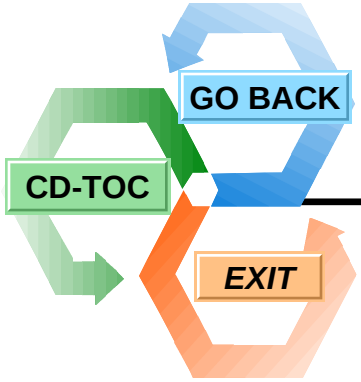

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ALCYON™

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Troubleshooting Guide

Abbott Laboratories
Abbott Park, IL 60064
30-1503/R2

NOTES

PROPRIETARY INFORMATION

Proprietary Statement

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REVISION STATUS

Revision Status			
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30-0004	5/98	Original Issue	Original Issue
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This guide was developed and produced by Worldwide Customer Service and Medical Writing in Irving, TX.

Table of Contents

GENERAL INFORMATION

Introduction

The **ALCYON™ Troubleshooting Guide** contains a standard approach and tools for resolving customer problems related to the performance of the ALCYON Analyzer.

Objectives

The objectives of the Guide are to:

- Provide Abbott Representatives with a standard "troubleshooting" approach for resolving problems that customers are having with the ALCYON Analyzer.
- Provide a standard set of tools through which the Abbott troubleshooting approach can be consistently and effectively applied.

There are nine sections in this guide:

- **Table of Contents**: This section includes a conventional table of contents which provides the user with the primary starting point for most troubleshooting activities.
- **General Information:** This section includes information on the objectives and content of this guide.
- **General Troubleshooting**: This section includes common troubleshooting procedures.
- **Detailed Multi-Constituent Controls Troubleshooting**: This section contains information which is specific for the co-labeled Abbott / Bio-Rad Controls.
- **Analytical Errors**: These errors produce an alarm and are displayed on the screen or printed on the report.
- **Operational Errors**: These errors are hardware related and appear as a scrolling message on the first line of the screen.

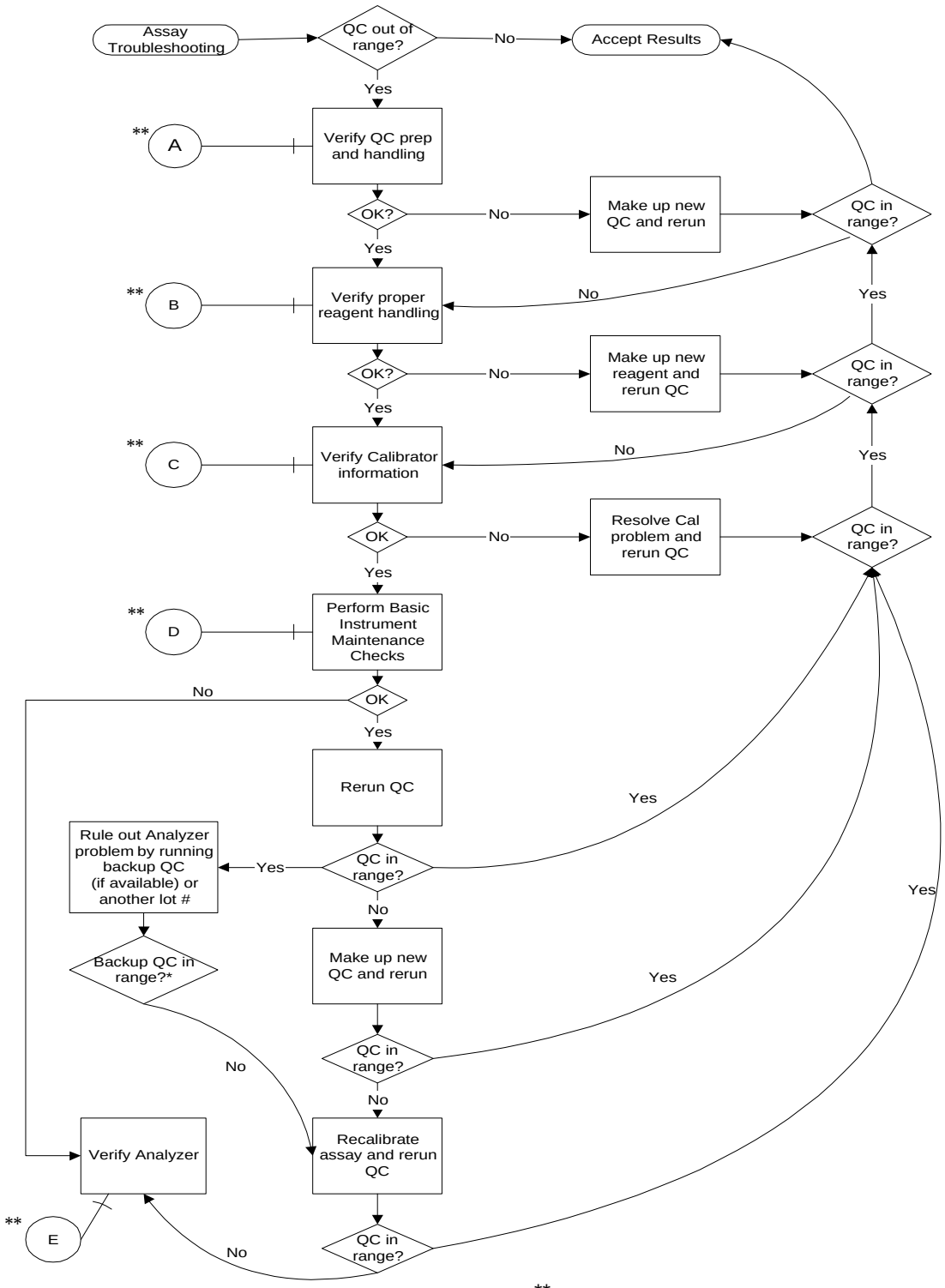
- **Observed Conditions**: These conditions do not generate analyzer alarms or errors and must be detected by the Operator. This section is divided into General Observed Conditions and Assay-Specific Observed Conditions.

- **Helpful Information**: This section contains useful information and may be used to answer customer questions.

- **Software Map**: This section contains information used in navigating through the ALCYON Analyzer software.

GENERAL TROUBLESHOOTING

Assay Troubleshooting Flowchart



*Follow laboratory protocol for accepting alternate QC results. ** Detailed steps on following pages.

A. Verify QC Preparation and Handling

Follow the table below to ensure proper QC preparation and handling.

Step	Check for...
1	Proper storage of QC material
2	Expiration date of QC material
3	Recent QC or reagent lot number change
4	QC file parameters correct
5	Recent shift or trend in QC data
6	Assayed or unassayed QC
7	Manufacturer's claims for analyte stability
8	Appropriate QC range if determined by the customer
9	Peer group QC statistics

B. Verify Proper Reagent Handling

Step	Verify that...
1	The reagent is within listed expiration date.
2	The reagent is stored at the correct temperature (on and off the Analyzer).
3	The reagent was not frozen.
4	Reagents stored onboard the Analyzer are mixed once each shift.
5	There is no precipitate in the reagent.
6	Reagents from different containers or reagent lots were not mixed, and that Reagent Containers were not re-used.
7	The probes are seated correctly.
8	The reagent has not been stored longer than the recommended storage claim.
9	There is proper reagent volume in the Reagent Container and reagent appearance is OK.

NOTE: Instability or deterioration of the reagent should be suspected if the linearity of the standard curve falls below the linearity claim stated in the assay-specific **ALCYON Reagent Application Sheet**, or if the reagent blank reads generate URB or RBL errors.

C. Verify Calibrator Information

Step	Verify that...
1	The Calibration Factor and intercept are acceptable. (Refer to the **ALCYON Reagent Application Sheets** for Cal Factor information.)
2	The correct calibrator values are entered into the **Calibration** screen. (Refer to the **Calibrator Application Sheet**.)
3	The calibrators are within their recommended expiration date.
4	The correct assay configuration parameters are in place.
5	The correct Reagent Container is placed in the correct position on the Reagent Carousel.
6	The cooled quadrant is functioning correctly.
7	The calibrators were prepared and stored properly.
8	The correct calibrator levels were placed in the correct position on the Sample Carousel during calibration.
9	Probes are dispensing correctly by performing the Probe Priming Procedure. Refer to *Section 9, Service and Maintenance* of the **ALCYON Operations Manual**.

D. Perform Basic Instrument Maintenance Checks

Step	Verify that...
1	Cooled positions on the Reagent Carousel are cooling.
2	The Reagent Preheater is warm to the touch.
3	The Reaction Cuvette Temperature Control is correct.
4	The Water Container is filled.
5	Probes are dispensing correctly by performing the Probe Priming Procedure. Refer to *Section 9, Service and Maintenance* of the **ALCYON Operations Manual**.
6	ISE Module is functioning properly. Refer to **Troubleshooting ISE Issues** in this guide.
7	The wash water is Type II or better.

E. Verify the Analyzer

Step	Verify that...
1	Maintenance and daily checks have been performed.
2	The Analyzer is not located in an area that could experience dramatic changes in temperature *(i.e.*, near a door entrance, air conditioner or heater vent, freezer door, fan, etc.)
3	The Analyzer Reaction Cuvette Temperature Control reads 37 ± 0.2°C.
4	Environmental conditions such as temperature and humidity of the lab do not exceed specifications. Refer to *Section 4, Performance Characteristics and Specifications* of the **ALCYON Operations Manual**.
5	Cuvettes and progress curves related to the result in question appear normal. Inspect cuvette for correct color, reagent volume, bubbles, cracks, and particulate matter.
6	Probe Priming was performed prior to initiating a run if the Analyzer has been idle.

F. Troubleshooting Reproducibility and Precision Issues

Step	Action:
1	View the raw absorbances for the results exhibiting poor reproducibility. Check for change in the reagent blank absorbances (RB1 & RB2). Look for unusual absorbance after the sample is added until the end of the delay. Compare the reaction profiles of the questionable result to that of a known acceptable result. From the MAIN MENU, select: • **Results** • **Absorbance Data** • **View Cuvette Absorbance** To display the absorbances of the test, highlight the chosen result and press **<Enter>**. The Analyzer displays the absorbances of all the measures at 12 second intervals for the 6 wavelengths. The primary wavelength is indicated by a checkmark. To display the graph of this result, press **<F5>**. Look for an unusual progress curve shape. Refer to *Appendix A* of the **ALCYON Operations Manual** for correct progress curve shapes. Press **<Print Screen>** to print the raw absorbances and graph. **NOTE:** Only the absorbances of the last 108 cuvettes are available. The absorbances are not available if the Analyzer has been powered **OFF**.
2	Wash the probes to remove excess bubbles from the Analyzer. From the MAIN MENU, select: • **Maintenance** • **Wash Probes** Wash the probes until all of the bubbles are removed from the Analyzer.
3	Check the probes. If damaged, replace. Refer to **Probe Replacement** in *Section 9, Service and Maintenance* of the **ALCYON Operations Manual**.
4	Check the pistons and syringes. Refer to **Checking Syringe Pistons** and **Replacing a Syringe Piston** in *Section 9, Service and Maintenance* of the **ALCYON Operations Manual**.
5	Examine the Reaction Cuvettes. Power the Analyzer **OFF** and remove the cuvettes from the Reaction Carousel. Find the segment of the cuvette exhibiting poor reproducibility. • Verify consistent volumes for all like chemistries. For inconsistent volumes, see steps 2 - 4 above. • Look for color consistency throughout the individual cuvette wells. For inconsistent color throughout the cuvette well, there may be a problem with the Mixer. Refer to **Troubleshooting Mixer,** later in this section.

G. Troubleshooting ISE Issues

Step	Verify that...
1	The volume of ISE Reference Solution, ISE Stabilizing Solution, and ISE diluent is sufficient. Inspect for debris.
2	ISE Maintenance has been performed.
3	The electrodes are in the correct order, (Ref, Na^+, K^+, Cl^-).
4	The cable connection to each electrode is secure.
5	The electrodes and pump tubing are seated correctly.
6	The Analyzer has been inspected for leaks and dried salt build-up around connectors.
7	All five O-Rings are present. Replace if needed.
8	There are no bubbles in the tubing. Flush lines if needed.
9	The ISE Probe is seated correctly (collar as far down as possible).
10	The ISE Sample Tubing is positioned in the Pinch Valve.
11	The ISE Sample Tubing does not have kinks.
12	The Mixer functions properly. If a problem is suspected, contact Field Service.
13	After Weekly Maintenance, the Reference and Wash Pumps are run sufficiently to ensure there is Stabilizing Solution in the Electrode Train.
14	Offsets are adjusted with the ISE Module Door closed.
15	There are no crimps in the ISE Stabilizing Solution tubing (tubing from the bottle).
16	ISE Offset Knobs have not been completely turned in one direction; if so, cycle power before adjusting.
17	The ISE assays are recalibrated if ambient temperature has changed ± 2°C since the last calibration.
18	The Stabilizing Solution is protected from excessive heat or cooling; do not place the Stabilizing Solution bottle near fans, heaters, etc.

NOTE: For additional information, refer to the ISE Troubleshooting Flowchart in *Section 10, Troubleshooting and Diagnostics* of the **ALCYON Operations Manual**.

H. Detailed Multi-Constituent Controls Troubleshooting

This troubleshooting section is specific for the co-labeled Abbott / Bio-Rad Controls.

Basic Troubleshooting:	
Expiration Date	• Check expiration on control bottles • Have the controls been reconstituted or thawed and stored longer than the assay-specific **ALCYON Reagent Application Sheet** or text insert recommends?
Storage	• Has the product been frozen? Frost-free freezers are not recommended due to exposure to freeze / thaw cycles. • Some products have reconstituted / frozen stability claims (check text inserts or **ALCYON Reagent Application Sheet**s). However, no claims are made for frozen aliquots! Customers are advised to verify stability with their chosen container and fill volume. General guideline: frozen aliquots should be prepared with a minimum of 0.5 mL for one-time use. The smallest tube size available is suggested to minimize air space.
Reconstitution	• Water Use distilled or deionized water. • Pipettes Use a volumetric pipette or accurately calibrated pipettor. Verify pipettor has been calibrated according to laboratory requirements.
Handling	• Controls should be returned to the refrigerator immediately after use. • Do not vortex controls. We have no data to support the use of mixers or rockers. • Handling is product specific. Refer to the assay-specific **ALCYON Reagent Application Sheet** or text insert for handling of each control product.

