

# Basic Operator Training Manual List No. 7D34-04

# **NOTES**

# Student Workbook Identification Student Name

Student Employee Number

# **Revision Status**

| Document<br>Control Number | Revision Date | Section Revised | Pages Revised and<br>Added |
|----------------------------|---------------|-----------------|----------------------------|
| 30-0825—R1                 | 5/98          | Original Issue  | Original Issue             |
| 30-1057—R2                 | 6/98          | All Sections    | All Pages                  |
| 30-1440—R3                 | 12/98         | All Sections    | All Pages                  |
| 30-1710—R4                 | 4/99          | All Sections    | All Pages                  |
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This guide was developed and produced by Abbott Worldwide Customer Service and Medical Writing in Irving, TX.

# **Training Log Signatures**

| Date | Student<br>Signature | Trainer<br>Signature | Comments | Module |
|------|----------------------|----------------------|----------|--------|
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# **Secondary Manual Disclaimer**

Any product information in this document should be used in conjunction with the latest version of the **ALCYON Operations Manual**. If any discrepancies in information exist within this document or any other, the latest version of the Operations Manual takes precedence.

# **Proprietary Statement**

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### Dear ALCYON Customer,

Congratulations on the purchase of the ALCYON Analyzer. This Analyzer is designed to automate your laboratory chemistry testing environment by providing random access analysis of up to 300 tests per hour, over a range of capabilities that include End-Point, Zero-Order Kinetic (Kinetic 0), and First-Order Kinetic (Kinetic 1) chemistries. When equipped with an Ion-Selective Electrode (ISE) module, the ALCYON Analyzer performs potentiometric testing for the determination of sodium (Na<sup>+</sup>), potassium (K<sup>+</sup>), and chloride (Cl<sup>-</sup>).

The ALCYON Analyzer is backed by dedicated professionals who excel in engineering, technical support, and training. Abbott Laboratories looks forward to serving you in any way possible. This service is available by contacting your Abbott Representative.

The purpose of this workbook is to provide you with self-guided training for basic operation of the ALCYON Analyzer. You can work alone, or with the assistance of your laboratory's supervisor.

Once you have successfully completed all three modules, you should be able to perform basic operation of the ALCYON Analyzer, including routine maintenance procedures.

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# Introduction

### Overview

The ALCYON Basic Operator Training Program is part of an ongoing approach designed to provide optimum use of the Analyzer. As a foundation for this process, this program provides the Operator with basic tools for effective use of the ALCYON Analyzer in a working environment.

## **Training Manual Goals**

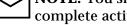
The primary goals of the ALCYON Basic Operator Training Manual are to present:

- Functions of ALCYON Analyzer components
- Activities for learning basic operating procedures
- Procedures for Analyzer management

### **Contents of Each Module**

Each module contains the following:

- Objectives
- Completion time
- Activities
- Review questions



**NOTE:** You should have access to the following to complete activities contained in this manual:

- ALCYON Analyzer
- ALCYON Operations Manual
- ALCYON Quick Reference Guide
- ALCYON Reagent Application Manual

# **Organization Of Training**

## **ALCYON Analyzer Training Program**

The information in the ALCYON Basic Operator Training Program is presented using the following materials:

ALCYON Basic Operator Training Manual
ALCYON Operations Manual
ALCYON Quick Reference Guide
ALCYON Reagent Application Manual

### **ALCYON Basic Operator Training Manual**

The **ALCYON Basic Operator Training Manual** directs activities and can be used as a training tool for secondary Operators. The manual is organized in modules. Sample printouts presented throughout the manual are used to acquaint the Operator with the format and content of various types of ALCYON Analyzer reports.

The **ALCYON Basic Operator Training Manual** presents information in procedural format, used to orient the Operator to Analyzer functions. This manual includes a glossary that defines terms used during training and those associated with the clinical laboratory environment.

### **ALCYON Operations Manual**

The **ALCYON Operations Manual** is the comprehensive reference to the operation and maintenance of the ALCYON Analyzer.

During training, references will be made to sections of the **ALCYON Operations Manual**. Training emphasizes use of the manual to solve problems. When using the **ALCYON Basic Operator Training Manual**, you should become familiar with the organization and presentation of material that will make the **ALCYON Operations Manual** a valuable resource for operation of the ALCYON Analyzer.

### **ALCYON Quick Reference Guide**

The ALCYON Quick Reference Guide is a concise guide to the most frequently used procedures on the ALCYON Analyzer. The procedures are taken directly from the ALCYON Operations Manual without extraneous information.

### **ALCYON Reagent Application Manual**

The ALCYON Reagent Application Manual contains the assay-specific ALCYON Reagent Application Sheets for Abbott ALCYON reagents used on the ALCYON Analyzer.

### **Icons**

Special prompts in the form of small graphics or icons are used to describe the nature of particular content. The following is a brief description of the graphics and icons used in the **ALCYON Basic Operator Training Manual**:



OPEN BOOK —This icon indicates additional reference material that will be helpful during training activities. This icon instructs the student to refer to sections of the ALCYON Operations Manual, ALCYON Quick Reference Guide, or ALCYON Reagent Application Manual.



**ACTIVITY**—This icon indicates instructional material presented through trainer / administrator and participant interaction.



**HOUR GLASS** —This icon indicates the approximate presentation or completion time for a module or module section.



**NOTE**—This icon indicates important information, or information that represents an exception to conventional methods.

### **Hazards**

Operation, maintenance and servicing of the ALCYON Analyzer may expose individuals to potential safety and health hazards. This section describes the types and locations of potential hazards that could cause physical harm to an Operator.

Warnings are found throughout this manual to alert the Operator to potential hazards. For comprehensive information regarding potential hazards associated with ALCYON Analyzer operation, refer to *Section 8, Hazards* of the **ALCYON Operations Manual**.

The standard warning conventions, including hazard signal words and icons are described as follows:



**CAUTION:** Denotes potential hazards that could result in minor injury. Also used for conditions or activities that could interfere with proper functioning or performance of the Analyzer.



**WARNING:** Denotes a hazard which could result in moderate to serious injury.



WARNING: Potential Biohazard. Consider all clinical specimens, reagents, controls, etc., that contain human blood and surfaces or components that have come into contact with human blood and the above materials as potentially infectious. Wear gloves, lab coats, and safety glasses, and follow other biosafety practices as specified in *OSHA Bloodborne Pathogen Rule (29 CFR 1910.1030)* or other equivalent biosafety procedures.

# **Biosafety Issues**

Refer to *Section 8, Hazards* of the **ALCYON Operations Manual**.

### **Probes**

Probes, such as the sample probe or ISE probe, are sharp and potentially contaminated with infectious materials. Avoid contact with tips of the probes.

# **Handling Spills**

Clean spills of potentially infectious materials in accordance with established biosafety practices. A generally accepted procedure for cleaning such spills is to:

- Absorb the spill with toweling or other absorbent material.
- Wipe the area with a detergent solution.
- Wipe the area with an appropriate disinfectant, such as 0.1% sodium hypochlorite solution (2% bleach solution).

### Instrument Decontamination

Instruments must be decontaminated prior to servicing or shipment, per *OSHA Bloodborne Pathogen Rule* (29 CFR 1910.1030). For further information, refer to *Section 8, Hazards* of the **ALCYON Operations Manual**.

# **Handling Waste**

Dispose of all clinical specimens, reagents, controls, calibrators, standards, cuvettes, and other disposables that may be contaminated, in accordance with local, state, and federal regulations.

| Waste Type                          | Description of Disposal   |
|-------------------------------------|---|
| Sharps, such as contaminated probes | Place in an appropriately marked, puncture-resistant container prior to treatment and disposal.   |
| Liquid Waste                        | Prior to the addition of a disinfectant and disposal, neutralize liquid waste containing acid. The addition of a disinfectant to the waste container helps to eliminate growth of any infectious organisms present. |
| Solid Waste                         | Generally accepted procedures for the treatment of potentially infectious solid waste include incineration and autoclaving. If an autoclave is used, verify the effectiveness of its decontamination cycle.         |

# **Customer Support**

# **Abbott Laboratories Diagnostics Division**

United States: 1-800-527-1869

Canada: 1-800-387-8378

International: Contact your local Customer Support

Representative.

# **NOTES**

Module 1 System Overview

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|                           | Module 1 Review Questions                    | 14 |  |  |

# **Objectives**

Upon completion of these activities, you should be able to:

- 1. Locate, identify, and describe ALCYON Analyzer components.
- 2. Identify accessories used with the ALCYON Analyzer.
- 3. Navigate efficiently through System software.
- 4. Set up or modify Reagent Carousel configurations.
- 5. Configure profiles.

# **Completion Time**



1-1/2 to 2 hours

# **Activity 1-1: Basic Analyzer Components**

# **Purpose**

To locate and describe ALCYON Analyzer components.

## **Objectives**

Upon completion of this activity, you should be able to locate and describe the following components:

- Cuvette Management Center
- ISE Module (Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>)
- ISE Probe
- Optical System
- Pipetting Systems
- Processing Center
- Reaction Cuvettes
- Reaction Cuvette Temperature Control
- · Reagent Carousel
- Reagent Containers (26 mL, 12 mL)
- Reagent Preheater
- · Reagent Probe
- Reagent Syringe
- Sample Bar Code Reader
- Sample Carousel
- Sample Probe
- Sample Syringe
- Sampling and Reagent Center
- System Control Center
- Waste Container
- Water Container



**ALCYON Operations Manual** 

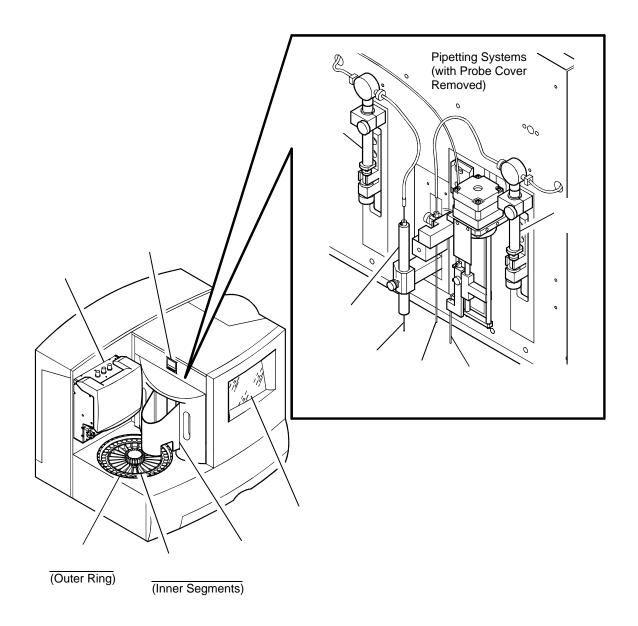
# **Activity**



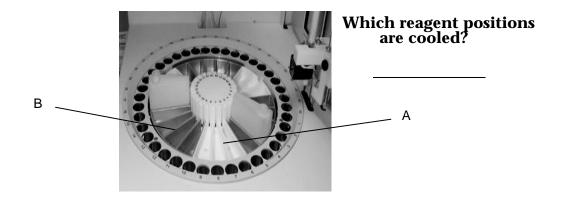
Perform the following steps at the ALCYON Analyzer:

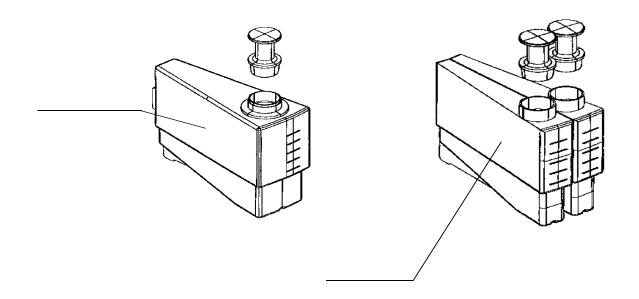
- Using Analyzer Description in Section 1, Use or Function of the ALCYON Operations Manual, review the function of the following ALCYON Analyzer components:
  - Cuvette Management Center
  - ISE Module (Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>)
  - ISE Probe
  - Optical System
  - Pipetting Systems
  - Processing Center
  - Reaction Cuvettes
  - Reaction Cuvette Temperature Control
  - Reagent Carousel
  - Reagent Containers (26 mL, 12 mL)
  - Reagent Preheater
  - Reagent Probe
  - Reagent Syringe
  - Sample Bar Code Reader
  - Sample Carousel
  - Sample Probe
  - Sample Syringe
  - Sampling and Reagent Center
  - System Control Center
  - Waste Container
  - Water Container
- 2. Using this manual, locate the components on the ALCYON Analyzer, as indicated on the following pages. Write the component names in the spaces provided.

