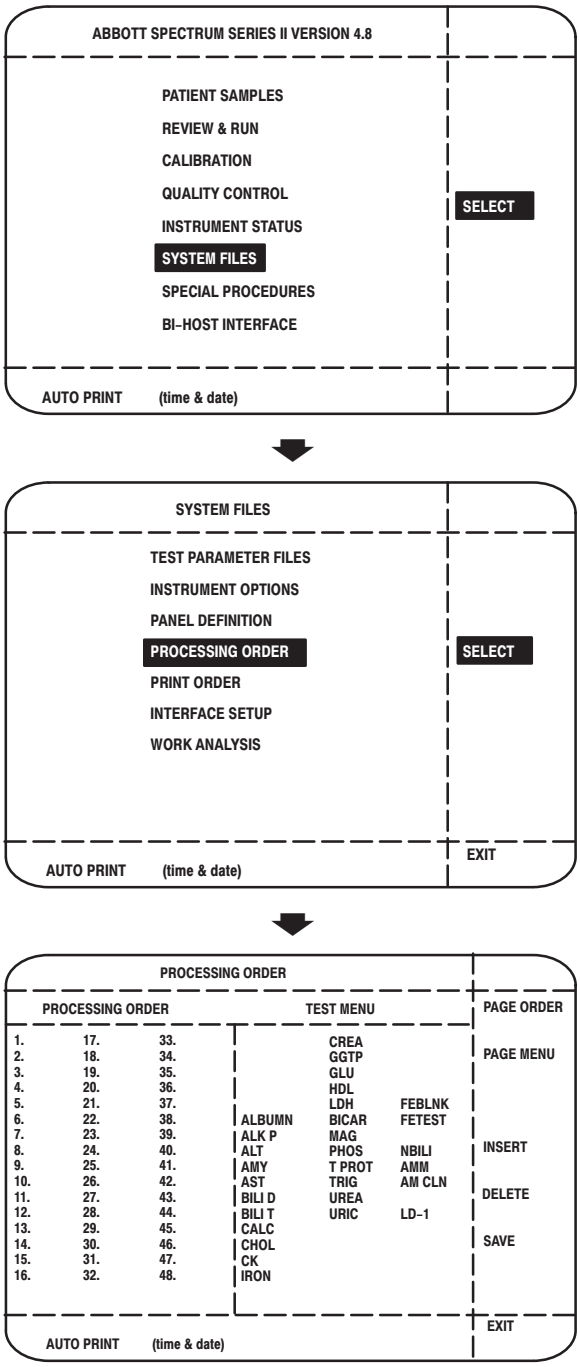


Figure 3-30 Processing Order Screen Flow Map

Print Order

Introduction

The Print Order screen displays when PRINT ORDER is selected from the System Files screen. Refer to Figure 3-31 for the Print Order Screen Flow Map.

This screen permits edit of the order in which assay results are printed on the Patient Report. Additionally, the printing of primary, secondary, or both sets of units may be selected, in a single- or double-spaced printing format.

When no Print Order is established, the results print according to the Test File Number.

Data Entry Fields

PRINT UNITS	A field used to select units to be printed on the Patient Report. The CYCLE key is pressed to display options (PRIMARY, SECONDARY, or BOTH).
DOUBLE SPACE	A field used to select double-spaced printing format. (System defaults to single spaced.)
PRINT ORDER	A field used to display and edit the Print Order.
TEST MENU	A field used to display the assays (in Test File Order) when no Print Order is established.

Touch Screen Fields

PAGE ORDER	Displays the next page of the Print Order.
PAGE MENU	Displays the next page of the Test Menu.
INSERT	Allows an assay from the Test Menu to be inserted in the Print Order.
DELETE	Allows deletion of an assay from the Print Order.
SAVE	Stores the Print Order.
EXIT	Displays the System Files screen.

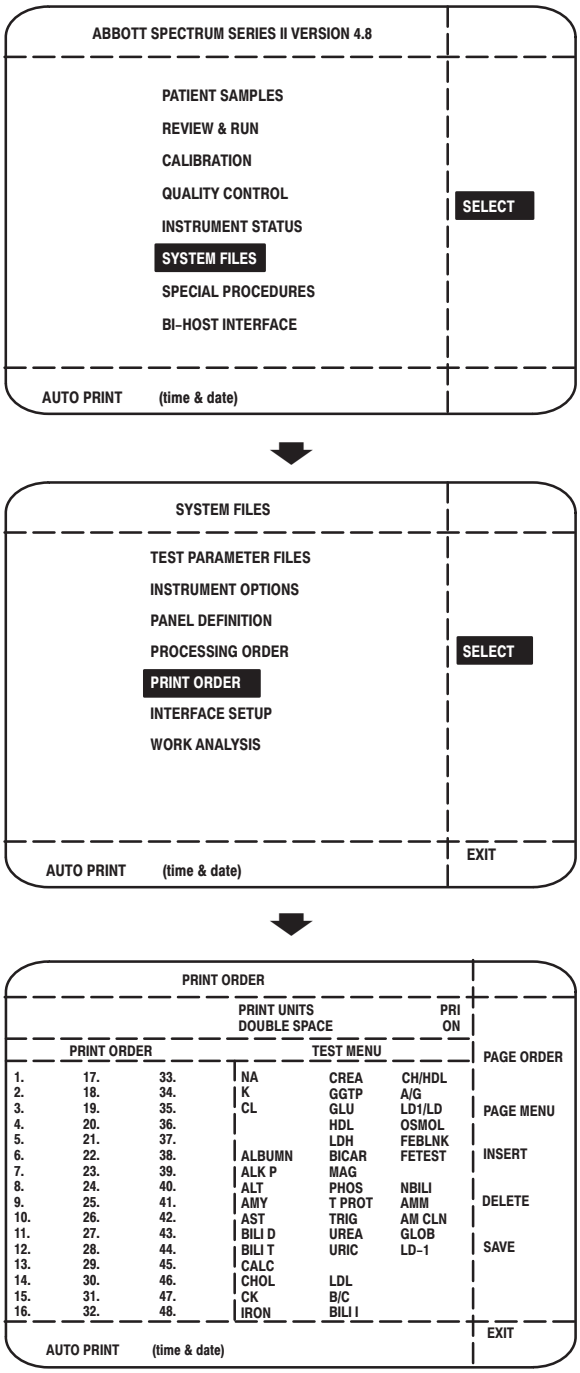


Figure 3-31 Print Order Screen Flow Map

Interface Setup

Introduction

The Interface Setup screen displays when INTERFACE SETUP is selected from the System Files screen. Refer to Figure 3-32 for the Interface Setup Screen Flow Map. Interface Setup screens may not be entered when the ACTIVITY field is highlighted or the System is transmitting data to the host computer.

The interface setup function allows the System to interface uni-directionally or bi-directionally with a host computer. The screens are used to select the baud rate, stop bits, parity, data bits, and transfer delay parameters for the Ad Read, uni-directional host, and bi-directional host communications.

If the ABBOTT SPECTRUM SERIES II System is to be interfaced to a host computer, verify the host computer is set based upon current interface specifications, available from Abbott Laboratories.

Ad Read Data Entry Fields

BAUD RATE	A field used to select baud rate. The CYCLE key is pressed to display the appropriate option (75, 110, 134.5, 150, 300, 600, 1200, 1800, 2000, 2400, 4800, 9600, or 19200).
STOP BITS	A field used to select stop bits. The CYCLE key is pressed to display the appropriate option (1 or 2).
PARITY	A field used to select parity. The CYCLE key is pressed to display the appropriate option (EVEN, ODD, or NONE).
DATA BITS	A field used to select data bits. The CYCLE key is pressed to display the appropriate option (7 or 8).

Uni-Directional Host Data Entry Fields

BAUD RATE	A field used to select baud rate. The CYCLE key is pressed to display the appropriate option (75, 110, 134.5, 150, 300, 600, or 1200).
STOP BITS	A field used to select stop bits. The CYCLE key is pressed to display the appropriate option (1 or 2).
PARITY	A field used to select parity. The CYCLE key is pressed to display the appropriate option (EVEN, ODD, or NONE).
DATA BITS	A field used to select data bits. The CYCLE key is pressed to display the appropriate option (7 or 8).
DELAY (SEC)	A field used to enter the time, in seconds, between transmission of each patient report. (Valid entries are 0–255.)

Bi-Directional Host Data Entry Fields

BAUD RATE	A field used to select baud rate. The CYCLE key is pressed to display the appropriate option (75, 110, 134.5, 150, 300, 600, or 1200).
STOP BITS	A field used to select stop bits. The CYCLE key is pressed to display the appropriate option (1 or 2).
PARITY	A field used to select parity. The CYCLE key is pressed to display the appropriate option (EVEN, ODD, or NONE).
DATA BITS	A field used to select data bits. The CYCLE key is pressed to display the appropriate option (7 or 8).

Touch Screen Fields

NEXT	Displays available Interface Setup screens.
SAVE	Stores screen edits. The power must be cycled before the System uses the new parameters.
EXIT	Displays the System Files screen.

Interface Setup

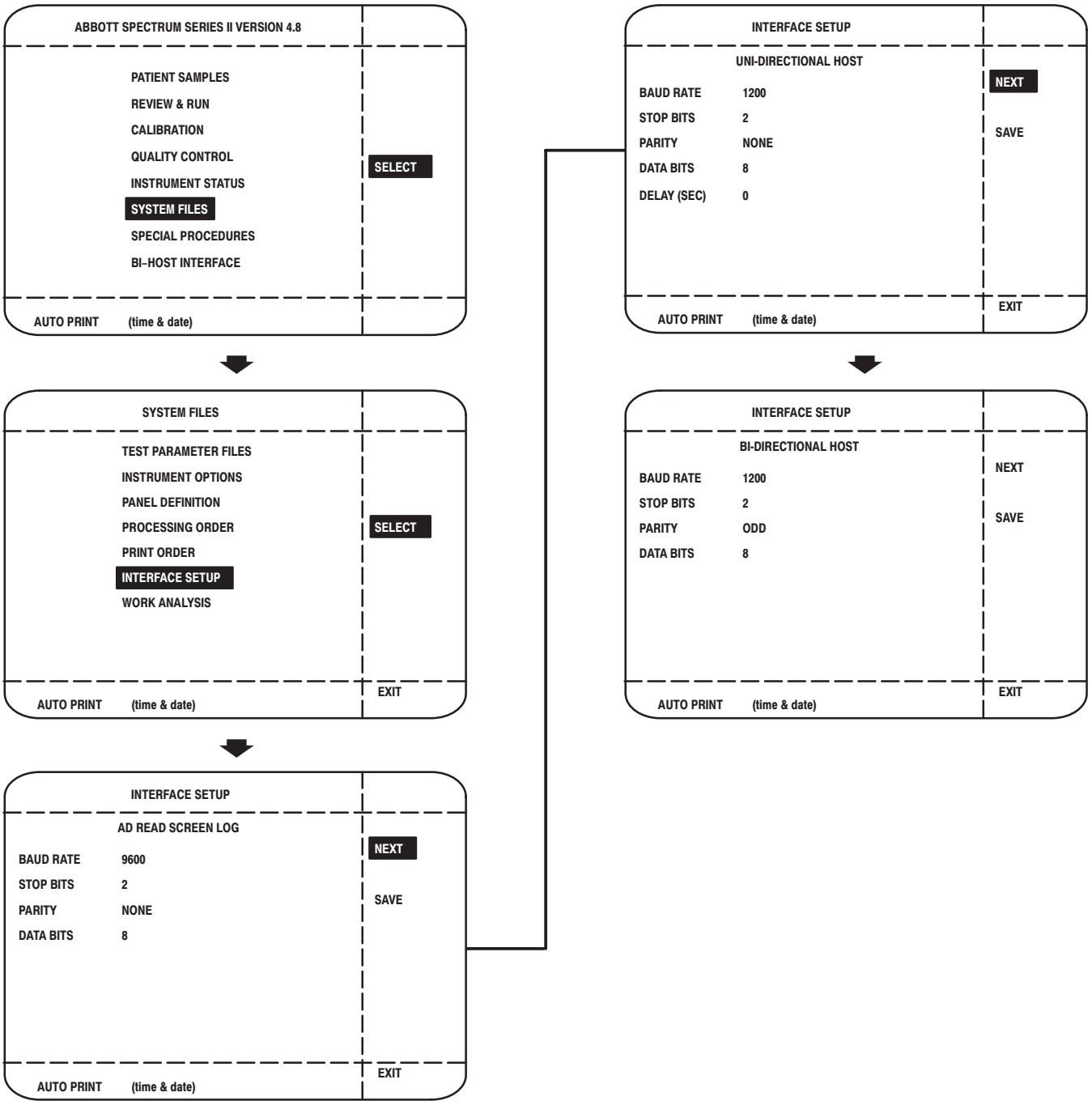


Figure 3-32 Interface Setup Screen Flow Map

Introduction

The Workload Analysis screen displays when WORK ANALYSIS is selected from the System Files screen. Refer to Figure 3-34 for the Workload Analysis Screen Flow Map.

Workload Analysis is a password-protected function which provides cumulative totals and resettable totals of assays run on the System. The files may be displayed and printed without entering the password. However, the password must be entered to access the Workload Analysis Files for resetting counters. If the password is not entered, CODE 00508 NO PASSWORD GIVEN CANNOT RESET COUNTERS displays.

The System tabulates the cumulative totals and active totals for each assay defined in the Test Parameter Files. The cumulative total is the number of each assay run since the DATE INITIATED field was activated. These counters cannot be reset by the user and are a permanent record of assays run.

Active counters can be reset and provide assay totals for specific time periods, determined by the user. A further breakdown of the assays tabulated by the active counters can be viewed on the Workload Distribution screen.

A report, containing information in Workload Analysis and Workload Distribution screens, may be printed.

NOTE

THE NUMBERS SHOWN ON THE DISPLAY RESET AUTOMATICALLY AT 4.2 BILLION. ALWAYS REFERENCE NUMBERS ON THE PRINTOUT WHEN THE MOST ACCURATE DATA IS REQUIRED.

Touch Screen Fields

CURRENT DATE	Displays the current date.
RESET DATE	Displays the date the resettable counters were last reset.
DATE INITIATED	Displays the date the cumulative, nonresettable counters were activated.
ACTIVE TEST TOTAL	Displays the total number of all tests counted since the last reset.
SYSTEM TO DATE	Displays the total number of all tests counted since the date initiated.
TEST	Displays the name of the assay.
ACTIVE TOTAL	Displays the total number of each assay counted since the last reset.

Workload Analysis

Touch Screen Fields (continued)

CUMULATIVE TOTAL — Displays the total number of each assay counted since the date initiated.

NEXT PAGE — Displays the next page of the Workload Analysis screen, if available.

PREVIOUS PAGE — Displays the previous page of the Workload Analysis screen, if available.

PRINT REPORT — Generates a report which contains the data displayed on both the Workload Analysis screen and the Workload Distribution screen.

Refer to Figure 3-33 for a sample Workload Analysis Report.