Customer Concern	Troubleshooting	Recommendation or Resolution
Control values do not fall within the data range sheet.	• Verify that there are no issues with shipping or storage. • Review Basic Troubleshooting (p. 17). • How many data points does the customer have? (Should be at least 10 - 20.) Calculate the mean. Does the mean fall within the data sheet range? If yes, the values are acceptable. If no, check peer data.	
	Does the customer match the peer group range? The peer range reflects performance of our control with current reagent and calibrators lots. If the customer's values fall within the peer group range and the peer range does not match the data sheet range, there may have been some changes to the assay or reagent.	The customer may establish the lab's own mean and range using the peer data as a target, provided there are sufficient peer data (minimum of 3 labs, 20 data points, good CVs). Peer data can be used, until the lab has collected 20 data points to establish its own mean and range.
	• If the customer's values do not match the data sheet or the peer group range—is the customer using a factor in their Analyzer? • If not, send a fresh vial of the same lot of control to rule out compromised product.	• If the fresh vial recovers the same as their in-house product, troubleshoot the Instrument, reagents, and calibrators. • If the fresh vial recovers in range, the customer's product may be compromised and needs to be replaced.

Customer Concern	Troubleshooting	Recommendation or Resolution
Control values have shifted out of customer's established range.	• Verify there are no issues with shipping or storage. • Is the shift occurring in all levels of control? All vials? All boxes? (Suggest the customer check a vial from more than one box.) • If the shift is related to a particular box or shipment, you may send a fresh vial to rule out compromised product due to shipping or storage. The customer should run the fresh vial in parallel with their in-house material.	If the fresh sample falls in range and the in-house material does not, the product may need to be replaced.
	If the fresh sample also shows the shift: • Did the shift happen when the customer started a new reagent lot? If yes- • Did the customer run patient crossovers from the old reagent lot to the new? If there are no available patient samples, you may suggest proficiency material. • Did the peer group shift? Since peer data run a month behind, the monthly data may not show the shift yet.	• If the patients or the proficiency material also show the shift, troubleshoot the Instrument, reagents, and calibrators. • Communicate issue to QC contact. (U.S. would alert the Technical Team Specialist, Rest of World Support would alert their World Wide Customer Service.)
	If the controls shifted but the patients or proficiency material did not—this may be a "matrix effect". (Matrix effect is a response or reaction to a reagent or calibrator, which is shown by a control but not a patient sample.)	Customers should document their control and patient data and reestablish their new mean and range for the new reagent and calibrator.

Customer Concern	Troubleshooting	Recommendation or Resolution
Poor precision	• What was the customer's precision when they established their range? Has that changed? • When did the increased CVs start? With a new reagent after maintenance performed or parts replaced? • Compare the customer's CVs to the peer group CVs. Customer's CVs should be equal to or less than peer group CVs. • Look at "claimed CVs" for the Instrument, run-to-run, and within run. The customer cannot expect their precision to be better than the assay package insert or the **ALCYON Reagent Application Sheet** claims. • Suggest a patient precision check, within run, and/or run-to-run.	• If the patient CVs are much greater than the assay package insert or the **ALCYON Reagent Application Sheet** claimed CVs, troubleshoot the Instrument and reagent. **NOTE:** Assay package insert or **ALCYON Reagent Application Sheet** precision claims are guidelines only. • If the customer's CVs are greater than peer group CVs, check the handling or storage of the control product.

Customer Concern	Troubleshooting	Recommendation or Resolution
Controls are not meeting the stability claims on the **ALCYON Reagent Application Sheet** or text insert. OPEN VIAL STABILITY	(Open vial stability is defined from time of reconstitution or opening of thawed vial.) • Review handling. The most common cause of control values changing in the open vial is the control sitting too long at room temperature. Refer to the Storage and Stability Section and the Limitations Section of the **ALCYON Reagent Application Sheet** or text insert. • Check shipping and storage. • Calculate the % drop from day one to the last day of the stability claim. Example: Liquid Assayed Chemistry has 15 days stability at 2 - 8° C. If the customer's data show a trend down in recovery before 15 days, calculate the % drop from day one to day 15. The general rule for stability is a 10% or less drop with some exceptions (tied to the Instrument CV). Example: Glucose established mean = 300 mg/dL Value after 15 days = 290 mg/dL 300 - 290 = 10 mg/dL 300 x 10% = 30 mg/dL (300 - 30 = 270 mg/dL) A decrease of 10 mg/dL is within acceptable limits. (10% is an internal guideline we use to decide whether to investigate a possible product problem and is not information given to the customer.)	If the decrease in customer's data is approaching 10% or greater, open a Level II complaint and communicate the issue to the QC contact. (U.S. would alert their Technical Team Specialist, Rest of World Support would alert their Worldwide Customer Service.)

Customer Concern	Troubleshooting	Recommendation or Resolution
Controls are not meeting the stability claims on the **ALCYON Reagent Application Sheet** or text insert CLOSED VIAL STABILITY	(Closed vial stability = shelf life of product.) Customer's complaint would be that the monthly means are decreasing over time. • Check the assay-specific **ALCYON Reagent Application Sheet** or text insert for any stability limitations. • Check storage—if the customer has received only one shipment, send a fresh vial to rule out compromise to the product during shipping or storage.	If the fresh vial is in range, the product may need to be replaced.
	• Calculate the % decrease from the time of establishing a mean to the present month. (See example for Open Vial Stability.) • If the decrease in values is across multiple shipments, check peer data. Have the peer group data dropped? Check monthly vs. cumulative data.	If the decrease is 10% or greater (from the time the mean is established to the time of the complaint), open a Level II complaint and communicate the issue to the QC contact. (U.S. would alert their Technical Team Specialist, Rest of World Support would alert their Worldwide Customer Service.)

FYI for Technical Support: Value Assignment Information

Package insert ranges are established by two methods:

1. If the Instrument / reagent / kit manufacturer provides the values, we recommend they run a minimum of 20 replicates per level for each analyte, obtained from separate assays over a period of at least 10 days, using various lots of reagents. We use the range recommended by the manufacturer. If they do not give us a range, we use a ± 20% range with the exception of the following analytes:

Calcium	± 10%
Chloride	± 10%
Lithium	± 10%
Magnesium	± 15% for serum ± 20 for urine
Phosphorus	± 10% for serum ± 20 for urine
Potassium	± 10%
Sodium	± 10%

2. If individual laboratories assay the control, we send to a minimum of three laboratories and ask for five data points generated on separate runs from separate bottles. We calculate a mean from the data submitted and use a ± 20% range with the same exceptions as above.

NOTE: Refer to the Assignment of Values section printed on the data sheets (clinical chemistry MCCs) or text inserts (immunoassay MCCs) for instruction on interpreting value assignment data. This section provides the following guideline: “Individual laboratory means should fall within the corresponding acceptable range.” Therefore, the lab is not expected to find all the individual data points to fall within the range. The Assignment of Values section also advises the customer: “It is recommended that each laboratory establish its own mean and acceptable range and use those provided only as guides.”

Troubleshooting with UNITY™	
What is UNITY?	UNITY is a proprietary QC data management system that provides interlaboratory comparison reports based on data collected from thousands of laboratories worldwide. UNITY is administered and maintained by the Bio-Rad QC Program Department.
How do customers participate in UNITY?	Customers may choose to use UNITY-PC or UNITY-POST. UNITY-PC is an easy-to-use software program that allows laboratories to enter QC data by keyboard, direct from the instrument, or LIS (subject to interface). Monthly data are submitted to Bio-Rad via disk or modem. If requested, customers can be sent pre-coded disks to set up all applicable tests at once. UNITY-POST allows laboratories to manually record QC data on pre-printed forms that are then mailed to Bio-Rad each month. Both options give the laboratory the choice of submitting individual point data or a monthly summary. Easy-to-read interlaboratory reports and statistical summaries are mailed back to the user within 14 days. UNITY-PC offers the user a much more comprehensive package in terms of a data management program. All issues or questions related to the UNITY program are the responsibility of your Bio-Rad QC Program Representative. Contact the QC Program staff at Bio-Rad Laboratories.
Why is UNITY important to Abbott CSC?	Peer group data can assist in troubleshooting customer complaints.
What UNITY resources can Abbott CSC use to help troubleshoot?	The UNITY Manufacturer Report for Abbott is the primary troubleshooting tool. It is a worldwide report offered each month in separate conventional and SI unit versions. It contains statistical data for each MCC lot number for which Abbott customers are reporting data to UNITY. Statistics include the mean, 1SD, CV, # points, and # labs, reported for the month and cumulative to date.

Troubleshooting with UNITY™	
How do I read the Abbott Manufacturers Report?	<u>In the header of the report:</u> • Find the correct lot number. • Check "data for" and "printed" dates to verify that you are using the most current report. • Note the units (conventional or SI). <u>In the body of the report:</u> Data are presented for each peer group, defined by six categories: analyte, method, instrument, reagent, units, and temperature (for enzymes only). Within each category, the choices are listed alphabetically. • Find the analyte. • Find the method or the instrument. Although the method is listed before the instrument, you may want to look for the instrument first, since customers know their instrument but may not know their method. Finding the instrument first means that you may have to look through more than one method category. Knowing the methods for the Abbott instruments facilitates locating the data. • Find the reagent. Although other reagent manufacturers may be listed, the "Dedicated Reagent" category is the most common. • Ensure that you are using the correct units and temperature (for enzymes only) categories. These are listed next to each method listing, directly under the analyte.

Troubleshooting with UNITY™	
How do I interpret the data?	<u>Detecting a SHIFT in the peer group mean:</u> A ½ SD shift in the monthly peer group mean (compared to the cumulative mean) could be significant. A smaller shift in mean could indicate the start of a shift in the peer group. Check the Abbott Manufacturer's report the following month to see if a larger shift is present. It is also helpful to compare peer data to the original data published in the data sheet. • Is the customer observing a shift in their control mean that is similar to the shift seen in the monthly peer group? Is their mean within 2 SD of the monthly peer mean? You may want to let the customer know that the peer group is also showing a shift in values. **NOTE:** Occasionally you may notice 2 separate peer groups for particular instrument for the same analyte (listed as "dedicated" and "alternate formulation / standardization"). The alternate formulation / standardization code is used when there is a significant shift in control recovery due to reformulation or standardization of a test method, to separate it from the "dedicated" peer group. **NOTE:** When using peer data you should be careful to evaluate the integrity of these data. Occasionally "bad" data may be processed by UNITY and corrupt the peer group. Check the mean, SD, and CVs to make sure they appear reasonable before giving any data to a customer. <u>Evaluating precision:</u> Compare customer's SD and CVs with the peer group's SD and CVs. The customer's individual SD and CVs should be less than or equal to the monthly or cumulative SD and CVs for their peer group. • If the customer's SDs or CVs are greater than those of their peer group, refer to the Troubleshooting Section on Poor Precision.

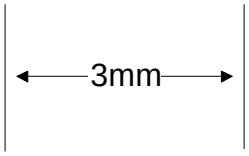
BASIC FIELD SERVICE PROCEDURES

A. Troubleshooting Mixer / Mixer Adjustment

Perform this procedure to check and adjust the mixing action of the Mixer. The materials required are:

- A sheet of white paper
- Frequency Counter

WARNING: This procedure is not intended for customer use! Customers should not access the Diagnostic Software under any circumstances. This procedure should only be performed by an Abbott Field Service Representative.

Setup:	
1	On a sheet of white paper, make two marks 3 mm apart as shown below:  **NOTE:** The drawing above is not to scale, and is not representative of the correct distance.
2	Install a cuvette into each position on the carousel.
Verify Mixer Operation:	
1	Turn the Main Power Switch **ON.**
2	At the **Boot-Up Selection** menu, select: • **2 - Diagnostic Software**
3	Select the **Sample Transfer** menu: • **C - Sample Transfer** Disengage the Sample Transfer Motors: • **J - Transfer Module Disengaging**
4	Manually move the arm up and over the Sample Carousel. (This allows better view of mixing action.)
5	From the **Sample Transfer** menu: • **L - Mixing Adjustment**
6	From the **Mixer** menu: • **A - Run**

Verify Mixer Operation, continued:	
7	The Sample Probe should vibrate right to left. If the Sample Probe does not vibrate, verify that it is installed properly.
8	Visually verify the proper operation of the Mixer. • The mixing action must meet two (2) requirements: a. It should visually appear as three probes. b. The mixing action should be approximately 3 mm. • Use the sheet of paper marked earlier to measure the 3 mm action.
Mixer Adjustment:	
1	From the **Mixer** menu: • Select the frequency to adjust the mixing (vibration of the probe) to meet the necessary requirements (frequency). **• C - Higher Frequency** **• D - Lower Frequency** • When the adjustment is acceptable, stop the mixing: **• B - Stop** • Verify the Mixer adjustment with the correct frequency. Should be 70 - 75 hz. • Save the value: **• E - Store Frequency**
Verify Mixing in Reaction Well and Wash Well (Automatic Mode):	
1	Turn the Main Power Switch **ON**
2	At the **Boot-Up Selection** menu, select: **• 2- Diagnostic System** From the MAIN MENU: **• C - Sample Transfer** **• B - Complete Initialization** **• L - Mixing Adjustment** **• F - Verification** The Reagent and Sample Arms are initialized and the Mixer mixes in the Wash Well, then the first and twelfth cuvette in each segment.

Verify Mixing in Reaction Well and Wash Well (Automatic Mode), continued:	
3	Audibly verify that the Mixer **does not** hit the wall of the Wash Well or any part of the Reaction Cuvette. • If contact is made with either item or wall, further adjustment is necessary. • Select End: **• E - End** • Perform Sample Transfer Arm alignment. If the problem persists, contact Field Service.
Verify Mixing in Reaction Well and Wash Well (Manual Mode):	
1	From the Sample Transfer Menu: **• B - Complete Initialization** **• C - Pre-Programmed Up and Down Movements**
2	Use the following commands to move the Sample Probe to the Reaction Well: • Above: **• A - Washing** • Backward or Forward Movement: **• N - No** • First Movement (U)p or (D)own: **• U - Up** • Validate entries and move the probe: **• F10**
3	Move the Sample Probe from the Wash Cup: • To the Sample Carousel, aspiration position: **• D** • Then to the Reaction Carousel: **• E**
4	Use the following commands to lower the Sample Probe: **• C - Pre-Programmed Movements** • Above: **• C - Reaction Carousel** • Backward and Forward Movement: **• N - No** **• [Enter]** • First Movement (U)p or (D)own: **• D - Down** • Validate movement and move the Sample Probe: **• F10**

Verify Mixing in Reaction Well and Wash Well (Manual Mode), continued:	
5	With the probe in the Reaction Well, perform the following from the **Sample Transfer** menu: • **L - Mixing** • Run the Mixer: • **A** • Listen for the Mixer contacting the cuvette. • If contact is made, further adjustment is necessary. • If no further adjustment is necessary: • **B - Stop** • **Esc** • **B - Complete Initialization** (to return the arm to the Wash Well)

B. Temperature Adjustment / Verification

Perform this procedure to adjust and verify the operation of the Reaction Cuvette Temperature Controller. The materials required are:

- Calibrated Digital Thermometer
- Cuvettes (9)
- Deionized Water

WARNING: This procedure is not intended for customer use! Customers should not access the Diagnostic Software under any circumstances. This procedure should only be performed by an Abbott Field Service Representative.