# **Identify the Indicated Components:**

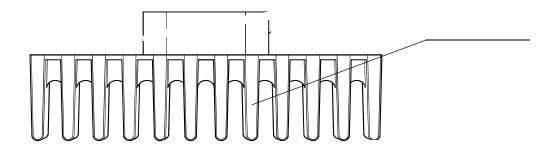


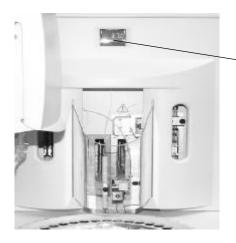
# **Identify the Indicated Components:**





# **Identify the Indicated Components:**





# **Activity 1-2: Basic Navigation**

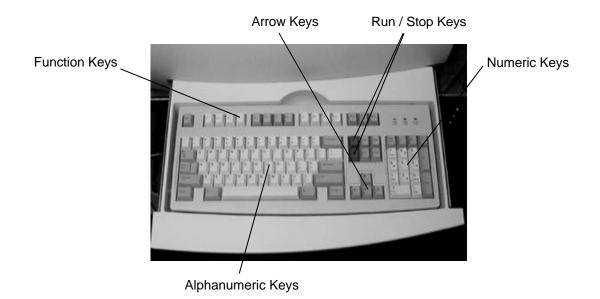
# **Purpose**

To understand the various methods of navigation through the software (screens).

# **Objectives**

Upon completion of this activity, you should be able to navigate through ALCYON Analyzer software using the following options:

- 1. Touchscreen
- 2. Keyboard
  - Arrow keys
  - · Function keys
  - Numeric keys
  - Alphanumeric keys
  - Run / stop keys



### **Navigation Options**

The following options may be used to make a selection from a menu:

- Use the arrow keys, scroll to the desired option and press
- Select the desired option by touching the screen.



### **ALCYON Operations Manual**

### **Activity**



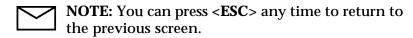
The following activity illustrates various navigation options.

Perform the following steps at the ALYCON Analyzer to become familiar with navigation options.

With the MAIN MENU displayed as shown below, perform the following steps:



 Touch Configuration or press <↓> on the keyboard to highlight Configuration on the MAIN MENU. Press <Enter> to select.



Select System Configuration, then System Settings.

- 3. Verify the date and time information.
  - If date and time information is correct, proceed to step 7.
  - If date and time information is *not* correct, proceed to step 4.
- 4. Select the line to be changed. The Analyzer places a box around the selected information.
- 5. Enter the correct information.
- 6. Press **<Enter>** to accept the new information.
- 7. Press **<F10**> to confirm the information. Press **<ESC**> to return to the MAIN MENU.

For additional navigation information, refer to **Onscreen Navigation** in *Section 3, Principles of Operation* of the **ALCYON Operations Manual.** 

# **Activity 1-3: Working with Reagent Carousels**

## **Purpose**

To demonstrate configuration of Reagent Carousels.

# **Objective**

Upon completion of this activity, you should be able to:

- Create or edit Reagent Carousel configuration on the ALCYON Analyzer.
- Identify standard Reagent Carousel configurations for your laboratory.



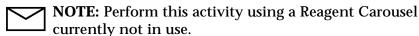
# **ALCYON Operations Manual**

**ALCYON Quick Reference Guide** 

## **Activity**



Perform the steps for Creating Profiles and Creating or Modifying Reagent Carousels described in Section 2, Installation Procedures and Special Requirements of the ALCYON Operations Manual or Creating / Modifying Reagent Carousel in the ALCYON Quick Reference Guide.



The steps for this activity are as follows:

- 1. Create a Reagent Carousel.
- 2. Create a profile.



- 3. Edit the Reagent Carousel.
- 4. Designate this Reagent Carousel the current (default) carousel.

Refer to the exercise on the next page.

# **Exercise**

# Working with Reagent Carousels\*

| Co  | omplete the follow | ving exercise using:                                 |
|-----|--------------------|--|
|     | $\bigcap$          | <b>ALCYON Quick Reference Guide</b>                  |
|     |                    | <b>ALCYON Operations Manual</b>                      |
|     |                    |  |
| 1.  | Create a Reagent   | t Carousel with the following reagents:              |
|     |                    | Reagent Carousel #5                                  |
|     |                    |  |
|     |                    |  |
|     |                    |  |
|     |                    |  |
|     |                    |  |
| 2.  | Create a profile   | on Reagent Carousel #5 using the following reagents: |
|     |                    |  |
|     |                    | <del></del>  |
|     |                    |  |
| 3.  | Modify Reagent     | Carousel #5 by adding the following reagents:        |
|     |                    |  |
|     |                    |  |
|     |                    | <del></del>  |
|     |                    |  |
| 4.  | Designate Reage    | nt Carousel #5 the current (default) carousel.       |
|     |                    |  |
| * ^ | All Doogont Caray  | sals are instructor defined                          |
| F   | an keagent Carou   | sels are instructor defined.                         |

# **Module 1 Review Questions**

| Vrite | e your answers in the spaces provided.   |
|-------|--|
| 1.    | How many positions are available on the Sample Carousel?   |
| 2.    | What sizes and types of sample cups and tubes can the Sample Carousel accommodate  |
| 3.    | How many of the following Reagent Carousel positions can be found on the ALCYON Analyzer?  |
|       | a. Cooled positions b. Ambient positions   |
| 4.    | Name the two pipetting systems housed on the ALCYON Analyzer.  |
| 5.    | What is the average volume of distilled or deionized water used during one hour of normal continuous operation of the ALCYON Analyzer? |
| 6.    | How many reaction cuvettes can the reaction carousel accommodate?  |
| 7.    | List the temperatures at which the reaction cuvette temperature control may be set.  |
| 8.    | What two options may be used to make a selection from a menu?  a.  |

b.

| 9. | How many Reagent | Carousels can be configured | on the ALCYON Analyzer? |
|----|------------------|-----------------------------|-------------------------|
|    | , ,              | 8                           | J                       |
|    |                  |                             |                         |

10. List the steps for configuring the current (default) Reagent Carousel setting.

| 1. | 3. |
|----|----|
| 2. | 4. |

# **NOTES**

Module 2 Basic Operations

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# **Objectives**

Upon completion of these activities, you should be able to:

- 1. Perform the tasks on the Daily Checklist.
- 2. Order and run routine and STAT patient orders.
- 3. Run patient samples by selecting **Profiles** and **Ratios**.
- 4. Review patient sample results.
- 5. Recognize a valid progress graph.
- 6. Configure and process calibrators.
- 7. Configure and process controls.
- 8. Process an ISE run.

### **New Vocabulary Words**

- Complete Files
- Correlation limit
- Diluents
- Dilution for urine
- Incomplete Files
- Profiles
- Raw data
- Systematic dilution
- Worklist

# **Completion Time**



2-1/2 to 3 hours

# **Activity 2-1: Analyzer Preparation**

## **Purpose**

To become familiar with ALCYON Analyzer set-up.

### **Objectives**

Upon completion of this activity, you should be able to prepare the Analyzer for use.



ALCYON Operations Manual ALCYON Quick Reference Guide

## **Activity**

Perform the following steps at the ALCYON Analyzer:



**WARNING: Potential Biohazard.** Refer to *Section 8, Hazards* of the **ALCYON Operations Manual**.

1. Verify the following preparation procedures were performed prior to initializing the ALCYON Analyzer.



**NOTE:** Preparation procedures should be performed by each Operator periodically throughout the day.

# **Daily Checklist**

- FOR ISE MODULES ONLY: Perform the Start Wash Pump Procedure followed by the Start Reference Pump Procedure.
- Turn on the lamp (initialize the Analyzer), if necessary.



**NOTE:** If interfaced to a Host computer, the Host will need to reinitialize the connection after the Analyzer initializes.

- Remove condensation from cooled reagent positions, if necessary.
- Verify the cooled positions on the Reagent Carousel are cooling, by touching each segment.
- Verify the reagent preheater is warm to the touch.
- Verify the temperature of the reaction cuvette temperature control ( $30.0/37.0 \pm 0.2$ °C).



- Load new cuvettes on the automatic cuvette load / unload module.
- Remove and discard used reaction cuvettes from the automatic cuvette load / unload module.
- Fill the water container. Reinstall the water gauge in the water container.
- Empty the waste container, if the Analyzer is not directly connected to a drain.
- Inspect the reagent containers for leaks or cracks prior to use.
- Verify there is sufficient reagent in the reagent containers.
- Mix the reagents by gently inverting.
- Place reagent containers on the Reagent Carousel and verify correct placement by comparing to the Current Reagent Carousel Modification screen.
- Remove the plugs from the reagent containers.
- FOR ISE MODULES ONLY: Verify there is sufficient ISE reference solution and ISE stabilizing solution.
- FOR ISE MODULES ONLY: Mix the ISE stabilizing solution by manually rocking the bottle.
  - NOTE: Ensure precautions are taken to prevent liquid from leaking from the holes in the cap. Do not invert the bottle.
- FOR ISE MODULES ONLY: Check for dried salt deposits on the reference solution bottle, waste cup, and tubing. Clean if necessary.
- 2. Read **Operator Preparation** in *Section 5, Operating Instructions* of the **ALCYON Operations Manual**.

# **Activity 2-2: General Operating Utilities**

### **Purpose**

To understand general operating utilities of the ALCYON Analyzer.

## **Objective**

Upon completion of this activity, you should be able to:

- · Identify the cause of Analyzer initiated pauses.
- Determine the appropriate action required in order to resume ALCYON Analyzer operation.