WORKLOAD ANALYSIS

CURRENT DATE & TIME	RESET DATE	DATE INITIATED
12:32 PM 24-JUN-95	24-JUN-95	24-JUNE-90

ACTIVE TOTAL 2349 SYSTEM TO DATE TOTAL 2349

TEST	TEST NUM	STAT	ROUTINE	CONTROL	CALIB	ACTIVE TOTAL	CUMULATIVE TOTAL
NA	1	0	106	133	66	305	305
K	2	0	105	133	66	304	304
CL	3	0	105	133	66	304	304
ALBUMN	6	0	1	22	4	27	27
ALK P	7	0	0	72	1	73	73
ALT	8	0	0	20	1	21	21
AST	10	0	5	116	3	124	124
BILI D	11	0	0	0	0	0	0
BILI T	12	0	0	0	0	0	0
CALC	13	0	1	90	16	107	107
CHOL	14	0	0	20	3	23	23
CK	15	0	0	60	1	61	61
IRON	16	0	1	0	4	5	5
CREA	17	0	6	112	4	122	122
GGTP	18	0	0	0	0	0	0
GLU	19	0	44	112	17	173	173
HDL	20	0	0	0	0	0	0
LDH	21	0	0	72	1	73	73
BICAR	22	0	12	0	15	27	27
MAG	23	0	0	0	0	0	0
PHOS	24	0	37	30	3	70	70
T PROT	25	0	1	20	4	25	25
TRIG	26	0	0	20	3	23	23
UREA	27	0	2	20	20	42	42

Figure 3-33 Workload Analysis Report

Touch Screen Fields (continued)

RESET AND PRINT REPORT	Executes a Master Reset. All resettable counters are reset to zero (0). To protect against accidental resetting of the counters, the field is password protected. In addition, a Y/N prompt displays below the field when it is touched. To reset the counters, type Y (Yes) and press ENTER. To avoid resetting the counters, type N (No) and press ENTER. A current Workload Analysis Report prints if AUTO PRINT is ON, the printer is on, and SELECT is illuminated.
WORKLOAD DIST	Displays the Workload Distribution screen.
SAMPLE DIST	Displays the Sample Distribution screen.
EXIT	Displays the System Files screen.

Workload Analysis

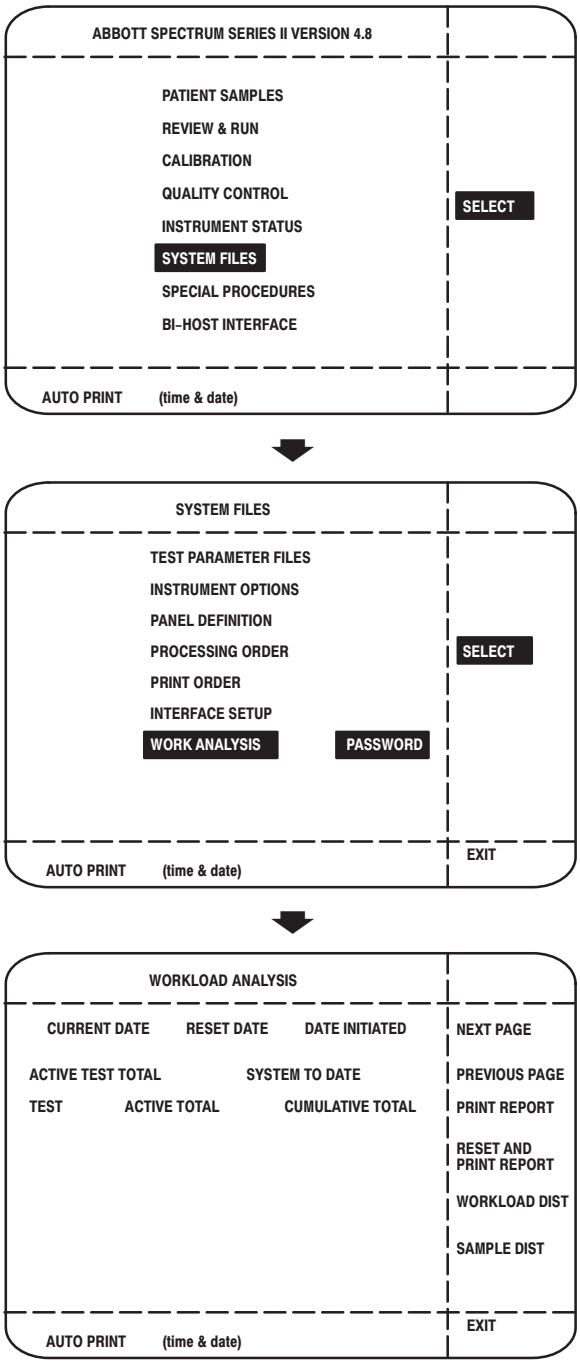


Figure 3-34 Workload Analysis Screen Flow Map

Workload Distribution

Introduction

The Workload Distribution screen displays when WORKLOAD DIST is selected from the Workload Analysis screen. Refer to Figure 3-35 for the Workload Distribution Screen Flow Map.

Each assay defined in the Test Parameter Files is displayed in one of the following categories: STAT, ROUTINE, CONTROL, or CALIB. A total of all assays completed is displayed for each of the four categories.

A report, containing information in the Workload Analysis and Workload Distribution screens, may be printed from the Workload Analysis screen.

NOTE

THE NUMBERS SHOWN ON THE DISPLAY RESET AUTOMATICALLY AT 4.2 BILLION. ALWAYS REFERENCE NUMBERS ON THE PRINTOUT WHEN THE MOST ACCURATE DATA IS REQUIRED.

Touch Screen Fields

TEST	Lists all assays defined in the Test Parameter Files.
STAT	Displays the number of STAT SIDs for each assay.
ROUTINE	Displays the number of routine SIDs for each assay.
CONTROL	Displays the number of controls for each assay.
CALIB	Displays the number of calibrators for each assay.
TOTAL	Displays the total number of STAT, ROUTINE, CONTROL, and CALIB assays.
NEXT PAGE	Displays the next page of the Workload Distribution screen, if available.
PREVIOUS PAGE	Displays the previous page of the Workload Distribution screen, if available.
EXIT	Displays the Workload Analysis screen.

Workload Distribution

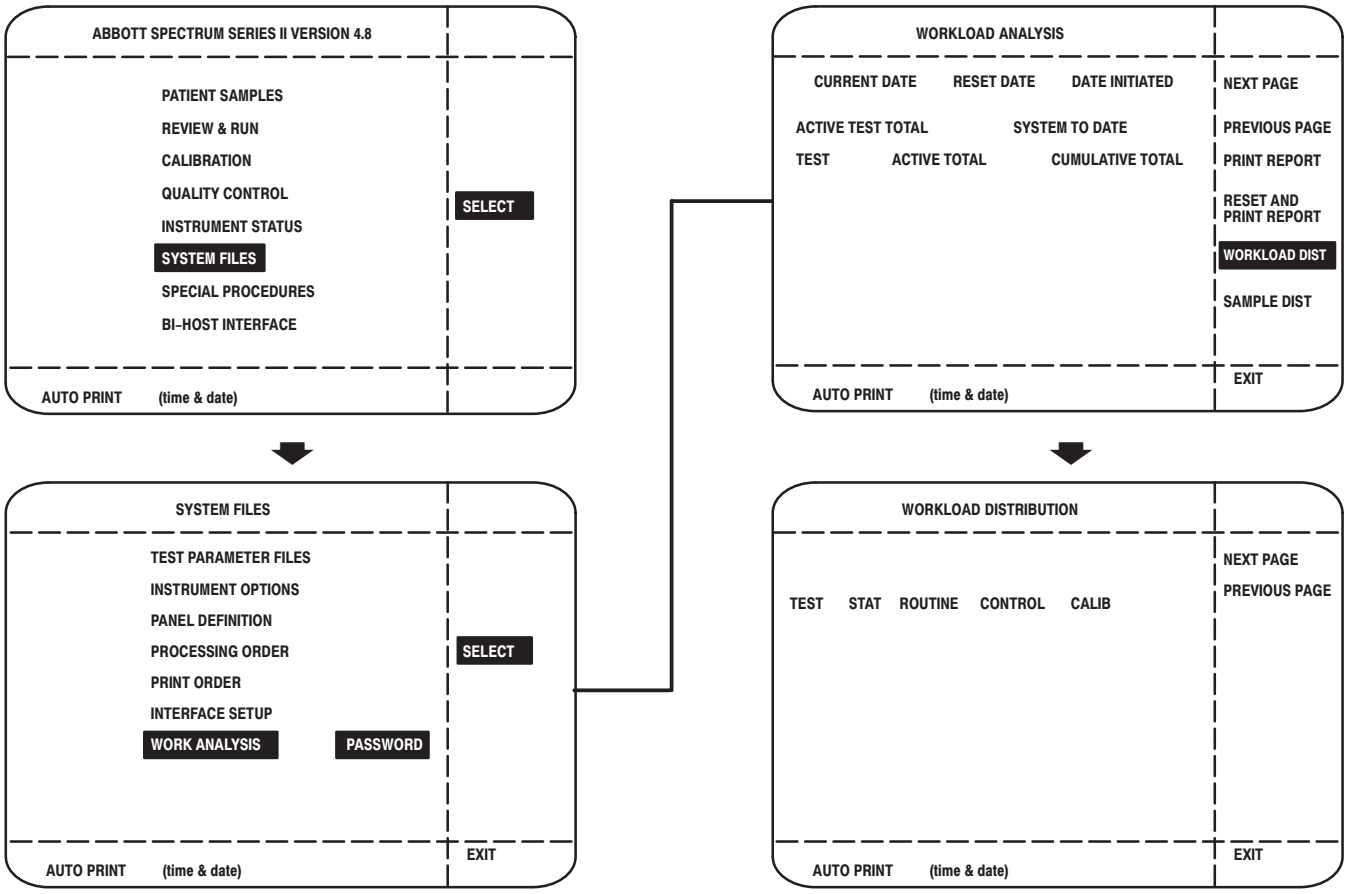


Figure 3-35 Workload Distribution Screen Flow Map

Introduction

The Sample Distribution screen displays when SAMPLE DIST is selected from the Workload Analysis screen. Refer to Figure 3-37 for the Sample Distribution Screen Flow Map.

Sample Distribution is a password-protected function which provides cumulative totals and resettable totals of samples run on the System. The files may be displayed and printed without entering the password. However, the password must be entered to access the Sample Distribution Files for resetting counters. If RUNNING displays in the ACTIVITY field, CODE 00154 SYSTEM IS RUNNING displays. If the password is not entered, CODE 00508 NO PASSWORD GIVEN CANNOT RESET COUNTERS displays.

When a SID is entered into the System, it is counted in one of the following categories: ROUTINE, STAT, or CONTROL. If a previously entered SID is designated as a control, the CONTROL count is not incremented. For each category, the percentage of the total is displayed, with its active total and cumulative total.

Active counters can be reset and provide a sample distribution for specific time periods, determined by the user. Cumulative counters cannot be reset by the user and are a permanent record of the number and type of samples run.

A report containing the sample information may be printed.

NOTE

THE NUMBERS SHOWN ON THE DISPLAY RESET AUTOMATICALLY AT 4.2 BILLION. ALWAYS REFERENCE NUMBERS ON THE PRINTOUT WHEN THE MOST ACCURATE DATA IS REQUIRED.

Touch Screen Fields

CURRENT DATE	Displays the current date.
RESET DATE	Displays the date the resettable counters were last reset.
DATE INITIATED	Displays the date the cumulative, nonresettable counters were activated.
SAMPLE TYPE	Displays the categories of samples entered.
ACTIVE TOTALS	Displays the total number of SIDs per category entered into the System since the last reset.
PERCENT OF ACTIVE TOTAL	Displays the number of SIDs entered for each category as a percentage of the total number of SIDs entered for all categories since the last reset.

Sample Distribution

Touch Screen Fields (continued)

CUMULATIVE TOTALS

Displays the total number of SIDs entered into the System since the date initiated.

PRINT REPORT

Generates a report (Figure 3-36) containing all data displayed on the Sample Distribution screen.

SAMPLE DISTRIBUTION

CURRENT DATE	RESET DATE	DATE INITIATED
09–JUL–95	01–MAR–95	09–JUL–94

SAMPLE TYPE	ACTIVE TOTALS	PERCENT OF ACTIVE TOTAL	CUMULATIVE TOTALS
TOTAL SAMPLES	280		280
ROUTINE	250	89	250
STAT	5	1	5
CONTROL	25	8	25

Figure 3-36 Sample Distribution Report

RESET AND PRINT REPORT

Executes a Master Reset. All resettable counters are reset to zero (0). To protect against accidental resetting of the counters, the field is password protected. In addition, a Y/N prompt displays below the field when it is touched. To reset the counters, type Y (Yes) and press ENTER. To avoid resetting the counters, type N (No) and press ENTER. A current Sample Distribution Report prints if AUTO PRINT is ON, the printer is on, and SELECT is illuminated.

EXIT

Displays the Workload Analysis screen.

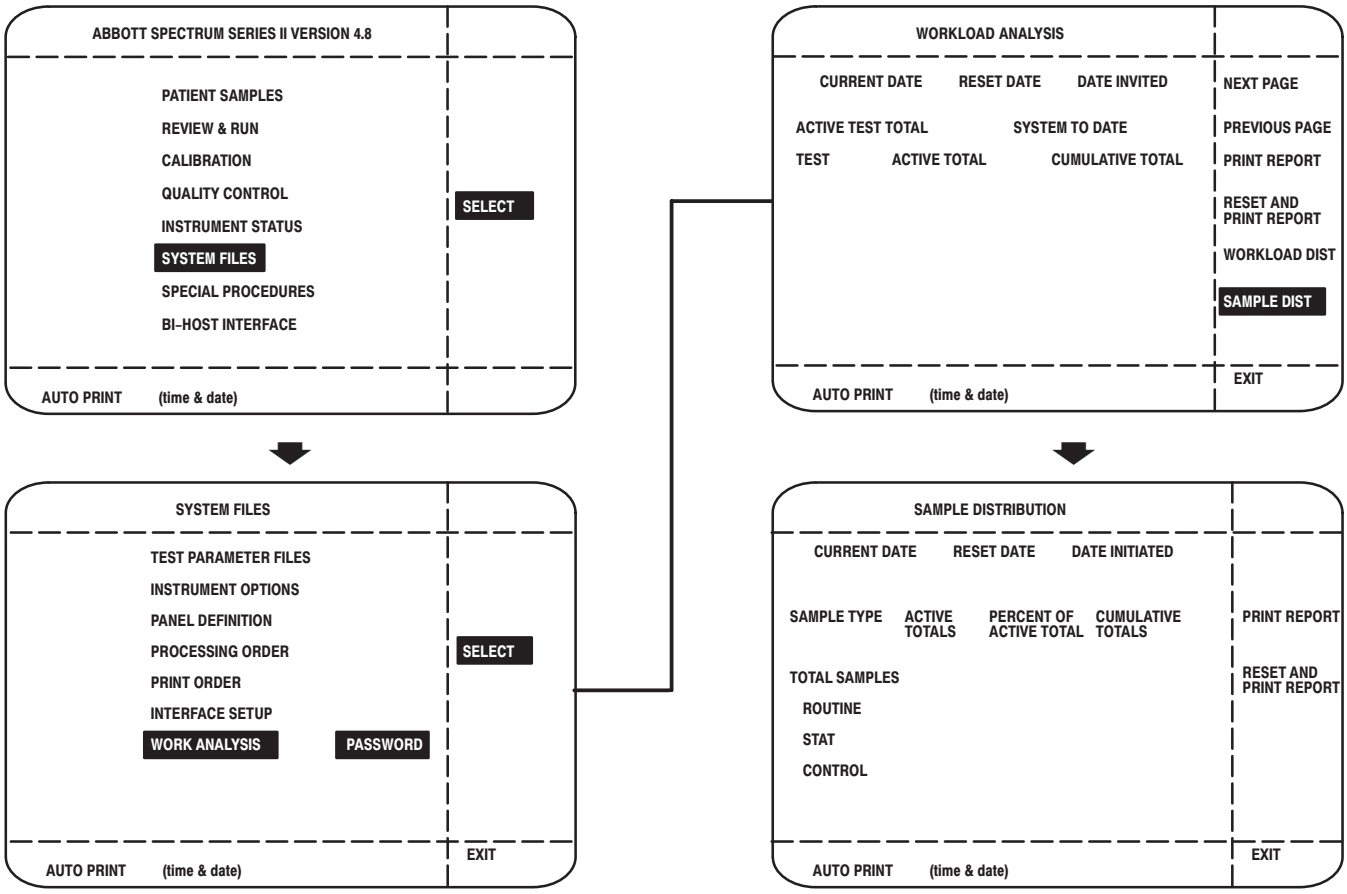


Figure 3-37 Sample Distribution Screen Flow Map

Special Procedures

Introduction

The Special Procedures screen displays when SPECIAL PROCEDURES is selected from the Main menu. Refer to Figure 3-38 for the Special Procedures Screen Flow Map.