Temperature Adjustment / Verification:	
1	Ensure all covers are installed on the Instrument.
2	Perform System Startup.
3	Allow System temperature to stabilize for 20 minutes.
4	While the Instrument temperature stabilizes, perform the following setup: • Access Diagnostic Software • From the MAIN MENU: • **H - Wheels Disengaging** • **B - Reaction Carousel** • **F - Wheel Rotation Several Steps**

Temperature Adjustment / Verification, continued:	
5	Set parameters to: Direction (0 = to Home) 1 Number of Steps 1000 Speed 300 Backward & Forward Y Stop Active (Y/N) N
6	Dispense 300 µL of DI water into each cell of a Reaction Cuvette.
7	Manually rotate the Reaction Carousel to access position 4.
8	Place the cuvette with water in the Reaction Carousel position 4.
9	Place empty cuvettes in all other segments of the Reaction Carousel.
10	Manually rotate cuvette position 1 to the unloader position. This causes position 4 to incubate by the optics during step 11.
11	Rotate the Reaction Carousel: • **F10** - to continuously rotate the Reaction Carousel • Allow the Reaction Carousel to rotate for six minutes • **S** - to stop Reaction Carousel rotation
12	Manually rotate cuvette position 4 to the unloader position.
13	Measure the liquid temperature of cells 1, 4, 8, and 12. (1 is toward the back of the Instrument.)
14	Remove cuvette #4 to allow it to cool.
15	Calculate the mean and Standard Deviation: Specifications: mean = 36.5 ± 0.1°C SD = ≤ 0.1 Subtract the mean value from 36.5 to derive offset adjustment value to be used later in the procedure.

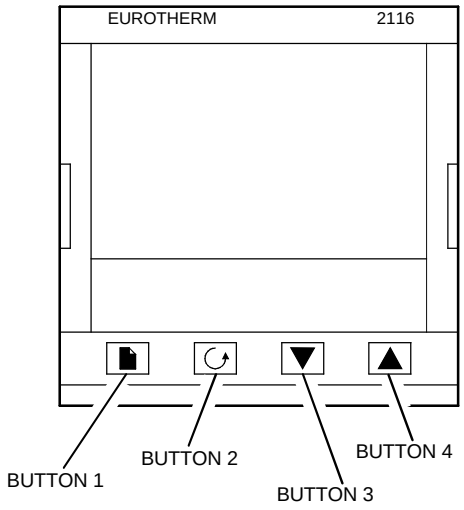
Temperature Adjustment / Verification, continued:	
16	At the Temperature Controller front panel, (see diagram below) execute the procedure outlined in Table 1:1. 
17	Wait 15 minutes for the temperature to stabilize.
18	Repeat steps 6 through 11 until measured temperature meets specification. **NOTE:** After the initial offset adjustment, the fine tuning of the temperature offset can be done in 1/10 degree intervals (using the arrow keys pressed once or twice, etc.).
19	Once the temperature matches, return the Controller to operator mode and execute the procedure in Table 2:1.
20	Allow 20 minutes to reset the temperature and ensure the display reads 37.0.
21	When programming the Temperature Controller, if the buttons do not respond as illustrated, verify the Temperature Controller firmware version. (Refer to the procedure on page 35 in this guide.)

Table 1:1 Temperature Control Program Routine

Press:	Displayed:
Button 1	**ACCS**
Button 2	**CodE**
Button 4	1, will change to: **PASS**, then will change to: **CodE**
Button 2	**Goto**
Button 4	**ConF**, will change to: **Goto**
Button 2	**ConF**
Button 4	2, will change to: **PASS**, then will change to: **ConF**
Button 1	**CAL**
Button 2	**ADJ**
Button 4	**YES**

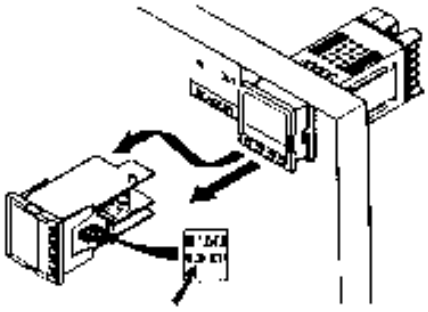
Press:	Displayed:
Button 2	**OFS.L**
Buttons 3 and 4	Adjust the "**Offset Low**" with buttons 3 and 4 by the value noted in step 15. Adjust more negative to raise temperature, more positive to lower the temperature of the liquid in the cuvettes.
Button 2	**OFS.H**
Buttons 3 and 4	Adjust the "**Offset High**" with buttons 3 and 4 by the value noted in step 15. Adjust more negative to raise temperature and more positive to lower the temperature of the liquid in the cuvettes.
Button 1	**Exit**
Button 4	**YES**

Table 2:1 Temperature Control Program Routine, continued

Press:	**Displayed:**
Button 1	**ACCS**
Button 2	**CodE**
Button 4	1, will change to: **PASS**, then will change to: **CodE**
Button 2	**Goto**
Button 4	**Full**, will change to: **Goto**
Button 1	**IP**
Button 2	**CAL**
Button 4	**USEr**
Button 2	**IP**
Button 1	**ACCS**
Button 2	**Goto**

Table 3:1 Temperature Control Program Routine, continued

Press:	**Displayed:**
Button 4	**ConF**, then will change to: **Goto**
Button 2	**ConF**
Button 4	2, then will change to: **PASS,** then will change to **ConF**
Button 1	**CAL**
Button 2	**ADJ**
Button 4	**NO**
Button 1	**Elit**
Button 4	**YES**

Temperature Adjustment/Verification, continued: Verifying Firmware Version	
1	Remove all patient samples from Sample Carousel.
2	Switch **OFF** the Main Power Switch.
3	Remove the Reaction Cuvette Temperature Controller.
4	Rotate the Temperature Controller to view firmware version. (See Figure below.)  Firmware Revision Location • The appropriate firmware version should be: EUROTHERM Ver. 1.20. • If firmware version is any other, replace the Temperature Controller and notify ALCYON CSE. **NOTE:** When reapplying power to the Analyzer, allow 20 minutes for the Analyzer temperature to stabilize.
5	Reinstall / replace the Temperature Controller.
6	Turn the Main Power Switch **ON**.

ANALYTICAL ERRORS

0NL Linearity Error in Zero-Order Kinetic

Probable Cause(s)	Corrective Action(s)
Reagent	Perform General Troubleshooting Procedures.
High limit entered incorrectly in the **Assay Configuration** screen.	Verify that the correct high limit value is entered in the **Assay Configuration** screen.
High concentration in sample.	Rerun this sample with appropriate dilution.
Air bubble moving into the Reaction Cuvette.	• Check probes for straight stream. • Perform Probe Priming / Washing Procedure. Refer to *Section 9, Service and Maintenance* of the **ALCYON Operations Manual**.

1UN Kinetic / Unstable

Probable Cause(s)	Corrective Action(s)
Reagent	Perform General Troubleshooting Procedures A.
Tolerance factor and/or compensation factor may be entered incorrectly.	Verify that the correct tolerance factor and/ or compensation factor is entered in the methods.
High concentration in sample.	Rerun this sample with appropriate dilution.
Air bubble moving into the Reaction Cuvette.	Check probes for straight stream. Perform Probe Priming / Washing Procedure. Refer to *Section 9, Service and Maintenance* of the **ALCYON Operations Manual**.

AE Antigen Excess

Probable Cause(s)	Corrective Action(s)
Sample with high concentration.	The Analyzer automatically reruns this sample if the antigen excess test parameter for End-Point chemistries is entered in the **Assay Configuration** screen.

AOC Absorbance Out of Curve Logit Development Calibration (Not an Analytical Error)

Probable Cause(s)	Corrective Action(s)
The absorbance of the sample is less than the absorbance of the second calibrator.	NA

ANA Analysis not Possible (Not an Analytical Error)

Probable Cause(s)	Corrective Action(s)
Sample has status of "In Process"; sample is processing, but has not been completed.	NA

ATT Stand By (Not an Analytical Error)

Probable Cause(s)	Corrective Action(s)
This flag appears while the Analyzer is calculating a result with rule validation.	NA

BUB Air Bubbles in Electrodes

Probable Cause(s)	Corrective Action(s)
O-Ring is missing between electrodes.	Verify the presence of all five O-Rings.
Bubbles in electrode.	• Perform Adjust Electrode Offset Procedure. Refer to *Section 9, Service and Maintenance* of the **ALCYON Operations Manual**. • Check that the ISE Probe is not positioned too high. • Verify that the ISE Probe is not damaged (*i.e.*, no liquid or air leakage). • Verify the pressure of the Peristaltic Wash Pump. • Verify electrode alignment. Check all ISE sample line connection points. • Check flow volume. • Replace Reference Pump tubing. • Replace Wash Pump tubing.

CER Ratio Calculation Impossible (Not an Analytical Error)

Probable Cause(s)	Corrective Action(s)
The ratio result cannot be calculated. One or more of the assays are flagged.	Rerun the flagged assays after correcting the error.
One or more components of the ratio were not completed.	Rerun the sample.
Corrupted ratio file: "nonsense" data appears in the Ratio File after ratio formulas.	Delete "nonsense" (requires a Level 2 password) and repeat ratios.

CIP Calculation In Process (Not an Analytical Error)

Probable Cause(s)	Corrective Action(s)
Calculation in process.	NA

COL Control Out of Limit

Probable Cause(s)	Corrective Action(s)
Out of range (low or high)	Verify the control ranges defined.
Out of range (m-val, m+val).	Verify the % validation defined. Repeat calibration.
Control	Verify the control used. Check: • Reconstitution • Expiration date • Storage conditions • Stability, etc.

DEP Substrate Depletion

Probable Cause(s)	Corrective Action(s)
Sample with high concentration.	The Analyzer automatically reruns this sample if the dilution factor for Kin 0 and Kin 1 chemistries is entered in the **Assay Configuration** screen.

DER Reagent Capacitive Detection Error

Probable Cause(s)	Corrective Action(s)
Reagent Probe installed incorrectly.	• Verify that the Reagent Probe is installed correctly. • Reinstall the Reagent Probe. Refer to **Probe Replacement** in *Section 9, Service and Maintenance* of the **ALCYON Operations Manual**.
Level sense failure.	Contact Field Service.

DES Sample Capacitive Detection Error

Probable Cause(s)	Corrective Action(s)
Sample Probe installed incorrectly.	• Verify that the Sample Probe is installed correctly. • Reinstall the Sample Probe. Refer to **Probe Replacement** in *Section 9, Service and Maintenance* of the **ALCYON Operations Manual**.
Level sense failure.	Contact Field Service.

DIL Diluted Sample (Not an Analytical Error)

Probable Cause(s)	Corrective Action(s)
This flag is printed on the result for a diluted sample that has reached the dilution limit. •If the chemistry's diluent is onboard, the sample was automatically diluted by the Analyzer. •If the result for the diluted sample (before multiplication by dilution ratio) is still higher than the dilution limit, the flag "Dilution limit reached" is still printed on the result, and the Operator must ask for a higher dilution in the Incomplete File. •If the result for the diluted sample (before multiplication by the dilution ratio) is lower than the dilution limit, the result is printed without any flag.	NA

DIV Divergence in Reaction Curve

Probable Cause(s)	Corrective Action(s)
Bubbles in Reaction Cuvette. Reaction not mixed properly.	• Look at the reaction graph. • Visually check for the presence of bubbles in the Reaction Cuvette. • Perform General Troubleshooting Procedures F. • Contact Field Service.
Problem with optical alignment.	Contact Field Service.

EP Instability on End-Point

Probable Cause(s)	Corrective Action(s)
Sample with high concentration.	• Look at the reaction curve in Incomplete Files and verify that the reaction is completely finished. • If absorbances are still increasing at the end of the reaction, rerun the sample with the appropriate dilution.
Air bubble in Reaction Cuvette.	Perform General Troubleshooting Procedures F.
No sample added.	Perform General Troubleshooting Procedures F**.**
Tolerance factor incorrect in the **Assay Configuration** screen.	• ABS|M-T| > Tolerance factor. • Verify that the correct value is entered in the **Assay Configuration** screen.

HRE High Rerun Limit Reached (Not an Analytical Error)

Probable Cause(s)	Corrective Action(s)
Depending on Print Options configuration, if the printing of Incomplete Files is not activated, the Analyzer only prints the rerun result for Complete Files.	NA
This flag is generated when a result is higher than the high rerun limit entered in the **Dilution / Rerun** screen. The sample is automatically rerun. The flag displays on the first result and the rerun, if the rerun result is higher than the high rerun limit.	

LOD Lack of Diluent

Probable Cause(s)	Corrective Action(s)
Insufficient level of diluent.	Check the level of the diluent and adjust if necessary.
Improper Reagent Probe positioning.	Ensure the Reagent Probe is seated correctly.
Reagent Probe failure.	Change the Reagent Probe. Refer to **Probe Replacement** in *Section 9, Service and Maintenance* of the **ALCYON Operations Manual.**
Level sense failure.	Contact Field Service.

LOR Lack of Reagent

Probable Cause(s)	Corrective Action(s)
Insufficient reagent level.	Check the reagent level and adjust if necessary.
Improper Reagent Probe positioning.	Ensure the Reagent Probe is seated correctly.
Reagent probe failure.	Change the Reagent Probe. Refer to **Probe Replacement** in *Section 9, Service and Maintenance* of the **ALCYON Operations Manual.**
Level sense failure.	Contact Field Service.

LOS Lack of Sample

Probable Cause(s)	Corrective Action(s)
Insufficient sample volume.	Check the volume in the Sample Cup and adjust if necessary.
Improper Sample Probe positioning.	Ensure the Sample Probe is seated correctly.
Sample Probe plastic insulation is removed.	Change the Sample Probe. Refer to **Probe Replacement** in *Section 9, Service and Maintenance* of the **ALCYON Operations Manual.**
Level sense failure.	Contact Field Service.

LRE Low Rerun Limit Reached (Not an Analytical Error)

Probable Cause(s)	Corrective Action(s)
Depending on Print Options configuration, if the printing of Incomplete Files is not activated, the Analyzer only prints the rerun result for Complete Files.	NA
This flag is generated when a result is lower than the low rerun limit entered in the **Dilution / Rerun** screen. The sample is automatically rerun. The flag displays on the first result and the rerun, if the rerun result is lower than the low rerun limit.	