## **ALCYON Operations Manual**

### **Activity**



Perform the following steps at the ALCYON Analyzer:

- 1. Refer to **Pausing / Resuming Operations** in *Section 5*, *Operating Instructions* of the **ALCYON Operations Manual**.
- 2. Access the **Pause** screen by selecting **<Stop / Shutdown>**, then **<Pause / Resume>**.
- 3. Remove the water gauge from the water container.
- 4. Observe the **Pause / Resume** screen. What is the Pause status for "Water Tank Empty"? \_\_\_\_\_\_
  What is the corrective action? \_\_\_\_\_\_
- 5. Perform the corrective action to resume operation.

## **Activity 2-3: Test Entry**

### **Purpose**

To order routine and STAT orders.

#### Objective

Upon completion of this activity, you should be able to:

- Identify information necessary for entering a test.
- Order and process routine tests.
- Order and process STAT orders.



**ALCYON Operations Manual ALCYON Quick Reference Guide** 

#### **Activity**

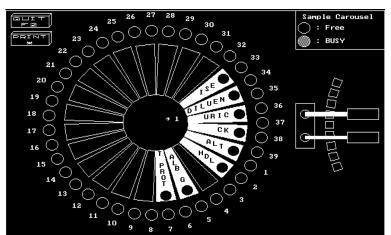


**WARNING: Potential Biohazard.** Refer to *Section 8, Hazards* of the **ALCYON Operations Manual**.



Perform the following steps at the ALCYON Analyzer to practice entering tests:

- 1. Refer to **Ordering and Running Tests** in *Section 5*, *Operating Instructions* of the **ALCYON Operations Manual** or *Ordering Patients (Routine, Profiles, STATs, Ratios)* in the **ALCYON Quick Reference Guide**.
- 2. Begin at the MAIN MENU; press <**F2**> to view the location of chemistries on the Reagent Carousel.



The screen displays a representation of the Reagent Carousel as illustrated below.

**NOTE:** The chemistries defined on the Analyzer may vary from the ones pictured above.



**NOTE:** If using sample cups, inspect for cracks or leaks prior to use.

- 3. Use distilled or deionized water or control sera as a test "sample" for the activity.
- 4. Inspect samples for foam, bubbles, fibrin, or other particulate matter. Use one (1) wooden application stick per sample to remove.
- 5. Follow the exercise to complete the steps to order and run routine tests. Refer to Ordering and Running Tests in Section 5, Operating Instructions of the ALCYON Operations Manual or Ordering Patients (Routine, Profiles, STATs, Ratios) in the ALCYON Quick Reference Guide.



**NOTE:** Default settings on the Analyzer may not require entry of specific information (*i.e.*, doctor name).

# **Exercise**

## **Test Entry**

| Perform the followi | ng exercise using:                  |
|---------------------|-------------------------------------|
|                     | <b>ALCYON Operations Manual</b>     |
|                     | <b>ALCYON Quick Reference Guide</b> |

Order and run the following:

| ID      | Name     | Tests* | Status  |
|---------|----------|--------|---------|
| 1111111 | Joe      |        | Routine |
|         |          |        |         |
| 222222  | John     |        | STAT    |
|         |          |        |         |
| 3333333 | Sally    |        | Routine |
|         |          |        |         |
| 444444  | Annie    |        | Routine |
|         |          |        |         |
| 555555  | Jenny    |        | STAT    |
|         |          |        |         |
| 6666666 | Patricia |        | STAT    |

<sup>\*</sup>Instuctor defined

# **Activity 2-4: Test Entry for Profiles and Ratios**

**Purpose** 

To process patient samples by profiles and ratios.

**Objectives** 

Upon completion of this activity, you should be able to process patient samples by profiles and ratios.

**ALCYON Operations Manual ALCYON Quick Reference Guide** 

**Activity** 



Follow the exercise to complete the steps for selecting and running profiles or ratios.

# **Exercise**

## **Test Entry for Profiles and Ratios**

| Perform the f | following exercise using:           |
|---------------|-------------------------------------|
|               | <b>ALYCON Operations Manual</b>     |
|               | <b>ALCYON Quick Reference Guide</b> |

Order and run the following:

| ID     | Name     | Profiles / Ratios* |
|--------|----------|--------------------|
| 123456 | Jill Ann |                    |
|        |          |                    |
| 234567 | Jennifer |                    |
|        |          |                    |
| 345678 | Sam      |                    |
|        |          |                    |
| 456789 | Allison  |                    |
|        |          |                    |
| 567890 | Patrick  |                    |

<sup>\*</sup>Instructor defined

## **Activity 2-5: Reviewing Patient Sample Results**

### **Purpose**

To locate Complete Files and Incomplete Files after results are generated.

#### **Objectives**

Upon completion of this activity, you should be able to:

- Search for Complete Files and Incomplete Files results.
- Process Incomplete Files (files which require Operator intervention to fully process).
- Review or print Complete Files results.



ALCYON Operations Manual ALCYON Quick Reference Guide

#### Activity



Follow the steps described in **Reviewing Results** in *Section 5*, *Operating Instructions* of the **ALCYON Operations Manual** or *Reviewing Results* in the **ALCYON Quick Reference Guide**.

- 1. Perform a search for the patient results entered during Activity 2-3: Test Entry and Activity 2-4: Test Entry for Profiles and Ratios. Follow instruction provided in Searching for Individual Files in Section 5, Operating Instructions of the ALCYON Operations Manual or Reviewing Results in the ALCYON Quick Reference Guide.
- 2. Determine whether the results are in Complete Files or Incomplete Files, and complete the exercise.

## **Exercise**

## **Reviewing Patient Sample Results**

- If results are in Incomplete Files, determine the reason and write it below.
- If results are sent to Complete Files, review the results and write them below.

| Patient | Complete<br>Files | Incomplete<br>Files | Reason | Results |
|---------|-------------------|---------------------|--------|---------|
| 1111111 |                   |                     |        |         |
| 222222  |                   |                     |        |         |
| 3333333 |                   |                     |        |         |
| 444444  |                   |                     |        |         |
| 555555  |                   |                     |        |         |
| 6666666 |                   |                     |        |         |
| 123456  |                   |                     |        |         |
| 234567  |                   |                     |        |         |
| 345678  |                   |                     |        |         |
| 456789  |                   |                     |        |         |
| 567890  |                   |                     |        |         |

# **Activity 2-6: Theory**

### **Purpose**

To understand the chemistry types which can be run on the ALCYON Analyzer.

#### **Objectives**

Upon completion of this activity, you should be able to:

- Differentiate between the three chemistry types.
- Recognize a valid progress curve / graph.
- Recognize assay(s) from each chemistry type (optional).
- Define the error checks for each chemistry type (optional).
- Understand assay parameters associated with the error checks (optional).
- Configure assay parameters as needed (optional).



ALCYON Operations Manual
ALCYON Quick Reference Guide
ALCYON Reagent Application Manual

#### **Activity**



Refer to *Appendix A, ALCYON Chemistry Methods* of the **ALCYON Operations Manual**.

The steps for this activity are as follows:

- 1. Read information on each chemistry type.
- 2. Draw a graph representing each chemistry type.
- 3. Record the chemistry type for reagents used in *Activity 2-3*.
- 4. Record the error checks for each chemistry type.

# **Exercise**

## Theory

| <b>e</b> i | rform the following exercis                   | se using:  |
|------------|---|--|
|            |   | ALCYON Operations Manual                                   |
|            |   | ALCYON Quick Reference Guide                               |
|            |   | ALCYON Reagent Application Manual                          |
|            | In your own words, defindraw a graph of each: | e the three chemistry types run on the ALCYON Analyzer and |
|            | End-Point                                     |  |
|            |   |  |
|            |   |  |
|            |   |  |
|            |   |  |
|            | Zero-Order Kinetic (Kin 0                     | )  |
|            |   |  |
|            |   |  |
|            |   |  |
|            |   |  |
|            | First-Order Kinetic (Kin 1)                   |  |
|            |   |  |
|            |   |  |
|            |   |  |

2. Write the chemistry types for reagents used in *Activity 2-3* (optional).

(Hint: The chemistry type can be found in the ALCYON Reagent Application Manual.)

| Reagent Name | Chemistry Type |
|--------------|----------------|
|              |                |
|              |                |
|              |                |
|              |                |
|              |                |
|              |                |
|              |                |
|              |                |
|              |                |

| 3. | write the error of | checks for each | cnemistry an | ia the associate | ea parameter | (optional). |
|----|--------------------|-----------------|--------------|------------------|--------------|-------------|
|    | End-Point          |                 |              |                  |              |             |

| error check     |      |             |                   |  |
|-----------------|------|-------------|-------------------|--|
| parameter       |      |             |                   |  |
| Zero-Order Kir  | etic |             |                   |  |
| error check     |      |             | <br>              |  |
| parameter       |      |             | <br>              |  |
| First-Order Kin | etic |             |                   |  |
| error check     |      | · ————————— | <br>· <del></del> |  |
| parameter       |      |             |                   |  |

4. Edit the units, decimal, lower and higher normal values on the following assay(s) (optional):

\_\_\_\_\_\_

#### REMEMBER TO EDIT THE PARAMETERS BACK TO THE ORIGINAL VALUES!

## **Activity 2-7: Calibration**

#### **Purpose**

To calibrate the ALCYON Analyzer using Single-Point or Multi-Point calibration modes.

#### Objective

Upon completion of this activity, you should be able to:

- Configure calibrations.
- Distinguish between Single-Point and Multi-Point calibration modes.
- Run Single-Point and Multi-Point calibration modes.
- · Review the calibration report.



#### **ALCYON Operations Manual**

#### **ALCYON Quick Reference Guide**

Calibrator Package Insert (or values supplied by the instructor)

### **Activity**



Perform the following steps at the ALCYON Analyzer to run a calibration. Refer to *Section 6, Calibration Procedures* of the **ALCYON Operations Manual** or *Configuring Calibration* and *Running a Multi-Point Calibration* in the **ALCYON Quick Reference Guide**.

The steps for this activity are as follows:

- 1. Configure calibration.
  - a. Enter the calibrator name and lot number.

Calibrator package inserts provide data used to enter the calibrator name and lot number.

b. Enter calibration parameters.

Calibrator package inserts and the **ALCYON Reagent Application Manual** provide data used to enter calibration parameters.

2. Order and run a Multi-Point calibration.

Run a Multi-Point calibration on reagents used in *Activities 2-3* and *2-4*.

3. Review calibration results.

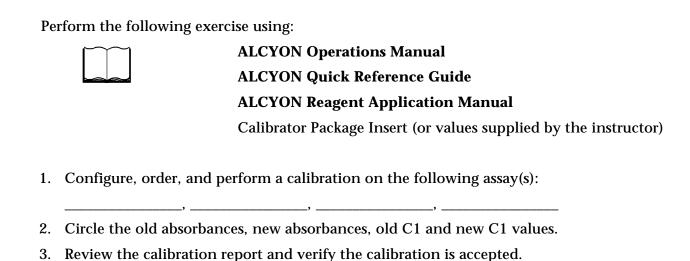
Refer to **Reviewing the Post-Calibration Report** in *Section 6, Calibration Procedures* of the **ALCYON Operations Manual** or *Reviewing Calibration Results* in the **ALCYON Quick Reference Guide** to confirm calibration criteria.