From this screen, robotics and diagnostics screens are accessed. The cuvette change procedure is completed from this screen.

Touch Screen Fields

ROBOTICS	Touch this field and SELECT to display the Robotics screens, which are used to set and verify the robotic positions (probes, arms, and carousels). Refer to Probe Positioning & Robotic Training in the Maintenance & Troubleshooting Manual for additional information.
CUVETTE CHANGE	A status code directs the operator to change cuvette segments. Touch this field and SELECT. CODE 00109 CUVETTE CHANGED displays.
AD OFFSET	Touch this field and SELECT to display the Ad Offset screen.
AD READ	Touch this field and SELECT to display the Ad Read Parameters screen.
BARCODE INDEX	Touch this field and SELECT to display the Reagent Barcode Entry screen, used to assign a new barcode number to a specific reagent.
BARCODE TEST	Touch this field and SELECT to display the Barcode Test screen, used to read and verify the reagent barcode labels on board. This feature is used in troubleshooting the barcode reader.
WASH MATRIX	Touch this field and SELECT to display the Wash Matrix, which is used to select before and after probe wash sequences for a maximum of 60 reagents.
SELECT	Used in conjunction with a screen name to display the screen.
EXIT	Displays the Main menu.

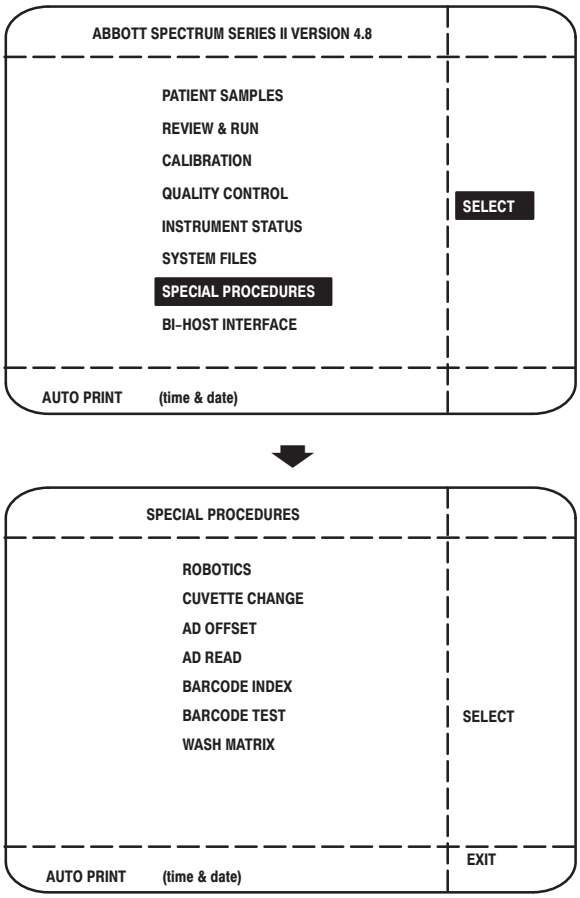


Figure 3-38 Special Procedures Screen Flow Map

Robotics

Introduction

The Robotics screen displays when ROBOTICS is selected from the Special Procedures screen. Refer to Figure 3-39 for the Robotics Screen Flow Map.

The Robotics screens are used to train the sample, reagent, and mixer arms. A Pumps & Valves screen is available for monitoring pressures, water levels, and valve positions. Step tables are accessible for viewing the robotic training positions for the sample, reagent, and mixer arms.

Touch Screen Fields

HOME ROBOTICS	Touch this field and SELECT to return robotics to the home position.
SAMPLE ARM	Touch this field and SELECT to display the Sample Arm screen, used to verify sample arm training.
REAGENT ARM	Touch this field and SELECT to display the Reagent Arm screen, used to verify reagent arm training.
MIX ARM	Touch this field and SELECT to display the Mix Arm screen, used to verify mixer arm training.
PUMPS & VALVES	Touch this field and SELECT to display the Pumps & Valves screen, used to verify the status of sample diluent and incubator water levels, and sample diluent and inlet water pressure. Valves for the incubator, mixer, and reagent wash cups and sample diluent may be opened and closed. The waste pump may be turned off and on.
OTHER DEVICES	Touch this field and SELECT to display the Other Devices screen, used to verify robotic positions for the sample and reagent syringes, sample and cuvette carousels, and calibration wheel.
STEP TABLES	Touch this field and SELECT to display the Sample & Mix Arm Table screen, used to verify the trained robotic step positions for the sample, reagent, and mixer arms.
SELECT	Used in conjunction with a screen name to display the screen.
EXIT	Displays the Special Procedures screen.

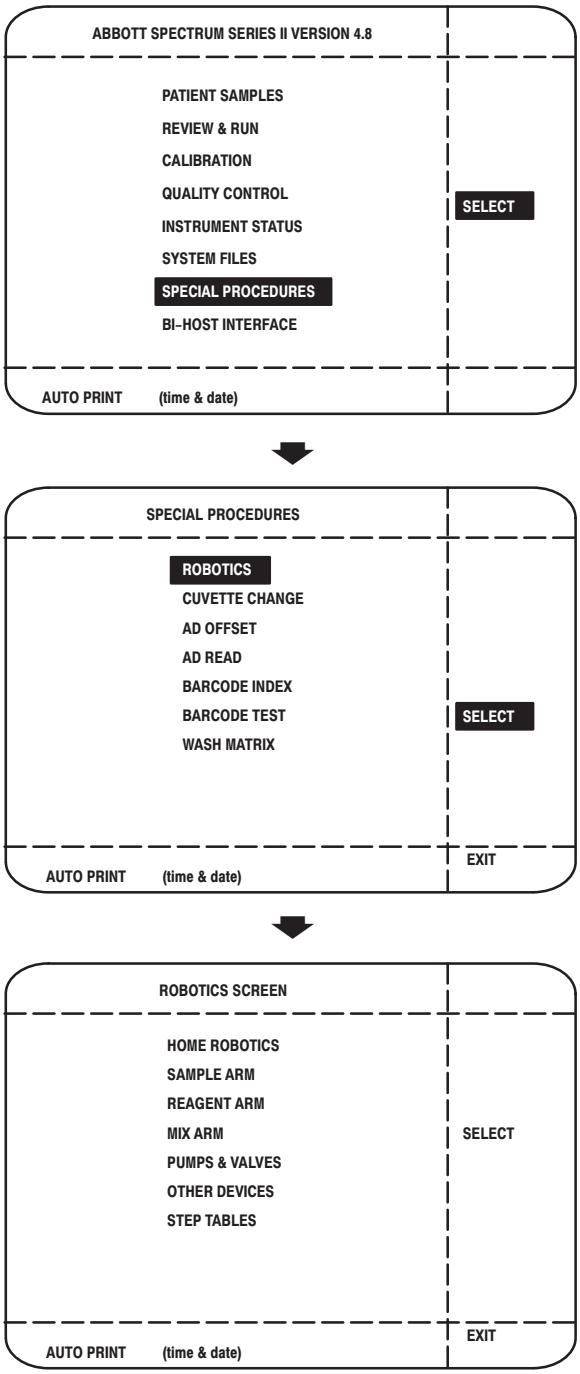


Figure 3-39 Robotics Screen Flow Map

Robotics Sample Arm

Introduction

The Sample Arm screen displays when SAMPLE ARM is selected from the Robotics screen. Refer to Figure 3-40 for the Sample Arm Screen Flow Map.

This screen is used to perform robotic training of the sample arm and to verify proper fluid sensitivity. Refer to Probe Positioning & Robotic Training in the Maintenance & Troubleshooting Manual for specific procedures.

Data Entry Field

CUVETTE #	A field used to enter the cuvette number to be moved to the light path.

Touch Screen Fields

VERTICAL #	Displays the vertical step number for the sample arm, and a status: • CLEARf – No limits detected • HOMEf – Home limit detected • UPPERf – Upper limit detected • FLUIDf – Fluid sensed
INNER CUP TOP	Moves the sample arm over the inner ring of the sample carousel.
INNER CUP FLUID	Lowers the sample arm to the position where fluid is sensed; used to verify correct fluid sensitivity adjustment.
INNER CUP BOTTOM	Lowers the sample arm to the trained bottom of the sample cup.
OUTER CUP TOP	Moves the sample arm over the outer ring of the sample carousel.
OUTER CUP FLUID	Lowers the sample arm to the position where fluid is sensed; used to verify correct fluid sensitivity adjustment.
OUTER CUP BOTTOM	Lowers the sample arm to the trained bottom of the sample cup.
WASH CUP TOP	Moves the sample arm over the wash station to the home position.
WASH CUP BOTTOM	Lowers the sample arm to the trained bottom of the wash cup.
CUVETTE TOP	Moves the sample arm over the cuvette carousel.
CUVETTE BOTTOM	Lowers the sample arm to the trained cuvette bottom.

Touch Screen Fields (continued)

HORIZONTAL #	Displays the horizontal step number for the sample arm, and a status: • CLEAR – No limits detected • HOME – Home limit detected • LEFT – Left limit detected • RIGHT – Right limit detected
SAMPLE CAROUSEL #	Moves the desired sample position number to the sampling position.
PUMP DILUENT	Dispenses a single purge of sample diluent.
VERT. #	Displays the sample arm vertical step number.
HORZ. #	Displays the sample arm horizontal step number.
ADJUST POSITION	
UP	Raises the sample arm one robotic step.
DOWN	Lowers the sample arm one robotic step.
LEFT	Moves the sample arm left one robotic step.
RIGHT	Moves the sample arm right one robotic step.
HOME ROBOTICS	Returns robotics to the home position.
SAMPLE ARM	Re-displays the Sample Arm screen.
REAGENT ARM	Displays the Reagent Arm screen.
MIX ARM	Displays the Mix Arm screen.
PUMPS & VALVES	Displays the Pumps & Valves screen.
OTHER DEVICES	Displays the Other Devices screen.
STEP TABLES	Displays the Sample & Mix Arm Table screen.
EXIT	Stores edits, and displays the Robotics screen.

Robotics Sample Arm

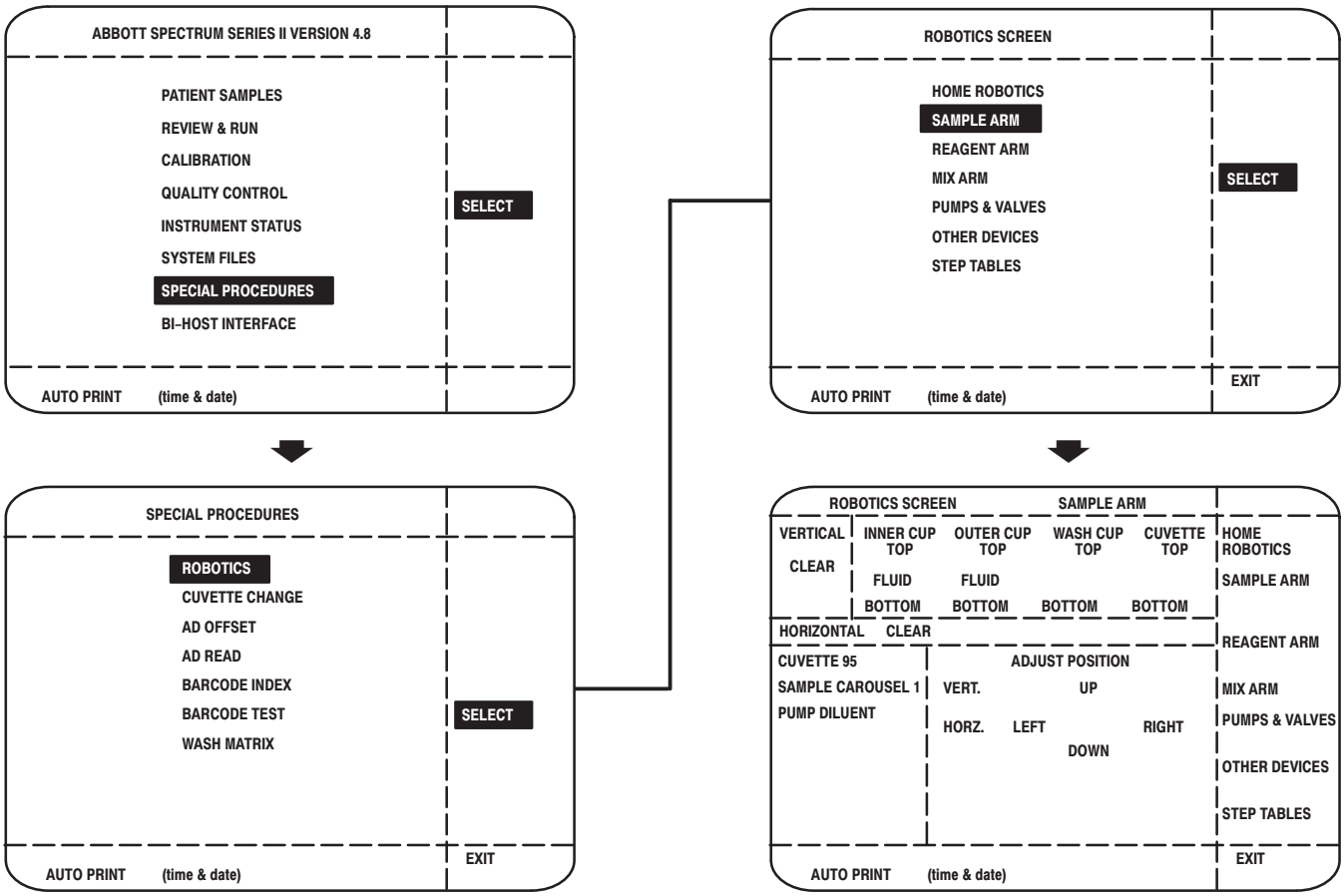


Figure 3-40 Sample Arm Screen Flow Map

Robotics Reagent Arm

Introduction

The Reagent Arm screen displays when REAGENT ARM is selected from the Robotics screen. Refer to Figure 3-41 for the Reagent Arm Screen Flow Map.

This screen is used to perform robotic training of the reagent arm and to verify proper fluid sensitivity. Refer to Probe Positioning & Robotic Training in the Maintenance & Troubleshooting Manual for specific procedures.

Data Entry Field

CUVETTE #

A field used to enter the cuvette number to be moved to the reagent dispense position.