NAN Not a Number (Not an Analytical Error)

Probable Cause(s)	Corrective Action(s)
All Control Results flagged with an error.	• Delete the control by selecting **Controls and Results**. Highlight the control / test to be deleted and press **<F3>**. • Rerun controls.
This flag is generated if the control result concentrations are all 0.	

NEG Negative Optical Density

Probable Cause(s)	Corrective Action(s)
Lamp is off.	Ensure the lamp has been **ON** for at least 20 minutes.
Lamp needs to be replaced.	• Replace the lamp. • If the error is not resolved, contact Field Service.
Reaction is completely opaque (*i.e.*, lipemic) for wavelength used.	• Check Method Description to ensure that the correct wavelength is entered. • Perform General Troubleshooting Procedures F.
Interference due to fluorescent materials in the sample. (Can occur at wavelengths of 405 nm or lower.)	Refer to patient history.

NR2 No 2nd Reagent

Probable Cause(s)	Corrective Action(s)
Insufficient level of second reagent (Dual Reagent chemistry).	Check the reagent volume and adjust if necessary.
Improper Reagent Probe positioning.	Ensure Reagent Probe is seated correctly.
Timing issue.	Rerun sample.
Request for Pause / Resume before 2nd reagent addition.	• Check the reagent volume and adjust if necessary. • Verify Analyzer is in Pause. • Rerun test after performing **Pause / Resume**.
Reagent Probe failure.	Replace the Reagent Probe.
Level sense failure.	Contact Field Service.

OK (Not an Analytical Error)

Probable Cause(s)	Corrective Action(s)
Printed on all results without an error code.	NA

ORR Out of Range Results (ISE Assays Only)

Probable Cause(s)	Corrective Action(s)
Higher Limit exceeded.	Sample is automatically rerun and the message "Result Out of Range" is printed on the report.

RBL Reagent Blank Out of Limit

Probable Cause(s)	Corrective Action(s)
Reagent	• Perform General Troubleshooting Procedures. • Perform General Troubleshooting Procedures F.
Bubbles	• Check reagent for bubbles. • Perform Probe Priming / Washing. Refer to **Probe Priming / Washing Procedure** in *Section 9, Service and Maintenance* of the **ALCYON Operations Manual**. • Perform General Troubleshooting Procedures F.
Values entered incorrectly for Low Reagent Blank and High Reagent Blank.	Verify the Method Description to ensure that the correct value was entered. Correct if necessary.

ROR Rerun on Validation Rule (Not an Analytical Error)

Probable Cause(s)	Corrective Action(s)
The result of this sample was rerun by rule (reflex testing).	NA

SAT Saturation in Measurements

Probable Cause(s)	Corrective Action(s)
For colorimetric tests — problem with A/D Board.	Contact Field Service to troubleshoot the lamp.
For ISE tests — poorly mixed or improperly diluted sample.	• Ensure the ISE Probe is seated correctly. • Verify the mixer is functioning properly.
For ISE tests — problem with ISE Board.	• Perform ISE General Troubleshooting. Refer to *Section 9, Service and Maintenance* of the **ALCYON Operations Manual**. • Repeat all ISE tests on the sample.

T_R Designates Sample to Rerun (Not an Analytical Error)

Probable Cause(s)	Corrective Action(s)
This flag appears on the **Incomplete Files** screen when initiating a sample for rerun, dilution, etc.	NA

UNS / VSB

Probable Cause(s)	Corrective Action(s)
Low or no Stabilizing Solution in Electrode Train due to: • Insufficient volume of Stabilizing Solution in bottle.	• Replace the Stabilizing Solution. • Start the Wash Pump for one minute. • Start the Reference Pump until a steady stream of fluid is seen dispensing into the Waste Cup when the Reference Pump is turning.
• ISE Wash Well not filling with Stabilizing Solution.	• Check for pinched or crimped tubing. • Ensure that the intake tubing in the Stabilizing Solution bottle is below the surface of the liquid and not wedged against the side or bottom of the bottle. • Reseat or replace the Wash Pump tubing.
• ISE Probe not seated correctly.	Ensure that the ISE Probe is seated with the metal collar as far down as possible.
• ISE Probe tubing crimped or leaking.	Replace the ISE Probe.
• O-Rings missing	Check for the presence of all 5 O-Rings—replace if necessary.
• Tubing going into or out of Electrode Train leaking	Ensure that the tubing is secure and not leaking.
• Reference and/or Wash Pump tubing twisted, stretched, not seated properly.	• Reseat the pump tubing. • Replace the pump tubing. • Verify that there is a steady stream of fluid dispensing into the Waste Cup when **<F3>** in the **OFFSETS** screen is pressed. **<F3>** x 4 ≈ 1 mL.
Bubbles in Reference Electrode Housing	• Perform Reference Solution Start Procedure Refer to *Section 9, Service and Maintenance* of the **ALCYON Operations Manual.** • Slowly unscrew the Reference Electrode from the housing and observe for small bubbles coming from the capillary in the housing. If no bubbles are observed, soak the Reference Electrode Housing in bleach for 15 minutes; rinse with water and shake dry. Reinstall the electrode and repeat the first two steps of this corrective action. • Replace the Reference Electrode Housing. • Replace #9 tubing if bubbles continue to form in the Reference Electrode Housing.

Probable Cause(s)	Corrective Action(s)
Salt build-up on top of the Reference Solution bottle, at the Waste Cup, between electrodes, or at tubing connections.	• Resolve cause of the leak. • Clean off the salt build-up.
Sample or Diluent level low.	Verify that the sample volume is adequate and that there is sufficient ISE Sample Diluent.
"Tolerance" or "Stabilizer Drift Max" settings too low.	Check Assay Configuration to ensure that the correct value was entered. Edit if necessary.
Faulty Reference Electrode	Replace the Reference Electrode. Refer to ISE Electrode Replacement in *Section 9, Service and Maintenance* of the **ALCYON Operations Manual.**
Movement by sample column during measurement.	• Remove the tubing from the Pinch Valve and massage; replace tubing into the Pinch Valve. • If not resolved, contact Field Service to check the Pinch Valve.
Improper mixing of sample (UNS)	• Remove cuvettes and observe for layering. • Contact Field Service to check the mixer.
Tubing touching metallic part of ISE Module.	Ensure that the tubings (#9, #0, #8, or #7) are not in contact with any metallic part of the ISE Module.
Maintenance needed.	Perform Daily, Weekly, or Monthly Maintenance.

URB Unstable Reagent Blank

Probable Cause(s)	Corrective Action(s)
Reagent	Perform General Troubleshooting Procedures F.
Bubbles	• Check reagents for bubbles. • Perform Priming / Washing Probes Procedure. Refer to *Section 9, Service and Maintenance* of the **ALCYON Operations Manual.** • Perform General Troubleshooting Procedures F.
Contaminated / Dirty Reaction Cuvettes.	Replace Reaction Cuvettes and rerun assay.
Values entered incorrectly for Maximum Deviation.	Check Assay Configuration to ensure that the correct value was entered.

CALIBRATION ERROR MESSAGES

The following statements are explanations of the numbered error messages. They are not seen on the screen or printed on the calibration report. An example of what prints on the report is: Unable to fit a curve: **ERROR = 12**.

1 **Impossible Resolution of Equations Set**
2 **Impossible Resolution of Equations Set**
3 **Impossible Resolution of Equations Set**
4 **Impossible Resolution of Equations Set**
5 **The Correlation Factor is Null**
6 **The Correlation Factor is Lower Than Limit**
7 **Impossible Calculation—2 Absorbances are Equal**
8 **Impossible Calculation—The Number of Calibration Points is Strictly Lower Than 3**
9 **Impossible Calculation—A Calibration Point has a Concentration Equal to 0**
10 **Impossible Calculation—An Absorbance is Null**
11 **Impossible Calculation—Too Few Points**
12 **Calibration Curve is Not Monotonous (Monotonic)**
13 **Calibration Curve is Not Valid in the Chosen Interval**

NOTE: Refer to **OBSERVED CONDITIONS (Assay-Specific)** for assay-specific calibration errors.

Probable Cause(s)	Corrective Action(s)
The previous calibration failed.	New calibration required for test.
Reagent	Perform General Troubleshooting Procedures.
Calibrator(s)	Verify the calibrator(s) used. Check: • Reconstitution • Expiration date • Storage conditions • Stability, etc.
Incorrect entry(ies) on the **Calibrator Configuration** screen.	Check that correct parameters have been programmed. Verify: • Calibration curve model • Polynomial degree • Correlation limit • Main calibrator • Calibrator(s) dilution • Calibrator(s) concentration
Incorrect entry(ies) on the **Auto-Dilution Limit / Rerun Limits** screen. (applicable to Error 12)	During calibration, ensure the dilution limit and rerun limits are set appropriately. Dilution limit is typically the linear high value.

OPERATIONAL ERRORS

When a problem occurs, the following banner appears on the first line of the ALCYON Analyzer screen with an audible alarm:

WARNING! System is stopped: diagnostic no. xx/yyy

Where:

"xx"—the ERROR NUMBER

"yyy"—the NUMERICAL DATA, written in hexadecimal format; the meaning depends on the error number.

CAUTION: Before powering **ON** the Analyzer, verify that the Sample and Reagent Probe Drive Racks are positioned correctly. The Sample and Reagent Probes **must** be positioned in the Wash Well or in the Cuvette Segment; the Drive Racks **must** be pushed at least halfway down.

	Probable Cause(s)	Corrective Action(s)
0	Motor controller already busy.	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer, then switch back **ON**. • If error persists, contact Field Service.
1	Automatic Cuvette Load / Unload Module low position not detected.	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer, manually unload the cuvettes, then switch back **ON**. • If error persists, contact Field Service.
2	Automatic Cuvette Load / Unload Module high position not detected.	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer, manually move the load module in a middle position, then switch back **ON**. • If error persists, contact Field Service.
3	Sample Arm high position not detected.	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer, manually move the arm inside the Wash Well, then switch back **ON**. • If error persists, contact Field Service.
4	Reagent Arm high position not detected.	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer, manually move the arm inside the Wash Well, then switch back **ON**. • If error persists, contact Field Service.
5	Sample Probe out of Reaction Cuvette.	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer, manually move the arm inside the Wash Well, then switch back **ON.** • If error persists, contact Field Service.
6	Reagent Probe out of Reaction Cuvette.	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer, manually move the arm inside the Wash Well, then switch back **ON.** • If error persists, contact Field Service.
7	A/D output data not ready.	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer, then switch back **ON**. • If error persists, contact Field Service.
8	Sample Arm out of horizontal home.	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer, manually move the arm inside the Wash Well, then switch back **ON**. • If error persists, contact Field Service.

	Probable Cause(s)	Corrective Action(s)
9	Reagent Arm out of horizontal home.	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer, manually move the arm inside the Wash Well, then switch back **ON**. • If error persists, contact Field Service.
10	Sample Arm out of vertical home.	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer, push the arm down slightly, then switch back **ON**. • If error persists, contact Field Service.
11	Reagent Arm out of vertical home.	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer, push the arm down slightly, then switch back **ON**. • If error persists, contact Field Service.
12	Sample Arm horizontal home not detected.	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer, manually move the arm inside the Wash Well, then switch back **ON**. • If error persists, contact Field Service.
13	Reagent Arm horizontal home not detected.	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer, manually move the arm inside the Wash Well, then switch back **ON**. • If error persists, contact Field Service.
14	Sample Syringe empty position not reached.	• Cycle power. • Clean the syringe module with alcohol. Follow the instructions in the maintenance procedure Cleaning Syringe Drive Screws. Refer to *Section 9, Service and Maintenance* of the **ALCYON Operations Manual**. • Replace the Syringe Piston. • If the problem still persists, replace the syringe. • Contact Field Service.
15	Reagent Syringe empty position not reached.	• Cycle power. • Clean the syringe module with alcohol. Follow the instructions in the maintenance procedure Cleaning Syringe Drive Screws. Refer to *Section 9, Service and Maintenance* of the **ALCYON Operations Manual**. • Replace the Syringe Piston. • If the problem still persists, replace the syringe. • Contact Field Service.

	Probable Cause(s)	Corrective Action(s)
16	Sample Carousel home not detected.	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer, then switch back **ON**. • If error persists, contact Field Service.
17	Reagent Carousel home not detected.	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer, then switch back **ON**. • If error persists, contact Field Service.
18	Reaction Carousel home not detected.	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer, then switch back **ON**. • If error persists, contact Field Service.
19	Sample Syringe not empty.	Clean the syringe module with alcohol. Follow the instructions in the maintenance procedure Cleaning Syringe Drive Screws. Refer to *Section 9, Service and Maintenance* of the **ALCYON Operations Manual**.
20	Reagent Syringe not empty.	Contact Field Service.
21	Sample Carousel out of home position.	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer, then switch back **ON**. • If error persists, contact Field Service.
22	Reagent Carousel out of home position.	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer, then switch back **ON**. • If error persists, contact Field Service.
23	Reaction Carousel out of home position.	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer, then switch back **ON**. • If error persists, contact Field Service.
24	A/D converter not ready to accept the data from colorimeter.	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer, then switch back **ON**. • If error persists, contact Field Service.
25	Problem with Sample Arm Sensor, ISE Probe not able to position over wash position or over cuvette position. Possible hardware problem.	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer, check the position of the probe tubing, then switch back **ON**. • If error persists, contact Field Service.

	Probable Cause(s)	Corrective Action(s)
26	Problem with Sample Arm Sensor, ISE Probe not able to position over wash position. Possible hardware problem.	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer, check the position of the ISE Probe tubing, then switch back **ON**. • If error persists, contact Field Service.
27	Problem with Sample Arm Sensor, ISE Probe not able to position over cuvette position. Possible hardware problem.	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer, check the position of the ISE Probe tubing, then switch back **ON**. • If error persists, contact Field Service.
28	Problem with Sample Arm Sensor, ISE Probe not able to position over wash position or over cuvette position. Possible hardware problem.	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer, check the position of the ISE Probe tubing, then switch back **ON**. • If error persists, contact Field Service.
29	Sample Arm stopped by capacitive detection out of tube or cup.	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer, put the arm in upper position, then switch back **ON**. • If error persists, contact Field Service.
30	Reagent Arm stopped by capacitive detection out of container.	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer, put the arm in upper position, then switch back **ON**. • If error persists, contact Field Service.
31	System reading an optical density of 0, Lamp **OFF**, or problem with optical system.	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer, then switch back **ON**. • Perform the Adjust Colorimeter Procedure. • If the problem persists, replace the lamp. • If error persists, contact Field Service.
	Calibrators or controls ordered and run with the lamp **OFF**.	Turn the lamp **ON**. Rerun calibrators and controls.