**NOTE:** To run a Single-Point calibration, refer to **Running a Single-Point Calibration** in *Section 6, Calibration Procedures* of the **ALCYON Operations Manual**.

## **Exercise**

#### **Calibration**



# **Activity 2-8: Controls**

### **Purpose**

To configure and run controls.

### **Objectives**

Upon completion of this activity, you should be able to:

- Configure control values.
- Order and process controls.
- Start a control run.



### **ALCYON Operations Manual**

**ALCYON Quick Reference Guide** 

Control Package Insert (or values supplied by the instructor)

### Activity



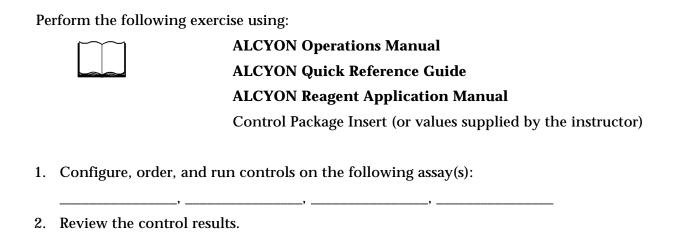
Perform the following steps at the ALCYON Analyzer. Refer to **Defining Control Values** and **Starting a Control Run** in Section 5, Operating Instructions of the ALCYON Operations Manual or Defining Control Values and Running Controls in the ALCYON Quick Reference Guide.

The steps for this activity are as follows:

- 1. Configure controls using the control package insert.
  - **NOTE:** The maximum number of control definitions that can be entered is 19.
- 2. Order and run controls. Run controls on reagents used in *Activities 2-3* and *2-4*.
- 3. Review the control results, reports, and graphs.

## **Exercise**

#### **Controls**



## **Activity 2-9: ISE Module**

### **Purpose**

To order ISE samples.

### **Objective**

Upon completion of this activity, you should be able to:

- Describe the theory / flow of the ISE system.
- Order and run patient samples, controls, and calibrators.
- Review patient, control, and calibration results.
- Configure ISE parameters (optional).



ALCYON Operations Manual
ALCYON Quick Reference Guide
ALCYON Reagent Application Manual

#### **Activity**



Refer to Section 3, Principles of Operation of the ALCYON Operations Manual.

The steps for this activity are as follows:

- 1. Read **ISE Theory of Operation**.
- 2. Order and run calibration, controls, and patient samples.
- 3. Review the calibration, controls, and patient results.
- 4. Configure ISE parameters (optional).

## **Exercise**

#### **ISE**

Perform the following exercise using:

- ALCYON Operations Manual
  ALCYON Quick Reference Guide
  ALCYON Reagent Application Manual
- 1. Read ISE Theory of Operation.
- 2. Refer to the ISE fluid flow diagrams on the following pages.
- 3. Configure, order, and run an ISE calibration.
- 4. Order and run controls for the ISE, referring to the ALCYON Quick Reference Guide.
- 5. Order and run Na<sup>+</sup>, K<sup>+</sup>, and Cl<sup>-</sup> on the patients in *Activity 2-4*.

#### Create a new file with the same sample ID.

| ID     | Name     | ISE (Na <sup>+</sup> , K <sup>+</sup> , Cl <sup>-</sup> ) |
|--------|----------|---|
| 123456 | Jill Ann |   |
|        |          |   |
| 234567 | Jennifer |   |
|        |          |   |
| 345678 | Sam      |   |
|        |          |   |
| 456789 | Allison  |   |
|        |          |   |
| 567890 | Patrick  |   |

6. Review the calibration, controls, and patient results. Complete the following information for the patient samples.

| Patient | Complete<br>Files | Incomplete<br>Files | Reason | Results |
|---------|-------------------|---------------------|--------|---------|
| 123456  |                   |                     |        |         |
| 234567  |                   |                     |        |         |
| 345678  |                   |                     |        |         |
| 456789  |                   |                     |        |         |
| 567890  |                   |                     |        |         |

7. Edit the units, decimal, lower, and higher normal values on  $Na^+$ ,  $K^+$ , and  $Cl^-$  (optional).

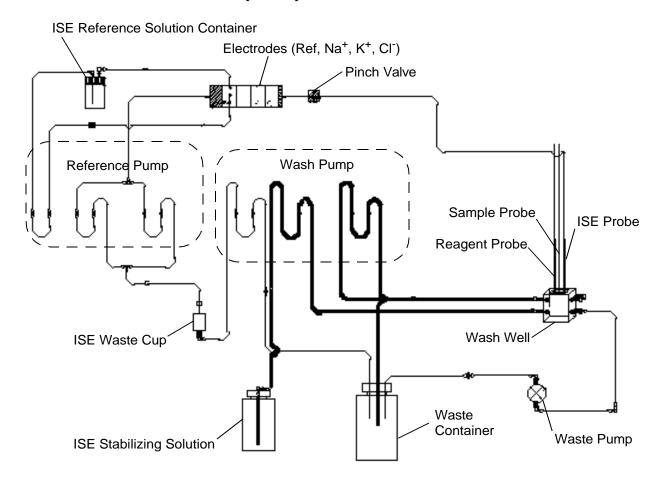
REMEMBER TO EDIT THE PARAMETERS BACK TO THE ORIGINAL VALUES!

## **Refer to the ISE Fluid Flow Diagrams**

### ISE Flow of Sample Through the System

#### Stage 1:

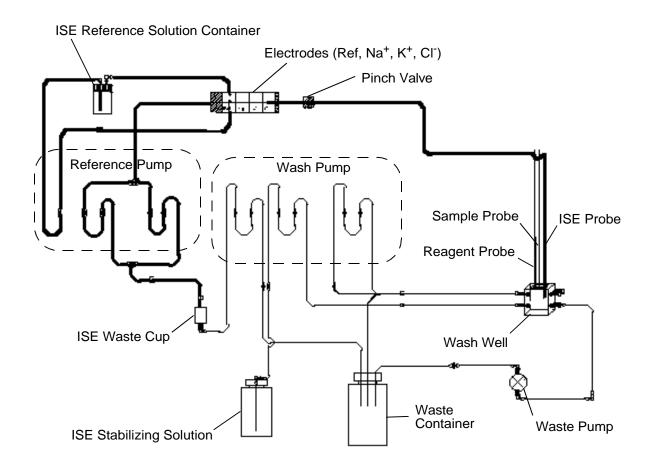
The wash pump begins, the ISE stabilizing solution fills the wash well, and the ISE waste cup is emptied.



Cycle 1: The reagent probe dispenses 300  $\mu L$  ISE sample diluent into a cuvette.

#### Stage 2:

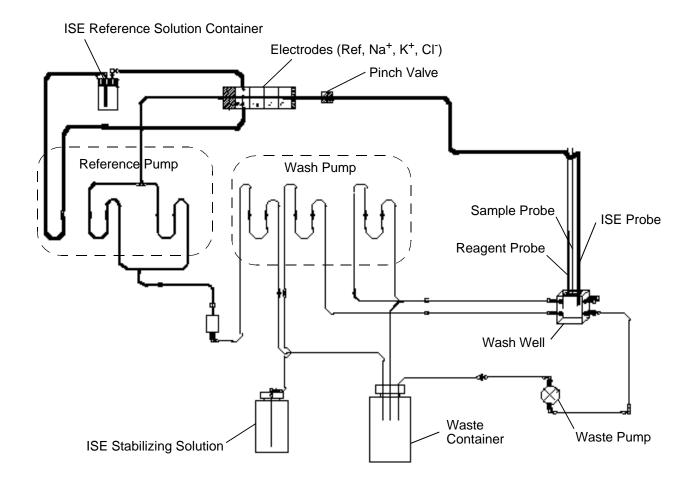
The reference pump begins and the ISE stabilizing solution flows through the ISE fluid path. At the same time the ISE reference solution is aspirated through the reference electrode housing and continually recirculates back to the ISE reference solution container. This action keeps the ISE reference solution in the reference electrode in contact with the fluid path and ensures fresh ISE reference solution on every transfer.



Cycle 2: ISE stabilizing solution is pulled through the ISE probe and transferred to the electrodes. The sample probe aspirates and dispenses 30  $\mu$ L sample into the same cuvette as the ISE sample diluent, resulting in a 1:11 dilution. The solution is mixed.

## Stage 3:

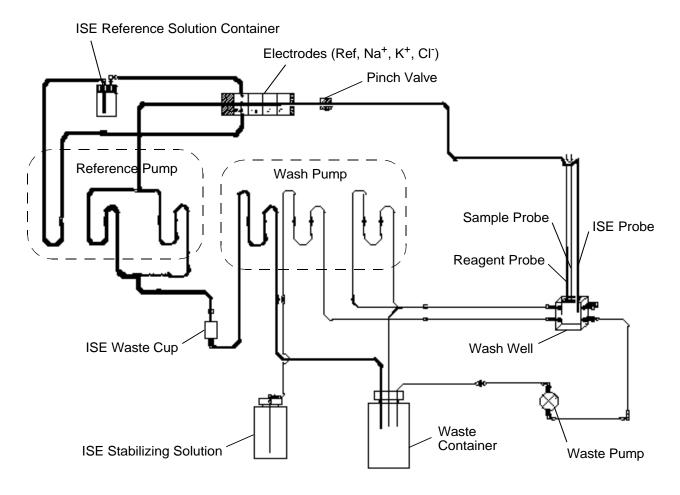
The reference pump begins and the ISE reference solution is circulated through the reference electrode housing.



**Cycle 3:** The reference pump pulls the diluted sample through the ISE probe and into the electrodes.

## Stage 4:

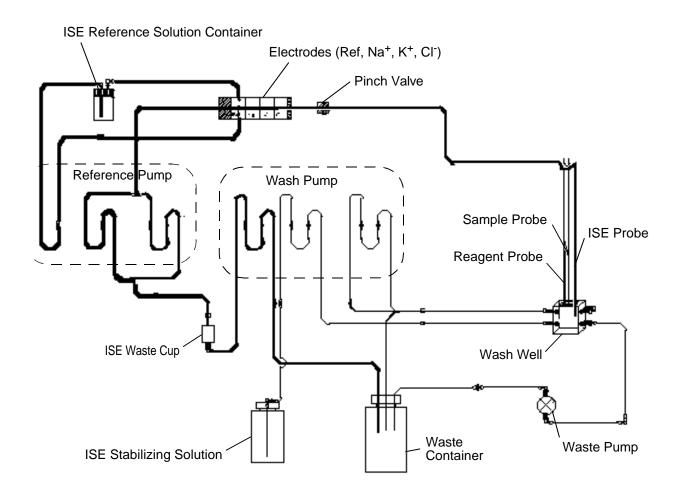
The ALCYON Analyzer aspirates approximately 150  $\mu$ L ISE stabilizing solution following the sample transfer to ensure the diluted sample is transferred inside the ISE electrode train. Sample measurement on each electrode begins.



**Cycle 4:** The reference pump pulls stabilizing solution from the wash well through the ISE probe and measures the diluted sample.