Touch Screen Fields

VERTICAL #

Displays the vertical step number for the reagent arm, and a status:

- CLEARf – No limits detected
- HOMEf – Home limit detected
- UPPERf – Upper limit detected
- FLUIDf – Fluid sensed

DISPENSE #

Moves the reagent arm over the cuvette in the dispense location indicated.

DISPENSE # TOP

Moves the reagent arm over the cuvette.

DISPENSE # FLUID

Lowers the reagent arm to the position where fluid is sensed; used to verify correct fluid sensitivity adjustment.

DISPENSE # BOTTOM

Lowers the reagent arm to the trained bottom of the cuvette.

WASH CUP TOP

Moves the reagent arm over the wash station to the home position.

WASH CUP FLUID

Lowers the reagent arm into the wash cup to the position where fluid is sensed.

WASH CUP BOTTOM

Lowers the reagent arm to the trained bottom of the wash cup.

REAGENT #

Moves the reagent arm over the reagent tray position number indicated.

REAGENT TOP

Moves the reagent arm over the entered reagent cartridge number.

REAGENT FLUID

Lowers the reagent arm to the position where fluid is sensed; used to verify correct fluid sensitivity adjustment.

Robotics Reagent Arm

Touch Screen Fields (continued)

REAGENT BOTTOM	Lowers the reagent arm to the trained bottom of the reagent cartridge.
HORZ. INNER #	Displays the reagent arm horizontal inner step number, and a status: • CLEAR – No limits detected • HOME – Home limit detected • LEFT – Left limit detected • RIGHT – Right limit detected
HORZ. OUTER #	Displays the reagent arm horizontal outer step number, and a status: • CLEAR – No limits detected • HOME – Home limit detected • LEFT – Left limit detected • RIGHT – Right limit detected
WASH OFF/ON	Closes or opens the reagent wash station valve to control water flow. When OFF is touched, ON displays.
WASH CYCLE	Performs a reagent probe wash cycle.
VERT. #	Displays the reagent arm vertical step number.
ADJUST POSITION	
UP	Raises the reagent arm one robotic step.
DOWN	Lowers the reagent arm one robotic step.
LEFT (INNER)	Moves the inner reagent arm left one robotic step.
RIGHT (INNER)	Moves the inner reagent arm right one robotic step.
LEFT (OUTER)	Moves the outer reagent arm left one robotic step.
RIGHT (OUTER)	Moves the outer reagent arm right one robotic step.

Touch Screen Fields (continued)

HOME ROBOTICS	Returns robotics to the home position.
SAMPLE ARM	Displays the Sample Arm screen.
REAGENT ARM	Re-displays the Reagent Arm screen.
MIX ARM	Displays the Mix Arm screen.
PUMPS & VALVES	Displays the Pumps & Valves screen.
OTHER DEVICES	Displays the Other Devices screen.
STEP TABLES	Displays the Sample & Mix Arm Table screen.
EXIT	Stores edits, and displays the Robotics screen.

Robotics Reagent Arm

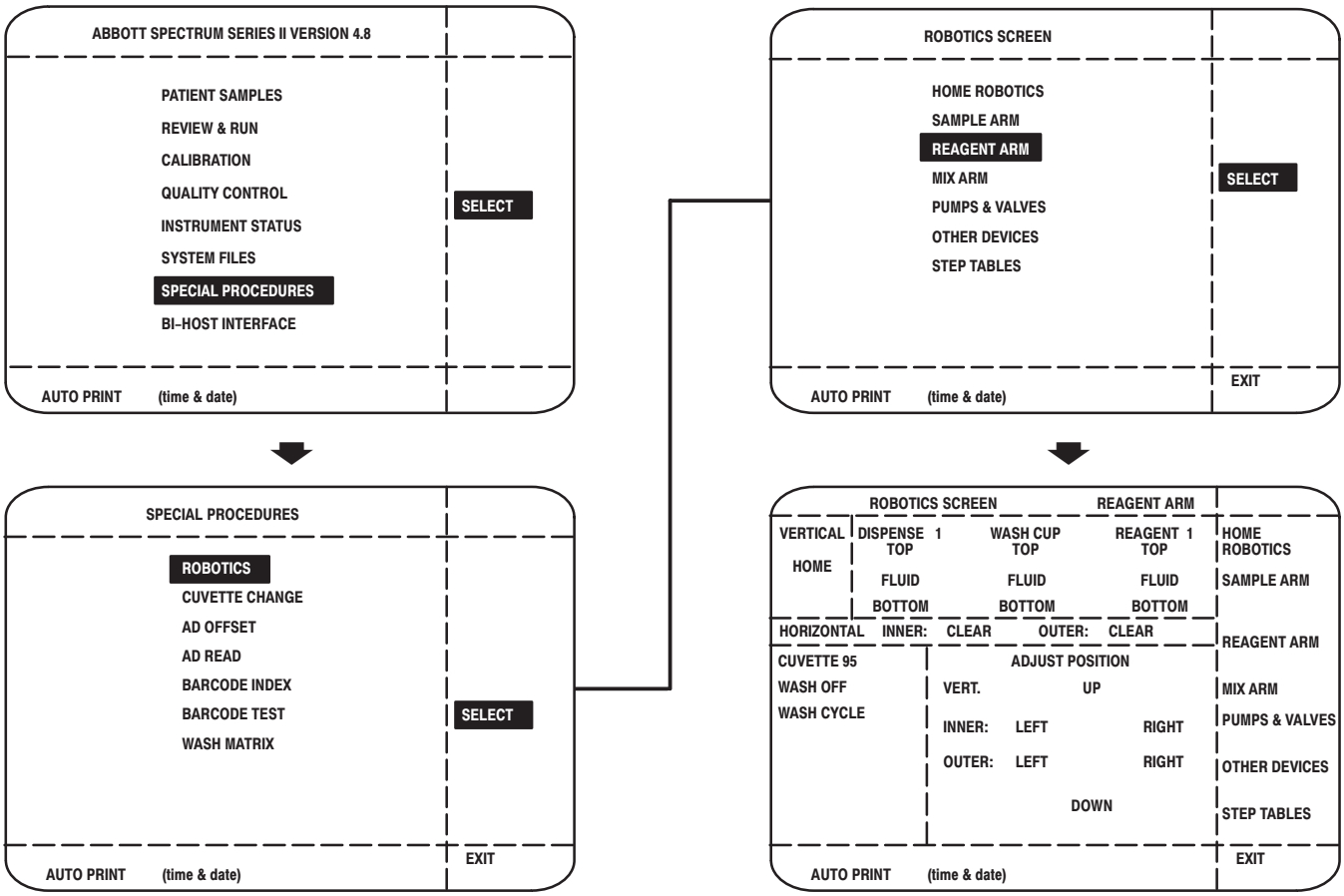


Figure 3-41 Reagent Arm Screen Flow Map

Introduction

The Mix Arm screen displays when MIX ARM is selected from the Robotics screen. Refer to Figure 3-42 for the Mix Arm Screen Flow Map.

This screen is used to perform robotic training of the mixer arm. Refer to Probe Positioning & Robotic Training in the Maintenance & Troubleshooting Manual for specific procedures.

Data Entry Field

CUVETTE #	A field used to enter the position number to which the cuvette carousel will be moved.

Touch Screen Fields

VERTICAL #	Displays the vertical step number for the mixer arm, and a status: • CLEARf – No limits detected • HOMEf – Home limit detected • LOWER – Lower limit detected • HOME LOWER – Home and lower limit detected simultaneously
CUVETTE TOP	Moves the mixer arm over the cuvette, where mixer stroke is verified.
CUVETTE BOTTOM	Lowers the mixer arm to the trained bottom of the cuvette.
WASH CUP TOP	Moves the mixer arm over the wash station to the home position.
WASH CUP BOTTOM	Lowers the mixer arm to the trained bottom of the wash cup.
HORIZONTAL #	Displays the mixer arm horizontal step number, and a status: • CLEARf – No limits detected • HOMEf – Home limit detected • LEFTf – Left limit detected • RIGHTf – Right limit detected
WASH OFF/ON	Closes or opens the mixer wash station valve to control water flow. When OFF is touched, ON displays.
MIXER OFF/ON	Turns the mixer off or on. When OFF is touched, ON displays.
VERT. #	Displays the mixer arm vertical step number.
HORZ. #	Displays the mixer arm horizontal step number.

Robotics Mix Arm

Touch Screen Fields (continued)

ADJUST POSITION	
UP	Raises the mixer arm one robotic step.
DOWN	Lowers the mixer arm one robotic step.
LEFT	Moves the mixer arm left one robotic step.
RIGHT	Moves the mixer arm right one robotic step.
HOME ROBOTICS	Returns robotics to the home position.
SAMPLE ARM	Displays the Sample Arm screen.
REAGENT ARM	Displays the Reagent Arm screen.
MIX ARM	Re-displays the Mix Arm screen.
PUMPS & VALVES	Displays the Pumps & Valves screen.
OTHER DEVICES	Displays the Other Devices screen.
STEP TABLES	Displays the Sample & Mix Arm Table screen.
EXIT	Stores edits, and displays the Robotics screen.

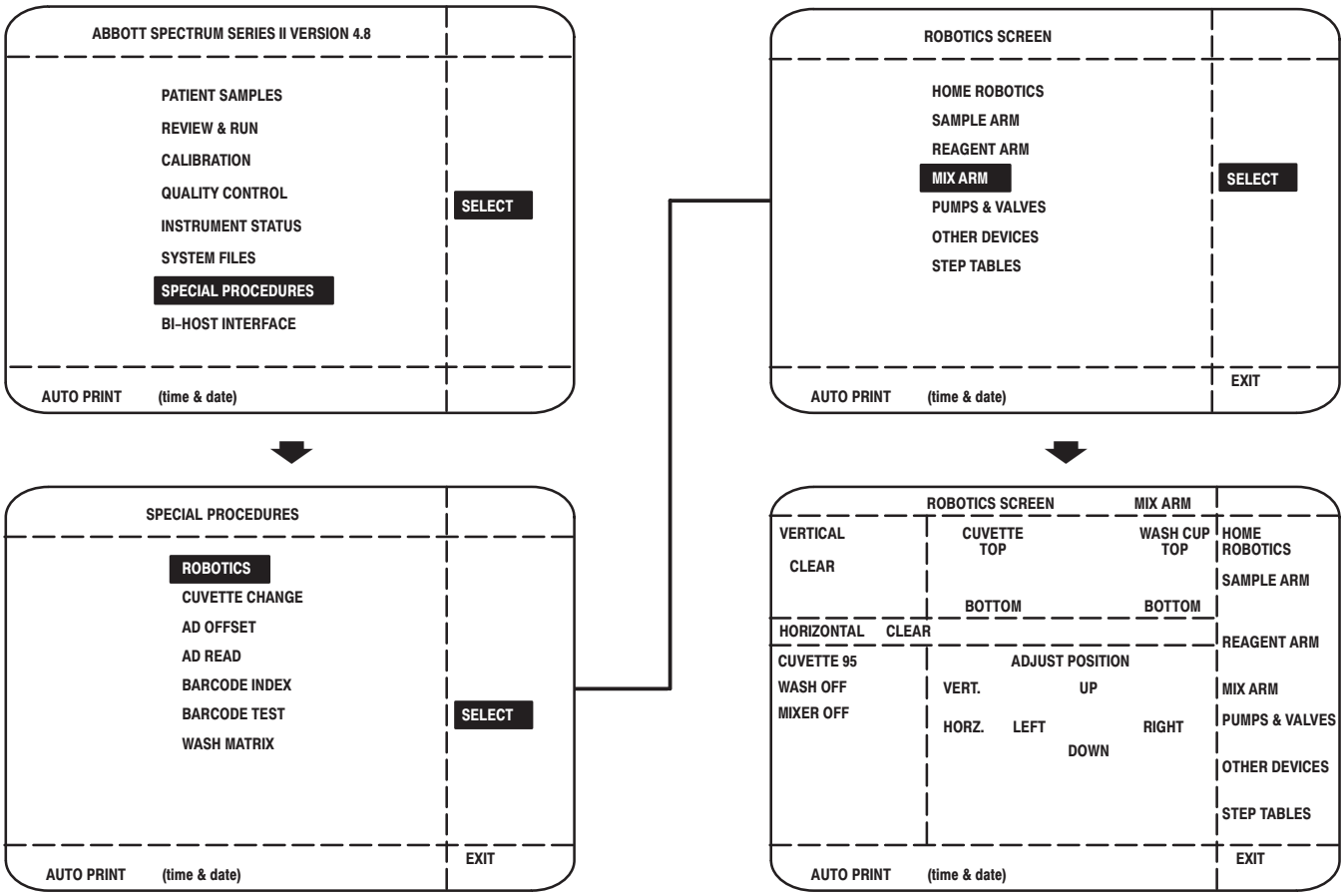


Figure 3-42 Mix Arm Screen Flow Map

Robotics Pumps & Valves

Introduction

The Pumps & Valves screen displays when PUMPS & VALVES is selected from the Robotics screen. Refer to Figure 3-43 for the Pumps & Valves Screen Flow Map.

This screen is used during maintenance procedures and troubleshooting.

Touch Screen Fields

DILUENT LEVEL	Displays the status of the sample diluent level (OK or LOW).
DILUENT PRESSURE	Displays the status of the sample diluent pressure (OK, LOW, or HIGH).
WATER PRESSURE	Displays the status of the inlet water pressure (OK, LOW, or HIGH).
INCUBATOR LEVEL	Displays the status of the incubator water level (OK or LOW).
DILUENT VALVE CLOSED/OPENED	Regulates water flow from the sample diluent reservoir to the sample probe. When CLOSED is touched, OPENED displays.
DILUENT PUMP SINGLE STROKE/PURGE	Circulates sample diluent through the diluent system. SINGLE STROKE dispenses one cycle of sample diluent; PURGE dispenses approximately 5.8mL of water. When SINGLE STROKE is touched, PURGE # PURGES displays. Entry of a numerical value is required.
REAGENT WASH VALVE CLOSED/OPENED	Controls the flow of water in the reagent wash cup. When CLOSED is touched, OPENED displays.

Touch Screen Fields (continued)

MIX WASH VALVE CLOSED/OPENED	Controls the flow of water in the mixer wash cup. When CLOSED is touched, OPENED displays.
INCUBATOR VALVE CLOSED/OPENED	Controls the flow of water in the incubator. When CLOSED is touched, OPENED displays.
WASTE PUMP OFF/ON	Controls the waste pump, which drains water from the wash cups and overflow from the incubator. When OFF is touched, ON displays.
HOME ROBOTICS	Returns robotics to the home position.
SAMPLE ARM	Displays the Sample Arm screen.
REAGENT ARM	Displays the Reagent Arm screen.
MIX ARM	Displays the Mix Arm screen.
PUMPS & VALVES	Updates the Pumps & Valves screen.
OTHER DEVICES	Displays the Other Devices screen.
STEP TABLES	Displays the Sample & Mix Arm Table screen.
EXIT	Displays the Robotics screen.

NOTE

BEFORE EXITING THIS SCREEN, ALL VALVES MUST BE CLOSED. THE VALVES WILL NOT CLOSE WHEN EXIT IS TOUCHED. TOUCH **PUMPS & VALVES** TO UPDATE THE STATUS.