OBSERVED CONDITIONS (General)

Blank Control Reports for CT0 Print Multiple Times

Probable Cause(s)	Corrective Action(s)
Cause unknown	• Use the Main Power Switch (located on the rear-left side) to power **OFF** the Analyzer; then switch back **ON**. • Reorder and rerun controls.
Blank Control Reports print for every assay selected in the **Control Run** menu.	
"Controls: 1" displays in the Progress field of MAIN MENU.	

Bubbles in ISE Tubing (left side of electrode) Assembly During Offset Adjustment

Probable Cause(s)	Corrective Action(s)
Electrodes not seated tightly.	Ensure the electrodes are tightly seated, the electrode clamp is closed, and arrows are aligned.
O-Rings missing or not seated correctly.	Replace or reseat the O-Rings.
Stabilizing Solution not aspirated.	• Ensure the intake tubing in the Stabilizing Solution bottle is below the surface of the liquid and is not wedged against the side or bottom of the bottle. • Ensure the ISE Wash Cup is filling approximately half full with Stabilizing Solution. • Ensure the tubing connections are secure. • Change the ISE Probe.

Bubbles in ISE Tubing (Y-Junction above ISE Reference Pump) During Offset Adjustment

Probable Cause(s)	Corrective Action(s)
Y-junction tubing leaking or not seated properly.	Ensure the tubing connection at the Y-junction is secure. Replace the tubing.

Bubbles Observed in Syringe

Probable Cause(s)	Corrective Action(s)
Valve ports not tight.	Tighten the valve ports as tight as possible.
T-junction to valve tubing pinched.	Replace the tubing. Refer to Sample Syringe to Valve Tubing Procedure in *Section 9, Service and Maintenance* of the **ALCYON Operations Manual.**
Bubbles in wash tubing.	Perform Probe Priming / Washing Procedure. Refer to *Section 9, Service and Maintenance* of the **ALCYON Operations Manual.**
Worn piston	Replace piston.
Worn syringe	Replace syringe.

Cannot Run this Control on this Reagent Carousel

Probable Cause(s)	Corrective Action(s)
Control configured with a 0.00 in the Low, High, or % Validation field.	Enter a control range and % Validation. If one of these parameters (Low, High, or Validation) is 0.00, the control cannot be run.

Calibration Factor and Results Lower than Expected

Probable Cause(s)	Corrective Action(s)
Calibrators, controls, and patient samples are not at the same temperature.	Bring calibrators, controls, and patient samples to room temperature before analyzing.

"CHAMP INCONNU=AFFICHE, NUMPLAT, =2=" Seen on Worklist Screen; Esc Key Does Not Function

Probable Cause(s)	Corrective Action(s)
Under investigation.	• Use the **[↑]** and **[↓]** keys to exit the screen. • Resume operations.

"Chemistry cannot be modified during analysis" message when trying to edit Calibration Configuration; Nothing in process

Probable Cause(s)	Corrective Action(s)
Unknown	Change current Reagent Carousel to a different number. Edit Calibration Configuration. Reset current Reagent Carousel configuration. or: Cycle power; edit Calibration Configuration.

Control Results Screen—Cumulative Data Display Mean Value or NAN; SD and CV Display Value of Zero

Probable Cause(s)	Corrective Action(s)
Seen with greater than 120 results in Control Results.	Exit the **Control Results** screen and access again. Mean, SD, and %CV values are correct.
Paging up after scrolling down the list of Control Results.	

Control Results—Cumulative Data Displayed on Screen Does not Match Printed <F3> Cumulative Data

Probable Cause(s)	Corrective Action(s)
Seen with greater than 120 results in Control Results.	For greater than 120 results, manually calculate or refer to the cumulative data printed by pressing **<F3>**.
Cumulative data on screen is calculated using 120 results.	
Cumulative data on printout are calculated using ALL results.	

Cuvettes Jammed in Loading Area

Probable Cause(s)	Corrective Action(s)
Automatic Cuvette Load / Unload Module dirty.	Clean the Automatic Cuvette Load / Unload Module. Refer to **Cleaning the Automatic Cuvette Load / Unload Module** in *Section 9, Service and Maintenance* of the **ALCYON Operations Manual.**
Automatic Cuvette Load / Unload Module not adjusted correctly.	Contact Field Service to adjust Automatic Cuvette Load / Unload Module so that there is 34 mm between the two metallic rods.

Enzyme Control Drifts—All Enzyme Controls Shift in the Same Direction (up or down)

Probable Cause(s)	Corrective Action(s)
Reaction temperature problem.	Check Reaction Cuvette Temperature Control. Reading should be 37 ± 0.2°C. If not, contact Field Service.

ISE Offset Adjustments Drift More Than 5 Counts per 30 Seconds

Probable Cause(s)	Corrective Action(s)
Dirty electrodes • Problem with Cl^- • Problem with Na^+ and/or K^+	Perform cleaning and conditioning procedures. Clean Cl^- Electrode with the ISE Stylet. (Do not use the stylet on the Na^+ or K^+ Electrodes.) Perform conditioning procedure. Perform cleaning procedure.
Salt build-up	Clean salt build-up on ISE Reference Solution bottle, Waste Cup, or tubing.
ISE Reference Solution tubing (#0, #9, or #8) and/or ISE Waste Cup tubing (#7) are touching metal	Ensure the tubing is not touching any metallic part of the ISE Module.
Bad ISE Pump tubing	Replace the ISE Pump tubing.
Bad Reference Electrode	Replace the Reference Electrode.
Bad ISE Electrode Cable	Replace the ISE Electrode Cable.

ISE Offset Adjustment Screen Displays "Green, Red, Blue"

Probable Cause(s)	Corrective Action(s)
ISE assays not defined on an ISE System. A non-ISE Methods Disk was restored on an ISE System.	Define ISE assays on the **ISE Configuration** screen. ISE Offset adjustments then display "Na, K, Cl". (Refer to the assay-specific **ALCYON Reagent Application Sheets** for parameter details.)

ISE Offsets Display at 327 / -327

Probable Cause(s)	Corrective Action(s)
No Stabilizing Solution.	• Ensure that there is sufficient Stabilizing Solution and that the correct solution is being used. • Run the Wash Pump and then the Reference Pump for at least one minute each. • Ensure that fluid is dispensing into the ISE Waste Cup by pressing **<F3>** in the **OFFSET** screen.
Electrodes not connected to cables when the Analyzer is initialized.	Ensure the electrodes are properly connected to cables and reinitialize.
No Stabilizing Solution in the Electrode Train when System is initialized.	• Perform Wash Start Procedure for one minute. • Perform Start Reference Pump Procedure for one minute. • Perform Shutdown Procedure. • Power **ON** the Analyzer.
Bubbles in Reference Electrode.	Perform Start Reference Pump Procedure to remove the bubbles.
Bad Reference Electrode.	Replace the Reference Electrode.
Bad Amplifier Board.	Contact Field Service.

LOST Errors with Adequate Sample in Cup

Probable Cause(s)	Corrective Action(s)
Improper Sample Probe positioning.	Ensure the Sample Probe is seated correctly. Refer to *Section 9, Service and Maintenance* of the **ALCYON Operations Manual**.
Damaged Sample Probe.	Inspect / replace the Sample Probe.
A/D Board.	Contact Field Service to replace the A/D Board.

Lock-Up Screen Frame Appears with No Words on Screen

Probable Cause(s)	Corrective Action(s)
Under investigation.	• Allow up to 15 minutes for the System to continue. • Cycle power to continue immediately.

Lock-Up When CTRL-ALT-STOP is Used to Reboot

Probable Cause(s)	Corrective Action(s)
Incorrect procedure used to reboot the Analyzer.	• Do NOT use CTRL-ALT-STOP to reboot the Analyzer. • Perform proper Shutdown Procedure. • Perform the procedure, To Switch OFF the Main Power, followed by the Power Up Procedure.

Lock-Up While in <F2> Display Screen; Seen During Control Printing and When Interfaced to a Host

Probable Cause(s)	Corrective Action(s)
Under investigation.	• Cycle power. • Resume operations.

Monitor Display Blank

Probable Cause(s)	Corrective Action(s)
No power to the Analyzer.	• Verify that the power cord is plugged into the Analyzer and into the wall outlet. • Check fuse; replace if necessary. Refer to *Section 9, Service and Maintenance* of the **ALCYON Operations Manual**.
System malfunction.	Contact Field Service.

Multiple Controls Out of Range

Probable Cause(s)	Corrective Action(s)
Control integrity.	Perform General Troubleshooting Procedures F in this guide.
Valve ports not tight.	Tighten valve ports as tight as possible.
T-junction to valve tubing pinched.	Replace the tubing. Refer to **Sample Syringe to Valve Tubing Procedure** in *Section 9, Service and Maintenance* of the **ALCYON Operations Manual**.
Bubbles in syringe or wash tubing.	Perform Probe Priming / Washing Procedure. Refer to *Section 9, Service and Maintenance* of the **ALCYON Operations Manual**.

"Name Already Used!" Displays when <F4> is Selected to Print the Worklist

Probable Cause(s)	Corrective Action(s)
Software	Press **<F4>** again and the Worklist prints.

Name Field in List Run Screen Only Displays 19 Characters; 20 Characters May be Downloaded

Probable Cause(s)	Corrective Action(s)
Software	For informational purpose only; this does not affect patient results.

Negative Results for Down Reaction Enzyme Assays

Probable Cause(s)	Corrective Action(s)
Cal Factor was not multiplied by -1.	Change C1 value in the **Calibration Configuration** screen to a negative number.
Kinetic Blank results too high.	Perform Kinetic Blank Procedure using new reagent.

No <F10> Conf. Option Available From Ratio or Profile List in New Patient Order Screen

Probable Cause(s)	Corrective Action(s)
<Enter> or the down arrow key was pressed too quickly when a new patient order was entered. Cursor moves to Ratio Selection box. If **<F4>** Ratios or **<F7>** Profiles are selected, the **<F10>** Conf. option is not available.	Exit the **New Patient Order** screen and then access the **New Patient Order** screen to re-enter patient order.
	Do not press **<Enter>** or the down arrow key until the cursor has moved to the next field.

Not in Validation Error on Controls When Controls are Within Validation

Probable Cause(s)	Corrective Action(s)
Controls are being run for the first time; there is no previous value with which to compare the control.	Rerun controls.
Mean is NAN.	Delete Control File and rerun controls.

Patient Orders Do Not Appear in the Worklist

Probable Cause(s)	Corrective Action(s)
Corrupted Worklist file.	• Select **Results**, then **Delete Group**. • Toggle Worklist to YES by pressing **<F3>**; Incomplete, Complete, and Archive should be set to NO. • Press **<F10>**; press **<F10>** again. • Press **<Enter>**. • If not resolved, perform corrective action procedures for **Shutdown Screen Appears When Initializing**. Patient orders need to be re-entered on the **New Patient Order** screen.

Ratio and Profile Selections not Accessible

Probable Cause(s)	Corrective Action(s)
Seen when default Reagent Carousel number is changed in the **New Patient Order** screen.	Change the current Reagent Carousel number in the **Reagent Carousel** screen.

Ratio Ordered and Additional Test is Run

Probable Cause(s)	Corrective Action(s)
Cause unknown. Seen when the first ratio is ordered after the Analyzer is initialized.	• Delete additional test from the Incomplete or Complete Files. • Order a "dummy" sample, after initialization, with ratio selected. The problem does not occur for additional samples ordered.

Reaction Cuvette Temperature Control Fluctuating or Out of Specification

Probable Cause(s)	Corrective Action(s)
Reaction temperature problem.	Contact Field Service if the temperature is erratic.

Reports not Printing in Correct Format

Probable Cause(s)	Corrective Action(s)
Print Option "Report Printing Mode" set to condensed.	Set "Report Printing Mode" to Normal.
Dipswitches on printer not configured correctly.	Ensure the dipswitches are configured as follows: 1 - OFF 5 - OFF 2 - ON 6 - OFF 3 - OFF 7 - OFF 4 - ON 8 - OFF

Runtime Error 202 at 3240:0632 Displayed on Screen

Probable Cause(s)	Corrective Action(s)
Stack overflow problem.	Cycle power.

Screen is Black with White Cursor in Upper Left-Hand Corner

Probable Cause(s)	Corrective Action(s)
Under investigation.	Cycle power.

Screen Displays "Runtime Error 233", Then "Please Turn off the Power" Screen; Seen When Ordering STATS Using the Touchscreen

Probable Cause(s)	Corrective Action(s)
Under investigation.	• Cycle power. • Resume operations.

Screen Locked Up At MAIN MENU

Probable Cause(s)	Corrective Action(s)
Under investigation.	Cycle power.

Shutdown Screen Appears When Initializing

Probable Cause(s)	Corrective Action(s)
Corrupted Worklist file.	• Cycle power. • At the **Start-Up** menu, select #5, **Reset Worklist**. • The corrupted Worklist file is deleted, and the System restarts. • Select **Results**, then **Delete Group**. • Toggle Worklist to YES by pressing **<F3>**; Incomplete, Complete and Archive should be set to NO. • Press **<F10>**; press **<F10>** again. • Press **<Enter>**.

System Lock-Up Followed by EMM386 Error

Probable Cause(s)	Corrective Action(s)
Blown 12v/5v fuse.	Contact Field Service.

OBSERVED CONDITIONS (Assay-Specific)

Ammonia

Issue(s)	Probable Cause(s)	Corrective Action(s)
Erratic results.	Improper specimen collection.	Ensure that the sample is plasma, prepared with lithium heparin or sodium heparin. (Ammonium heparin is unacceptable.) The Sample Tube must be full, and placed on ice immediately after collection.
Calibration 13 Error.	Limit of Quant is not set correctly.	Set LOQ to 0.0.

Bilirubin, Direct

Issue(s)	Probable Cause(s)	Corrective Action(s)
Erratic results.	Improper specimen collection.	Protect specimen from exposure to white or UV light as soon as it is collected.
Manual dilution and auto dilution results do not correlate.	Manual dilution was made with reagent blank.	Use saline for manual dilutions. The reagent blank causes the direct bilirubin in the sample to decrease with time.

Bilirubin, Total

Issue(s)	Probable Cause(s)	Corrective Action(s)
Erratic results.	Improper specimen collection.	Protect specimen from exposure to white or UV light as soon as it is collected.
Manual dilution and auto dilution results do not correlate.	Manual dilution was made with reagent blank.	Use saline for manual dilutions. The reagent blank causes the direct bilirubin in the sample to decrease with time.

CO_2

Issue(s)	Probable Cause(s)	Corrective Action(s)
Calibration 13 Error.	Limit of Quant is not set correctly.	Set LOQ to 0.0.

Calcium

Issue(s)	Probable Cause(s)	Corrective Action(s)
Erratic results.	Bleach in the Analyzer water line and/or the Water Container.	Verify that bleach has been completely flushed from the Analyzer water line and from the Water Container. **Bleach dramatically interferes with Calcium results.**
	Tap water used.	Use distilled or deionized water.