#### Stage 5:

The ISE stabilizing solution is transferred through the ISE electrodes and a measurement is taken on the wash solution.



**Cycle 5:** The ISE stabilizing solution is pulled from the wash well by the reference pump through the ISE probe. This cycle rinses the ISE electrodes and measures the ISE stabilizing solution.

# **Module 2 Review Questions**

| When ordering tests, why would the character "*" appear after the chemistry na                     |
|--|
| What is the maximum number of samples that can be processed at one time?                           |
| What activity should be performed prior to daily maintenance, and periodically throughout the day? |
| List three reasons why a patient test file may be labeled Incomplete Files.                        |
| How long are Complete Files held until they are archived?  |
| How many chemistry types can be run on the Analyzer?   |
| What are the names of the chemistry types?   |
| What types of calibration can be performed on the Analyzer?  |
| Does the ISE module use direct or indirect potentiometric analysis?                                |
| What is the dilution ratio of an ISE sample?   |

Module 3 System Management

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# **Objectives**

Upon completion of these activities, you should be able to:

- 1. Perform and document basic maintenance procedures.
- 2. Perform troubleshooting procedures.
- 3. Determine the cause of an error.
- 4. Perform appropriate corrective action for the error.
- 5. Configure site-specific System settings.
- 6. Observe Host interface demonstration (optional).
- 7. Perform System verification (optional).

#### **New Vocabulary Words**

- Bidirectional mode
- Stylet

### **Completion Time**



2 to 2-1/2 hours

## **Activity 3-1: Analyzer Maintenance**

#### **Purpose**

To learn maintenance procedures for the ALCYON Analyzer.

#### **Objectives**

Upon completion of this activity, you should be able to:

- Perform maintenance procedures on the ALCYON Analyzer.
- Document all maintenance procedures in the ALCYON Maintenance Log.

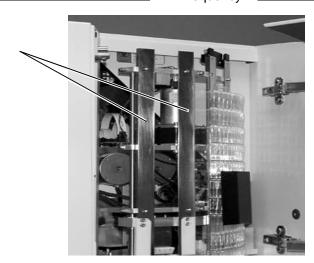
Refer to Section 9, Service and Maintenance of the ALCYON Operations Manual and the ALCYON Maintenance Log.

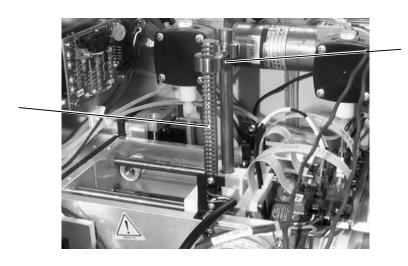
# Activity



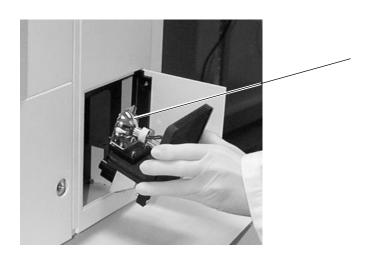
Perform the following steps at the ALCYON Analyzer.

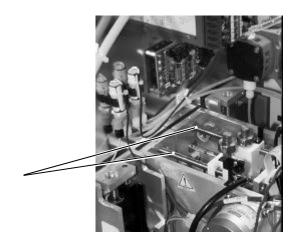
- 1. Read Section 9, Service and Maintenance of the ALCYON Operations Manual.
- 2. Perform each maintenance procedure described in *Section 9, Service and Maintenance,* while identifying the corresponding components on the Analyzer for daily maintenance. Weekly, Biweekly, Monthly, and As Needed Procedures may be performed as time permits.
- 3. Document all maintenance performed in the **ALCYON Maintenance Log**.
- 4. Identify the parts noted in the following pictures. List the maintenance frequency required for the part.

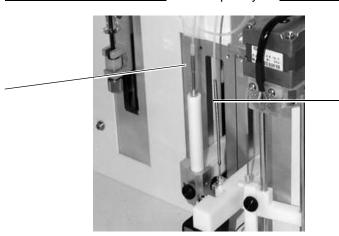


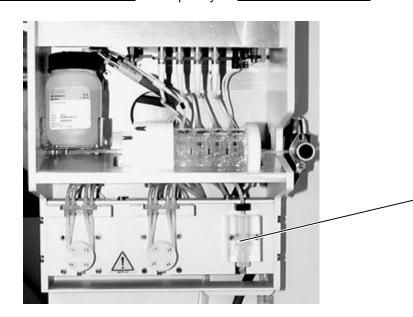












## **Activity 3-2: Troubleshooting**

#### **Purpose**

To identify and resolve alarms and error messages displayed by the ALCYON Analyzer.

#### **Objectives**

Upon completion of this activity, you should be able to:

- · Identify errors.
- Determine the cause of an error.
- Perform appropriate corrective action (for example, change reagents when expired).
- Verify resolution (for example, no error occurred after repeating the test).



#### **ALCYON Operations Manual**

#### **ALCYON Reagent Application Manual**

### **Activity**



Refer to *Section 10, Troubleshooting and Diagnostics* of the **ALCYON Operations Manual** to complete the case studies. Review the alarm or error code, significance of the alarm or error code, and necessary procedures to correct the error.

The steps for this activity are as follows:

- 1. Review the alarm or error code.
- 2. Locate the alarm or error code in *Section 10*, *Troubleshooting and Diagnostics* of the **ALCYON Operations Manual**.
- 3. Determine the appropriate corrective action to resolve the alarm or error code.
- 4. Resolve the error.

### Case Study

The purpose of the following case studies is to simulate a troubleshooting situation you may encounter in your laboratory.

## Case Study 1:

You programmed the following tests on Patient D: ALB, T PROT, CREAT, Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>. While reviewing the report you noticed two tests run on Patient D had error codes.

| 1.  | Will the patient results be found in Complete Files or Incomplete Files? Why?                                   |  |  |  |  |  |
|-----|---|--|--|--|--|--|
| 2.  | Did the patient results transmit to the Host computer?  |  |  |  |  |  |
| 3.  | The error code generated on ALB is RBL and the error code on T PROT is LOR. What do these error codes indicate? |  |  |  |  |  |
| Dat | a   |  |  |  |  |  |
|     | umin has been on the Analyzer for two days uncapped. It not used since placement on the Analyzer.               |  |  |  |  |  |
|     | al Protein has been on the Analyzer for two weeks. It is used by day, throughout the day.                       |  |  |  |  |  |
|     | Operator is new and failed to check anything prior to ning the sample.  |  |  |  |  |  |
| 4.  | What is the most likely cause for receiving the LOR error on T PROT?  |  |  |  |  |  |
| 5.  | What corrective action would you recommend for Albumin? Why?  |  |  |  |  |  |

#### Case Study 2:

Controls were run at the beginning of the day for all chemistries on the current carousel. The printed value for control X is 0.7. The printed value for control Y is 7.5.

#### **Data**

The control range entered in the Analyzer for control X is 0.8 - 1.3. The control range entered in the Analyzer for control Y is 4.8 - 7.1. The chemistry has not been calibrated for three weeks.

| 1. | Are the controls acceptable?                |
|----|---|
| 2. | What error code is generated on the report? |
| 3. | What corrective action should be performed? |
|    |   |

#### Case Study 3:

You have tried to calibrate Albumin twice with the following results.

Detailed absorbance results for each cuvette:

| Calibrator | Lot   | Old abs | abso<br>No. 1 | abso<br>No. 2 | abso<br>No. 3 |
|------------|-------|---------|---------------|---------------|---------------|
| MCC1       | 23879 | 0.0069  | 0.0069        | 0.0067        | 0.0069        |
| MCC2       | 23879 | 0.0158  | 0.0072        | 0.0071        | 0.0074        |
| MCC3       | 23879 | 0.0135  | 0.1761        | 0.0077        | 0.0095        |

Detailed absorbance results for each cuvette:

| Calibrator | Lot   | Old abs | abso<br>No. 1 | abso<br>No. 2 | abso<br>No. 3 |
|------------|-------|---------|---------------|---------------|---------------|
| MCC1       | 23879 | 0.0069  | 0.0085        | 0.0122        | 0.0091        |
| MCC2       | 23879 | 0.0158  | 0.0080        | 0.0181        | 0.0608        |
| MCC3       | 23879 | 0.0135  | 0.1020        | DIV           | 0.0938        |

From the above results, it appears:

- There is not an increase in absorbances for abso No. 1, abso No. 2, and abso No. 3.
- · There is very little reaction occurring.

#### **Data**

The sample probe was replaced yesterday.

The cuvettes were removed from the Analyzer to:

- Check the reaction volume of the chemistry in question (dispensing).
- Check for color consistency throughout the cuvette (mixing).

Examination of the cuvettes revealed the reaction color was not consistent throughout the cuvette.

What is the most likely cause of improper mixture of the reaction?

## **Activity 3-3: Analyzer Repair**

#### **Purpose**

To become familiar with replacement of malfunctioning / broken components.

### **Objectives**

Upon completion of this activity, you should be able to:

- Replace ALCYON Analyzer components when necessary.
- Verify component replacement was performed correctly.
- Document component replacement in the ALCYON Maintenance Log.



### **ALCYON Operations Manual**

#### Activity



### 1. Case Study 1:

You determine that improper installation of the sample probe caused the error in Case Study 3 of Activity 3-2: Troubleshooting.

Perform the corrective action (proper installation of the sample probe) to resolve the error in the preceding case study.

### 2. Case Study 2:

You initiate a run and the error message "Lamp Out" scrolls across the top of the screen.

- a. What corrective action should you perform to correct
- b. After changing the lamp, you still receive the same error. What should you do?
- 3. Remove and replace or reinstall all components on the Analyzer.
- 4. Perform the following exercise to verify components were installed correctly.

## **Exercise**

### **Analyzer Repair**

| Perform the following exercise using: |                          |   |  |  |  |
|---------------------------------------|--------------------------|---|--|--|--|
|                                       |                          | ALCYON Operations Manual  |  |  |  |
|                                       |                          | ALCYON Quick Reference Guide                                    |  |  |  |
| 1.                                    | Run controls on the foll | owing assay(s):   |  |  |  |
| 2.                                    | Review the control resul | ts. You may need to calibrate if the controls are out of range. |  |  |  |
|                                       |                          | Refer to Optional Calibration in Section 6, Calibration         |  |  |  |
|                                       |                          | Procedures of the ALCYON Operations Manual or Running a         |  |  |  |
|                                       |                          | Multi-Point Calibration in the ALCYON Quick Reference           |  |  |  |

Guide.

## **Activity 3-4: System Configuration**

### **Purpose**

To configure the ALCYON Analyzer with specific information necessary to meet laboratory requirements.

### **Objectives**

Upon completion of this activity, you should be able to:

- Configure Analyzer options and settings to meet laboratory requirements.
- Edit the options and settings as needed.

### **ALCYON Operations Manual**

# Activity



Refer to **Configuring the System** in *Section 2, Installation*Procedures and Special Requirements of the **ALCYON Operations**Manual.



**NOTE:** You may edit the options and settings to your laboratory's specific requirements instead of completing the activity.