Robotics Pumps & Valves

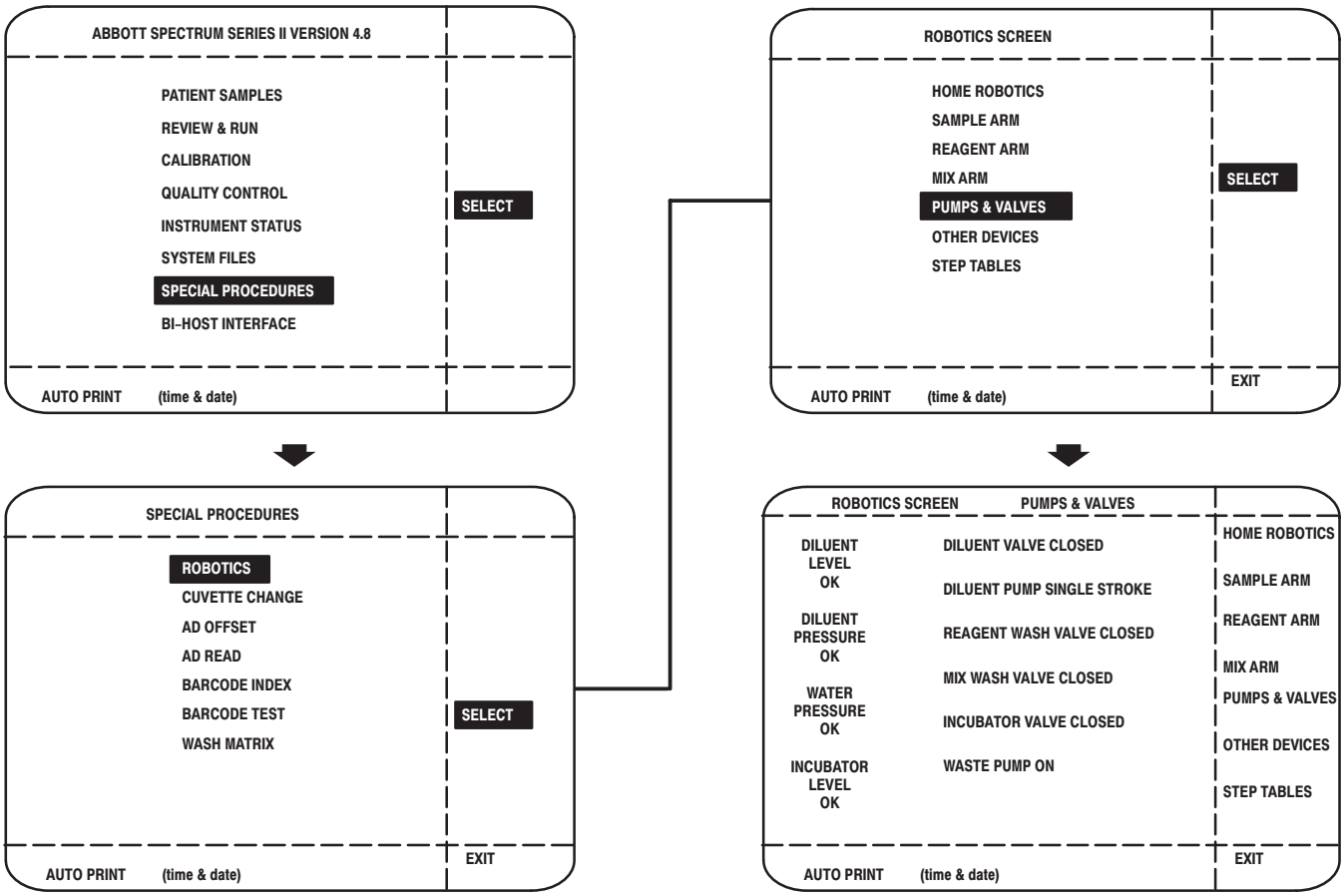


Figure 3-43 Pumps & Valves Screen Flow Map

Introduction

The Other Devices screen displays when OTHER DEVICES is selected from the Robotics screen. Refer to Figure 3-44 for the Other Devices Screen Flow Map.

This screen is used to observe the robotic positions of the reagent and sample syringes, calibration wheel, and sample and cuvette carousels.

Data Entry Fields

SAMPLE CAROUSEL #	A field used to enter the position number to which the sample carousel will be moved.
# HOME STATION	A field which displays the sample carousel robotic position number.
REACTION CUVETTE #	A field used to enter the position number to which the reaction cuvette will be moved.
# HOME STATION	A field which displays the cuvette carousel robotic position number.
CALIBRATION WHEEL	A field used to specify rotation of the calibration wheel. The CYCLE key is pressed to display the appropriate option (OPEN, BLOCKED 1, 400CU, 450CU, BLOCKED 2, BLOCKED 3, BLOCKED 4, or BLOCKED 5).
SHUTTER OPEN/CLOSE	A field used to open and close the shutter.
# HOME STATION	A field which displays the calibration wheel robotic position number.
SAMPLE SYRINGE ASPIRATE	A field used to raise the sample syringe.
# EMPTY	A field used to lower the sample syringe.

Robotics Other Devices

Data Entry Fields (continued)

# CLEAR/HOME	A field which displays the sample syringe robotic position number.
REAGENT SYRINGE ASPIRATE	A field used to raise the reagent syringe.
# EMPTY	A field used to lower the reagent syringe.
# CLEAR/HOME	A field which displays the reagent syringe robotic position number.

Touch Screen Fields

HOME ROBOTICS	Returns robotics to the home position.
SAMPLE ARM	Displays the Sample Arm screen.
REAGENT ARM	Displays the Reagent Arm screen.
MIX ARM	Displays the Mix Arm screen.
PUMPS & VALVES	Displays the Pumps & Valves screen.
OTHER DEVICES	Re-displays the Other Devices screen.
STEP TABLES	Displays the Sample & Mix Arm Table screen.
EXIT	Displays the Robotics screen.

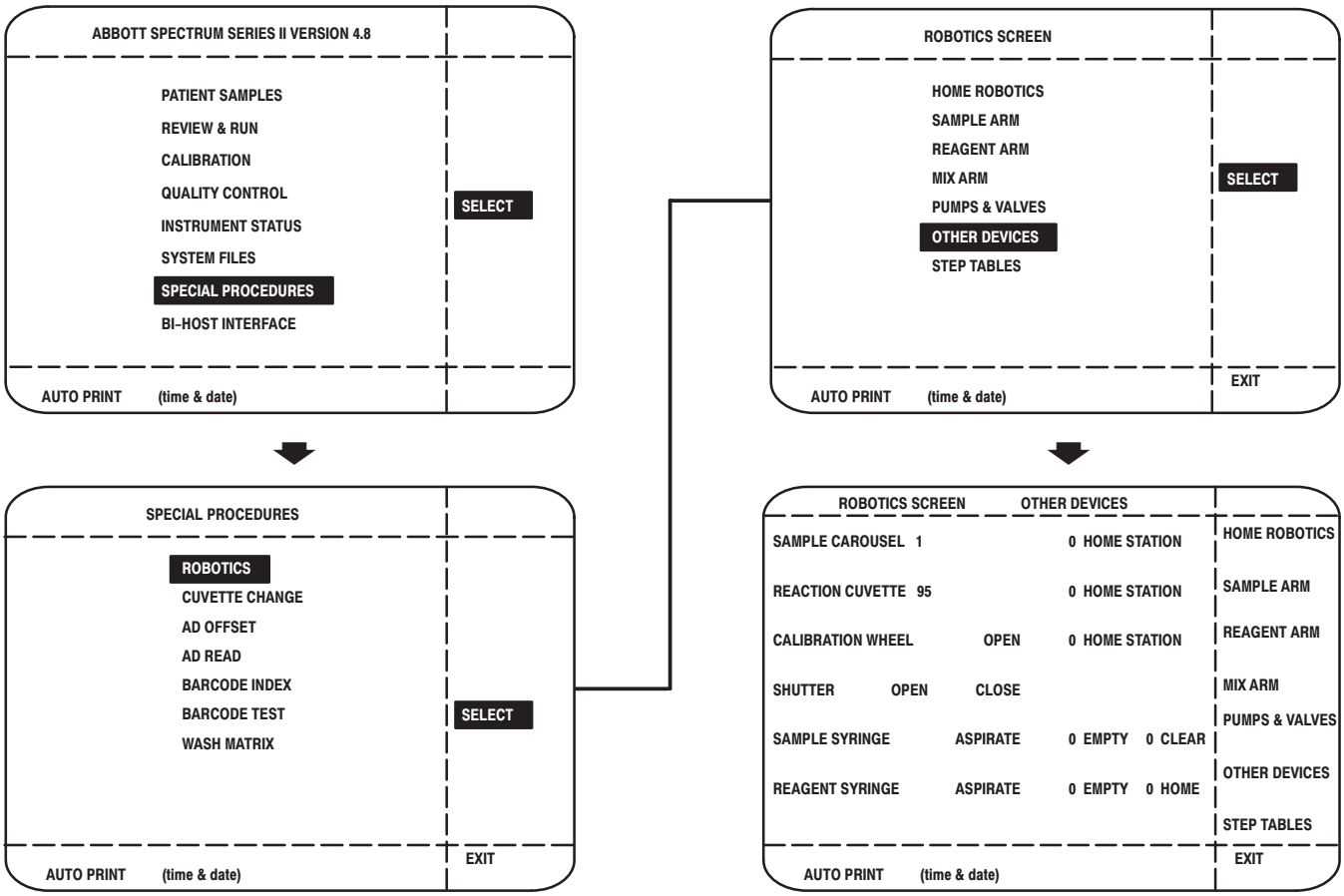


Figure 3-44 Other Devices Screen Flow Map

Robotics Step Tables

Introduction

The Robotics Step Tables are used to view robotic training positions for the sample, mixer, and reagent arms. Refer to Figure 3-45 for the Robotics Step Tables Flow Map.

The Sample & Mix Arm Table displays when STEP TABLES is selected from the Robotics screen. Robotic step numbers may be edited or entered in this screen.

Touch Screen Fields

HOME & SAVE	Stores screen edits; returns robotics to the home position.
REAGENT TABLE	Displays the Reagent Arm Table screen.
SAMPLE & MIX TABLE	Displays the Sample & Mix Arm Table screen.
EXIT	Displays the Robotics screen.

NOTE

STEP TABLE SCREEN EDITS ARE NOT STORED WHEN EXIT IS TOUCHED. TOUCH **HOME & SAVE** TO STORE EDITS.

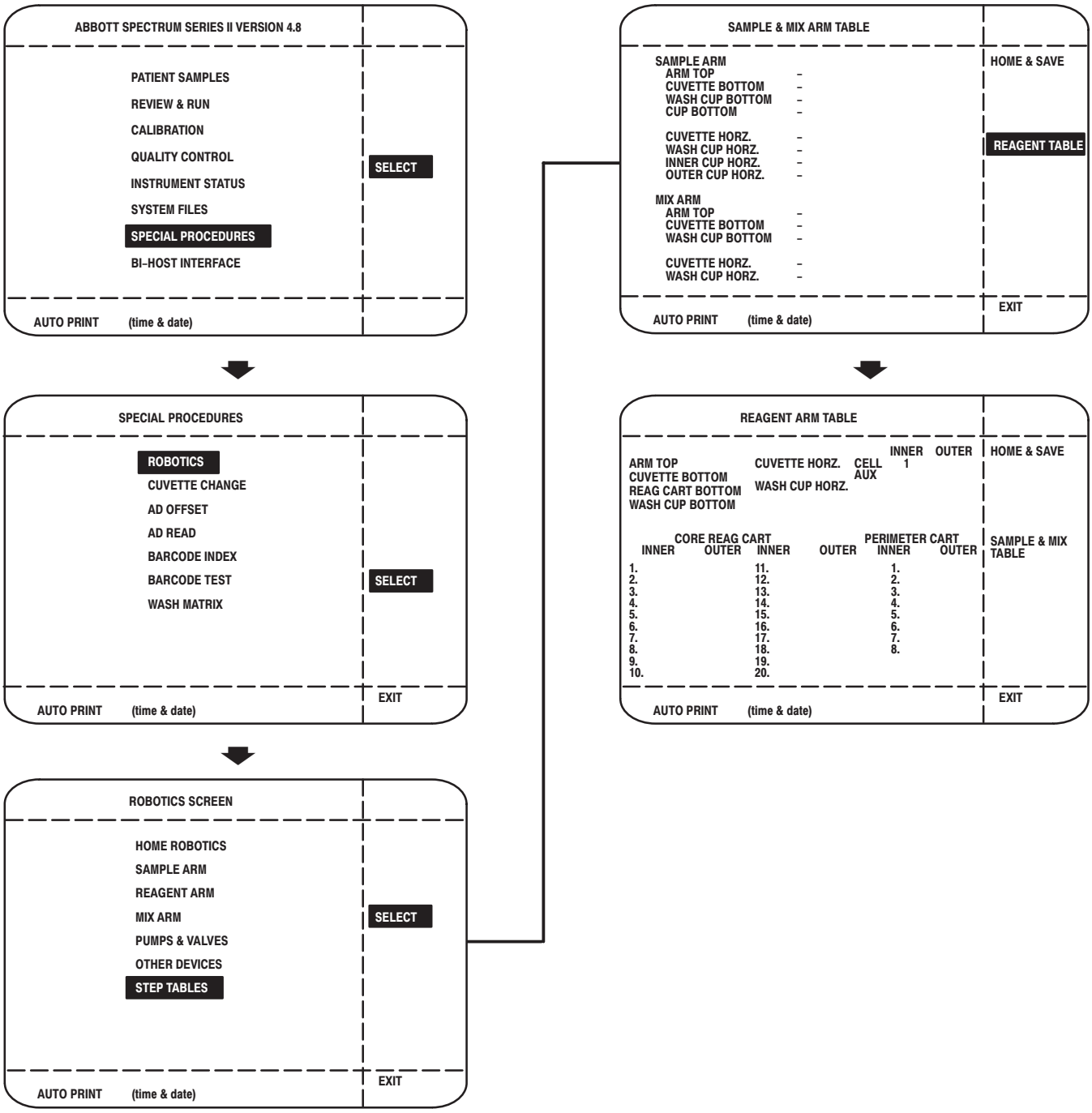


Figure 3-45 Robotics Step Tables Flow Map

Ad Offset

Introduction

The Ad Offset screen displays when AD OFFSET is selected from the Special Procedures screen. Refer to Figure 3-46 for the Ad Offset Screen Flow Map.

This screen provides information concerning the Photometer System, which is used during troubleshooting or maintenance (e.g., during source lamp replacement).

Touch Screen Fields

DARK CURRENTS, CH1, CH2	Displays the current numerical value the System has computed that will zero the photometer channels. This computation is performed routinely as chemistries are processed. The numbers have an acceptable range of 50–4050, but drift with electronic aging. If the number is outside this range, the wavelength or channel is not "auto-zeroing" correctly and requires service.
STRAY LIGHTS CH1, CH2	Displays routinely computed values that correct for stray light. Stray light corrections are shown only for 340nm and 364nm. The other wavelengths exhibit negligible effects from stray light.
BALANCE POINTS CH1, CH2	Displays monochromatic reads for each wavelength on each channel, through water. The reads are expressed in counts, with zero absorbance units corresponding to zero counts, and 3.0 absorbance units corresponding to 30,000 counts. These numbers are used in chemistry range checks.
MA/MA	Displays difference in Channel 1 and Channel 2 milliamps.
UA/UA	Displays difference in Channel 1 and Channel 2 microamps.
LIGHT ON	Turns the source lamp on.
LIGHT OFF	Turns the source lamp off.
RECALCULATE	Initiates a reread and recalculation of the optics and related electronics.
HOME SLAVE	Returns robotics to the home position.
EXIT	Displays the Special Procedures screen.