Creatinine

Issue(s)	Probable Cause(s)	Corrective Action(s)
Low end creatinine imprecision.	Reagent Probe and/or Sample Probe dirty or damaged.	• Inspect the Reagent Probe and Sample Probe for integrity. • Wipe down the Reagent Probe and the Sample Probe with an alcohol pad daily, especially with heavy use of creatinine reagent.
Erratic results.	Mixer Arm out of adjustment.	• Check the Mixer Arm for correct adjustment. • Check progress curves for unusual absorbance at any active read (RB2, 1st read, last read).

GGT

Issue(s)	Probable Cause(s)	Corrective Action(s)
Reagent deterioration.	R1A and working reagent are sensitive to light.	Store R1A and working reagent protected from light. Use a white Reagent Container.

Glucose

Issue(s)	Probable Cause(s)	Corrective Action(s)
Low results for CSF.	Sample not processed immediately.	Process sample immediately after collection.

Iron

Issue(s)	Probable Cause(s)	Corrective Action(s)
High iron results.	• Iron contamination of syringe, Vacutainer® tube, or other glassware. • Hemolysis • Iron contamination of water.	Obtain new sample. Use distilled or deionized water.
Reagent degradation.	Iron reagent not stored properly.	Store reagent protected from light and in an upright position; prolonged exposure to the reagent cap causes reagent to deteriorate.

LD

Issue(s)	Probable Cause(s)	Corrective Action(s)
LD results lower than competitive products.	ALCYON LD typically runs lower than other analyzers.	Enter the Slope Factor Value in Assay Configuration to correlate to another analyzer. See LD Slope Factors in the **HELPFUL INFORMATION** section of this guide.
Erratic results.	Improper specimen collection.	Do not use hemolyzed serum. RBC have 150 times more LD activity than serum.

LD-1

Issue(s)	Probable Cause(s)	Corrective Action(s)
Erratic results.	Improper specimen collection.	Do not use hemolyzed serum.

Magnesium

Issue(s)	Probable Cause(s)	Corrective Action(s)
Erratic results.	Excessive hemolysis.	Do not use hemolyzed serum.
	Short sample.	Check sampling system.

Phosphorus

Issue(s)	Probable Cause(s)	Corrective Action(s)
Erratic results.	Sample integrity or interferences.	• Check progress curves for unusual read absorbance at the first or last read. • Check for foam in the Reagent Container. • DIV flags may be an indication of progress curve instability.

Triglyceride

Issue(s)	Probable Cause(s)	Corrective Action(s)
Erratic results.	Reagent contaminated.	Check for possible contamination of the triglyceride reagent from substances containing glycerin, glyceraldehyde, or dihydroxyacetone.
	Calibration expired.	DIV flags may be an indication of progress curve instability.
	Improper reagent storage.	Exposure to ambient temperature for a prolonged period of time reduces the long term stability of the reagent.

Urea

Issue(s)	Probable Cause(s)	Corrective Action(s)
Erratic results.	Reagent contaminated with ammonia / bacteria.	• Verify that the reagent or sample has not been contaminated with ammonia. • Store urine specimens at 2 - 4°C until analysis. Urea is extremely susceptible to bacterial contamination; bacteria release ammonia.
Calibration 13 Error.	Reagent not mixed properly.	• Gently invert the R1 reagent before pouring into the Reagent Container. • Gently invert the Reagent Container each day before use.
	Limit of Quant set incorrectly.	Set LOQ to 0.0.

Uric Acid

Issue(s)	Probable Cause(s)	Corrective Action(s)
Erratic results.	Mixer speed.	Check Mixer speed.
	Reagent degradation.	• Check for turbidity. • Run controls.
	Ascorbic acid interference.	Verify by another method.

NOTE: Assays not listed in the tables above do not have issues identified at this time.

CHEMICAL REACTIONS FOR ALCYON ASSAYS

Assay	Reaction
Albumin BCG	Human Albumin + BCG $\longrightarrow$ Albumin - Dye Complex
Albumin BCP	Human Albumin + BCP $\longrightarrow$ Albumin - Dye Complex
Alkaline Phosphatase	p-NPP + H_2O $\xrightarrow[Mg^{+2}+\ Zn^{+2}]{ALP}$ p-Nitrophenol + phosphate
ALT Activated	L-Alanine + α-ketoglutarate $\xrightarrow{ALT}$ Pyruvate + L-glutamate pyruvate + NADH + H^+ $\xrightarrow{LDH}$ L-lactate + NAD^+
ALT Non-Activated	l-Alanine + α-Ketoglutarate $\xleftrightarrow{ALT}$ Pyruvate + Glutamate Pyruvate + NADH + H^+ $\xrightarrow{LD}$ Lactate + NAD^+
Ammonia	NH_3 + α-ketoglutarate + NH_xDPH + H^+ $\xrightarrow{GLDH}$ glutamate + NH_xDP^+ + H_2O
Amylase	10 CNPG3 $\xrightarrow{\alpha\text{-amylase}}$ 9 CNP + 1 $CNPG_2$
AST Activated	L-aspartate + α-ketoglutarate $\xrightarrow{AST}$ oxaloacetate + L-glutamate oxaloacetate + NADH + H^+ $\xrightarrow{MDH}$ malate + NAD^+
AST Non-Activated	L-Aspartate + α-Ketoglutarate $\xleftrightarrow{AST}$ Oxalacetate + Glutamate Oxalacetate + NADH $\xleftrightarrow{MD}$ Malate + NAD
Bilirubin, Direct	Conjugated bilirubin + diazotized sulfanilic acid $\longrightarrow$ acid azobilirubin
Bilirubin, Total	Conjugated & solubilized unconjugated bilirubin + diazotized sulfanilic acid $\longrightarrow$ acid azobilirubin
Calcium	2 Arsenazo III + 2 Ca^{++} $\longrightarrow$ Ca-Arsenazo Complex (blue-purple)
Carbon Dioxide	PEP + HCO_3^- $\xrightarrow[Mg^+]{PEPC}$ Oxalacetate + $H_2PO_4^-$ Oxalacetate + NADH + H^+ $\xrightarrow{MDH}$ Malate + NAD^+

Assay	Reaction
Cholesterol	Cholesterol Esters $\xrightarrow{CE}$ Cholesterol + Fatty acids Cholesterol + O_2 $\xrightarrow{CO}$ Cholest-4-en-3-one + H_2O_2 $2H_2O_2$ + HBA + 4-AAP $\xrightarrow{POD}$ Quinoneimine dye + $4H_2O$
CK	Creatinine phosphate + ADP $\xrightarrow{CK}$ creatine + ATP ATP + glucose $\xrightarrow{HK}$ glucose-6-phosphate + ADP Glucose-6-phosphate + NAD^+ $\xrightarrow{G\text{-}6\text{-}PDH}$ 6-phosphogluconate + NADH + H^+
Creatinine	Creatinine + alkaline picrate $\longrightarrow$ creatinine-picrate complex
GGT	γ-glutamyl-3-carboxy-4-nitroanilide + glycylglycine $\longrightarrow$ 5-amino-2-nitrobenzoate + γ-glutamylglycylglycine
Glucose	d-glucose + ATP $\xleftarrow[Mg^+]{HK}$ G-6-P + ADP G-6-P + NAD $\xrightarrow{G6PD}$ 6-phosphogluconate + NADH
HDL	HDL $\xrightarrow{Detergent}$ HDL disrupted HDL Cholesterol $\xrightarrow[Cholesterol\ Oxidase]{Cholesterol\ Esterase}$ $\triangle^4$ Cholestenone + H_2O_2 H_2O_2 + DSBmT + 4-AAP $\xrightarrow{Peroxidase}$ Color Development
Iron	Fe-transferrin $\xrightarrow{pH\ 4.5}$ Fe^{+3} + transferrin Fe^{+3} $\xrightarrow{hydroxylaminehydrochloride}$ Fe^{+2} Fe^{+2} + FERENE® $\longrightarrow$ Fe-FERENE Complex
LD	Lactate + NAD^+ $\xrightarrow{LD}$ Pyruvate + NADH + H^+
LD-1	L-Lactate + NAD^+ $\xrightarrow{LD\text{-}1}$ Pyruvate + NADH + H^+
Magnesium	Arsenazo Dye $\xrightarrow{Mg^{+2}}$ Mg-Arsenazo Dye Complex
Phosphorus	Phosphate + molybdate $\xrightarrow{H^+}$ heteropolyacid complex

Assay	Reaction
TIBC	$\text{Apotransferrin} + \text{excess } Fe^{+3} \xrightarrow{\text{Saturating Solution}} \text{Fe-transferrin} + Fe^{+3}$ $Fe^{+3} + \text{Fe-transferrin} + \text{alumina} \xrightarrow{\text{Adsorbent}} \text{Fe-transferrin} + \text{Fe-alumina}$
Total Protein	$X - \overset{\overset{O}{\|}}{C} - NH - X + Cu^{+2} \xrightarrow{OH^-} Cu^{+2}\text{– Protein Nitrogen Complex}$
Triglyceride	$\text{Triglyceride} + H_2O \xrightarrow{\text{Lipase}} \text{Glycerol} + \text{Free Fatty Acids}$ $\text{Glycerol} + ATP \xrightarrow{GK} \text{Glycerol-3-phosphate} + ADP$ $\text{Glycerol-3-phosphate} + O_2 \xrightarrow{GPO} DAP + H_2O_2$ $H_2O_2 + \text{4-AAP} + \text{4-CP} \xrightarrow{\text{Peroxidase}} \text{Quinoneimine dye} + 2H_2O_2$
Urea	$\text{Urea} + H_2O \xrightarrow{\text{Urease}} 2NH_3 + CO_2$ $NH_3 + \alpha\text{-ketoglutarate} + NADH \xrightarrow{GLDH} \text{l-Glutamate} + NAD$
Uric Acid	$\text{Uric Acid} + O_2 + H_2O \xrightarrow{\text{Uricase}} \text{Allantoin} + CO_2 + H_2O_2$ $H_2O_2 + \text{4-AAP} + \text{TBHB} \xrightarrow{\text{Peroxidase}} \text{Quinoneimine} + H_2O$

HELPFUL INFORMATION

Dilutions

The ALCYON Analyzer is capable of making different types of dilutions. Each of these dilutions are described below.

Dilutions programmed in Assay Configuration

Systematic Dilution

The dilution factor entered here applies to all samples run for that particular assay. This dilution factor should only be used in conjunction with the Calibrator Configuration dilution factor. It is used for assays that typically run higher than the linearity of the reagent. If the Systematic Dilution and the Calibrator Configuration Dilution match, then patients, QC, and calibrators are all diluted and results are calculated correctly.

WARNING: If a Systematic dilution is entered, but the Calibrator Configuration dilution is not entered, the results are not correctly calculated because the Analyzer does not multiply patient or QC results by the dilution factor.

Dilution for Urine

The dilution factor entered here applies to all urine samples (determined if "Y" is entered in the Urine field in the **New Patient Order** screen) for that assay. Before the result is multiplied by the dilution factor, it is compared to the "Dilution limits / Rerun limits" values; if the result is outside of these limits, it is further diluted by a system calculated dilution factor.

NOTE: The dilution factor for urine is not performed on controls.

e.g.: Dilution for Urine = 10
Dilution Limit = 99
Sample Concentration = 2000

The sample is automatically diluted by 10 and the result, before being multiplied, is equal to 200. Since 200 is greater than the dilution limit of 99, the Analyzer automatically dilutes the sample.

The Analyzer calculates the dilution factor by using the following formula:

Dilution Factor = Actual result in this case would be
200 ÷ 99 = 2.02
Dilution limit
(2.02 is rounded up to 2.25)

When the Analyzer reruns the sample, it is diluted by 10, then by 2.25, and the result is multiplied by two dilution factors (10 x 2.25).

Antigen Excess Dilution

This dilution is used for End-Point assays. If the System finds an antigen excess for a patient sample, this sample is automatically diluted by the dilution factor programmed in **Assay Configuration**.

Depletion Limit Dilution

This dilution is used for First-Order and Zero-Order Kinetic assays. If the depletion limit is reached on a patient sample, the sample is automatically diluted by four (default). The dilution factor may be edited from 1 to 40.

Dilutions programmed in New Patient Order

Dilutions may be programmed for individual samples and tests by programming them in the **New Patient Order** screen. The dilutions that may be programmed here are factors from 1 to 40, in increments of 0.25.

Dilution Limits

The dilution limit should correspond to the high end of linearity for an assay. The Analyzer automatically calculates the dilution factor to be used. The following formula is used:

$$\text{Dilution Factor} = \frac{\text{Actual result}}{\text{Dilution limit}}$$

The Analyzer rounds off to the next 0.25 increment.

The Analyzer makes a dilution by decreasing the sample volume if possible (it cannot be decreased lower than 2 µL). If the Analyzer cannot decrease the sample volume, it uses two cuvettes and makes the correct dilution in the first cuvette and then the reaction takes place in another cuvette using the diluted sample.

Passwords

The ALCYON Analyzer requires passwords for several troubleshooting procedures. Below is a list of the Level 1 and Level 2 passwords for 1999 and 2000.

These passwords are **confidential** and should only be provided to the customer when troubleshooting with an Abbott Representative.

MONTH (1999)	LEVEL 1 PASSWORD	LEVEL 2 PASSWORD
January	GPRTE	ENQSE
February	ENRTE	BMQSE
March	BMQTF	YLPSE
April	YLQTG	WKPSF
May	WKQUH	TJPTH
June	TJQVJ	RIPUJ
July	RJQWM	PHPVL
August	PIQXO	MHQXO
September	MHRZR	KGQYR
October	KHSBV	IGRAU
November	IGSDZ	GFSCY
December	GGTFD	EFTFC

MONTH (2000)	LEVEL 1 PASSWORD	LEVEL 2 PASSWORD
January	AABBC	AAABC
February	ABDGI	ABDFI
March	BDHMS	ADHLR
April	BGMVE	BFLTC
May	CISES	CIRCP
June	DLYOH	CKWMD
July	EOFZX	DNDWT
August	ESMLP	EQJHK
September	FVTXH	FUQTB
October	GYAKA	GXXFU
November	HCIXU	HAESN
December	IFPKO	HEMEG

Calibration Factor Description

End-Point and Kin 1 Assays

A Calibration Factor reference is provided in each assay-specific **ALCYON Reagent Application Sheet** in the Calibration Section. This reference was determined by averaging multiple Calibration Factors from multiple runs and multiple analyzers.

Customers should use this Calibration Factor as a reference only. Controls should be run to verify the calibration.