- 1. Edit System settings as follows:
  - Audible alarm: (No)

• Date format: (Specific to the location)

Date: (Current date)Time: (Current time)

Beep when all tests are finished: (Yes)

- 2. Edit print options as follows:
  - Form feed after each report: (Yes)
- 3. Edit the patient order as follows:
  - Doctor field active: (No)

## **Activity 3-5: Host Demonstration (Optional)**

**Purpose** 

To demonstrate sample processing when the ALCYON

Analyzer is linked to a Host computer.

**Objectives** 

Upon completion of this activity, you should be able to

process samples when linked to a Host computer.

**ALCYON Operations Manual** 

**ALCYON Host Interface Specifications** 

**Activity** 

Watch the Host interface demonstration performed by the instructor.

## **Activity 3-6: System Verification (Optional)**

### **Purpose**

To verify System performance.

### **Objectives**

Upon completion of this activity, you should be able to:

- Verify performance of the ALCYON Analyzer.
- Perform precision studies.

### **ALCYON Operations Manual**

**ALCYON Quick Reference Guide** 

### **Activity**



Refer to **Defining Control Values** and **Starting a Control Run** in *Section 5, Operating Instructions* of the **ALCYON Operations Manual,** or *Defining Control Values* and *Running Controls* in the **ALCYON Quick Reference Guide.** 

- 1. Determine the chemistry(ies) that will be used to verify performance.
- 2. Configure chemistry(ies) as controls on the available control list (1 19). (*i.e.*, ALB, GLU, or T PROT as PrecALB, PrecGLU, or PrecTPROT.)
- 3. Configure the low, high, and validation to: 0, 999, and 99% to prevent COL error messages.
- 4. Initiate the performance run with 18 aspirations selected.
- 5. Review the **Control** / **Results** screen for the appropriate controls (*i.e.*, PrecALB, PrecGLU, or PrecTPROT).
- Compare the mean, SD, and %CV to the assay-specific ALCYON Reagent Application Sheet for the individual chemistry at the correct control level.



NOTE: The run is performed using the Controls Menu screen so the Analyzer automatically calculates the mean, SD, and %CV.

## **Module 3 Review Questions**

Write your answers in the spaces provided.

| 1.         | Complete Files, which have been stored for three days, are automatically transferred to Archive Files status. What function, when performed, causes this to occur? |
|------------|--|
| 2.         | List the two reasons a control is labeled "Out of Limit".  |
| 3.         | What two things occur when a control is "Out of Limit"?  |
| <b>l</b> . | List the two major classifications of error messages or flags displayed by the ALCYON Analyzer.  |
| ó.         | To assist the Abbott Service Representative with diagnosing Analyzer problems, what three steps should the Operator perform?                                       |
|            |  |

Glossary

## **NOTES**

# Glossary

**Absorbance** Measurement of the optical density of a liquid determined by

spectrophotometric analysis.

**Accessory** Items that are used repeatedly (e.g., tubing, ISE electrodes,

adapters).

**Analyte** A substance undergoing analysis.

**Analyzer Initialization** Occurs when Analyzer is powered on; boot-up sequence.

**Archive Files** Complete Files which are more than three days old (per

calendar). Only results view is possible.

**Arrow Keys** Keys used to move the cursor.

**Aspirate** Physical action of drawing or removing liquid by suction.

**Assay** Analysis to determine the presence, absence, or quantity of

one or more analytes.

**Assay Calibration** The generation of a standard curve for use in determining

concentration of an analyte present in patient samples.

**Assay Configuration** File containing the settings used to perform an assay.

**Assay Parameter** A term that defines specific characteristics or verifies the

performance of an assay.

**Assay Type** Defines when reagents are dispensed, when readings are taken,

and the equation used to calculate results.

**Automated Cuvette** 

**Management Center** Consists of the reaction cuvettes and the automatic cuvette

load / unload module (holds 11 segments of reaction cuvettes). Automatically alerts the Operator (by audible alarm) when

cuvettes need to be added or removed.

**Batch Mode** Processing mode that allows all same type assays to be

processed together in sequential order.

**Batch Order** Order multiple samples with identical assay requests.

**Baud** Unit for measuring the speed of data transmission.

**Baud Rate** Rate of speed in data transmission.

**Bichromatic Measurement** Spectrophotometry that subtracts a secondary wavelength

absorbance reading from a primary wavelength absorbance

reading to obtain a delta absorbance reading.

**Bidirectional Mode** Operating mode used when the ALCYON Analyzer / Host

computer connection is initialized from the Host computer. Orders are downloaded to the Analyzer and results are

uploaded to the Host computer.

**Biohazard** An activity or area where the Operator may be exposed to

potentially infectious materials or substances.

**Biohazardous** Pertaining to biohazards.

**Biosafety** The practices, techniques, and safety equipment used to

reduce the risk of exposure to potentially infectious materials

and substances.

Bit Binary digit.

**Blank** Method used for correcting interferences.

**Calibration** Result of calibrating an instrument or assay.

**Calibration Curve** Defined in the ALCYON Analyzer when a group of samples

with known analyte concentrations (calibrators) are assayed and the measured absorbance is plotted against the known concentrations. When a control or sample is assayed, the software calculates the value of the control or sample from the

stored calibration curve for the analyte. Consists of Multi-Point calibration and main calibrations.

**Capacitance Level Detector** Determines liquid levels when sampling reagents and samples

to avoid the probe hitting the bottom of the reagent container,

sample tube, or cup.

**Carousel** A circular conveyor on which objects are placed.

**Caution** Denotes potential hazards that could result in minor injury.

Also used for conditions or activities that could interfere with

proper functioning or performance of the Analyzer.

**CE (CE Marking)** Meets applicable New Approach directives of the European

Union.

**Coefficients** The results of the calibration calculations for a given assay

(including slope, intercept, correlation coefficient, etc.).

**Complete Files** Results that are held for three days then transferred to Archive

Files. The transfer occurs automatically when the Analyzer is

initialized.

**Computer** Refers to 486 compatible computer with floppy disk drive and

RS-232 port built into the ALCYON Analyzer.

**Consumable** Items that are exhausted in the process of running tests

(e.g., ISE diluent solution, printer ribbon, reaction cuvettes,

sample cups); also called a "disposable".

**Correlation Limit** The difference between the true absorbance value read and the

theoretical ones found with the chosen model.

**Conditioning Cycle (ISE)** Maintenance procedure for the ISE electrodes where Na<sup>+</sup>

conditioning solution is cycled through the electrodes.

**Configuration** Editable software settings that provide the Analyzer with

information needed to meet a site's specific requirements.

**Cursor** A manually controlled figure on a computer display that

indicates a character to be revised or a position where data are

to be entered: a pointer.

**Data** The results of completed assays and user input.

**Default Value** Value used, if no other is entered.

**Deferred Files** Files that are created for tests held for future processing.

**Diagnostics and Troubleshooting** 

Provides methods for identifying and responding to error

codes and observed hardware and software problems.

**Digit** Number symbol, 0 through 9.

**Dilution for Urine** The dilution factor used for testing urine samples.

**Dispense** Delivery of a volume of reagent, sample, or diluent.

**Display Screen** Monitor.

**Disposable** Items that should be disposed of after use.

**Doctor (Field)** Software field for a physician's name.

**End-Point Reaction** Chemistry reaction that reaches equilibrium in a short period

of time and is read once the reaction in the cell has been

exhausted.

**Error Code** A number linked to a specific error message. An Operator

should use the error code when referencing the corresponding error message in *Section 10, Troubleshooting and Diagnostics*.

**Extinction Factor** Bichromatic absorbance change per unit of concentration

change of chromophore. This factor is specifically determined

for a wavelength pair and derived from linearity tests performed during the manufacture of the instrument.

Flag Symbol appended to a sample result that draws attention to a

particular characteristic of the result.

**First-Order Kinetic** Chemistry reaction that slowly reaches an End-Point. This

type of chemistry reaction can also be used in certain circumstances to incorporate a sample blank into End-Point chemistries. This type of assay minimizes the amount of

interference seen.

**Function Key** Key assigned to perform special functions within a program.

**Gauge** Senses the level of water in the water and waste containers.

Hard Drive A data storage system which contains the ALCYON Analyzer

operating software.

**Hardware** Physical components of the Analyzer.

**Hazardous Waste** Waste material presenting danger to the environment or to

humans.

**Hazards** Situations that could cause physical harm to a user or damage

to the Analyzer or laboratory environment.

**Host** An auxiliary computer system that can communicate back and

forth with the Analyzer.

**Hydraulic Circuit** The liquid circulatory system of the Analyzer; includes: probes,

tubing, pumps, and reagent / solution / water storage

containers.

**Incomplete Files** Files that require Operator intervention to determine whether

to retest, set dilution, modify the file manually, or validate

manually.

**Interfacing** Connecting the ALCYON Analyzer to a Host computer via an

RS-232 connection. Uses either bidirectional mode or unidirectional mode for initialization of the ALCYON

Analyzer.

**Ion-Selective Electrode** 

(ISE) Module Consists of: peristaltic pumps, electrodes, and pinch valve.

Positioned on the back wall of the ALCYON Analyzer. Used for

the determination of Na<sup>+</sup>, K<sup>+</sup>, and Cl<sup>-</sup> by indirect

potentiometry.

**Ion-Selective Electrode** 

(ISE) Technology Method using an ion-specific membrane, to develop an

electrical potential according to the Nernst equation.

**ISE** Ion-Selective Electrode.

**ISE Cleaning Solution** Weak detergent and buffer solution used weekly for cleaning.

**ISE Deproteinizer Solution** Bleach / water solution used during deproteinizing cycle.

**ISE Sample Diluent** Ionic buffer used to dilute the sample prior to running ISE

tests.

**ISE Reference Electrode Housing** 

The plastic portion of the Analyzer that holds the reference electrode, and includes the "channel" for the solution flow.

**ISE Maintenance Solutions** Consists of ISE deproteinizer solution, ISE Na<sup>+</sup> conditioning

solution, and ISE cleaning solution (used with the ISE

module).

ISE Na Conditioning Solution Ammonium bifluoride solution used during the conditioning

cycle.

**ISE Probe** Probe nearest the front of the Analyzer with an ISE module.

Aspirates sample and ISE stabilizing solution during utilization

of the ISE module.

**ISE Reference Electrode** 

**Shipping Cup** 

Protective cup that covers the sensing end of the reference electrode; used for shipping the reference electrode; also used

for storage of the electrode between uses.

**ISE Reference Solution** 

**Container** 

Contains the ISE reference solution in the ISE module; the

closure is called a cap.

**ISE Reference Solution** Potassium chloride solution used to keep the reference

electrode moist.

**ISE Stabilizing Solution** Buffer solution, run between each sample to keep the

electrodes in optimal condition. Aspirated from the washing

well.

**Keyboard** Used to access all the functions of the Analyzer.

**Limits, Dilution And Rerun** Causes the ALCYON Analyzer to automatically dilute or rerun

a sample which exceeds the specified limit. The result of the dilution or rerun is compared to the original result using a

determined confirmation percentage for validity.

**Linear High** Value above the stated linearity claim.

**Linear Low** Value below the stated linearity claim.

Laboratory Information System. A Host interface software

supplied and serviced by an ALCYON Analyzer user's third

party vendor.