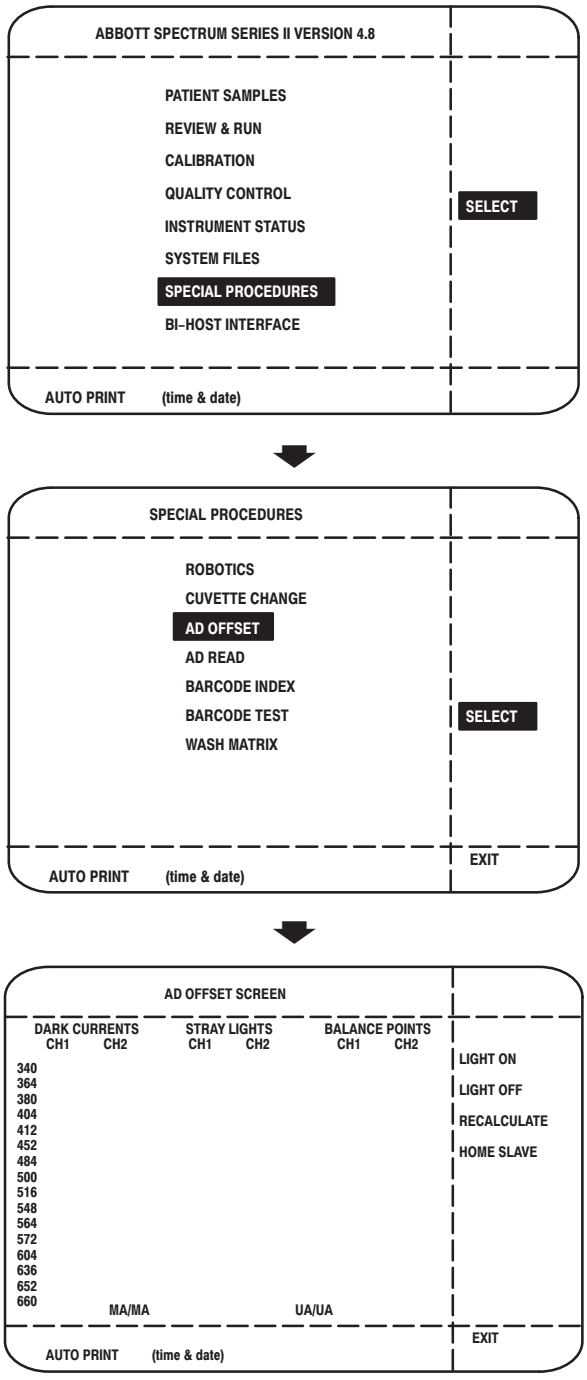


Figure 3-46 Ad Offset Screen Flow Map

Ad Read Parameters

Introduction

The Ad Read Parameters screen displays when AD READ is selected from the Special Procedures screen. Refer to Figure 3-47 for the Ad Read Parameters Screen Flow Map.

This screen is used to collect raw data on instrument-dispensed chemistries for new assay evaluation. The data is used to troubleshoot reagent problems or to check System optics. The screen may be edited to establish the type of measurement to be taken and the calculations required for that measurement.

Data Entry Fields

340/340 = 0.0000

Represents the 16 wavelengths detected by the photodiode array. The left column is Channel 1; the middle column is Channel 2; and the right column displays the measured value of each of the first two values. The Channel 1 and Channel 2 columns may be edited. Entry options include the 16 wavelengths detected by the photodiode array. MA - selects milliamps; UA - selects microamps.

CELL # TO #

A field used to enter the range of cells to be read. The numbers entered (1–96) correspond to the cuvette carousel cell numbers. The area between segments, called “spokes” (S1-S8), may be entered when the only measurement needed is optics.

REPEAT

A field used to specify the number of times to read the cells. Valid entries are 1-65535.

INTERVAL (SEC)

A field used to specify the time, in seconds, between read cycles. Valid entries are 0-600.

Data Entry Fields (continued)

MODE	A field used to select the method by which measurements are taken. The CYCLE key is pressed to display the appropriate option.
LOG AMP	The normal bichromatic read.
DELTA	Similar to LOG AMP, except the first read is stored and all other reads are calculated and displayed as a difference from the first read. A ∧ is displayed to indicate that the displayed value is a difference delta.
CHAN 1	The monochromatic read of Channel 1.
CHAN 2	The monochromatic read of Channel 2.
V REF	The 8-volt reference measurement rather than the diode array.
CAL WHEEL	A field used to select the filter to move into the optical path. The filters are used to standardize the optical electronics. Refer to Ad Offset in this section for additional information. The CYCLE key is pressed to display the appropriate option.
OPEN	The heat glass filter. All light is allowed to pass and heat is blocked.
BLOCKED 1–5	The light-blocking anodized aluminum plate.
400CU	The 400nm cut-off interference filter.
450CU	The 450nm cut-off interference filter.
LOG AD TO HOST	Enables measurements to be transferred to the personal computer interface. Interface specifications may be obtained from Abbott Laboratories. Refer to Interface Setup in this section for additional information.
SKIP SPOKES	A field which allows the alternative of reading spokes. The CYCLE key is pressed to display the appropriate option.
YES	Spoke reading is inappropriate.
NO	Spoke reading is appropriate.
LIGHT ON/OFF	A field used to control the source lamp. The CYCLE key is pressed to display the appropriate option (ON or OFF) and ENTER is pressed.

Ad Read Parameters

Data Entry Fields (continued)

SCALE FACTOR	A field used to select the method in which the measurements are calculated and displayed. The CYCLE key is pressed to display the appropriate option.
COUNTS	The values in counts.
VOLTS	The voltage measurement before it goes to the photodiode array.
AD HI RES	The 0-3.3 absorbance range with a resolution of 0.0001.
AD LO RES	The 0-9.99 absorbance range with a resolution of 0.0003.
NORMALIZE	The normal bichromatic read, except all reads are calculated and displayed after beginning, and the read is divided by the first read.

Touch Screen Fields

PC ONLINE	Not currently active.
START	Initiates the read cycle. The left side of the screen will not respond to edits.
STOP	Terminates the readings at the completion of the next read cycle.
HOME ROBOTICS	Returns robotics to the home position.
REVIEW DATA	Displays the Ad Read Data screen.
EXIT	Displays the Special Procedures screen.

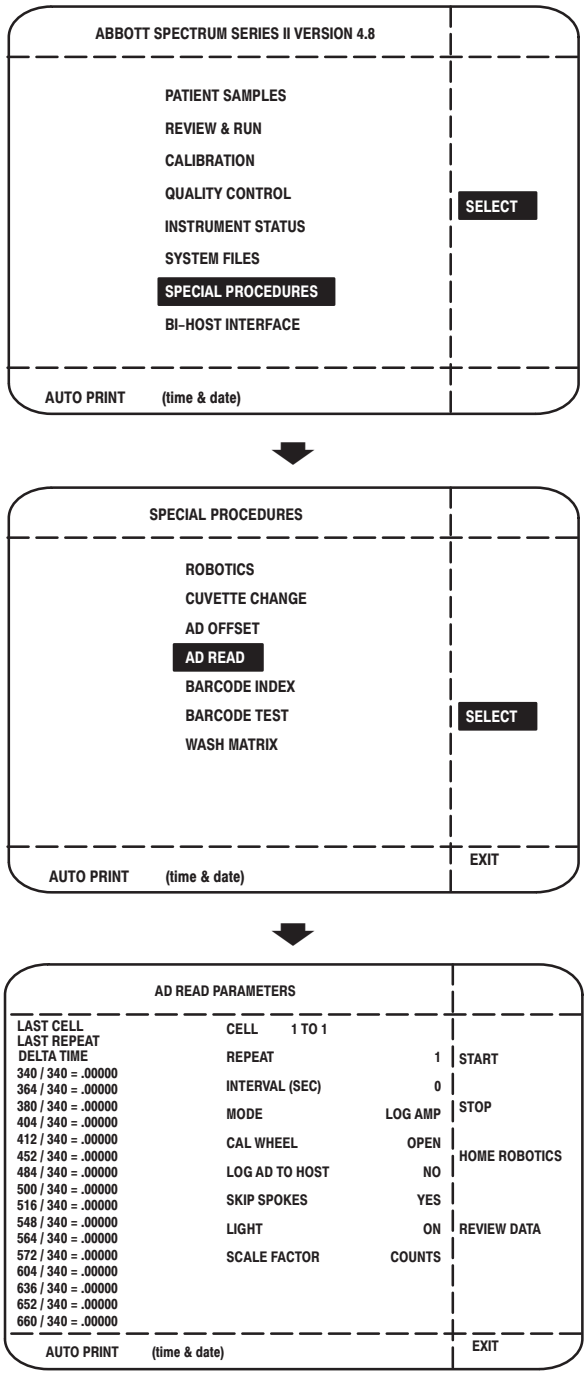


Figure 3-47 Ad Read Parameters Screen Flow Map

Ad Read Data

Introduction

The Ad Read Data screen displays when REVIEW DATA is touched from the AD Read Parameters screen. Refer to Figure 3-48 for the Ad Read Data Screen Flow Map.

This screen displays data from the last five collected reads.

Touch Screen Fields

CELL	Displays the cuvette carousel position that was read.
REPEAT	Identifies the series of reads for the cell position displayed above.

NOTE

MULTIPLE READINGS FOR THE SAME CELL POSITION MAY BE VIEWED BY TOUCHING **NEXT READ.**

START	Initiates the read cycles.
STOP	Terminates the readings at the completion of the next read cycle.
HOME ROBOTICS	Returns robotics to the home position.
PREVIOUS READ	Scrolls the readings backward by one and displays the previous readings. Fifty readings are stored in the circular buffer.
NEXT READ	Scrolls the readings forward by one and displays the most recent readings. Fifty readings are stored in the circular buffer.
EXIT	Displays the Ad Read Parameters screen.

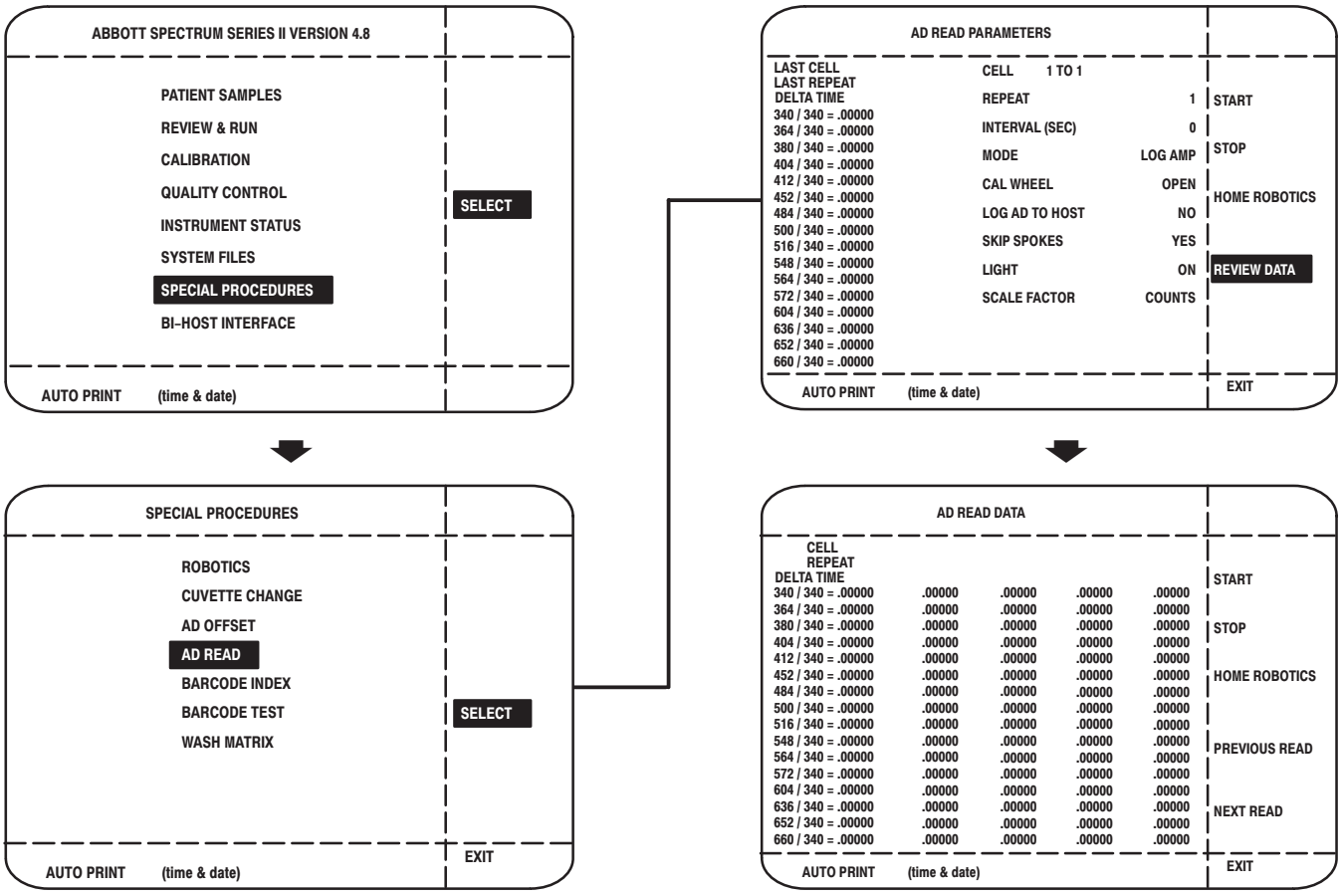


Figure 3-48 Ad Read Data Screen Flow Map

Reagent Barcode Index

Introduction

The Reagent Barcode Entry screen displays when BARCODE INDEX is selected from the Special Procedures screen. Refer to Figure 3-49 for the Reagent Barcode Entry Screen Flow Map.

This screen is used to assign a new barcode label to a specific reagent. The CORE REAG NAME and the PERIM REAG NAME must match the reagent name in the corresponding Test Parameter File or the barcode will not be recognized by the System. If the reagent name is changed in the assay Test Parameter File, it must also be changed in the Reagent Barcode Entry screen.

Numbers assigned to specific reagents cannot be changed. As new reagents are available, the Reagent Barcode Entry screen must be edited. Refer to the reagent package insert and the Reagent Manual for parameter definitions.

Data Entry Fields

REAGENT INDEX	A field used to enter the cartridge reference number assigned to each reagent cartridge. The valid range is 1-200. If a value exceeding this range is entered, the message CODE 00213 ILLEGAL REAGENT INDEX – MUST BE 1–200 ONLY displays.
CARTRIDGE TYPE	A field used to select the cartridge type. The CYCLE key is pressed to display the appropriate option (EMPTY, SINGLE, or DOUBLE).
CORE REAG NAME	A 10-character, alphanumeric field used to enter the core reagent name.
PERIM REAG NAME	A 10-character, alphanumeric field used to enter the perimeter reagent name.

Touch Screen Fields

NEXT ENTRY–SAVE CURRENT	Stores the current entry, if edited, and displays the next Reagent Index.
PREV ENTRY–SAVE CURRENT	Stores the current entry, if edited, and displays the previous Reagent Index.
NEXT ENTRY	Displays the next Reagent Index.
PREV ENTRY	Displays the previous Reagent Index.
SAVE FILE	Stores screen edits.
EXIT	Displays the Special Procedures screen.