Enzyme (Kin 0) Assays

The Calibration Factor for enzymes must be calculated and entered into the **Calibration Configuration** screen. Refer to the **ALCYON Operations Manual** or the assay-specific **ALCYON Reagent Application Sheets** for detailed instructions on calculating the Calibration Factor.

Analyte by Control Name

Liquid Assayed Chemistry Control 1 and Liquid Assayed Chemistry Control 2
Albumin BCG
Albumin BCP
Alkaline Phosphatase
ALT
ALT, Activated
Amylase
AST
AST, Activated
Bilirubin, Direct
Bilirubin, Total
Calcium
Carbon Dioxide
Cholesterol
Chloride
CK
Creatinine
GGT
Glucose
Iron
LD
Magnesium
Phosphorus
Potassium
Sodium
TIBC
Total Protein
Triglyceride
Urea Nitrogen
Uric Acid

Lyophilized Assayed Chemistry Control 1 and Lyophilized Assayed Chemistry Control 2
Albumin BCG
Albumin BCP
Alkaline Phosphatase
ALT
ALT, Activated
Amylase
AST
AST, Activated
Bilirubin, Direct
Bilirubin, Total
Calcium
Chloride
Cholesterol
CK
Carbon Dioxide
Creatinine
GGT
Glucose
Iron
LD
Magnesium
Phosphorus
Potassium
Sodium
TIBC
Total Protein
Urea Nitrogen
Uric Acid

Analyte by Control Name

Liquid Assayed Chemistry Control 3
Albumin BCG
Albumin BCP
Alkaline Phosphatase
ALT, Activated
ALT
Amylase
AST, Activated
AST
Calcium
Chloride
Cholesterol
CK
CO_2
Creatinine
GGT
Glucose
Iron
Lactic Acid
LD
Lipase
Magnesium
PAP
Phosphorus
Potassium
Sodium
TIBC
Total Protein
Urea
Uric Acid

Liquid Ammonia Control 1, 2, 3
Ammonia

Liquid Urine Chemistry Control 1 and 2
Amylase
Calcium
Chloride
Creatinine
Glucose
Magnesium
Microalbumin
Phosphorus
Potassium
Sodium
Total Protein
Urea Nitrogen

Liquid Pediatric Chemistry Control 1 and 2
Bilirubin, Direct
Bilirubin, Total
Calcium
Chloride
Glucose
Potassium
Sodium

Liquid Lipid Control 1 and 2
Cholesterol
HDL
LDL
Triglyceride

Liquid CSF Control 1 and 2
CSF Glucose
CSF Protein

Analyte by Calibrator Name

Abbott Multiconstituent Calibrators
Albumin BCG
Albumin BCP
Calcium
Cholesterol
Creatinine
Glucose
Phosphate
Total Protein
Triglyceride
Urea
Uric Acid

Abbott Liquid Bilirubin Calibrators
Direct Bilirubin
Total Bilirubin

Abbott HDL Cholesterol Calibrator
HDL

Abbott Carbon Dioxide Calibrator
Carbon Dioxide

Abbott Ammonia Calibrator
Ammonia

Abbott Urine / CSF Protein Calibrator
Urine / CSF Protein

Abbott Iron / Magnesium Calibrators
Iron
Magnesium

Physical Indications of Reagent Instability or Deterioration

The table below describes conditions that indicate there is a possible reagent stability issue, or that the reagent may be deteriorating. Probable causes include:

- The reagent has expired.
- The reagent has become contaminated.
- The reagent was not stored under the conditions described in the assay-specific **ALCYON Reagent Application Sheet**.
- The reagent may have been compromised during shipping.

In the event that these conditions are observed, the following corrective action(s) may be taken:

- Open a fresh bottle of reagent.
- Recalibrate the assay if necessary.
- Refer to the assay-specific **ALCYON Reagent Application Sheet** for proper storage conditions.

Reagent Name	Normal Appearance	Indication(s) of Instability or Deterioration
Albumin BCG	Non-turbid and dark yellow-green	Reagent appears turbid
Albumin BCP	Non-turbid and light yellow-green	A precipitate appears in the solution
Alkaline Phosphatase	• Reagent: Non-turbid and colorless • Additive: Clear and yellow	Reagent appears turbid
ALT Activated	Colorless	Reagent appears turbid
ALT Non-Activated	• Reagent: Non-turbid and colorless to straw colored • Additive: Non-turbid and colorless	Reagent appears turbid
AST Activated	Colorless	Reagent appears turbid

Reagent Name	Normal Appearance	Indication(s) of Instability or Deterioration
AST Non-Activated	• Reagent: Non-turbid and colorless to straw colored • Additive: Non-turbid and colorless • Working reagent: Clear Non-turbid and colorless	Reagent or Working Reagent appears turbid
Bilirubin, Direct	Non-turbid	Reagent appears turbid
Bilirubin, Total	Non-turbid	Reagent appears turbid
Calcium	Non-turbid	Reagent appears turbid
Carbon Dioxide	Non-turbid and colorless to straw colored	Reagent appears turbid
Cholesterol	Pale pink and clear	Reagent appears turbid
Creatinine	Non-turbid	Reagent appears turbid
GGT	• Reagent: Non-turbid and colorless • Additive: Non-turbid and yellow • Working Reagent: Non-turbid and light yellow	Reagent or Working Reagent appears turbid
Glucose	Non-turbid and colorless	Reagent appears turbid
LD	Reagent, Additive, and Working Reagent: Non-turbid and colorless	Reagent or Working Reagent appears turbid
LD-1	Non-turbid and free of particulate matter.	Reagent appears turbid
Magnesium	• Non-turbid and pink-red • Free of particulate matter	• Reagent appears turbid • Presence of a precipitate

Reagent Name	Normal Appearance	Indication(s) of Instability or Deterioration
Urine / CSF Protein	Non-turbid	Reagent appears turbid
Phosphorus	Non-turbid and colorless	• Reagent appears turbid • Presence of a precipitate
TIBC	Saturating solution is Non-turbid	Saturating solution appears turbid
Total Protein	Free of particulate matter	Presence of a precipitate
Triglyceride	Non-turbid and colorless	Reagent appears turbid
Urea	Non-turbid and colorless	Reagent appears turbid
Uric Acid	Non-turbid	Reagent appears turbid

ERROR CODE PRIORITIES

Only one error code is maintained in a patient file at a time. When several errors occur on the same result, the error with the highest priority appears and the others are hidden. Once this error is resolved the next error appears until all are resolved.

The error codes appear in the following order, decreasing in priority:

End-Point	0-Kinetic	1-Kinetic	ISE
CAL	CAL	CAL	CAL
EA	DIV (*)	DIV (*)	DES
NR2	EA	EA	DER
DES	NR2	NR2	LOS
LOS	DES	DES	LOD
LOD	DER	DER	NEG
LOR	LOS	LOS	BUB
NEG	LOD	LOD	SAT
RBL	LOR	LOR	UNS
URB	NEG	NEG	VSB
EP	RBL	RBL	AOC
DIV	URB	URB	ORR
AOC	DEP (*)	DEP (*)	HRE
DIL	0NL	1UN	LRE
HRE	AOC	AOC	COL
LRE	DIL	DIL	
COL	HRE	HRE	
	LRE	LRE	
	COL	COL	

(*) The DIV flag is not evaluated when the DEP flag is set; the DEP flag is not evaluated when at least one of the flags NR2, DES, DER, LOS, LOD, LOR, NEG, RBL, or URB is set. However, when the DIV flag is set, it is reported rather than the flags NR2, DES, DER, LOS, LOD, LOR, NEG, RBL, or URB.

LD SLOPE FACTORS

The ALCYON LD assay typically runs lower than most competitive products on the market. If an ALCYON customer would like to have results which correlate to their existing system or to another system, they may enter the following slope factors into the **Assay Configuration** screen.

System	Slope Factor
Abbott Spectrum	1.23
Beckman CX7/4CE/5CE	1.17
BMC/Hitachi 717	1.34
BMC/Hitachi 911	1.33
Chiron 550 Express	1.12
DADE Dimension	1.14
DADE Paramax	1.20
IL Monarch	1.08
Olympus Reply	1.06
Roche Cobas Mira	1.29
Schiapparelli ACE	1.05
Vitros 250	4.52

Identified slope factors were determined from 1997 CAP survey data using the average values for CAP samples.

Some customers may choose to conduct their own correlation study to determine a more exact slope factor for their lab.

All customers should verify result equivalency through patient and control sample recovery.

NOTE: If using Abbott ALCYON Controls, the control range values must also be multiplied by the slope factor.

LIMIT OF QUANTITATION FIELD

The Limit of Quantitation field in the **Auto-Dilution / Rerun Limits** screen is factory set to 0.01, with the exception of ammonia, CO_2, and urea which are down reactions and should be set to 0.0.

No flags are generated based on this value, therefore it is recommended that this field not be edited.

The purpose of this field in version 1.5 software is to prevent Calibration Error 13 from occurring when water is used as a calibrator.

NOTE: See the sample **ALCYON Reagent Application Sheet** in this manual for the testing protocols and definitions of Limit of Quantitation and Limit of Detection.

NOTE: The actual **ALCYON Reagent Application Sheets** for each assay Do Not contain these protocols and definitions for the Limit of Quantitation and Limit of Detection. They are provided in this troubleshooting guide to assist you in explaining the protocols to customers.

Lowest Reportable Value

Customers should refer to the assay-specific **ALCYON Reagent Application Sheets**. Refer to the values under the Limit of Detection section and the Limit of Quantitation section. The Lowest Reportable Value is the *greater* of these two values.

URINE / CSF PROTEIN

Clinical Significance

The role of the renal system in the conservation of plasma proteins has been recognized for some time. Under normal physiological conditions, small molecular weight proteins such as insulin pass through the glomeruli in relatively large amounts. Intermediate-size proteins, such as transferrin and albumin, also pass through but only in relatively small amounts. Most of these proteins are reabsorbed in the renal tubules such that normal urine contains less than 150 mg of protein per day. This also includes the protein of non-serum origin normally secreted by the distal tubule (muco protein) and collecting ducts. Increased levels of urinary protein, (proteinuria) usually more than 0.15 g per 24 hours (150 mg / 24 hours), is almost always indicative of disease.

Proteinuria may be classified as renal proteinuria or proteinuria with normal renal function. Renal proteinuria may be further classified as glomerular or tubular proteinuria.

Glomerular proteinuria is due to increased glomerular permeability (nephrotic syndrome) and may be seen in glomerular nephritis or secondary to other diseases, such as diabetic nephropathy. Albumin is usually the predominant protein in the urine. Tubular proteinuria may be due to renal tubular damage from any cause, especially pyelonephritis. Tubular proteinuria results in modest increases in the low molecular weight proteins if glomerular permeability is normal. Proteinuria with normal renal function may be the result of physiological increases in protein excretion or the production of abnormally large amounts of low molecular weight proteins. Increased protein excretion is seen during normal pregnancy, after strenuous exercise, or following prolonged maintenance of an upright posture (standing or sitting). Increases in low molecular weight proteins may be due to the production of Bence Jones protein, hemoglobinuria as a result of severe hemolysis, and myoglobinuria as a result of severe muscle damage.

"Abnormal Protein" Behavior with Urine / CSF Protein Reagent

"Abnormal proteins" are unique to urine in situations other than straight proteinuria due to glomerular membrane damage, *e.g.*, ~~in~~ nephritis. Such proteins include:

- Tamm-Horsfall and other secretory glycoproteins of the genito-urinary tract.
- Low molecular mass peptides / proteins, usually reabsorbed by tubules *i.e.*, tubular proteinuria, such as Beta 2 Microglobulin, (12KDa), Lysozyme (14KDa), Alpha 1 Acid glycoprotein ("Orosomucoid") (41KDa), β-N-acetyl-glucosamimidase.
- Immunoglobulin free light chains present in some myeloma patients, usually referred to as "Bence Jones" protein.

These have all been investigated on the basis of comparison of Urine Total Protein (UTP) values on a wide variety of pathological urines by BEC (Benzethonium Chloride) against a Ponceau-S Dye Trichloroacetic Acid Precipitation (P-S / TCA) procedure as reference. (Ref.1).

The following points can be made:

- Occasional samples show a high result due to the presence of Tamm-Horsfall glycoprotein in urine, which is measured by the alkaline BEC procedure, but is less reactive to acid precipitants such as TCA, Salicy / Sulphonic Acid (SSA), and P-S / TCA. While a true proteinuria, it has no clinical or pathological significance.
- Tubular proteinuria, characterized by a predominance of low molecular mass proteins, whether alone or mixed with glomerular proteinuria, showed higher results for UTP with BEC than with P-S / TCA. It is well recognized that TCA and SSA under-react with low MW proteins. (Ref. 2, 3.)
- In myeloma patients, Bence Jones protein in urine shows higher results with BEC than P-S / TCA when the light chains were kappa type.

This is in agreement with the findings of Shephard and Whiting (Ref. 4), who showed the BEC results were quantitatively more correct.

The recovery of Lambda type light chains was fractionally lower than quantitative (approximately 90%). Overall, BEC gives higher recovery of Bence Jones protein than P-S / TCA, and is more sensitive to light chains.

There have been a number of reports in the literature of false low and high results for UTP by BEC. This is observed when markedly elevated urines read low, *i.e.*, normal, and pathology may be missed (Ref. 5). The Urine / CSF Protein Reagent has been shown to read > 2 g/L with protein concentrations of 80 g/L in urine *i.e.*, serum values, totally eliminating any "hook effect". The pH of the buffer has been reduced and sodium hydroxide eliminated, resulting in less positive interference by some aminoglycoside antibiotics and greatly increased calibration stability of up to 30 days, depending on the analytical system used.

Known interferences are urines from patients on Hemacell, a plasma expander, which affects most urine protein methods to a similar extent.

An important consideration is the use of Multi-Point calibration to ensure calibration accuracy at low urine (and CSF) protein concentrations. At these levels the calibration curve is sigmoid, *i.e.*, nonlinear, and the **assumption of linearity** results in over estimation of the Urine Total Protein (UTP) around the critical medical decision limits of 0.10 to 0.20 g/L. Failure to recognize this behavior of BEC has led to the conclusions in the literature that BEC overestimates UTP at low levels.

Along with most turbidimetric methods, BEC shows increased reactivity with albumin over globulins. Using albumin and gamma globulin Cohn fractions of human serum, the reactivity of globulin to albumin was 0.7 to 1. This should not prove a problem in practice because in all situations in CSF and urine, the albumin fraction is dominant and a slight underestimation of globulins has minimal clinical significance. In the situation of multiple sclerosis, where there is isolated elevation of CSF globulins relative to albumin, the total protein estimation is non-diagnostic and oligoclonal bands on electropheresis is the only way to make a positive diagnosis. To compensate for the difference in reactivity, it is recommended that calibrators with a mix of albumin and globulin about 2 - 3:1 be used to approximate test sample matrix and improve accuracy.