**Lot** A distinguishable preparation of a reagent or commodity.

Maintenance Procedures performed daily, weekly, biweekly, monthly, and as

required, that keep the ALCYON Analyzer clean and running

at optimum condition.

**Maintenance**, **As Needed** As needed maintenance includes the following procedures:

probe replacement, printer ribbon replacement, sample syringe and valve tubing replacement, ISE reference electrode housing replacement, ISE electrode replacement, ISE probe replacement, lamp replacement, and O-ring replacement.

Maintenance, Biweekly ISE modules only: Clean reference electrode housing with

bleach (either household bleach or ISE deproteinizer solution

is acceptable).

Maintenance, Daily Daily maintenance includes the following procedures: probe

priming / washing, ISE offset check / adjust, ISE calibration,

ISE conditioning cycle, and ISE deproteinizing cycle.

**Maintenance, Monthly** Monthly maintenance includes the following procedures:

syringe and piston maintenance, probe drive rack cleaning, syringe drive screw cleaning, wash hydraulic circuit, and ISE

peristaltic pump tubing replacement.

Maintenance, Weekly Weekly maintenance includes the following procedures: water

container cleaning, automatic cuvette load / unload module optical sensor and guide rail cleaning, and ISE Cl<sup>-</sup> electrode

cleaning.

**Manual Entry** Use of the keyboard to enter data, such as sample ID.

**Modem** A device which allows for remote access to the Analyzer for

diagnostic purposes.

**Modes for Entering Tests** Routine entry mode: tests are entered at the Analyzer by the

Operator; Host interface mode: the Analyzer is connected to a Host computer for entering tests; STAT entry mode: when the

test results are required ASAP.

Multiparametric Multiple operative parameters available; 83 assay parameters

and 10 ratios; 3 ISE parameters and 10 diluents.

**Multi-Point Calibration** The calibration method used to calibrate a chemistry using

multiple calibration points.

**Numeric Key** Labeled from 0 to 9, used to enter numeric data.

**Operating Instructions** A step-by-step guide to daily operations of the ALCYON

Analyzer.

**Operational Precautions** 

and Limitations Conditions that can affect performance including,

environmental requirements, precautions, and limitations for the Analyzer and its components (e.g., electrical line voltage

surges, ambient temperature).

Operator ID An alphanumeric set of characters that specifically identifies

an Operator.

**Optical Detector** Detects whether a tube or a cup has been placed in the Sample

Carousel.

Optical System Consists of a static photometer (with six individual filter

positions) and a tungsten-halogen lamp. Each filter position

contains a specific filter and A/D converter.

O-Ring Rubber washer or ring used to seal a connection.

**%CV** Coefficient of variation, a calculation used to measure

reproducibility / precision.

Panel A group of tests.

**Parity** Method of checking whether binary numbers or characters are

correct by counting ONE bits.

Password Special code needed to access to certain functions or

procedures.

**Patient Identification Number** 

Number assigned to the patient for tracking purposes.

**Performance Characteristics** 

and Specifications The general physical, electrical, data communication, reader,

and processing specifications of the ALCYON Analyzer.

**Pipetting** The process of transferring liquid.

Pipetting System Consists of two separate systems; sample system (50 µL syringe

and sample probe) and reagent system (500  $\mu L$  syringe and reagent probe). Also includes: the reagent preheater and capacitance level detectors for both the sample and reagent

probes.

**Ports** Located on the back of the Analyzer; include inlets and outlets

for cables and tubing (sensor, printer, system, modem) and

supplies (water, reagents, waste).

**Press** A term used to instruct the Operator to use the keyboard for

input.

**Primary Tube** Tubes (93 - 120 mm in height) used when performing

venipuncture; may vary in size and may contain

anticoagulants.

**Principles of Operation** A brief explanation of the ALCYON Analyzer operational

theory, ISE theory, and an overview of the software.

**Printer** Provides a hard copy of data or test results, patient reports,

calibration, quality control, and maintenance procedures.

A hollow, stainless steel Teflon®-coated tube used to transport **Probe** 

sample, reagent, and reaction mixtures.

**Probe Wash Wells** Wells where the probes are washed inside and out with

distilled or deionized water.

**Processing Center** Consists of reaction cuvette temperature control, optical

system, and reaction carousel.

**Profile** A group of tests to be run together on a sample. Profiles can be

defined by the Operator.

**Purge** To rid the Analyzer or tubing of excess air or fluid.

Random Mode Processing mode in which tests are run by patient order.

**Random-Access** The capability to process tests in a random manner,

independent of the assay requested and dependent on the

sample status.

**Raw Absorbance** Absorbance measurements (data from the last 108 chemistries

are accessible).

**Reaction Chamber Temperature Display** 

Located on the inside wall of the Analyzer displaying the

reaction chamber temperature.

**Reaction Cuvette** The commodity in which the reaction occurs and through

which the absorbance read is taken. The movement of the cuvette is called "advancing". Reaction cuvettes are disposable segments of the reaction carousel, a segment has 12 reaction cuvettes and a carousel holds up to eight segments. Reaction cuvette pathlength =  $0.5 \, \text{cm}$ . Reaction cuvettes are held in place with guide rails in the automatic cuvette load / unload

module.

Reaction Cuvette

**Temperature Control** Programmable air bath regulated by using the control located

on the central wall of the ALCYON Analyzer.

**Reagent Carousel** The inner segments of sample / reagent center, consists of

15 cooled positions (gray) and nine ambient temperature

positions (white).

**Reagent Preheater** Built into the reagent pipetting system, ensures reagents are

dispensed at the approximate incubation temperature.

**Reagent Probe** A hollow, stainless steel Teflon<sup>®</sup>-coated tube used for

dispensing reagents and diluents.

**Reagent Syringe** Used to aspirate the reagent for dispensing; 500 μL.

**Reflex Test** Configuration option that uses Operator defined calculations

to automatically retest the original test(s) ordered and/or automatically run different test(s) based on the results of the

original test.

**Replicates** The number of times a sample, control, or calibrator is tested

by the Analyzer.

**Run Key** Green key located on the upper-right corner of the keyboard;

used to initiate an Analyzer run.

**Safety Glasses** Shatter-resistant eye protection worn in the laboratory.

**Safety Procedure** Course of action for the safety of persons and equipment.

**Sample** A patient specimen used for testing.

**Sample Carousel** The outer ring of sample / reagent center, consists of

39 universal positions.

Sample Cup Small, disposable plastic cup that holds sample, calibrators, or

controls.

**Sample Diluent** Solution used to dilute sample.

Sample Identification Number

Number used to identify a patient sample.

Sample Probe A hollow, stainless steel Teflon®-coated tube used to transport

patient samples or controls.

**Sample Syringe** Used to aspirate the sample for dispensing; 50 μL.

**Sample Tube** Glass tube closed at one end, used to collect and hold patient

samples.

Sample Volume of sample dispensed.

**Sampling** Process which combines sample and reagents for one assay;

occurs in the sampling center.

**Sampling Center** Area of the Analyzer where the user loads samples, controls,

calibrators, and reagents.

**Sampling / Reagent Center** Consists of the Sample and Reagent Carousels.

**Segment** One cuvette segment is comprised of a group of 12 reaction

cells.

Serum Clear yellowish fluid obtained upon separating whole blood

into its solid and liquid components.

**Service And Maintenance** Details the scheduled and non-scheduled maintenance of the

ALCYON Analyzer including decontamination, cleaning,

adjustments, verification, component replacement,

maintenance schedules, and logs.

**Shutdown** A process that allows the Analyzer to come to a controlled stop

before powering off.

**Single-Point Calibration** The calibration method used to calibrate one or several

chemistries with a single standard.

**Small Reagent Containers** Containers used for two reagent chemistries; 12 mL each side.

**Software** The entire set of programs, procedures, and related

documentation associated with the ALCYON Analyzer.

**STAT** A method for giving higher priority to a sample.

**STAT Tests** Tests in which results are required as soon as possible.

**Stop Bit** Bit transmitted after a specified string of characters.

**Stylet** Metal needle-like probe (used to clean the Cl<sup>-</sup> electrode).

**Supernatant** Liquid floating on top of another liquid or solid sediment or

precipitate.

**Syringe** Device used to aspirate and dispense liquids.

**System Control Center** Consists of computer, keyboard, printer, ports, power input,

and the Analyzer serial number.

**System Software** Logic that controls the Analyzer operation.

**Systematic Dilution** The dilution factor used for serum.

**Toggle** A function key with two functions. It switches from one to the

other when selected. For example, F3—STAT / Routine, on /

off, etc.

**Touch** A term used to instruct the Operator to use the touchscreen

monitor for input.

**Touchscreen** Screen that allows the user to make a selection by touching the

screen.

**Unidirectional Mode** Operating mode used when the ALCYON Analyzer / Host

computer connection is initialized from the Analyzer. Orders are manually entered on the Analyzer and results are uploaded

to the Host computer.

**Volume** Amount or content.

Warning Denotes a hazard which could result in moderate to serious

injury.

Warranty Period A period of one year, commencing twenty-one (21) days from

the date of shipment to the original purchaser, or until title is transferred from the original purchaser, whichever occurs first.

Wash Well in which the ISE probe, sample probe and reagent probe

are washed, inside and out, with distilled or deionized water.

**Waste Decontamination** Procedure used to disinfect waste.

**Water Container** Contains the Analyzer distilled or deionized water supply.

**Worklist** A list of pending tests.

**Worklist Mode** Routine entry of tests to be run later; used for: running one or

several files which were previously ordered, but deferred, running files which were transferred to the Worklist from

Incomplete Files.

**Zero-Order Kinetic** Chemistry reaction that measures the amount of change over

a specified time and is read while the reaction is taking place.

Not calibrated traditionally, utilizes a factor (from the

assay-specific **ALCYON Reagent Application Sheets**) entered in the software to establish calibration; usually enzyme assays.

## **NOTES**

**Appendix** 

## **NOTES**

# **Appendix**

### Reagents / Solutions

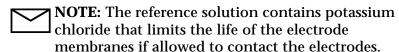
### Reagents

The ALCYON Analyzer is an open system, manufactured with general purpose features for use with secondary reagents.

### **ISE Analysis Solutions**

The ALCYON Analyzer with ISE module utilizes the following solutions when performing Na<sup>+</sup>, K<sup>+</sup>, and Cl<sup>-</sup> assays:

- **ISE stabilizing solution**—an aqueous solution containing specific amounts of sodium, potassium, and chloride ions aspirated between each sample to keep the electrodes moist and to ensure a proper baseline for measurement.
- **ISE sample diluent**—ionic buffer used to dilute the sample when running ISE tests.
- **ISE reference solution**—a potassium chloride solution used as electrolyte for the reference electrode.