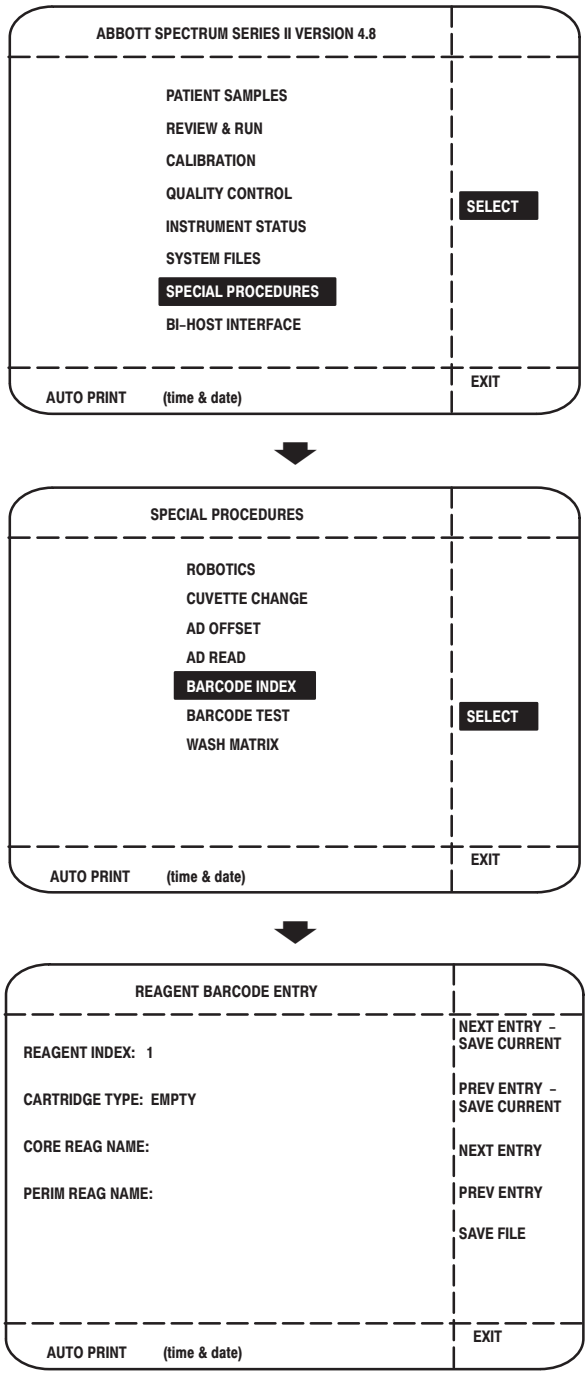


Figure 3-49 Reagent Barcode Entry Screen Flow Map

Barcode Test

Introduction

The Barcode Test screen displays when BARCODE TEST is selected from the Special Procedures screen. Refer to Figure 3-50 for the Barcode Test Screen Flow Map.

This screen is used to test the ability of the barcode reader to read the reagent barcode labels correctly. The barcode test is a diagnostic procedure to verify performance of the barcode reader. For additional information, refer to Observed Concerns, Barcode Reader Not Reading the Reagent Cartridges, in the Maintenance & Troubleshooting Manual.

The numbers at the top of the screen indicate the reagent tray position. Each time the reader scans the barcodes, numbers display at the bottom of the screen. The reader is scanning correctly when the displayed characters match the characters on the top of the reagent barcodes.

Touch Screen Fields

START — Initiates the barcode test.

ATTENTION

DO NOT ALLOW THE TEST TO PROCEED FOR LONGER THAN TEN MINUTES. THE BARCODE READER MAY SUSTAIN DAMAGE.

STOP — Terminates the barcode test.

EXIT — Displays the Special Procedures screen.

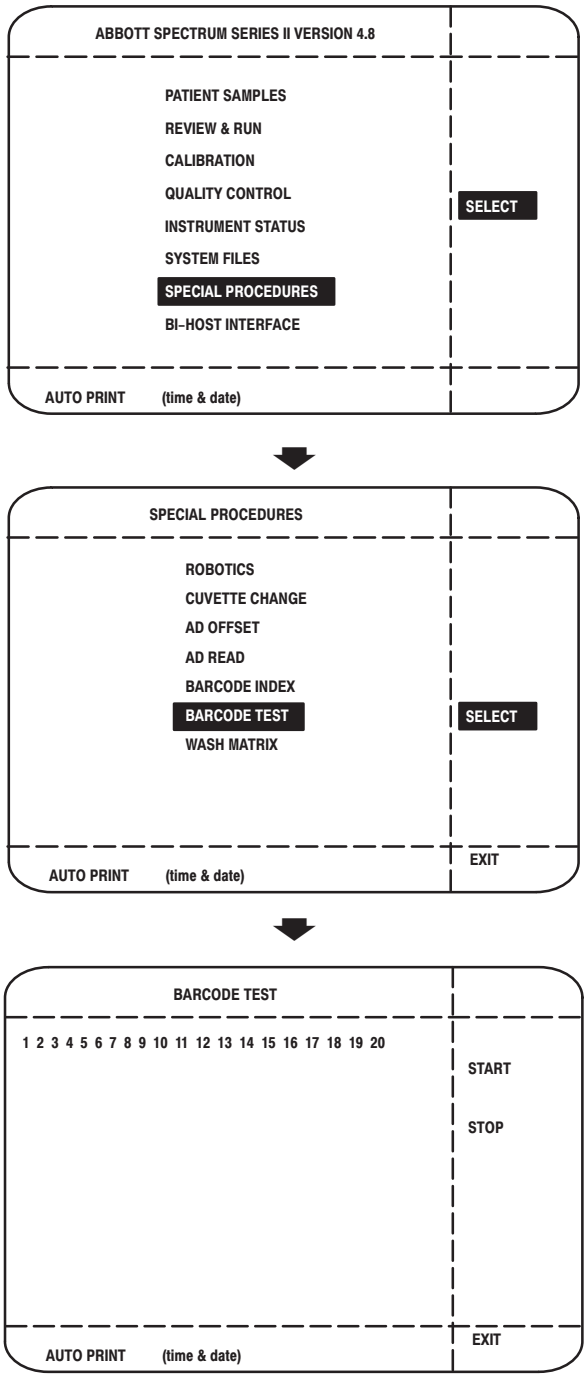


Figure 3-50 Barcode Test Screen Flow Map

Wash Matrix

Introduction

The Wash Matrix is designed to prevent reagent carryover between dispenses. The Reagent Probe Wash Cycles screen displays when WASH MATRIX is selected from the Special Procedures screen. Refer to Figure 3-51 for the Reagent Probe Wash Cycles Screen Flow Map.

This screen displays the number of wash cycles required before and after each reagent. When AFTER REAGENT is highlighted, the numbers displayed indicate the number of cycles required after the highlighted assay. When BEFORE REAGENT is highlighted, the numbers displayed indicate the number of cycles required before proceeding to the highlighted assay.

A maximum of 60 reagents are displayed in the wash matrix. If either the "before reagent" or the "after reagent" is not displayed in the Wash Matrix, the System defaults to the values in the Test Parameter Files for both assays. The AFTER WASH of one reagent is added to the BEFORE WASH of the next reagent. The combined value is the executed probe wash between the reagents.

NOTE

CONTENTS OF THE WASH MATRIX SHOULD BE EVALUATED PERIODICALLY.

The number of wash cycles may be edited from the Reagent Probe Wash Cycles screen when changes are indicated, e.g., new reagents are available from Abbott Laboratories or the reagent package insert indicates an edit is required. Refer to Specific Procedures, Wash Matrix, for additional information.

Touch Screen Fields

AFTER REAGENT	Indicates the number of cycles required after the selected assay.
BEFORE REAGENT	Indicates the number of cycles required before proceeding to the selected assay.
SAVE FILE	Stores screen edits.
EXIT	Displays the Special Procedures screen.

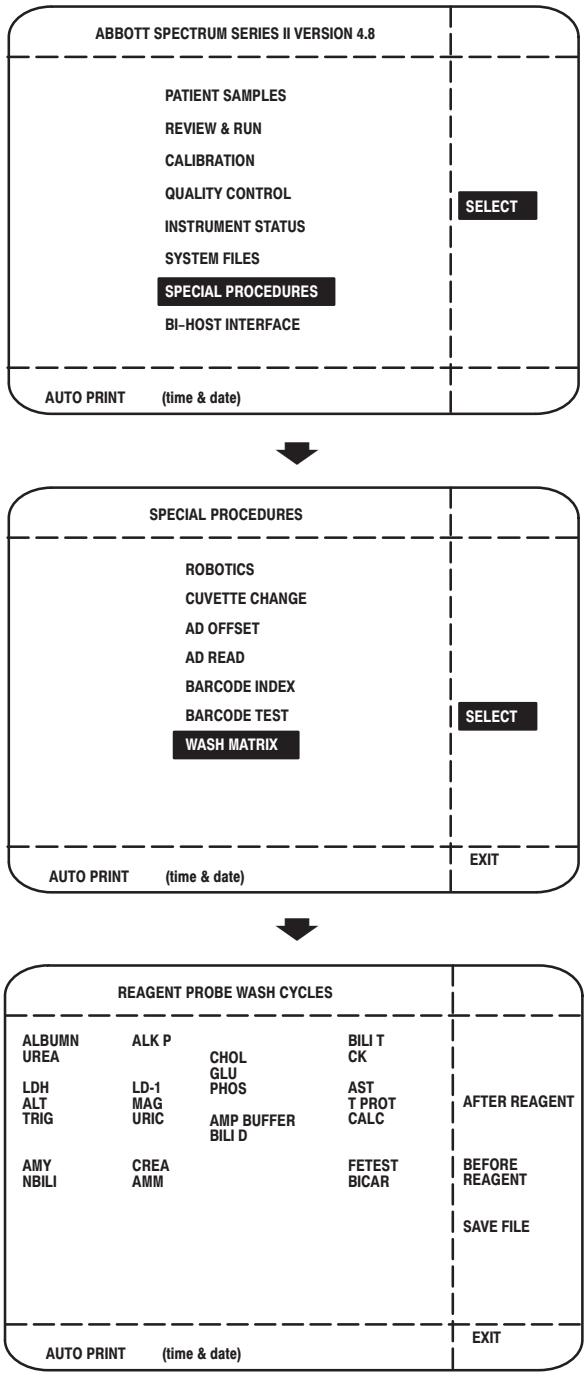


Figure 3-51 Reagent Probe Wash Cycles Screen Flow Map

Bi-Host Interface

Introduction

The Bi-Host Interface screen displays when BI-HOST INTERFACE is selected from the Main menu. Refer to Figure 3-52 for the Bi-Host Interface Screen Flow Map.

The Interface function allows patient samples to be downloaded to the ABBOTT SPECTRUM SERIES II System from a host computer which has been programmed to meet specifications set by Abbott Laboratories. (Specifications are available from Abbott Laboratories.) The System also has the ability to report patient results to the host computer.

Touch Screen Fields

AUTO SEND

A mode in which completed samples are automatically transmitted to the host computer. AUTO SEND is turned on and off by the host computer and may not be selected by the operator.

BREAK

Terminates the transmission if a communication error occurs. BREAK should not be selected for routine downloads. This feature is provided to allow operation to continue if the external host fails.

NOTE

IF TRANSMISSION IS INTERRUPTED OR A SUDDEN POWER LOSS OCCURS, CONTACT THE HOST REPRESENTATIVE TO ENSURE THE INTEGRITY OF DATA BEING TRANSMITTED.

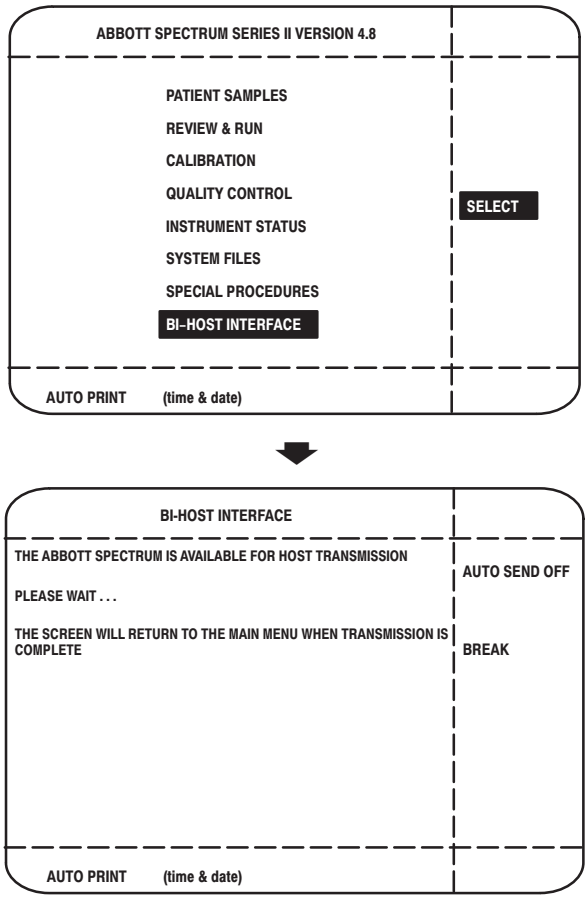


Figure 3-52 Bi-Host Interface Screen Flow Map

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Hazards

Introduction

This section contains information regarding general and System-specific hazards. Before operating the ABBOTT SPECTRUM SERIES II System, become thoroughly familiar with the information in this section. It is the operator's responsibility to review and follow safety precautions as defined in the product inserts.

Important Information

Users of the System must be familiar with and heed important precautionary and informational text, presented as follows:

WARNING	Indicates a clear and present danger to personnel or questionable result efficacy. Failure to comply may result in incorrect instrument performance leading to instrument failure, generation of erroneous results, or hazard to the operator.
WARNING Potential Biohazard	Indicates the actual or potential presence of a biological hazard.
WARNING Electrical Shock Hazard	Indicates possible danger from electrical shock.
CAUTION	Indicates a minor hazard situation where unsafe practices or a non-immediate or potential hazard presents a lesser threat of injury. Failure to comply may result in unexpected instrument performance or hazard to the operator.
ATTENTION	Indicates general information. Failure to comply may result in damage to the instrument.
NOTE	Indicates general information. Failure to comply will present no efficacy, performance, or safety issues.

Hazards

General Biosafety

Consider all clinical specimens and reagent 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 OSHA Bloodborne Pathogen Rule, 29 CFR 1910.1030, or other equivalent biosafety procedures.

Instrument Decontamination

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

- Service and maintenance
  - FSR service
  - Component replacement, e.g., probe change
- Shipment

Use the following procedure to decontaminate the instrument.

1. Touch HOME ROBOTICS to flush the probes and mixer 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 hospital disinfectant, such as 10% chlorine bleach solution.

Contaminated Sharps

Exercise caution when contacting the sample probe, reagent probe, and mixer arm tip. They are sharp and potentially contaminated with infectious materials. Avoid any contact with the probes or the mixer 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.

Sharps

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

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.

General Biosafety
(continued)

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.
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 hospital disinfectant, such as 10% chlorine bleach solution.

Electrical Safety

Operators must practice good habits of electrical safety for the safe operation of any system, such as the following:

- Periodically inspect electrical cabling into and on the System 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 System.
- 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

- 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, power remains on for the ISE module electronics.

Physical Safety

The operator must follow basic rules of mechanical equipment operation, including the following:

- 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.