References:

Ref. 1 Pesce MA and Strand CS. *Clinical Chemistry* 1973; 19:1265-1267.

Ref. 2 Waller KV et al. *Clinical Chemistry* 1989: 35:755-765.

Ref. 3 Beilby JP and O'Leary BA. *Clinical Chemistry* 1990; 36:565-567.

Ref. 4 Shephard MDS and Whiting MJ. *Ann. Clinical Biochemistry 1992; 29:411-417.*

Ref. 5 Crofton PM. *Ann. Clinical Biochemistry* 1989; 26:104-105.

SAMPLE REAGENT APPLICATION SHEET

Reagent Name List No. XXXX-XX

ALCYON™ 300/300i Analyzer

Reagent Application Sheet for Reagent Name

This application sheet contains information to run the Reagent Name assay on the ALCYON 300/300i Analyzer.

WARNING: During operation some parts will be moving and could cause injury.

INTENDED USE

Explains the purpose of the test and acceptable specimen types

SUMMARY AND EXPLANATION OF THE TEST

Provides a brief history of the analyte and its significance.

METHODOLOGY

Describes the chemical reactions that take place and how the analyte is measured.

REAGENTS

Provides kit configuration and how the reagent is supplied. (Ready-to-use, powder, liquid, etc.)

Materials Required But Not Provided

Lists additional reagents and accessories not included in the reagent kit, which may be necessary to run the assay

Reactive Ingredients

Lists the ingredients in the reagents and their concentrations.

Precautions For Users

Lists hazard information and instructions for maintaining reagent integrity.

SPECIMEN HANDLING

Lists suitable specimen types as well as collection and storage instructions.

REAGENT HANDLING AND STORAGE

Provides reagent preparation instructions where applicable, onboard stability, how to load reagents onto the ALCYON, how to enter the reagent configuration, and a Reagent Usage Guide which provides an estimation of tests per kit.

Reagent and Cal Curve Stability: Testing Protocol

- One lot of reagent.
- Tested on one instrument.
- Three levels of controls (normal, abnormal, linear high) were tested in replicates of four at seven day intervals for 35 days.
- Reagent is poured into a container and left on the instrument in the appropriate position without a cap for 10 hours. The container is then capped and stored at 2-8°C or 15-30°C, depending on the reagent requirements, for 10 hours. This is repeated until the samples being tested fail a testpoint.
- All data passes or fails based on the calibration performed on the first day of the study. Recalibrations were not used to extend the onboard stability.

CALIBRATION

Discusses frequency of calibration, calibration stability, how to calculate calibration factors, the name of the extinction factor to be used, ie. PNP, and kinetic blanking determination.

QUALITY CONTROL

Provides instructions on quality control requirements and frequency for running controls.

RESULTS

Refer to *Appendix A* of the **ALCYON Operations Manual** for information on results calculations.

LIMITATIONS OF THE PROCEDURE

See the SPECIMEN HANDLING and PERFORMANCE CHARACTERISTICS sections of this application sheet.

EXPECTED VALUES

Provides reference ranges acquired from current texts. (Each laboratory should establish their own ranges based on their patient population).

Dilution Information

To dilute samples outside of the linearity of the assay, use the specified diluent recommended in the Method Description section of this application sheet. The ALCYON 300/300i Analyzer has an Automatic Dilution feature, refer to **Setting Detection, Dilution, and Rerun Limits** in *Section 2, Installation Procedures and Special Requirements* of the **ALCYON Operations Manual**.

SAMPLE REAGENT APPLICATION SHEET (continued)

Reagent Name List No. XXXX-XX

PERFORMANCE CHARACTERISTICS

Provides information on linearity, limit of quantitation/limit of detection, precision data, method comparison, and interfering substances. The sections that follow contain information on testing protocols used to determine these performance characteristics.

Note **The actual Reagent Application Sheets will not contain information on testing protocols.**

Linearity

Linearity was performed in accordance with NCCLS Protocol EP6-P.

- One lot reagent.
- Tested on one instrument.
- Typically, a minimum of five standard levels were used.
- Depending on the assay, a commercially prepared linearity set may have been used, or the levels were manually prepared in the lab.
- Each level was tested in replicates of four.
- Reagents were heat stressed (three days at 37°C) prior to testing.

Limit of Detection

The limit of detection represents the lowest measurable concentration that can be distinguished from zero. The limit of detection claim is defined as the mean of the saline or water plus two times the standard deviation (of the water or saline replicates).

Limit of Quantitation

The limit of quantitation is defined as the concentration of analyte that can be measured with a CV of 20%.

- One lot of reagent.
- Tested on three instruments.
- A minimum of four different levels of sample were used. In addition, saline or water was also tested.
- Each level was tested in replicates of 10, twice a day (two hours between runs).
- The data from all instruments is pooled.
- The claim is based on the theoretical concentration at which the % CV exceeds 20%. A best fit line is used to extrapolate the concentration where the % CV is 20%.

Precision

Precision for serum was performed in accordance with NCCLS Protocol EP5-T2. Precision for urine and cerebrospinal fluid (CSF) were performed in accordance with NCCLS Protocol EP10-T2.

- One lot of reagent.
- Tested on three instruments.
- Serum testing: Controls were tested in replicates of two, twice a day, with a minimum of two hours between runs, and the control levels were alternated during each run (1,2,1,2 etc.). This was repeated for 20 days.
- Urine and CSF application precision studies were tested for five days. Each day the controls were tested with a minimum of two replicates, twice a day (two hours between runs).
- Urine/CSF protein precision studies were tested for 20 days, in accordance with NCCLS Protocol EP5-T2.

Method Comparison

Method Comparison was performed in accordance with NCCLS Protocol EP9-A.

- One lot of reagent.
- Tested on one instrument.
- Each sample tested in replicates of two, however, only the first value was used in the evaluation.

Interfering Substances

Data on interfering substances was generated in accordance with NCCLS Protocol EP7-P.

- One lot of reagent.
- Tested on one instrument.
- The test pools were adjusted to be within 30% of the medical decision level prior to adding the interferent solutions.
- Test pools for urine were adjusted to be within 30% of the concentration found in commercially available Abnormal Urine control prior to adding the interferent solutions.
- Each level was tested in replicates of four.
- Interference solutions were tested the day they were prepared.

ALCYON 300/300i METHOD DESCRIPTION

Describes instrument parameter settings for the assay and gives parameters for other specimen types if applicable.

CALIBRATION CONFIGURATION

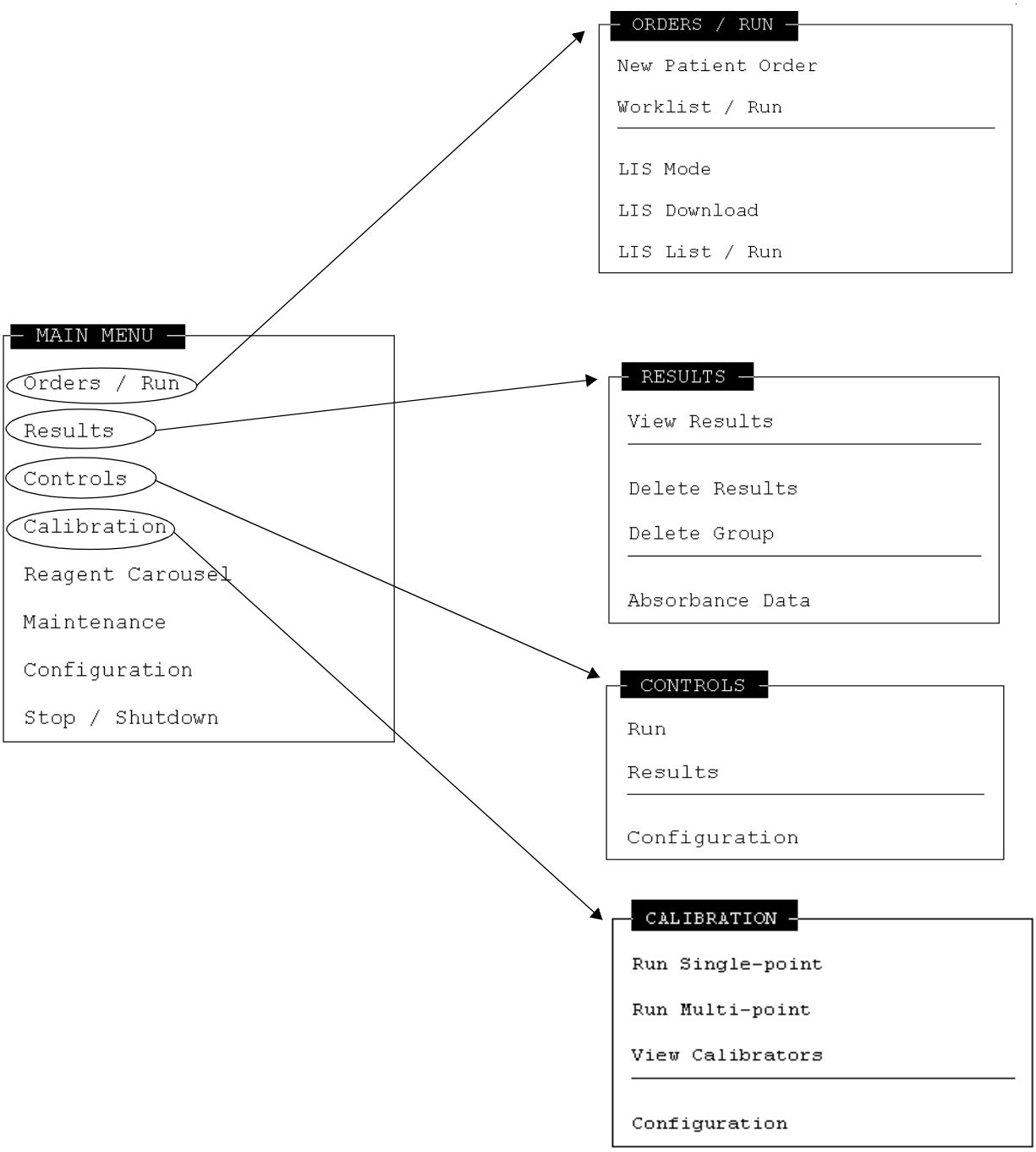
Describes type of calibration curve, polynomial degree, correlation limit and main calibrator.

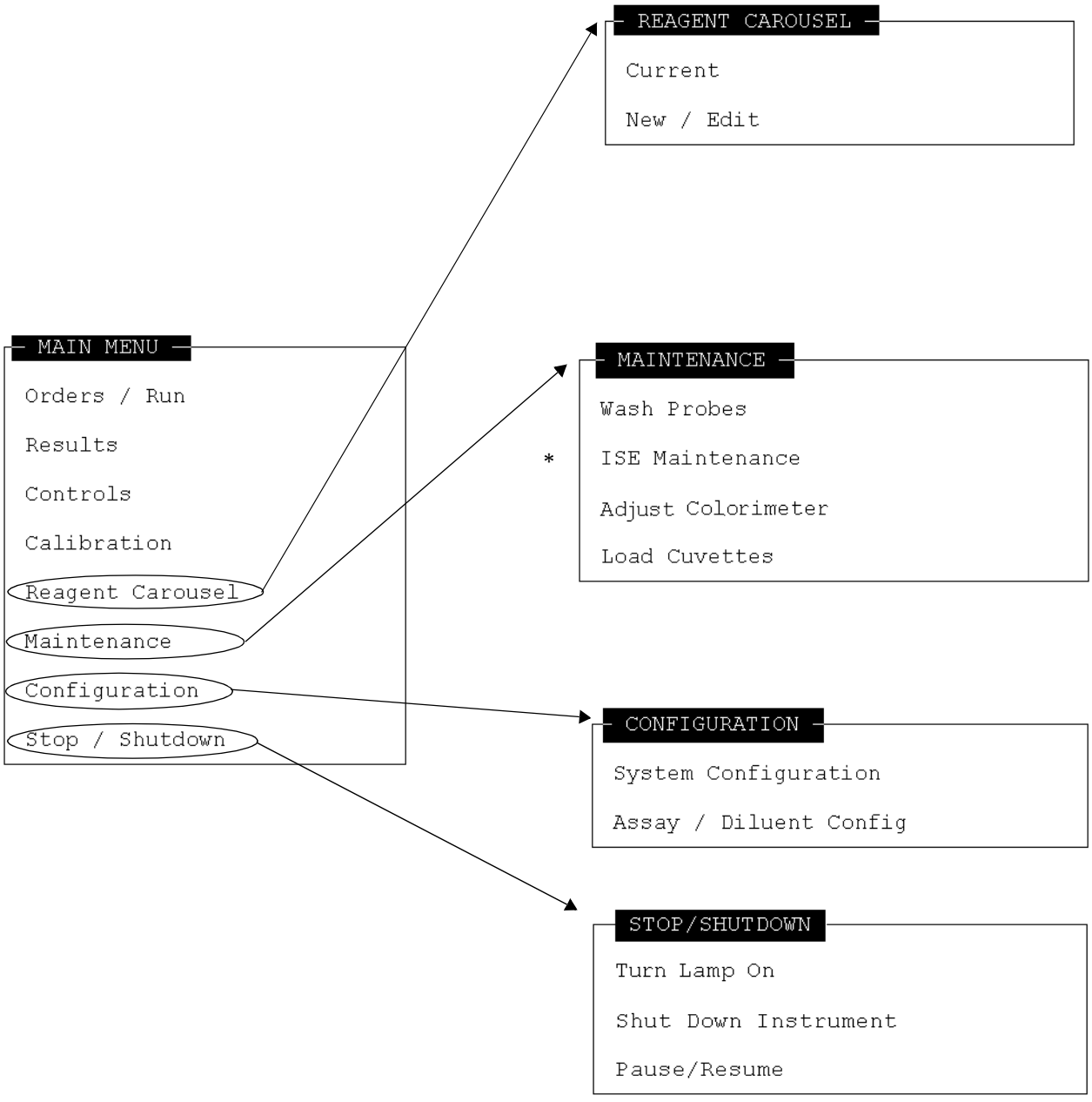
REFERENCES

NOTES

SOFTWARE MAP

The following diagrams show the MAIN MENU and its submenus, providing a mapping of the ALCYON Analyzer System software.




MAIN MENU
Orders / Run
Results
Controls
Calibration
Reagent Carousel
Maintenance
Configuration
Stop / Shutdown
REAGENT CAROUSEL
Current
New / Edit
MAINTENANCE
Wash Probes
* ISE Maintenance
Adjust Colorimeter
Load Cuvettes
CONFIGURATION
System Configuration
Assay / Diluent Config
STOP/SHUTDOWN
Turn Lamp On
Shut Down Instrument
Pause/Resume

NOTES