#### **ISE Maintenance Solutions**

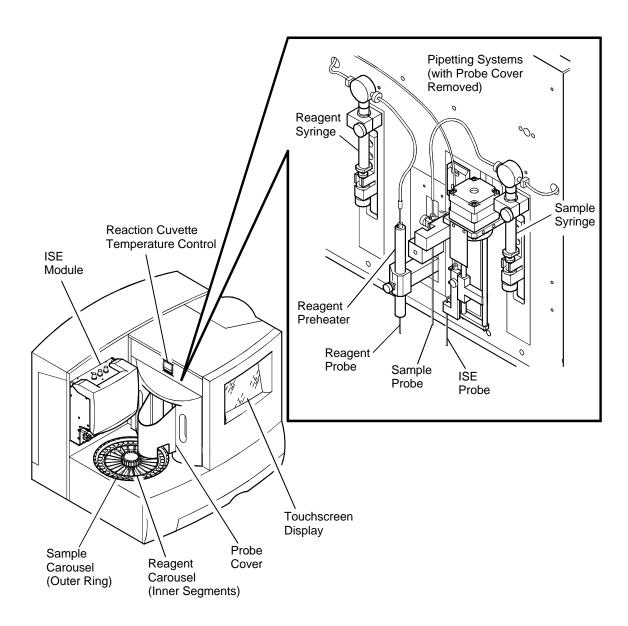
- **ISE deproteinizer solution**—bleach solution used for daily maintenance.
- **ISE Na**<sup>+</sup> **conditioning solution**—used for daily maintenance.
- ISE cleaning solution—weak detergent used weekly for cleaning.

## **NOTES**

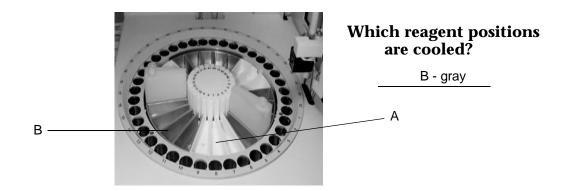
**ALCYON Basic Operator Training Manual Answer Key** 

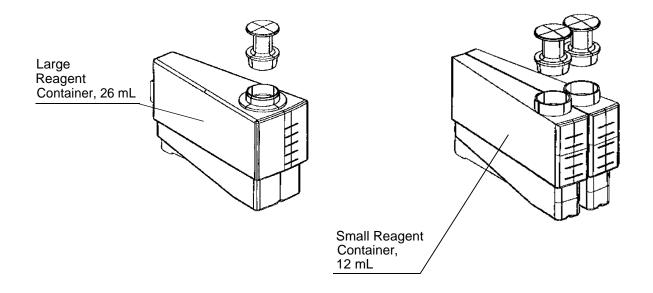
## **NOTES**

# **Identify the Indicated Components:**

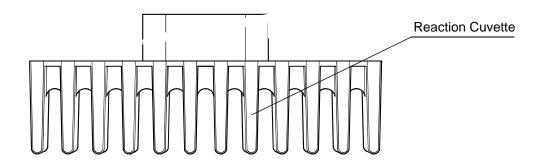


# **Identify the Indicated Components:**





# **Identify the Indicated Components:**





Reaction Cuvette Temperature Control

### **Module 1 Review Questions**

Write your answers in the spaces provided.

1. How many positions are available on the Sample Carousel?

39

2. What sizes and types of sample cups and tubes can the Sample Carousel accommodate?

| 5 mL tube  | 2 mL sample cup      |
|------------|----------------------|
| 7 mL tube  | 0.7 mL pediatric cup |
| 10 mL tube |                      |

3. How many of the following Reagent Carousel positions can be found on the ALCYON Analyzer?

| a. | Cooled positions  | 15 |
|----|-------------------|----|
| b. | Ambient positions | 9  |

4. Name the two pipetting systems housed on the ALCYON Analyzer.

Sample system
Reagent system

5. What is the average volume of distilled or deionized water used during one hour of normal continuous operation of the ALCYON Analyzer?

Between 3 - 4 liters

- 6. How many reaction cuvettes can the reaction carousel accommodate?8 segments with 12 cuvettes each
- 7. List the temperatures at which the reaction cuvette temperature control may be set.  $30.0 \text{ or } 37.0^{\circ}\text{C}$
- 8. What two options may be used to make a selection from a menu?
  - a. Keyboard
  - b. Touchscreen

 $9. \ \ How many \ Reagent \ Carousels \ can \ be \ configured \ on \ the \ ALCYON \ Analyzer?$ 

5

10. List the steps for configuring the current (default) Reagent Carousel setting.

1. Reagent Carousel

3. Enter the Reagent Carousel # (1 - 5)

2. Current

4. **<F10>** 

### **Module 2 Review Questions**

Write your answers in the spaces provided.

| 1. | When ordering tests, why would the character "*" appear after the chemistry name? |
|----|---|
|    | It indicates the chemistry's diluent is not programmed on the current             |
|    | Reagent Carousel. (These characters "*" will always appear in the DIL             |
|    | column for ISE tests.)  |
| 2. | What is the maximum number of samples that can be processed at one time? 39       |
|    |   |

3. What activity should be performed prior to daily maintenance, and periodically throughout the day?

**Daily Checklist** 

4. List three reasons why a patient test file may be labeled Incomplete Files.

Need to retest

Need a dilution

Need to validate manually

- 5. How long are Complete Files held until they are archived?3 days
- 6. How many chemistry types can be run on the Analyzer?

3

7. What are the names of the chemistry types?

**End-Point** 

Zero-Order Kinetic (Kin 0)

First-Order Kinetic (Kin 1)

8. What types of calibration can be performed on the Analyzer?

Single-Point

Multi-Point

9. Does the ISE module use direct or indirect potentiometric analysis? Indirect

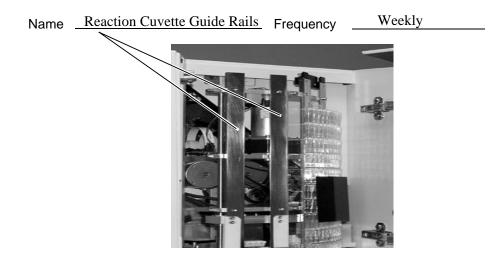
10. What is the dilution ratio of an ISE sample?

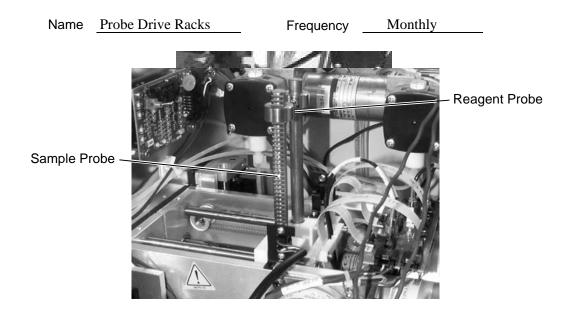
1:11 (300 µL buffer/30 µL sample)

## **Module 3 Case Studies**

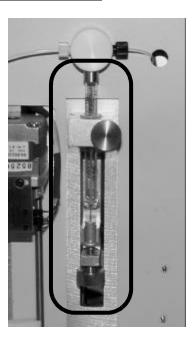
### **Activity 3-1: Analyzer Maintenance**

Identify the parts noted in the following pictures. List the maintenance frequency required for the part.

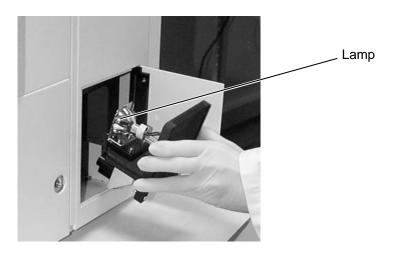


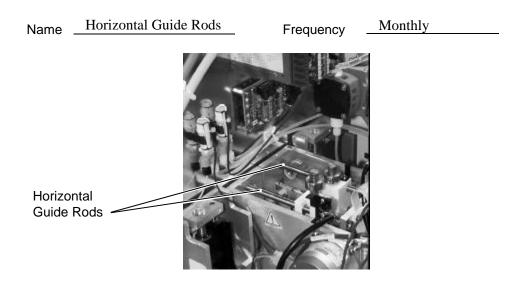


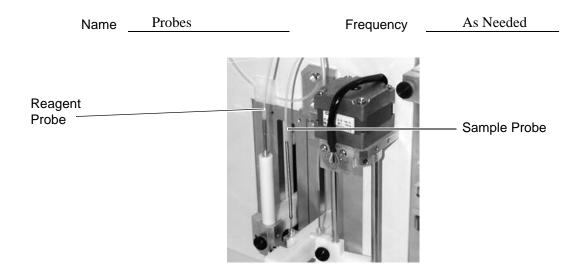
Name Piston & Syringe Frequency Monthly



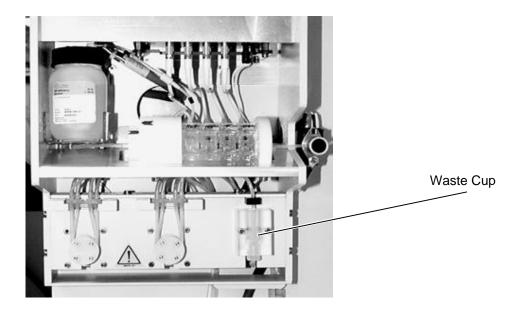
Name <u>Lamp</u> Frequency As Needed







Name Waste Cup Frequency Daily



### **Activity 3-2: Troubleshooting**

#### Case Study 1:

1. Will the patient results be found in Complete Files or Incomplete Files? Why?

Incomplete Files, because one alarm or error causes the

file to transfer to the Incomplete Files.

2. Did the patient results transmit to the Host computer?

No

3. The error code generated on ALB is RBL and the error code on T PROT is LOR. What do these error codes indicate?

RBL - Reagent Blank Out of Limit

LOR - Lack of Reagent

4. What is the most likely cause for receiving the LOR error on T PROT?

Insufficient reagent

5. What corrective action would you recommend for Albumin? Why?

Discard the old reagent.

Prepare new reagent and place it in the Analyzer.

(The reagent may have evaporated.)

### Case Study 2:

1. Are the controls acceptable?

No

2. What error code is generated on the report?

COL, Low or COL, High

3. What corrective action should be performed?

Recalibrate the chemistry and rerun the controls.

### Case Study 3:

1. What is the most likely cause of improper mixture of the reaction?

The sample probe is installed improperly.

The probe is not going through the mixer.

### **Activity 3-3: System Repair**

#### Case Study 2:

a. What corrective action should you perform to correct this error?

Replace the lamp and perform colorimeter adjustment.

b. After changing the lamp, you still receive the same error. What should you do?

Contact your Abbott Representative.

### **Module 3 Review Questions**

Write your answers in the spaces provided.

1. Complete Files, which have been stored for three days, are automatically transferred to Archive File status. What function, when performed, causes this to occur?

When the Analyzer is initialized.

2. List the two reasons a control is labeled "Out of Limit".

Out of range (low control values, high control values)

Out of range (m-val, m+val)

3. What two things occur when a control is "Out of Limit"?

All patient results with the "Out of Limit" chemistry

are sent to Incomplete Files and an alarm occurs.

4. List the two major classifications of error messages or flags displayed by the ALCYON Analyzer.

Analytical

Operational

5. To assist the Abbott Service Representative with diagnosing Analyzer problems, what three steps should the Operator perform?

Record the error message.

Check position of modules (arms, carousels, syringes, etc.).

Do not power off the Analyzer until instructed by your Abbott

Representative.

## **NOTES**