Hazards

Special Handling Precautions

Follow the procedures below to:

- Prevent fibrin formation in serum samples
- Run electrolyte assays using plasma

Fibrin

Fibrin in serum specimens can cause assay results to be either erroneously high or low. Excess sample deposits caused by partial aspiration of serum laden with fibrin clots can cause an obstruction.

To prevent fibrin formation in serum samples:

- Review and adhere to instructions or precautions accompanying serum separator tubes.
- Use serum filters, if needed, to aid in the removal of fibrin.
- Inspect patient samples for fibrin clots or unspun gel material prior to placing the sample in the sample cups.

Electrolyte Assays

If plasma is desired for ISE assays, follow the precautions below.

- Lithium heparin should be used as an anticoagulant. Sodium heparin can cause falsely elevated results.
- Ethylene glycol destroys all electrodes.
- Chlorphenol is toxic to the chloride electrode.
- Ammonium bicarbonate causes high sodium results and low potassium results.
- Azides cause chloride to drift high.

Glossary

% C.V.	Calculation used to measure reproducibility/precision.
absorbance	Measurement of the optical density of a liquid determined by spectrophotometric analysis.
absorbance difference	Difference between the primary and secondary wavelengths.
A_d	Absorbance difference.
AFT	Aspirate flow time.
alarm	Audible tone sounded when the instrument requires operator action.
alphanumeric	Character set containing letters, digits, and punctuation marks.
analyte	Substance measured by chemical analysis.
arrow keys	Keys used to move the cursor.
aspirate	Physical action of drawing or removing liquid by suction.
aspirate flow time	Time required for the beginning of the sample fluid to reach the air detector.
assay	Analytical process or test to determine the presence or concentration of an analyte in an unknown specimen.
assay type	Defines when reagents are dispensed, when readings are taken, and the equation used to calculate results.
autoclave	Strong, pressurized, steam-heated vessel, for sterilization.
aux assay	Assay that requires more than one reagent dispense at different time intervals.
aux dispense	Second or third reagent dispense that is required by a given test.
auxiliary	Indicates a second system.
AUX PENDING	Status, displayed in the ACTIVITY field, that indicates the System is waiting for the second or third reagent to be dispensed.
aux reagent	Assay with two or three reagents.
balance points	Zero absorbance levels electronically generated for any given bichromatic pair of wavelengths.
barcode	Special code designed to be read by a scanner.
barcode labels	Labels that contain a code that can be read by a scanner.
barcode reader	Device used to read barcode labels.
Batch mode	Processing mode that allows all same type assays to be processed together in sequential order, based on carousel position number.
baud	Unit for measuring the speed of data transmission.
baud rate	Rate of speed in data transmission.
bichromatic measurement	Spectrophotometry that subtracts a secondary wavelength absorbance reading from a primary wavelength absorbance reading to obtain a delta absorbance reading.
bi-directional interface	Communications medium that allows two-way communication between a host device and a peripheral device.
bi-host interface	Hardware or software communications medium that allows two-way communications between a host device and a peripheral device.

Glossary

biohazardous	Pertaining to materials that are a threat to human health or to the well-being of the environment.
bit	Binary digit.
blank	Method used for correcting interferences.
C of C	Coefficient of correlation.
calibration	Result of calibrating an instrument or assay.
calibration curve	Curve stored in memory of known values and rates that is referenced for unknown samples.
calibration interval	Time period during which the calibration curve is good.
calibration type	Defines the mathematical relationship applied to calculate the coefficients used to determine analyte concentration and specifies the constraints on the value of these coefficients.
calibration wheel	Wheel, containing lenses and filters, that resides in the light path between the cuvette cell and the detector.
calibrator	Solution with an assigned value.
Cal On Command	Procedure for manually selecting and running assay calibrations.
cartridge	Component used to store reagent.
cartridge type	Defines the size of the reagent container by specifying the volume of the container.
coefficient	Numerical measure of a physical or chemical property that is constant for a system.
coefficient of correlation	Indicator of goodness of fit of the data set being measured.
coefficient of variation	Calculation of standard deviation divided by mean.
collection tube	Glass tube for collecting and storing blood samples.
COM	Status that indicates the assay is complete.
component assay	Assay that, with other assays, comprises a ratio.
concentration	Amount of a substance contained per unit volume.
contaminate	Make impure by contact.
control	Standard of known reactivity used to monitor the performance and efficacy of the assay.
core vial	Vial located in the inside position of a dual reagent cartridge.
cumulative total	Running tally of all counts or values used for statistical purposes.
cursor	Location indicator on the touch screen.
cuvette	High-quality glass or plastic container.
cuvette carousel	Ring or carousel used to hold cuvettes.
cuvette status panel	Panel that displays the number of used and unused cuvettes loaded on the System.
dark current	Measurement of electrical noise in the optics.
data entry field	Portion of display where data is entered and displayed.

dead volume	Residual amount of reagent or sample that is necessary to ensure that proper dispense occurs.
decontaminate	Remove contamination or chemicals.
default value	Value used if no other is input.
delta A_d	Difference between two A_d measurements. The delta absorbance is used in conjunction with calibration data to calculate concentration or activity.
diagnostics	Utilities designed to test the electronics, optics, detection capacity, and dispense functions within the System.
digit	Number symbol, 0 through 9.
diluent	Solution used to dilute a sample.
diluent purge	Action of circulating diluent through the sample tubing.
diluent valve	Device that switches the fluid flow on and off.
dilution protocol	Procedure for performing a particular dilution ratio.
dilution ratio	Ratio of total volume to sample volume.
dispense	Delivery of a volume of reagent, sample, or diluent.
DP	Dilution protocol.
dual reagent assay	Assay that requires two reagent dispenses at different time intervals.
dual reagent cartridge	Reagent container comprised of a core vial and a perimeter vial.
E.F.	Extinction factor.
electrode	Ion selective component that measures the voltage activity of sodium, potassium, and chloride.
electrode carrier	Housing that holds electrodes.
electrode train	All electrodes connected in a series.
end point assay	Assay that reaches equilibrium in a short period of time.
ENT	Status that indicates the assay has been entered but not currently scheduled by the System.
extinction factor	Bichromatic absorbance change per unit of concentration change of chromophore. This factor is specifically determined for a wavelength pair and derived from linearity tests performed during the manufacture of the instrument.
FFT	Fill flow time.
fibrin	Protein that gives the semisolid character to a blood clot.
first read time	Time that the first reading takes place in a System test.
flag	Symbol appended to a sample result that draws attention to a particular characteristic of the result.
Flex-B	Flexible batch.
Flexible Batch mode	Instrument processing order that schedules assays for optimum throughput.
flush	Function that circulates fluid through a system.

Glossary

flush valve	Valve used to remove fluid from a system.
function key	Key assigned to perform special functions within a program.
HALT key	Key used as an emergency stop for the System. Activation of Halt aborts System activities immediately.
hazardous waste	Waste material presenting danger to the environment or to humans.
header	Text that appears in the top margin of printed pages (e.g., hospital name and address).
holographic grating	Optical grating that splits the light beam coming from the cuvette cell into specific wavelength beams, that are then focused on the diode array.
home position	Position of the robotics arm when the cycle is complete and the System is in the ready state.
host computer	Central computer in a timesharing or distributed processing environment.
IA	Initial absorbance.
incubator	Unit maintaining a specific level of heat.
infrared	Indicates electromagnetic radiation visible by light.
initial absorbance	First reading taken on reagent when no sample has been dispensed.
interconnects	Components that connect two or more assemblies together.
interface setup	Parameter entered to make a computer interface match the operating requirements of the computer and the system to which it is to be connected.
ion selective electrode technology	Method, using an ion-specific membrane, to develop an electrical potential according to the Nernst equation.
ISE	Ion selective electrode.
ISE maintenance mode	Troubleshooting mode for the ISE module that gives real-time readouts of each electrode, in millivolts.
ISE module	System component that draws samples directly from the carousel to perform sodium, potassium, and chloride measurements, using ion selective electrode technology.
ISE septum	Component of the ISE module that allows separate ports of entry for Standards A and B, while allowing the ISE sample probe to aspirate sample or standard as needed.
kinetic blank	Blank cell used in calibration.
LE	Low energy or spectral correction.
LH	Linear high.
LL	Linear low.
linear high	Value above the stated linearity claim.
linear low	Value below the stated linearity claim.
linear regression	Analytical technique.
linearity	Range over which absorbance versus concentration approximates a straight line.

loadlist	Calibrator—List of available or needed calibrators/standards on the System. Reagent—List of available or needed reagents on the System. Sample—List of specific SIDs loaded on the sample carousel.
low energy	Flag that indicates insufficient light is entering the photometer.
MA	Maximum absorbance or Rate C. of C. flag.
MAINTENANCE	Status, displayed in the ACTIVITY field, that indicates a maintenance routine is being performed.
manual entry	Use of the keyboard to enter data, such as a sample ID.
math model	Mathematical formula used in a test file to determine or measure reactions.
matrix	Information in row and column form.
maximum absorbance	Highest allowable optical density value.
mean	Calculated average for a set of numbers.
membrane	Thin layer of tissue.
minimum absorbance	Lowest acceptable optical density reading.
mixer	Robotic component that agitates the sample and the reagent in the cuvette cell.
NCCLS	National Commission for Clinical Laboratory Standards; an organization that has created documentation to standardize the way tasks are performed in the laboratory.
numeric key	Key, labeled from 0 to 9, used to enter numeric data.
O-ring	Rubber washer or ring used to seal a connection.
offline	Refers to test results manually entered into a system but not run on that system.
optics	Subsystem comprised of the lamp, light path, lenses, calibration wheel, mirrors, holographic grating, and the photodiode array.
panel	Group of tests.
parameter	Variable appearing in a mathematical expression.
parity	Method of checking if binary numbers or characters are correct by counting the ONE bits.
partial ISE	Selectable option that allows use of one or two channels of the ISE, rather than all three channels.
password	Special code provided at login time to identify a user.
patient identification number	Number assigned to the patient for tracking purposes.
PAUSE key	Key used to interrupt reagent and sample dispense procedures; optical readings of assays in progress continue.
percentage	Proportion in relationship to a whole.
perimeter vial	Vial located in the outer position of a dual reagent cartridge.
photodiode	Component that detects light.

Glossary

photodiode array	Multiple photodiodes electrically attached and functioning together.
PID	Patient identification number.
primary wavelength	Chosen wavelength where the chromophore has a maximum, or near maximum, absorbance. *See also* bichromatic measurement.
print order	Order in which tests are printed, as defined in the Print Order screen.
probe	Instrument component used for dispensing or aspirating.
probe wash	Number of cycles a probe is washed between dispenses.
processing order	Order in which tests are run, as defined in the Processing Order screen.
purge	To rid the System or tubing of excess air or fluid.
QC	Quality control.
quad rings	Ring seal.
quality control	Method of evaluating products by comparing them to a predetermined range.
Random mode	Processing mode in which tests are run by patient order.
range	Area between known limits.
rate reaction	Chemistry reaction that measures the amount of change over a specified time.
ratio	Comparison of two measurements.
reaction cell	Container where a chemical reaction takes place.
READING	Status, displayed in the ACTIVITY field, that indicates the sample carousel has been accessed and is no longer required for processing.
reagent	Substance used to produce a chemical reaction in order to direct, measure, or produce other substances.
reagent barcode reader	Electronic device used to read barcode labels on reagent cartridges.
reagent blank	Optical reading that determines the absorbance due to the reagent.
reagent cartridge	Container used to store reagent.
reagent lot number	Specific lot number given to a reagent cartridge at the time of manufacture.
reagent probe	Probe used for dispensing reagent by the reagent arm.
reagent syringe	Syringe used by the reagent assembly for dispensing reagent.
reagent tray	Component that houses reagent cartridges.
reference cal factor	Parameter used to convert absorbance to concentration.
resolution	Measurement of the sensitivity of an instrument to determine small changes in absorbance.
RUNNING	Status, displayed in the ACTIVITY field, that indicates the sample, reagent, or mix arms are in operation.
safety glasses	Shatter-resistant eye protection worn in the laboratory.
safety procedure	Course of action for the safety of persons and equipment.

sample	Specimen, or one of a group.
sample carousel	Carousel that holds patient samples, controls, and calibrators.
sample carousel ID kit	Kit containing labels to identify a carousel.
sample cup	Small, disposable plastic cup that holds sample, calibrators, or controls.
sample diluent	Solution used to dilute sample.
sample diluent 35-micron filter	Filter used to remove particulate matter from the tubing.
sample diluent pump	Pump that forces diluent to the sample syringe and probe for dispensing and washing.
sample diluent reservoir	Container that holds the necessary amount of diluent for System operation.
sample diluent valve	Valve that opens and closes the diluent tubing in the sample dispense system.
sample identification number	Number used to identify patient specimen.
sample probe	Probe used for dispensing patient samples or controls.
sample syringe	Syringe used to aspirate and dispense samples or patient specimens.
sample tube	Glass tube closed at one end used to collect and hold patient samples.
sample tubing	Tubing that connects the sample syringe to the sample probe.
sample volume	Volume of sample dispensed.
SCH	Status that indicates the assay has been scheduled for processing.
SD	Standard deviation.
secondary wavelength	Second wavelength in a bichromatic measurement. *See also* bichromatic measurement.
segment	One cuvette segment is comprised of a group of 12 reaction cells.
serum	Clear yellowish fluid obtained upon separating whole blood into its solid and liquid components.
serum blank	Baseline optical measurement of the serum and reagent mixture used to compensate for interfering substances in final results.
SID	Sample identification number.
software	Instructions programmed into a computer to control System operation.
source lamp	Light source directed through the reaction mixture.
spectrophotometer	Instrument to determine intensities of various wavelengths of light.
spoke	Support position on the cuvette carousel.
standard	Solution of known concentrations against which unknowns may be run.
standard deviation	Calculation used to determine variance from the mean.
STAT	Assay requiring immediate results.
status code	Code that indicates a given condition.

Glossary

stepper motor	Type of electrical motor used to drive all robotics subassemblies.
step table	Table that lists trained positions of the robotics.
stop bit	Bit transmitted after a specified string of characters.
stray light	Light from any source other than the light directed at the photometer.
supernatant	Liquid floating on top of another liquid or a solid sediment or precipitate.
syringe	Device used to supply a liquid.
Tandem mode	Processing order that prioritizes sample processing based on the number of assays ordered for each sample.
temperature calibration	Procedure used to adjust the incubator to a specific temperature.
test parameter file	File containing the settings used to perform an assay.
tolerance	Allowed difference from a specified value or standard.
touch screen	Screen that allows the user to make a selection by touching the screen.
tubing	Component within an instrument used to transport substances.
Type II water	Water with a resistivity of 1 megohm or greater, a microbiological content of 1000 or less colony-forming units/mL, carbon filtered, and free of particles as defined by NCCLS.
uni-directional interface	Communications medium that allows data to be sent to a host device.
value	Assigned or calculated numerical quantity.
volume	Amount or content.
volume correction of blanks	Calculation that volume corrects all blank readings.
wash cup	Well in which the sample probe, reagent probe, or mixer arm tip is rinsed.
waste decontamination	Procedure used to disinfect waste.
water quality station	Component that regulates and filters water from deionization tanks; source of water for the incubator, mixer arm tip wash station, and reagent probe wash station.
wavelength	Length, in nanometers, of one cycle of a sine wave.
Y-intercept	Parameter determined from a calibration curve and used in the calculation of result concentrations.

Symbols

% C.V.. *See* percentage coefficient of variation

% Tol of Cal. *See* percentage tolerance of calibration

% Tol of Cal Factor. *See* percentage tolerance of calibration factor

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